Copyrights and Disclaimers

Any comments or suggestions regarding this publication should be forwarded to Immucor Medizinische Diagnostik GmbH, Robert-Bosch-Strasse 32, D-63303 Dreieich, Germany (doccontrol-de@immucor.com).

by Immucor or its affiliated dealers. All warnings and cautions must be reviewed by the Operator prior to using the NEO Iris for the first time.

Document Revision History

Date	Version	Chapters	Description
MAY 2016	NEO Iris_EU-001-100	N/A	First Version of NEO Iris Operating Manual
JUL 2016	NEO Iris_EU-001-101	Chapter 12: Limitations of Use and Warnings Attachment 1	Update of the limitations on interfering substances for Lipemia and Icterus (Levels defined)
JUN 2017	June 2017	Copyrights and Disclaimers	Manufacturer new address and Document Revision History
	NEO Iris_EU-001-101	Chapter 1: Introduction to the NEO Iris	About the NEO Iris – Intended use Change Instrument label including the CE logo
	NEO Iris_EU-001-102 (A-I)	Attachment 1: NEO Iris Operator Manual	Manufacturer new address and Document Revision History List of assays updated Change the Anti-A positive cutoff range for samples from 70 to 100 to 58 to 100 for ABO assays
	NEO Iris_EU-001-101 (A-II)	Attachment 2: NEO Iris Operator Manual	Manufacturer new address Remove FDA clearance claim
	November 2018	Copyrights and	Update of DRH

Date	Version	Chapters	Description
NOV 2018		Disclaimers	
	NEO Iris_EU-001-101	02-03-TOC_about_NEO_Iris_EU	Warning included (Hot surface)
	NEO Iris_EU-001-102	Chapter 1: Introduction to the NEO Iris	References included for: - CMOS cameras - Change from CSA to Nemko certification in label
	NEO Iris_EU-001-101	Chapter 2: Harware Components	Reference included: Complementary Metal-Oxide Semiconductor (CMOS)
	NEO Iris_EU-001-101	Chapter 3: System Software Navigation	Autologoff notes included in Logging in section
	NEO Iris_EU-001-101	Chapter 5: Instrument Startup	Autologoff section included
	NEO Iris_EU-001-101	Chapter 10: Maintaining the NEO Iris	Limitation included in Maintenance Overview section
	NEO Iris_EU-001-102	Chapter 12: Limitations of Use and Warnings	Limitation included in: - Instrument Start-up - Maintaining the NEO Iris - Preparing the NEO Iris for the First Use
	NEO Iris_EU-001-101	Appendix A: Preparing the NEO Iris for the First Use	Update in: - Warning and Limitations - Standards
	NEO Iris_EU-001-101	Appendix C: Hardware	Update in General Data and Personal Computer tables

Date	Version	Chapters	Description
		Technical Data	
	NEO Iris_EU-001-101	Glossary of Terms	CCD camera reference removed
	NEO Iris_EU-001-103	Attachment 1	Capture-CMV included
DEC 2020	NEO Iris_EU-001-102	Chapter 10: Maintaining the NEO Iris	Updated recommended cleaning solution in the following maintenance tasks: - Daily: 'Cleaning the Instrument' - Weekly: 'Cleaning the Pipettor Wash Towers' - Weekly: 'Cleaning the Common Waste Container' - Monthly: 'Decontaminate Tubings' including specifications for sodium hypochlorite and steps to prepare solution. Revised instructions for performing the monthly 'Decontaminate Tubings' maintenance task.
MAY 2021	NEO Iris_EU-001-102	Appendix C: Hardware Technical Data	Update of Operating System (to Windows 10) in Personal Computer table
MAR 2023	NEO Iris_EU-001-102	Chapter 12	Update to include reference to reagent Instructions for Use related to the anticoagulants
	NEO Iris_EU-004-103	Attachment 1	

Table of Contents

About This Manual

In This Section

The *NEO Iris Operator Manual* is designed to guide the NEO Iris™ operator through all procedures required to use and maintain the NEO Iris, including operating procedures, maintenance, and troubleshooting.

This chapter provides high-level information about how this manual is organized.

How This Manual Is Organized

In This Section

This section describes the organization of this manual, including:

- Format
- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons
- Front Pages
- Chapters

Format

This manual is divided into chapters that describe specific aspects of the NEO IRIS structure or functionality.

Notational Conventions

This manual uses a page numbering system that includes a prefix of the chapter number hyphenated with the page number. Sequential lists that describe step-by-step procedures are included as numbered lists.

The footer of each page contains the current manual version identified using a nine character hyphenated format. The first three characters (NEO) identify the instrument. The second set of three characters identifies this document as the operator manual (001). The final set of three characters identifies the version of the operator manual. 100 designates version 1; 200 designates a full version 2 update; and so on.

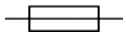
If changes are made to individual chapters in between full manual version updates, then chapter version numbers are incremented by single digits. For example, 101 is the first update of a chapter falling between a full manual update from version 1 to version 2.

Limitations of Use and Warnings

Limitations of use and warnings are located throughout this manual, specifically in the body of the text where they are most relevant to the information. An icon draws your attention to limitations of use and warnings. **Chapter 12 – Limitations of Use and Warnings** contains a complete list of all of the limitations of use and warnings in this manual.

Use of Icons

Some of the following safety symbols may be displayed on the NEO Iris or may appear in the manual to alert you of warnings or limitations of use, or to direct you to information. Examples are shown below.

Symbol	Type of Warning	Related to...
	Laser beam safety warning	Laser beam safety issues
	Alternating current	Power supply
	Direct current	Power supply
	Protective conductor terminal	Power supply
	Fuse	Power supply
	On (supply)	Power supply
	Off (supply)	Power supply
	Limitations and Warnings	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed
	Warning, risk of electric shock	Potential hazard related to power supply
	Warning, risk of crushing or pinching	Potential hazard resulting in possible injury
	Hot surface warning	Y-Motors at pipettor arms
	Consult instructions for use	
	In Vitro Diagnostic medical device (IVD)	

	Biological risks
	Manufacturer
	Manufacturing date
	Separate collection for electrical and electronic equipment
EC REP	Authorized Representative in the European Community
SN	Serial number
REF	Catalog number

Front Pages

The front pages of this manual include the Copyrights and Disclaimers page and the Table of Contents.

Chapters

The Table of Contents sequentially lists all chapter contents. The first page of each chapter lists the contents of that chapter.

Chapter 1: Introduction to the NEO Iris

In This Chapter

This chapter provides an introduction to the NEO Iris.

About the NEO Iris

Intended Use

The Neo Iris (NEO Iris) is a microprocessor-controlled instrument to fully automate immunohematology in vitro diagnostic testing of human blood. The NEO Iris automates test processing, result interpretation and data management functions. The NEO Iris is designed to automate standard immunohematology assays using a microplate-based platform. Assays include ABO grouping and Rh (D) typing, detection/identification of IgG red blood cell antibodies, compatibility testing, red blood cell phenotyping, antigen screening and infectious disease screening, such as Cytomegalovirus (CMV).

The NEO Iris is part of the Galileo Family of instruments and is intended for use only with the reagents described in **Attachment 1 for Neo Iris Operator Manual**.

IVD

Limitation: The Neo Iris is for in vitro diagnostic use.

Principles of Operation

The NEO Iris is designed to automate standard immunohematology assays and operate as a walk-away system, meaning you can leave the NEO Iris to operate independently for periods of time. This leaves you free to carry out other tasks in the laboratory. Several unified principles have been integrated into the NEO Iris system to support and to simplify the overall system operation.

The NEO Iris is a closed system and can only be used with specified Immucor products.

The NEO Iris is an ergonomically friendly and easy-to-use system. Features of the NEO Iris system have been designed to maximize operator efficiency and thereby minimize result errors.

The NEO Iris is a robotic instrument programmed to move microplates, liquid reagent fluids, and blood sample fluids to different bays and processing areas for a given assay in the correct sequence. Such bays and areas include incubator bays, the microplate washing station, the centrifuge, and the reader.

The NEO Iris plate reader uses CMOS cameras to capture an image of the microplate from underneath. The NEO Iris software calculates a reaction value for each well based on a multi feature image analysis. The NEO Iris then assigns a result and interpretation to the wells based on predefined criteria associated with the calculated reaction value. Some assay protocols require multiple test wells for a given blood sample interpretation, such as ABO and Rh (D) typing.

The NEO Iris uses software to drive its mechanics and data processing. The operator uses hardware in combination with the software to operate and maintain the NEO Iris.

Consistent Color Code

Purpose

In order to improve process control when loading or unloading the NEO Iris, many safeguards have been incorporated into the system. To indicate when it is safe to use a component, the NEO Iris uses Light Emitting Diodes (LEDs) with a consistent color code to indicate the status of specific components.

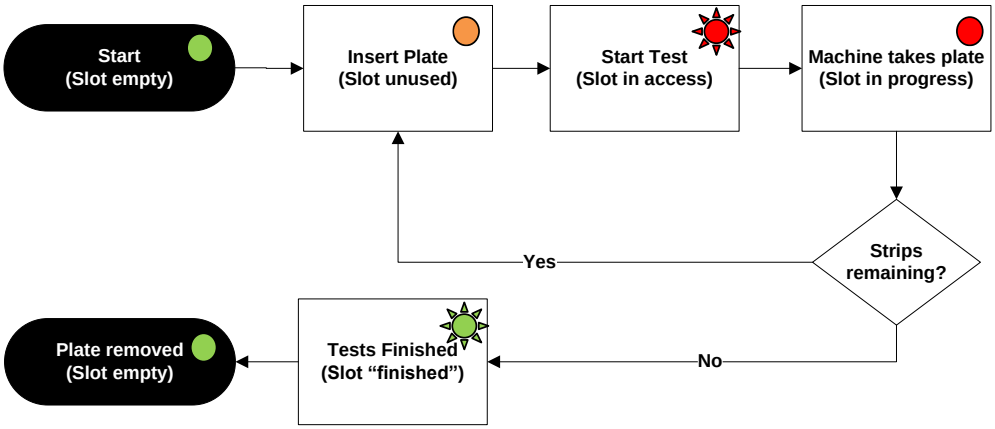
By following the consistent color code, you can continuously load and unload samples, microplates, and reagents onto the NEO Iris during operation. Continuous loading enables a high sample throughput while increasing the flexibility of the system.

This table describes each of the LED colors within the consistent color code.

Color	State	Meaning
	Green Continuous	You can place a suitable item into this position.
	Green Flashing	You should remove an item from this position.
	Orange Continuous	The system has not been requested to use this component and there are no errors.
	Orange Flashing	A warning has been issued for this component, an error occurred or you can remove a rack.
	Red Continuous	DO NOT place anything in this position.
	Red Flashing	DO NOT remove anything from this position.

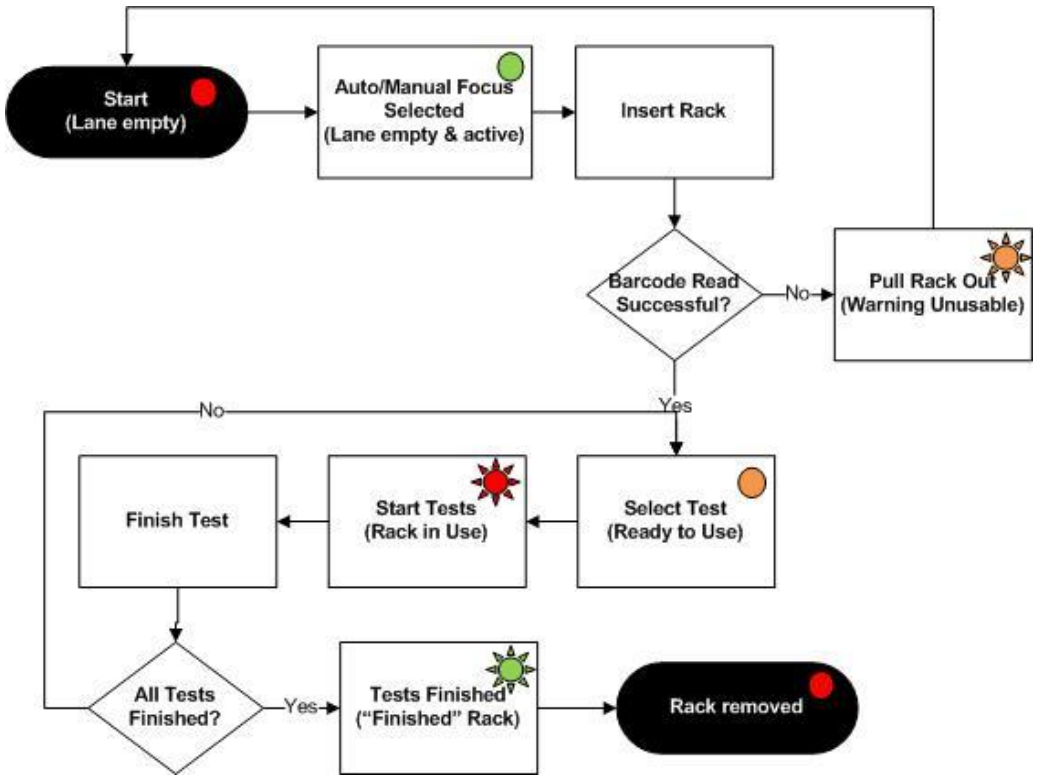
Color Scheme In the Plate Loading Tower

Implementation of the color scheme in the Plate Loading Tower produces the following states in the tower LEDs:


Start
(Slot empty)
Insert Plate
(Slot unused)
Start Test
(Slot in access)
Machine takes plate
(Slot in progress)
Strips
remaining?
Yes
No
Tests Finished
(Slot "finished")
Plate removed
(Slot empty)

Color Scheme In the 14-lane and 5-lane Bays

Implementation of the color scheme in the 14-lane and 5-lane bays produces the following states in the lane LEDs:



Barcodes

Purpose

The NEO Iris uses barcodes to identify reagents, microplates, and samples in the loading bays. Using barcode technology increases the number of steps that can be automated, thus decreasing handling errors. The NEO Iris supports the use of the following barcode symbologies:

- Codabar
- Code 128
- ISBT 128 (Concatenated barcodes are not supported)
- Code 39
- Interleaved 2 of 5

Note: To increase data security, Immucor recommends that you use a check digit in conjunction with sample barcodes.

Limitation: Barcodes can be no longer than 18 characters in length.

Limitation: Barcodes must have a module size larger than 0.2mm and a bar width ratio between 2.25:1 to 3:1.

Decodability grade (grading system of A to F; A being best, F is failing) of C or better is required for consistent reading of barcodes on the instrument. This grade measures the bar width consistency throughout the barcode label. It is usually an indication of print quality of the barcode label.

The minimum number of characters in the barcode is 3.

The length of the barcode is variable but must be completely visible with a quiet zone (white space on each end of the label) of 3 mm when placed in the sample or donor rack.

The minimum height of the barcode must be 10 mm.

If barcodes have parameters outside of these specifications, barcode misreads can occur on the instrument.

Pipe characters (|) are not permitted as part of a sample identification.

Limitation: If samples have barcode identification information that is eighteen (18) characters in length and the first three (3) characters are identical to the first three (3) characters of the assay control material in assays which include plate or run controls, then the sample will be interpreted as a replicate of the control material. In this case, either the plate will fail unnecessarily (if the sample reacts differently than expected for the corresponding control), or the plate will pass but no results for that sample will be produced (if the sample reacts as expected for the corresponding control). Such a condition can also be exhibited when an assay such as crossmatch or antigen screening assay generates a set of circumstances such that the combination of donor and primary sample barcode identification information adds up to eighteen (18) characters and the primary sample identification begins with the same first three (3) characters as one of the control material barcode identifications.

Reagent Barcodes

Reagent barcodes are used to identify reagents, controls and diluents.

The following information is encoded in the reagent barcode:

- Reagent ID – The type of reagent
- Lot number – Batch identifier
- Expiration Date – The last date that the reagent may be used
- Serial Number – Unique identifier for each vial

Microplate Barcodes

Microplate barcodes are located on the short side of the plate frame. The instrument has an internal plate barcode scanner that scans the plate frame to verify the plate ID when the instrument processes the samples. For more information about the internal barcode scanner, refer to **Chapter 2 –Hardware Components**.

There are two (2) different barcode schemes used on the sides of plates, of which only one is used on a given plate frame. The barcode scheme used on a given plate frame is dependent on when a given lot of a given product is manufactured. The schemes are named *Scheme 1* and *Scheme 2*.

Scheme 1

The following information is sequentially encoded in the plate frame barcode for *Scheme 1*:

- Plate code (indicating the type of plate) linked with the lot number (batch identifier).
- Plate serial number – the unique plate identifier.

  Scheme 1 does not have encoded information for the plate expiration date. The plate expiration date must be entered into the software manually. Refer to ***Chapter 3 – System Software Navigation*** *for information regarding the manual entry of plate expiration dates using the Expiry Date tab of the Plate Loading Tower dialog.*

Scheme 2

The following information is sequentially encoded in the plate frame barcode for *Scheme 2*:

- Three (3) digit product identifier. For example, 008 identifies Capture-R® Select plates.
- Five (5) character expiration date (DDDYY). The DDD portion is the numeric day within the year (YY). For example, February 1st 2010 would be represented as 03210.
- Three (3) digit lot number (batch identifier).
- Five (5) digit plate serial number – the unique plate identifier.

The instrument software combines the three (3) digit product identifier with the three (3) digit lot number to create the alpha-numeric lot number of the plate. The software uses a truth table to convert the product identifier to either one or two alpha character(s) that can be prefixed onto the three (3) digit lot number, the combination of which can be printed on reports. For example, SC represents Capture-R® Select plates. The printed alpha-numeric lot number of SC123 would actually be composed of 008 and 123. If a particular plate of this lot number had an expiration date of February 1st 2010 and it was the thirteenth (13th) plate manufactured, then the overall plate frame barcode would be 0080321012300013.

Scheme 2 has encoded information for the plate expiration date. The plate expiration date does not need to be entered into the software manually. The *Expiry Date* tab of the *Plate Loading Tower* dialog will automatically populate with date information when *Scheme 2* plate frame barcodes are scanned by the instrument. Refer to **Chapter 3 – System Software Navigation** for information regarding the *Expiry Date* tab of the *Plate Loading Tower* dialog.

Sample Barcodes

Sample barcodes are located on sample tubes and encode the sample ID. The sample ID can be mapped to information downloaded from the host Laboratory Information System (LIS).

Note: For correct reading of sample barcodes in the loading bay, the sample barcodes must be positioned between 20 mm and 105 mm (0.8 and 4.1 inches) from the bottom of the tube.

Reagents

The NEO Iris accesses all reagents, such as antisera and reagent red cells, through vials with lot numbered barcodes. The operator loads these vials into reagent racks which are slotted into the loading bay. For more information, refer to **Racks**.

The barcodes identify each vial individually so that the system can electronically monitor the fill level when the reagents are removed from the NEO Iris and then reused at a later time. When a reagent vial is empty, the software automatically moves to another bottle of the same reagent type if it is present on the instrument. When using barcoded reagents, the system automatically registers the position of the reagent so the reagent can be placed in any accessible position.

Note: For more information about loading reagents, refer to **Chapter 6 – Instrument Testing Operation**.

Racks

Purpose

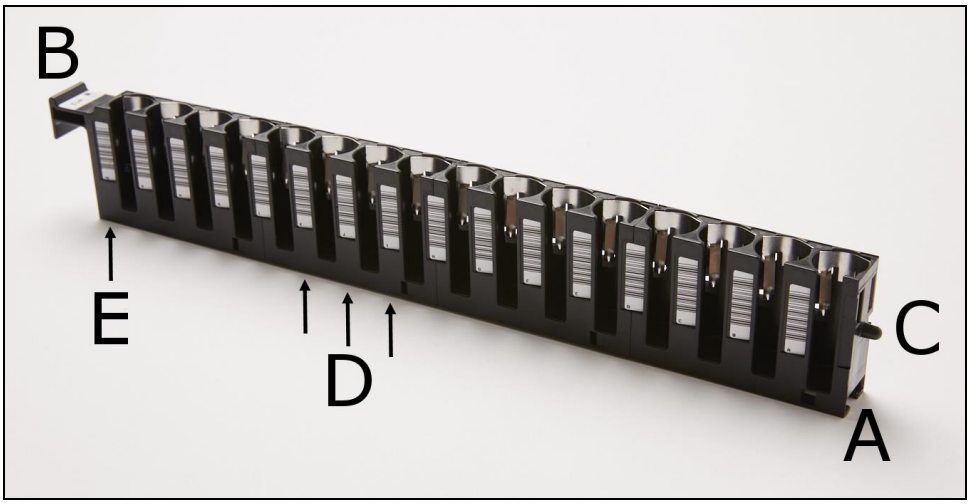
The NEO Iris uses racks for loading and unloading samples and reagents. You must place reagent vials and sample tubes in a rack and then slide the rack onto the NEO Iris. You can continuously load or unload racks from the NEO Iris during operation according to the consistent color code.

NEO Iris racks are equipped with a guide rail underneath to position them correctly in the loading bay, a handle at the back to facilitate handling, and a pin at the front that triggers a sensor to inform the system that the rack is loaded into position.

NEO Iris racks use barcodes so the system can identify them. Each rack position has its own positional barcode. On the left of the rack, next to the handle, is the overall rack barcode. The rack barcode encodes the pipetting coordinates to be used when aspirating from tubes loaded in this rack.

Parts of the Rack

The photograph below illustrates the parts of the rack.



- **A**: Guide rail
- **B**: Handle
- **C**: Pin
- **D**: Positional barcodes
- **E**: Rack barcode

Types of Racks

There are two lengths of NEO Iris racks:

- Racks for the 14-lane bay
- Racks for the 5-lane bay

The following table shows every type of NEO Iris rack available in these sizes.

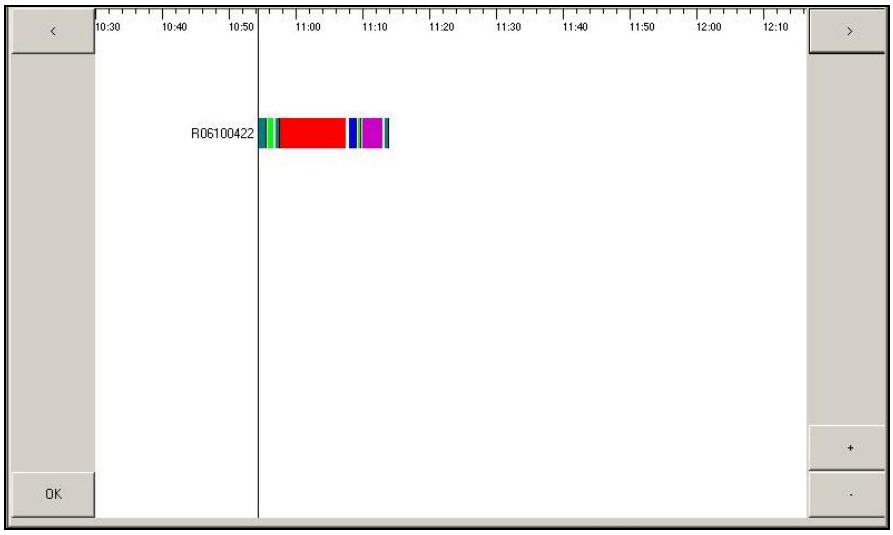
Bay Type	# of Positions	Rack Type	Tube or Vial Size
14-lane bay	16	Tube: A	Sample Rack: 16–17X100 mm tube
14-lane bay	16	Tube: B	Sample Rack: 12–13X75–100 mm tube
14-lane bay	16	Tube: C	Sample Rack: Pediatric tube custom rack
14-lane bay	16	Donor: D	Donor Rack: 12 mm diameter tube
14-lane bay	12	Reagent: R	10 ml reagent vial (occupies 2 lanes)
5-lane bay	9	Reagent: S	10 ml reagent vial (occupies 2 lanes).  **Note**: Not for use with controls.
5-lane bay	5	Reagent: T	57 ml (43 mm diameter) vial (occupies 3 lanes)

Limitation: A site visit by an Immucor representative is required to configure the Z position (downward) on the instrument for the C racks and the specific small-volume pediatric tubes in use at your site. C racks cannot be used on the instrument without this configuration. Sample probe crashes will occur without this configuration, when used in conjunction with the C racks. If differently sized small-volume pediatric tubes are subsequently used after the Z position configuration is performed using the originally designated small-volume pediatric tubes, re-configuration may be required to prevent possible sample probe crashes into the bottom of the new tubes.

Dynamic Scheduler

The dynamic scheduler is the sequence of events that the instrument must perform to complete the requested assays. The software calculates the schedule based upon the time constraints of the individual assay steps. The system identifies or displays all resources that need to be loaded in order to complete the schedule.

The schedule is represented by the software using an axis crossing a time scale and passing through bands of color. The scheduler axis line moves in real time from left to right to demonstrate time passing as the NEO Iris operates. Each plate being run has a sequence of differently color coded bars that represent the sequence of processing steps that the plate is designed to move through for a given assay. The axis line moves through the different color bars as time progresses. The scheduler will adjust to accommodate normal processing delays.



Each band of different color bars represents one plate. The plate identification is prefixed at the left of the color band.

Each given band is spatially placed in the window to represent what the plate's starting position was in the plate loading tower. Position 1 is designated as the bottom position and position 15 is designated as the top. Therefore, for example, the plate color band for tower position 3 would be lower in the window than that for tower position 8.

Refer to **Chapter 3 – System Software Navigation** for more information regarding the schedule.

Limitation: Time stamps for instrument activity may not be accurate around Daylight Saving Time (DST) when a given activity spans a time period falling on both sides of the actual change of time for DST. The following recommendations are published to provide guidance on how to mitigate these time stamp inaccuracies. Allow assays to finish if they are already running during the DST change and remove the racks once processing is complete. Do not interact with the instrument (e.g. loading plates or starting assays) during the DST time change. Initialize the instrument after the DST time change is finished prior to beginning any further assays.

Miscellaneous Information

Continual Access

The instrument is designed so that resources can be replenished and new assays started without interrupting the processing of in-progress or scheduled assays.

New samples, reagents, system liquid, and plates can be added during test processing. You can also remove completed samples, used reagent containers, plates, and liquid waste during test processing.

Instructions for replenishing samples and reagents during instrument operation are included in **Chapter 6: Instrument Testing Operation**. Instructions for replenishing system liquid during instrument operation and removing liquid waste are included in **Chapter 10: Maintaining the NEO Iris**.

Expected Results

The specific performance characteristics and the expected frequency of the possible assay results are described in the package inserts of each reagent or test well. The expected results are specific to the reagent or test wells in use. Refer to the package inserts for descriptions of expected results for reagents and test wells.

Biological, Electrical, Mechanical and Laser Beam Safety Precautions

Warning: Blood samples, liquid waste, used microplates, and consumed liquid reagent containers contain potentially biohazardous material.

Warning: Always wear protective gloves and clothing when handling blood samples, liquid waste, used microplates, or consumed liquid reagent containers. All blood samples, liquid waste, used microplates, and consumed liquid reagent containers must be discarded following the standard practice of the laboratory.

Warning: All blood products must be treated as potentially infectious. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

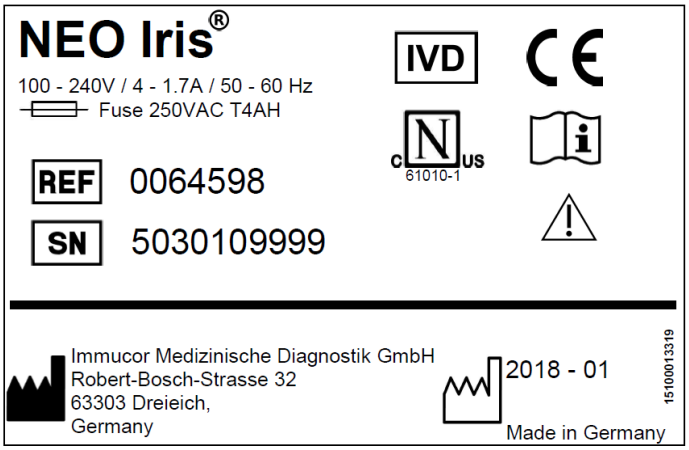
Warning: Follow basic electrical hazard awareness to reduce the risk of injury due to prohibited electricity exposure.

Warning: Follow all of the necessary precautions to prevent exposure to and potential injury from instrument mechanical movement. Keep all instrument protective covers in place when operating the instrument to reduce the risk of operator injury due to instrument mechanical movement.

Warning: Follow all of the necessary precautions to prevent exposure to and potential injury from barcode laser scanners. Do not look directly into the laser beam of scanners or any reflections of the beam from a mirror-like surface. Exposure to the laser beam light can cause eye damage and permanent injury.

Markings

The label is located next to the power socket on the bottom right side of the instrument. The information on the label includes, but is not limited to, the NEO Iris serial number.



Manufacturer Information

Immucor Medizinische Diagnostik GmbH
D-63303 Dreieich-Sprendlingen
Robert-Bosch-Strasse 32
Germany

Classification

CE The Neo Iris Instrument is classified as "self-declared" device according to IVD Regulation (EU) 2017/746

Technical Support

Please contact your local Technical Support or Immucor Technical Support International or at **+4961038056500** or via e-mail at **tech.support.int@immucor.com.**

Chapter 2: Hardware Components

In This Chapter

This chapter describes the functions and safety aspects of the NEO Iris hardware.

For technical data about the hardware, refer to Appendix C – Hardware Technical Data.

The NEO Iris

NEO Iris Photograph

The photograph below shows the NEO Iris as it is viewed from the front. The instrument unit is located on top of the cabinet. The computer monitor and keyboard are attached to the right side of the cabinet.

Personal Computer (PC)

Purpose

The NEO Iris software, installed on a stand-alone PC, controls the NEO Iris. The touch-screen PC monitor is located on the monitor table attached to the right side of the cabinet. The PC tower is located inside the cabinet.

For more information about the NEO Iris software, refer to **Chapter 3 – System Software Navigation**.

How It Works

In addition to the standard PC components, the NEO Iris PC is equipped with a touch-screen monitor and a trackball (mouse).

This PC is connected to the NEO Iris, and can also be linked to an external Laboratory Information System (LIS). This enables you to download test selections (worklists) to the NEO Iris and export test results from it to the LIS.

Attention: Do not install additional software or add-on hardware. This will void your warranty and service contract. Addition of unapproved software may affect the performance of the NEO Iris and provide a means of introducing computer viruses.

Monitor Photograph

The photograph below illustrates the touch-screen monitor and its associated parts.

Safety Feature

This PC is equipped with the following safety feature:

- The computer is attached to an uninterruptible power supply (UPS) with an integral power conditioner to provide a consistent source of electricity, and to provide short periods of backup power.

Cabinet

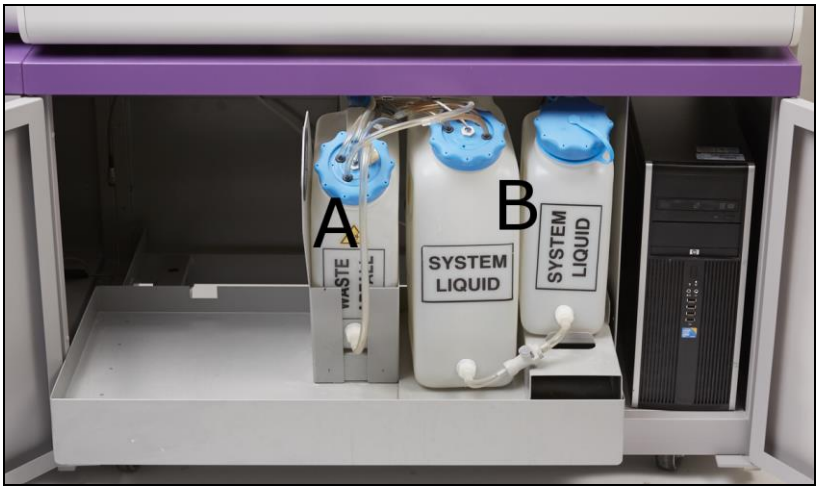
Purpose

The cabinet is an integral part of the NEO Iris. It provides a surface on which to safely place the instrument and serves as a compartment in which to store external system components.

The section below describes the cabinet parts.

Cabinet Photograph

The photograph below shows the cabinet and its parts.



- **A**: Common waste container
- **B**: System liquid containers

Cabinet Interior

The following design features are incorporated into the 20 liter and 10 liter system liquid containers:

- The 20 liter system liquid container is connected to the 10 liter refill container so that when the 10 liter refill container is filled with system liquid, the liquid from that container will passively drain into the 20 liter container.
- The system is designed such that only the 10 liter refill container is manually filled (using its large cap opening), and not the 20 liter container. The 20 liter container is the direct liquid reservoir for the NEO Iris and is passively filled (indirectly) from the 10 liter refill container, using gravitational equilibration. The equilibration time for the passive draining of a full 10 liter refill container into the 20 liter container is approximately five (5) minutes.
- The 10 liter refill container can be detached from the 20 liter container (using the in-line connectors) during operation, so that it can be filled off-line, as long as there is sufficient system liquid in the 20 liter container to process the assays in progress.
- As an alternative method of filling, a commercially obtained cube of system liquid can be directly connected (using the supplied in-line connector) to the 20 liter container, instead of using the 10 liter refill container. In this instance, the commercially obtained cube of system liquid must be elevated on the drawer to at least the same level as the 10 liter refill container so that passive gravitational draining equilibration can take place. The cube must be located in the space on the drawer to the left of the common waste container and requires an extended length of tubing to connect the cube to the detachable in-line connector.

Limitation: Immucor requires the use of phosphate buffered (approximately 15mM) isotonic saline, pH 6.5-7.5 (PBS), on the NEO Iris system. Reactions between an antibody and its antigen may be weakened if acidic or unbuffered saline is used.

Using saline and/or deionized water in PBS preparation from sources with systems in place to control proliferation of microbes helps to reduce the chance for microbial bioburden on the system. Excessive microbial bioburden can cause degradation of system or assay performance.

Safety Features

The cabinet is equipped with the following safety features:

- The 20 liter container has an integrated sensor to detect low levels of system liquid (cable circled in the photograph below).

- The base of the drawer is a sealed trough that retains any spills from the containers.
- The PC tower compartment is separated from the system liquid compartment, protecting the PC tower from splashed liquids.

Warning: Inadvertent operator collision with the cabinet doors or the pull out cabinet shelf can cause operator injury.

Cabinet Exterior

The following design features are incorporated into the exterior of the cabinet to ensure the correct positioning of the NEO Iris.

- Two welded rings on the top of the cabinet ensure the correct positioning of the instrument and prevent it from moving during operation.
- Two rubber-tipped spacers at the back of the cabinet ensure that enough space is left for ventilation, should the cabinet be placed in front of a wall.
- Foot mountings positioned close to the wheels ensure stability of the system during operation.

Attention: The instrument setup process involves critical positioning and stabilization of the cabinet and centrifuge. Moving the NEO Iris could affect these aspects of instrument setup and cause centrifuge balancing errors to occur. It is recommended that the NEO Iris not be moved once installed.

Hood

Purpose

The hood is located on the upper front of the instrument and is used as a protective shield for the operator, to help prevent operator accidents or injuries when the instrument is performing mechanical functions. However, if required, for example in the instances of some maintenance tasks, the hinged hood can be raised to give operator access to perform necessary tasks under controlled circumstances.

How It Works

The hood is a physical barrier that prevents operator intervention into the moving mechanical parts area of the main instrument when its components are in motion. If it is necessary to access the inside of the main instrument mechanical area, the hood can be raised up by manually pulling vertically up on the hand bar. The hood can then subsequently be lowered back into the physical barrier position by manually pulling down on the hand bar.

Hood Photographs

Hood in the down protective position

Hood in the up position, for access to the internal parts of the instrument

The photograph below shows the hand bar of the hood in detail.

Safety Features

The hood is equipped with the following safety features:

- The hood is a physical barrier that prevents operator intervention into the moving mechanical parts area of the main instrument when its components are in motion.
- The hood is linked to a sensor so that if the hood is raised under uncontrolled circumstances, such as while the mechanical parts of the main instrument are still in motion, then an audible alarm is sounded and an error message is generated which brings the instrument to an emergency stop.

Loading Tower

Purpose

You load and remove plates through the loading tower, located on the left side of the instrument and accessed from the front. You must load the plates into carrier frames first before placing them in the tower. These frames allow the transport system to move the plates and then load them into the various instrument modules required to complete the assays.

How It Works

The loading tower is a self-contained module that enables you to load and unload up to 15 plates. The tower features a translucent door.

The plate positions are designed for easy and safe insertion of the plates. The right hand rail of each position corresponds to the guiding groove of the plate carrier, thereby prohibiting incorrect loading of the plate carriers.

Ensure also that the plates are fully pushed down into the recess of the plate carrier. When using plate strips, ensure that the strips are properly placed in their white frames and that these frames are in turn fully pushed down into the carrier frame.

A mechanical stop at the rear of each position ensures that you cannot insert the plate too far. In addition, each position has an LED indicator that shows the status of that position in accordance with the instrument color-coding system. Refer to **Consistent Color Code** in Chapter 1: Introduction to the NEO Iris for more information.

Two guidance strips attached to the inside of the door ensure correct placement of the plates in their positions when the loading tower door is being closed.

Note: Closing the loading tower door initiates a barcode scan of a new plate after that new plate is loaded and the LED is orange.

Plate Loading Tower Alerts

Purpose

The purpose of the plate loading tower alerts is to indicate that you should not add or remove plates to or from the tower when the plate transport is accessing the tower.

Warning: Do not try to access the loading tower when the transport system is accessing the loading tower . You may cause a plate transport error or crash situation if you ignore the plate loading tower alerts.

Visual and Audible Alerts

When the plate transport is accessing the loading tower, all of the loading tower LEDs turn to continuous red.

Color	State	Meaning
Red	Continuous on all tower slot LEDs simultaneously.	DO NOT add or remove plates to or from the tower.

Additionally, during this time, if you open the loading tower front door, an audible constant tone alarm is generated that can only be silenced by the transport when it leaves the tower, or by you closing the front door before the transport leaves the tower.

It is recommended to keep the loading tower front door closed at all times, except when loading or unloading microplates.

Loading Tower Photograph

The photograph below shows the loading tower.

Safety Features

The loading tower is equipped with the following safety features:

- Integrated sensors continuously monitor the presence of plates in each position.
- LEDs indicate the status of each position at all times.

Transport System

Purpose

The transport system moves plates between the modules of the instrument, transporting them on frames called plate carriers. The transport system area is at the center of the instrument between the front and rear modules. In this area, the transport system can move the plates without interfering with any of the other modules. A barcode scanner is located within the transport system area, enabling automated scanning of barcodes affixed to the plates.

How It Works

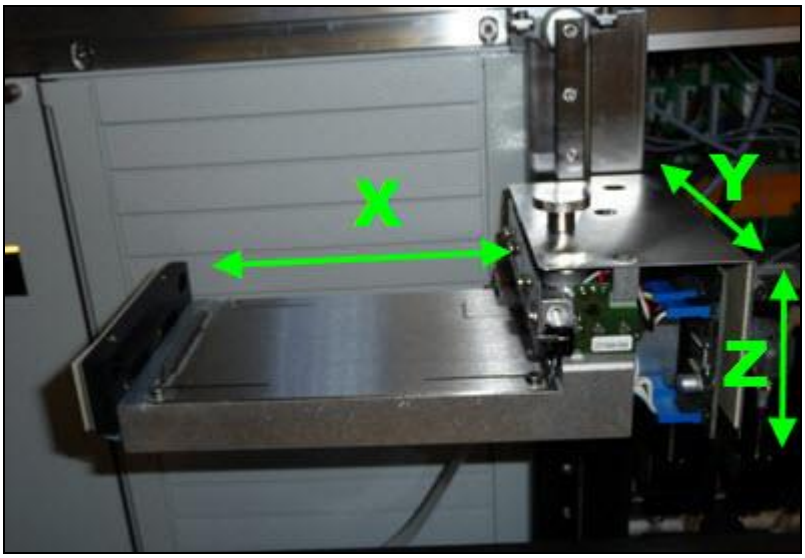
The transport system moves the plate and its plate carrier in the X, Y, and Z directions.

The transport system includes two rails that allow movement in the X-direction (left-right), one on the base of the instrument and one above the rear modules. The transport system also includes a mechanism that allows movement in the Z-direction (up and down). A Y–pusher is included in the transport system to move the plate forward and backwards, in the Y direction. Both rear and front target modules are accessible by the transport system.

During initialization of the NEO Iris, the transport system moves into home position (lower left, behind the centrifuge loading mechanism) in order to set all positioning sensors to home.

Transport System Photograph

The photograph below illustrates the transport system and its movement.



- **X**: Movement
- **Y**: Movement
- **Z**: Movement

Internal Plate Barcode Scanner

The plate barcode scanner is located behind the loading tower at the top of the instrument.

Plate barcode scanner

To scan a plate barcode, the transport system moves the plate to the barcode scanner.

Safety Features

The transport system is equipped with the following safety features:

- Integrated sensors monitor all movements of the transport system and verify that the programmed steps are executed successfully. These sensors detect any obstruction in the transport system.
- The transport system only operates when the hood is closed.
- The transport system recognizes plates using a barcode system.
- The software permits manual entry of plate barcode data, with automatic logging of the operator who performs the manual entry, if plate barcodes fail to be read due to poor plate barcode position or poor printed quality of the barcode.

Warning: Never attempt to reach the washer area while the NEO Iris is operating. You may disrupt the instrument or injure yourself. The instrument switches off power to the motors if resistance to movement is encountered.

Plate Carrier

Purpose

The system transports all plates on plate carriers. This allows the instrument to process plates of different physical dimensions.

How It Works

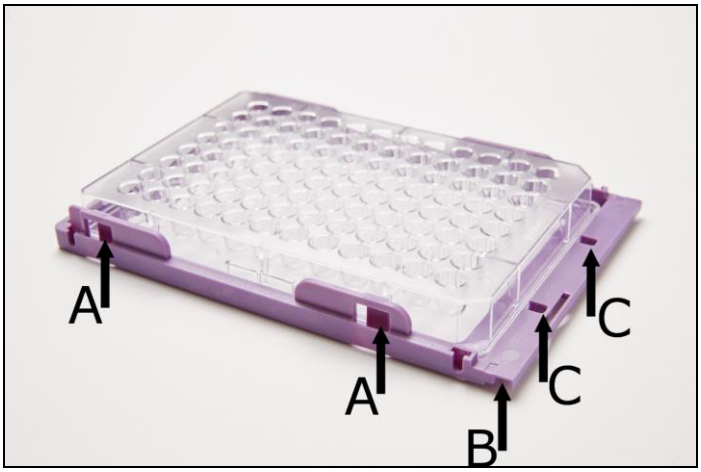
The plate carrier is a plastic frame containing springs and opposed mechanical stops on the inside of the frame to hold the plate firmly and correctly in place.

Attention: The A1 position and barcode label on the plate must face to the left (opposite the guiding groove). To avoid confusion, the upper left corner of the plate carrier is engraved with an A1. You must place the A1 position of the plate there.

The right-hand extension of the frame is comprised of a guiding groove and two holes. The guiding groove ensures correct movement and placement of the plate carrier in the modules. The two holes are engaged by pins of the transport system's Y pusher, which then pushes the plate carrier into, or pulls it out of, the different instrument modules.

Plate Carrier Photograph

The photograph below shows the plate carrier and its parts.



- **A**: Springs
- **B**: Guiding groove
- **C**: Holes for Y pusher pins

14-lane and 5-lane Bays

Purpose

The 14-lane and 5-lane bays are equipped to contain the samples and reagents required for pipetting. The bays are accessible from the front of the instrument, allowing the operator continuous access, even during instrument operation.

The 14-lane bay is in the center of the instrument and has fourteen lanes. The instrument also has a 5-lane bay, which has five lanes, on the right hand side of the instrument. The 5-lane bay is designed for use with reagents only. The 14-lane bay is designed for use with both samples and reagents.

How It Works

Although both of the bays differ in size, they both work the same way. The loading bays are comprised of rack lanes, indicator LEDs, and a barcode laser scanner.

The lanes of the bays are defined by a rail that corresponds to the guide rail on the respective sample or reagent racks. Two mushroom-shaped guide buttons in front of the rail ensure that the racks are positioned correctly as they slide into the lanes. For more information about racks, refer to **Racks** in Chapter 1 – Introduction to the NEO Iris.

Each lane is equipped with an LED that indicates the lane's status in accordance with the color-coding system. For more information, refer to **Consistent Color Code** in Chapter 1 – Introduction to the NEO Iris. The indicator LED is in the first guide button of each lane.

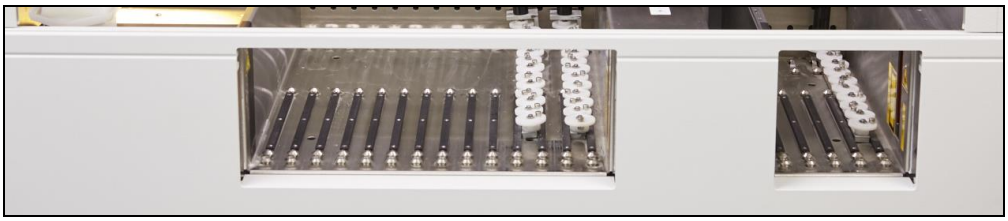
Warning: Do not remove a rack when the indicator LED is flashing red, as this can damage the pipetting system and invalidates all test results on samples in the rack. Also, do not load a rack when the LED is solid red. The barcodes are not read and the reagents or samples will not be used.

The barcode laser scanner for each bay is on the right-hand side of the bay at the front and can focus on each individual lane. It reads the rack and tube barcodes as a rack slides onto the loading bay.

Attention: Use the correct sample and reagent racks with the appropriately sized sample tubes and reagent vials. Using an inappropriately sized tube or vial results in improper volume tracking and flagged results due to inadequate aspiration.

14-lane and 5-lane Bays Photograph

The photograph below shows the 14-lane and 5-lane bays.



Safety Features

The 14-lane and 5-lane bays are equipped with the following safety features:

- Integrated sensors continuously monitor the presence of racks in the lanes and flag any rack removal or exchange.
- LEDs indicate the status of each lane at all times.
- Position barcodes on the rack prevent mix-up of sample or reagent vial barcodes and positions during rack loading.

Warning: Open field access is required to provide continuous access for sample/reagent loading during full system operation. Never try to access tubes or vials while their rack is still in the loading bay. Always pull their rack completely out before accessing individual positions.

Unauthorized access to the loading bay is strictly prohibited and could injure you.

Pipetting System

Purpose

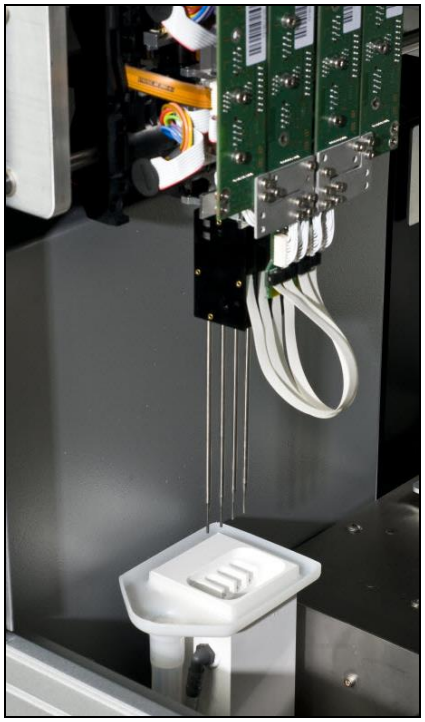
The pipetting system aspirates liquids from a defined source and dispenses them in a defined destination. Both loading bays can be defined as a source location. The plate pipetting stations can be defined as both a source location and a target.

How It Works

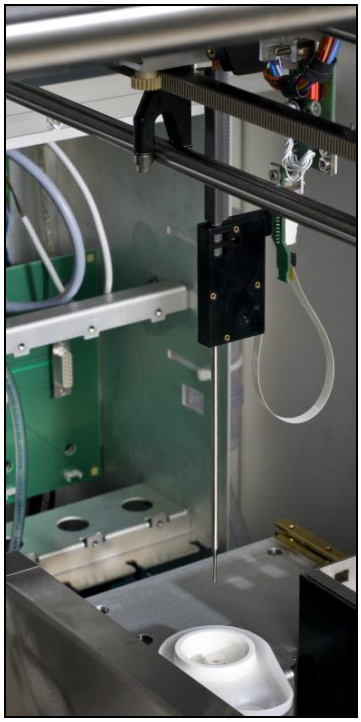
The pipetting system is comprised of the pipettors and the single probe and four probe wash stations.

Pipetting System Photographs

The photographs below show the pipetting system and its parts. Under normal circumstances, when the hood is down, the pipetting system components are not visible. However, when the hood is up, the components are visible.



Four probe (left-arm)



Single probe (right-arm)

Pipettors

The system has five probes mounted on two independent pipetting arms. The left arm holds four probes and is almost exclusively used to pipette samples. The right arm holds a single probe, which is primarily used for reagent pipetting. Some assays use the arms for samples and reagents.

Both of the pipettor arms are supported by a dual X-rail system. The two rails are located in the front and at the back of the main instrument body. Both pipettor arms move in the X-direction left and right across the rails.

The pipettors are fitted with steel probes. The left arm can access the entire 14-lane loading bay, but not the 5-lane loading bay. Each individual probe of the four set pipettors can aspirate up to 500 µl. This volume can be dispensed in single or multiple deliveries. The right arm can access the entire 14-lane loading bay and the 5-lane loading bay. The single probe can aspirate up to 1000 µl. This volume can be dispensed in single or multiple deliveries.

Attention: It is important to use the proper size syringe. Using the wrong size syringe can adversely affect pipetting accuracy and sensitivity. Run the Pipettor Verification Test described in **Performing the Pipettor Verification Test (PipTest)** in Chapter 10 – Maintaining the NEO Iris to confirm that the proper syringe is being used.

Warning: It is important to keep your hands away from the pipetting area to avoid potential injury due to the moving instrument.

All pipettors are equipped with both Liquid Level Detection (LLD) and clot detection in sample tubes, and LLD in reagent vials. The pipettors can detect volumes as low as 200 µl in sample tubes and 1.0 ml in reagent vials. If the pipettors detect no liquid or not enough liquid, or detect a clot, the system issues a warning and, depending on assay-defined settings, waits for your correction or skips the step. The system makes an entry in the log. If low or no liquid is detected then the system issues a warning and will abort the particular plate in question and other plates scheduled to use that reagent.

Limitation: At least 250 µl of packed red blood cells need to be present in a sample tube to ensure that the probe picks up red blood cells and not plasma (only for those assays that require red blood cells).

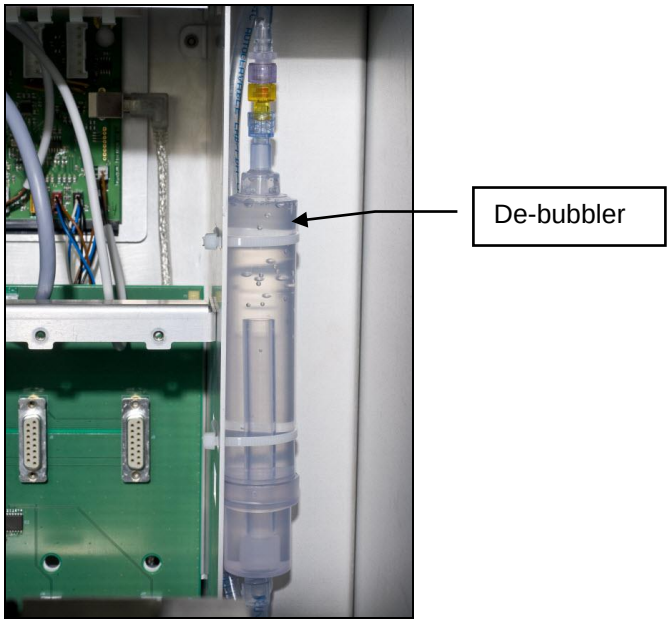
At least 500 µl of plasma or serum needs to be present in a sample tube to ensure that the probe picks up plasma or serum.

Attention: If the system detects a clot, it is important to check that the probe is not blocked, as this inhibits further pipetting and leads to operational failures. For more information, refer to **Chapter 6 – Instrument Testing Operation**.

During instrument initialization, both the pipettor arms and the pipettor pumps undergo a full motion check, during which they move into their home positions to set all positioning sensors to zero.

De-bubbler Module

The de-bubbler module is an integral part of the pipetting system.



De-bubbler module

The following design features are incorporated into the de-bubbler module.

- The de-bubbler module is located inside the NEO Iris, on the rear right-hand back corner, to the right of the dilutor syringes, as the instrument is viewed from the front.
- The de-bubbler module is a vertical clear plastic cylinder with tubing entering and exiting the cylinder from above and below.
- The de-bubbler is designed such that system liquid is pulled into the chamber by a pump that draws from the tubing at the top. Any bubbles that enter the chamber rise and are pulled out via the top tubing and are returned to the 20L system liquid container. The liquid at the bottom of the chamber remains free of bubbles. It is this liquid that is drawn from the bottom of the chamber that is used in the pipetting system.
- No PBS is wasted by the de-bubbler module during assay processing.

Probe Wash Stations

To prevent contamination due to carry-over between samples, the steel probes of the sample pipettors are washed in the wash stations after every dispense step.

You can also use the wash station to prime the liquid system prior to its first use.

Four Probe Wash Station

Single Probe Wash Station

The wash stations consist of an elevated plastic cup containing one or four rinse wells. Washing is a two-step process, as follows:

- The pipettors move to the waste position over the wash station cup where the remaining contents of the probes are emptied by flushing system liquid through and out of the probe.
- The pipettors move over and into the rinse wells and system liquid is pumped through the pipettor tubing. This action washes the inside and the lower outside end of the steel probes simultaneously.

Attention: The instrument cannot differentiate between water and system fluid. If deionized water is mistakenly used as the system fluid, the test results are invalid.

Attention: For the probe wash to work properly, the settings of the instrument, with regards to proper positioning of the probes inside the rinse wells, are crucial. For details, refer to **Checking Pipettor Reference** in Chapter 10 – Maintaining the NEO Iris.

After sampling red blood cells from the bottom of sample tubes, the system performs a special external rinse in the external rinse positions. The probes move to the bottom of the external rinse wells and the active wash pump rinses the outside of the probes by pumping system liquid. The probes move slowly out of the external rinse wells to achieve complete rinsing of the outside of the probes.

The system actively pumps waste liquid from the wash stations to the common waste container in the cabinet.

Safety Features

The pipetting system is equipped with the following safety features:

- Integrated sensors monitor the position of the pipettors as well as pipettor movement. If something hinders pipettor movement, the system displays an error message and movement stops.
- The pipettor arms are supported by a dual X-rail system that provides stability for the moving components.
- The probes are spring loaded to absorb minor bumps so that damage is minimized, should the probes be driven with force into an unexpected obstacle.
- Liquid level detection, clot detection, and aspiration tracking ensure accurate aspiration of liquids or adequate flagging of results.
- Syringes are visible to allow for inspection.
- Software controls limit collision of both pipetting arms.
- If the hood is opened while the instrument is processing, any pipettor arm movement stops and the instrument needs to be re-initialized.
- You can verify proper pipetting by observing correct reciprocal forward and reverse ABO hemagglutination reactions and also detecting red blood cells in test wells where they are not supposed to be delivered. Such inappropriate delivery of red blood cells could be due to, for example, when the plasma volume is too low and the probe picks up red blood cells instead of the intended plasma.
- Software controls monitor the addition of red blood cells, plasma (or serum), and reagents to test wells.
- After sampling red blood cells from the bottom of sample tubes, the system performs a special external rinse in the external rinse positions. The system also rinses the inside of the probe to remove plasma, red blood cells, and reagents in order to prevent contamination.
- The de-bubbler module removes any bubbles from the system liquid used in the pipetting system.
- Software monitors processing and post-processing allowable times for time sensitive assay steps and will invalidate results if exceeded.
- A filter in the liquid supply prevents the system from pipetting particulate material. Clogged probes result in high-pressure errors.

Incubator

Purpose

The incubator provides the appropriate environment for the incubation steps of the assays performed on the instrument. The incubator is located to the right of the reader at the back of the instrument.

How It Works

The incubator comprises 15 individual positions. These are divided into two different temperature zones—a room temperature zone (6 positions) and a 37°C zone (8 positions)—and a neutral insulator zone that separates the two different temperature zones.

The thermodynamics of the 37°C incubator bays require an actual temperature of 39°C to yield a test well temperature of 37°C. Each heating plate incorporates its own software controlled temperature sensor. The position between the temperature zones is intended as an insulator and cannot be used for incubation. This insulator is an active peltier element that inhibits heat transfer from the warmer to the cooler zone.

The incubation positions are heated from above and below by resistance foils integrated into the aluminum plates that separate the positions.

A flap, to retain heat, covers the opening of each position. Each flap opens individually to allow the transport system to slide in or remove a plate. Plate carriers are held securely inside the incubator by magnets at the back of each position.

Limitation: Laboratory ambient temperature and humidity affects the room temperature incubation bays, and an elevated ambient room temperature may disrupt assays that need to be incubated at specified temperature ranges, as published in the relevant package insert.

Incubator Photograph

The photograph below shows the incubator.

Safety Features

The incubator is equipped with the following safety features:

- Integrated sensors monitor the temperature and the presence of plates in each position.
- Sensors monitor the open/closed status of the front flaps.
- The heating power of the foils is limited so that even after a severe error leading to complete loss of temperature control, the system can only reach a maximum temperature of 70°C.
- Instrument software monitors and controls incubation time.
- The temperature distribution over a plate during incubation is less than 1°C from average. Results are invalidated if temperatures exceed the desired range.
- The instrument software does not permit the start of an assay that requires ambient temperature incubation if the incubator is too hot or too cold.

Washer

Purpose

The washer performs all plate-washing cycles required for an assay protocol.

Washer Module

The washer, located in the back of the instrument, comprises the wash head assembly, the pumps, the plate loading frame, and the overflow and prime troughs.

The transport system slides plates in plate carriers into the washer. Two magnets at the back of the washer ensure that the plates are correctly and securely positioned.

The wash head assembly, which moves left to right above the plate, aspirates liquid from the plate wells, and dispenses clean system liquid into them as required by the assay protocol. The wash head assembly comprises eight pairs of aspirating/dispensing needles. The aspirating needles are longer than the dispensing needles. The wash head assembly is lowered into the plate wells for each aspiration or dispensing step.

The priming trough is located on the left-hand side. The wash head assembly dispenses into this trough during washer priming. Aspiration of the priming liquid runs continuously through the aspiration function of the wash head. When the wash head assembly is not in use, it is positioned in the priming trough. The priming trough includes a Liquid Level Sensor (LLS) board that verifies liquid is at the expected level during aspiration and dispense checks. An alarm will be generated if the LLS detects an abnormality.

If a spill occurs because of an error, the overflow trough catches the spilled liquid. The overflow trough is equipped with a sensor mat that issues an alarm and stops the washer should the liquid fall into the trough during processing.

Safety Features

The washer is equipped with the following safety features:

- An integrated sensor monitors the pump for correct operation.
- A priming trough that is fitted with a Liquid Level Sensor (LLS) to ensure that spilled liquids are detected. The LLS is involved in wash verification and the detection of manifold failures.

- An overflow trough that catches spilled liquid.
- A liquid overflow detection mat is located below the plate washing area so that manifold fluid leaks over the washing area can be detected. A software error is generated if fluid is detected.
- Closed containers house potentially bio-hazardous waste materials. All connectors that could come in contact with bio-hazardous waste are fitted with check valves to prevent liquids from dripping upon disconnection.
- A priming step to flush bubbles from the lines prior to each plate wash.
- A manifold aspiration and dispense verification check is performed before and after every plate wash to make sure each well is washed and aspirated.
- Monitoring of system liquid levels that alerts you when the volume is low.
- The system monitors waste liquid level and alerts you when the volume is high and the container needs to be emptied.
- The instrument will not use the system liquid if the level sensing device is not connected.
- Monitoring of plate positions into and out of the washer. You are alerted of any jams.

Centrifuge

Purpose

The centrifuge module is located on the left-hand side of the NEO Iris as a detachable unit and performs two functions:

- The centrifuge spins the plates with g-forces up to 1200 xg.
- The centrifuge shakes the contents of the plate wells to resuspend sedimented red blood cells.

The centrifuge-loading unit to the left of the loading tower is a functional part of the centrifuge that transfers the plate from the main instrument into the centrifuge.

How It Works

Centrifugation - Plates can have different weights depending on the assay performed and whether the plate is fully or partially used. The centrifuge must be balanced at all times. The system achieves the balance by constantly monitoring the vibrations caused by the centrifugation. If the vibrations exceed a certain threshold, the system performs a balancing step during which it adjusts a counterweight to minimize vibration level while the centrifuge is spinning at constant speed. The system then further accelerates to the assay-defined g-force. The rotor is the arm in the centrifuge that spins the plate.

Shaking – The centrifuge module can also shake plates in order to mix the well contents.

Centrifuge Photograph

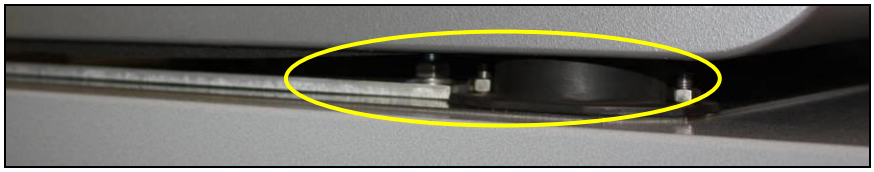
The photograph below shows the centrifuge.

Decoupling of the Centrifuge

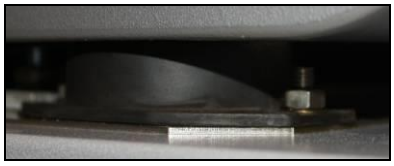
Centrifuge decoupling describes the physical separation of the centrifuge module from the main instrument. The decoupling of the centrifuge from the main instrument is done to alleviate centrifuge balancing problems that subsequently generate periodic balancing timeout errors. These timeout errors stop processing.

Decoupling is visible to you by the presence of

- a metal base plate beneath the centrifuge (circled in yellow in the photograph below), and



- black rubber feet in all four (4) bottom corners of the centrifuge.



Note: The rubber feet provide a flexible mounting for the centrifuge.

The use of decoupling helps to provide

- better vibration adjustment by the NEO, and
- reduction of vibration transfer to the main instrument, thereby reducing such vibrations from being transferred to the pipetting system and other modules of the main instrument.

Note: If you encounter balancing timeout errors, you should call Technical Support to report them regardless of the fact that your centrifuge has been decoupled.

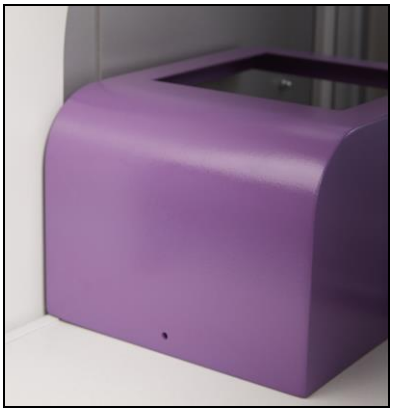
The following warning applies to your interactions with the centrifuge that has been decoupled from the main instrument.

Warning: You must not bump, knock, rest up against or otherwise come into physical contact with the centrifuge module because you may cause balancing errors or centrifuge loading and unloading issues. By causing these errors or issues, you could therefore interfere with assay processing. No items should be stored on top of the centrifuge cover including, but not limited to, sample or reagent racks, books, documents or other laboratory consumables and supplies.

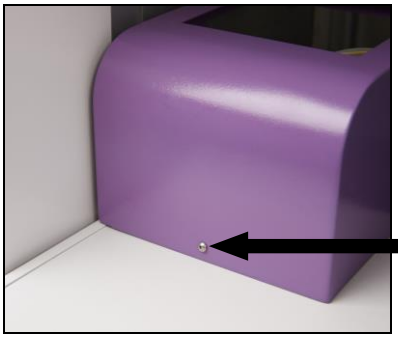
Safety Features

The centrifuge is equipped with the following safety features:

- The centrifuge is entirely enclosed within a containment barrier during operation.
- The centrifuge rotor housing withstands complete rotor disintegration at full speed with only minor dents. No parts will leave the housing.
- Integrated vibration sensors continuously monitor the centrifuge. Excessive vibrations activate the emergency brake of the centrifuge.
- Sensors monitor the centrifuge loading door and service hatch. The centrifuge cannot spin unless both doors are closed.
- The software monitors centrifuge speed. It flags too high and too low speed conditions.
- The centrifuge loading unit (CLU) has a plexiglass window in the top of the cover so that any CLU problems can be viewed by the operator without the need to remove the CLU cover.



- The CLU cover is fixed by a single rounded Allen head screw and an associated washer, in addition to VELCRO® fasteners, so that it is only removable by using a tool (2.5 mm Allen key). This is to prevent operator access to the inside of the centrifuge in the event of complete loss of software control leading to the centrifuge spinning and the loading door falling open. The screw (with the washer) is located on the lower middle of the front of the cover.



- The centrifuge is located on top of the cabinet with small foot risers to incorporate additional stability.
- The software will alert the user if there is an error loading or unloading a plate into the centrifuge.

Camera Reader

Purpose

The reader module is located in the rear of the instrument and takes an image of the plate.

How It Works

The reader uses Complementary Metal-Oxide Semiconductor (CMOS) cameras to take an image of the plate from underneath. The system calculates a value for each well based on a multi feature image analysis.

Limitation: The NEO Iris must be switched on at least 30 minutes prior to the first plate read to allow the reader lamp to warm up. Reading of plates prior to completion of this warming period can cause incorrect negative reading of weakly positive reactions.

Camera Reader Photograph

The photograph below shows the camera reader position with the door closed.

Safety Features

The camera reader is equipped with the following safety features:

- Potential air bubbles and foaming in the wells (where the camera takes an image) are minimized by the pipetting system, by use of the de-bubbler module and optimized aspiration/dispense procedures. Air bubbles in the test wells are located on the perimeter and do not interfere with reading of results.
- If the reader is unable to take an image the plate will automatically be aborted.
- The software recognizes incorrect plate placement and will not take an image if it is in the incorrect orientation.

Disposal Information

Liquid Waste

All liquid waste is collected in the common waste container located in the cabinet.

Warning: The liquid waste is potentially biohazardous material. Always wear protective gloves and clothing when handling the liquid waste. If any liquid waste is spilled, clean it up immediately following the standard practice of the laboratory.

Empty the common waste container using the procedure described in **Chapter 10 – Maintaining the NEO Iris**. Dispose of the contents according to the laboratory guidelines.

Solid Waste

The only solid waste produced by the NEO Iris is used plates and consumed liquid reagent vials.

Warning: Used plates and consumed liquid reagent vials contain potentially biohazardous material. Always wear protective gloves and clothing when handling used plates. If any liquid from a plate is spilled, clean it up immediately following the standard practice of the laboratory.

Plates are returned to the loading tower after they have been processed. Remove the plates from the loading tower and dispose of them according to the laboratory guidelines.

Note: Only remove plates from the loading tower when the indicator LED for that position is orange or flashing green.

Empty reagent vials can be disposed of after removing the reagent rack from the instrument.

Note: Only remove racks from the loading bay when the indicator LED for that position is orange or flashing green.

Chapter 3: System Software Navigation

In This Chapter

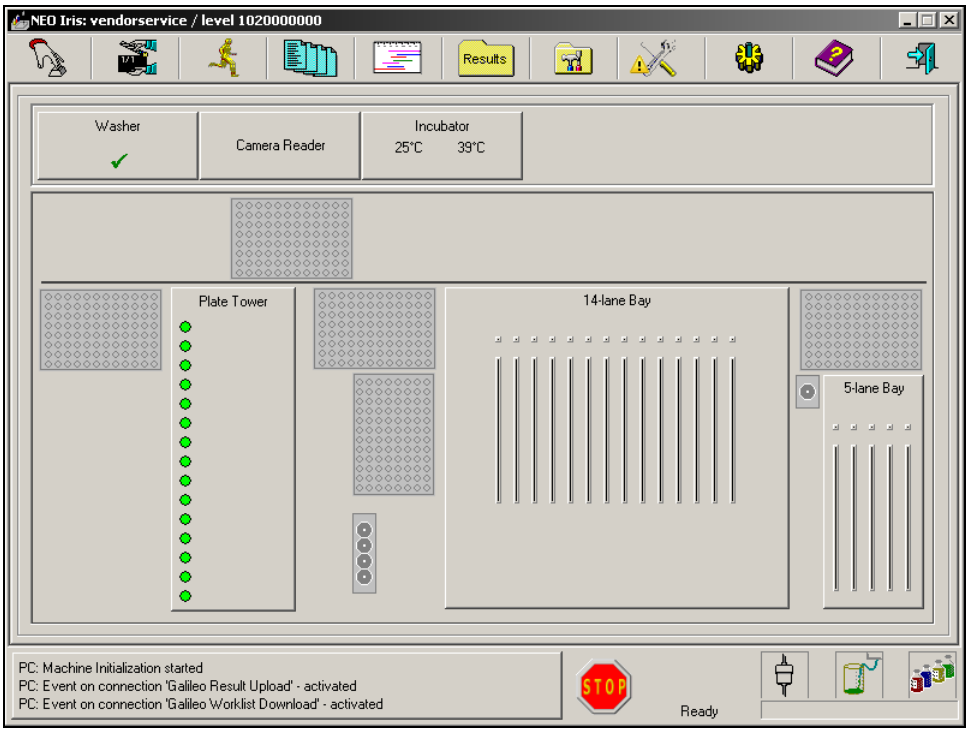
This chapter describes the NEO Iris software.

Navigation

Screen Layout

Main Screen Components

The instrument's graphical user interface, the Main Screen, reflects both the structure of the instrument and the pattern of the workflow. This makes it easier to navigate through the software as well as providing important information when relevant.



The screen is divided into three areas:

Main Menu Bar

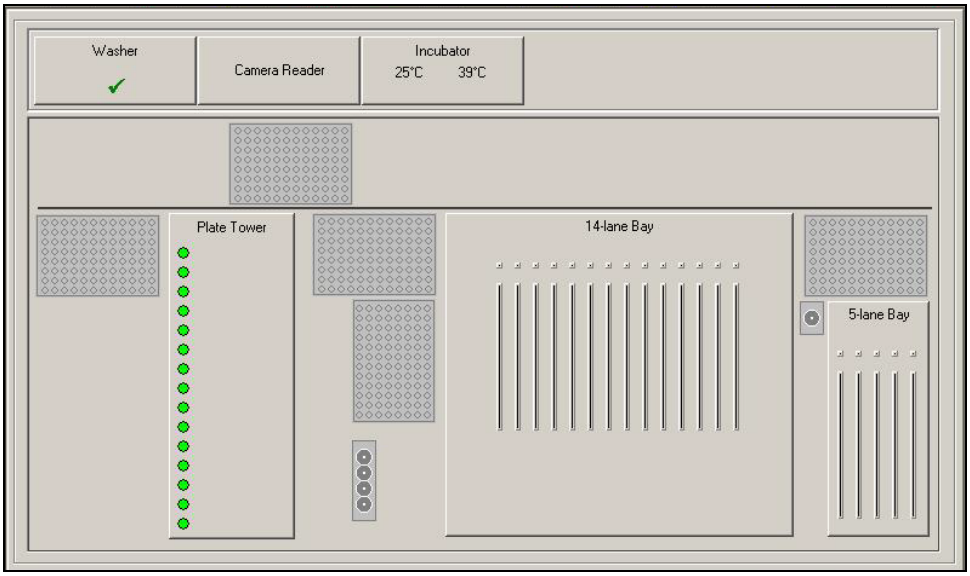
Machine Monitor

Status Bar

Main Menu Bar

The Main Menu Bar at the top of the screen provides access to system dialogs. You use the system dialogs to program system settings, perform maintenance, start an assay run, log in to and out of the system, and exit the system.

Machine Monitor



The Machine Monitor, below the Main Menu Bar, is the primary display area.

The Machine Monitor is a graphical top view of the instrument that provides an overview of the status of the modules and access to the module dialogs. You use the module dialogs to view and edit information about the module. For complete information about the Machine Monitor and the module dialogs, refer to Machine Monitor later in this chapter.

Status Bar

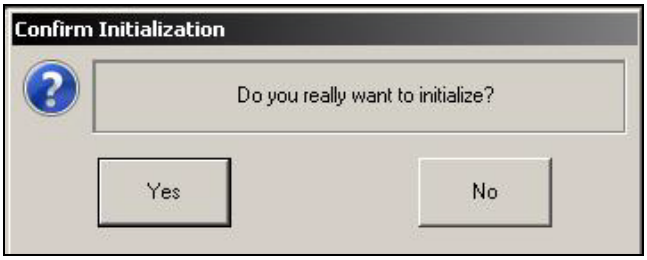
The Status Bar at the bottom of the screen is always visible, and provides an overview of the system status. The Status Bar includes, from left to right, a Log List button, the NEO Iris Emergency Stop button, some wording that indicates the overall status of the NEO Iris and three system status indicators.

The Log List button on the left side of the status bar displays a list of the last actions performed by the system. Press the Log List button to display the Log List dialog, which displays a full log list.

For more information about the Log List, the Emergency Stop button, the wording that indicates the overall status of the NEO Iris and the three system status indicators, refer to **Using the Status Bar** later in this chapter.

Confirmation Dialogs

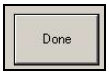
Confirmation dialogs are safety features in the operating software. The system displays these dialogs after you request certain actions.



The software prompts you to confirm that you wish to continue with the action. You must either click **Yes** if you want to continue or click **No** if you do not want to continue.

Common Buttons

The following buttons are standard command buttons used throughout the software. They always have the same function.

Button	Description
	Close the dialog and save any changes made.
	Close the dialog without saving any changes.
	Close the dialog.
	Print information from the dialog.

Navigation Options

Keyboard and Trackball

The PC uses a standard keyboard and trackball mouse. You can use the keyboard to type alphanumeric characters into the field and to navigate through the software.

To navigate through the software using the keyboard, press the **Tab** key on the keyboard to move from one element in the dialog to the next. Press **Enter** to execute the action of the element currently selected.

Selected?	Button	Text Box
Not selected		
Selected		

You can press the **Print Screen** key on the keyboard to print a paper copy of whatever area of the instrument software you are currently accessing on the computer monitor.

Touch Screen

The touch screen enables you to interact directly with the software. Most elements that you can access using the keyboard and mouse can also be accessed using the touch screen.

To use the touch screen, simply touch the element or button on the screen that you want to use, such as a menu bar button, list box, text box, or action button.

Note: When touching the screen, be sure to tap or press gently, and do not press excessively. Excessive or prolonged cumulative screen pressure can misalign the screen's responsiveness to touch or cause other issues such as software freezes.

When to Use

Throughout this manual, when you are instructed to click or press an element or button, you can do one of the following:

Touch the element or button directly on the screen.

Use the trackball to place the pointer over the item and click the left trackball button.

Use the **Tab** key to move through the dialog box to the element needed and press **Enter**.

For example, to display the *Login* dialog, click (or touch) the **Login** button on the Main Menu Bar.

Main Menu Bar

About the Main Menu Bar

Main Menu Bar icons

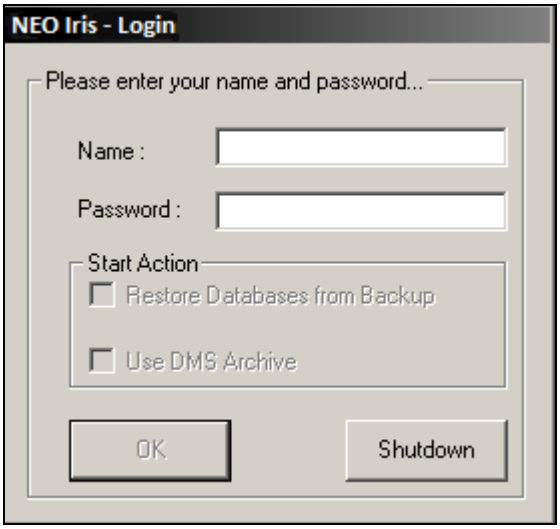
The table below describes the icons in the Main Menu Bar.

Icon	Name	Description
	Login	Allows you to log in to the system.
	Initialize Instrument	Allows you to initialize the instrument.
	Start Run Assistant	Provides an intuitive guide throughout the procedures necessary to start an assay run.
	Worklist Editor	Allows you to view, edit and request tests for samples in the software.
	Plate Status List and Graphical Schedule	Displays data about all plates that have been processed. You can also search for, view and delete plate data.
	Result Viewer	Allows you to view test results.
	Maintenance	Allows you to view and activate automated maintenance checks.
	Utilities	Allows you to view event logs and statistics, as well as archive and print reports.
	Instrument Settings	Allows you to program the system settings in order to configure the instrument to the individual needs of the laboratory.
	Version Information/Operator Manual/Help	Displays the electronic operator manual on the instrument computer. Also displays a list of the modules and software used on the instrument.
	Shutdown	Guides you through the procedure that you must perform before the system is shut down.

Logging In

The Login dialog allows you to log in to the system. Click the **Login** button on the Main Menu Bar to log in.

The system displays the Login dialog.

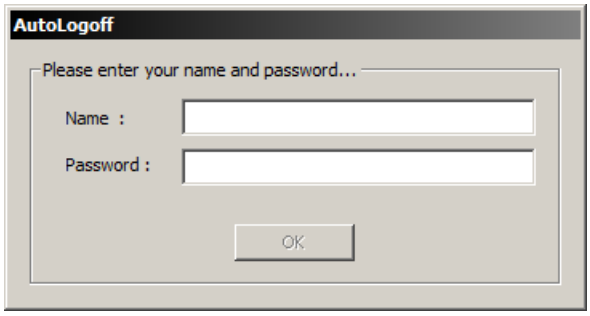


Once you are logged in, you can click the Login button again to log out. The system also displays the Login dialog during system startup.

The **Login** dialog contains the Name and Password fields. As soon as you type at least one character in both fields, the dialog activates the OK button.

The **Shutdown** button is only accessible at first login. This allows you to shut down the computer if start up was accidental.

Note: The system can be configured to perform an automatic Logoff (Option available in Instrument Control Software version 1.8 and higher). The software will activate an **AutoLogoff** locking screen after a certain period of inactivity (in minutes). The duration of the inactivity period prior to Auto Logoff is configured by Immucor personnel.



The **AutoLogoff** dialog contains the Name and Password fields. As soon as you type at least one character in both fields, the dialog activates the OK button.

Click the **OK** button to unlock the system.

For information about how to log in to the instrument, refer to **Logging In, Chapter 5 – Instrument Start-Up**.

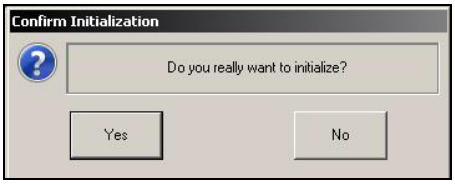
For information about setting user names, passwords, and access rights, refer to **Assigning Passwords and User Access Rights** in **Chapter 4 - Security**.

Initializing the Instrument

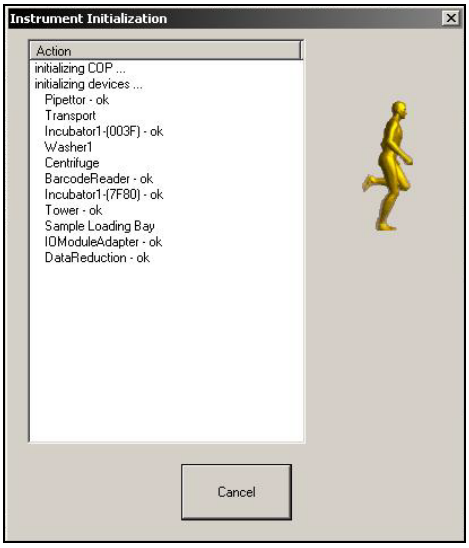
The **Initialize Instrument** button allows you to initialize the NEO Iris. Initialization is used to perform critical equipment verifications and resets prior to allowing the NEO Iris to be used for the necessary maintenance tasks and subsequent assay processing. Initialization resets the whole system, primes all tubing, returns all modules to their home positions, and moves any plates on the NEO Iris back to the plate loading tower.

Press the **Initialize Instrument** button to initialize the NEO Iris.

The system displays the *Confirm Initialization* dialog for you to confirm initialization.



The *Confirm Initialization* dialog is closed by pressing the **No** button. The *Instrument Initialization* dialog is displayed by pressing the **Yes** button of the *Confirm Initialization* dialog. The *Instrument Initialization* dialog sequentially lists all individual initialization activities in the *Action* list as they are performed by the NEO Iris.



Once initialization is complete, the *Instrument Initialization* dialog is no longer displayed. Initialization can be stopped prior to its completion by pressing the **Cancel** button of the *Instrument Initialization* dialog.

The system automatically initializes each time you turn on the NEO Iris. However, it may be necessary to request initialization manually, for example, after leaving the instrument in standby for a long period, or as a last method to recover from a fatal error situation that you cannot otherwise correct.

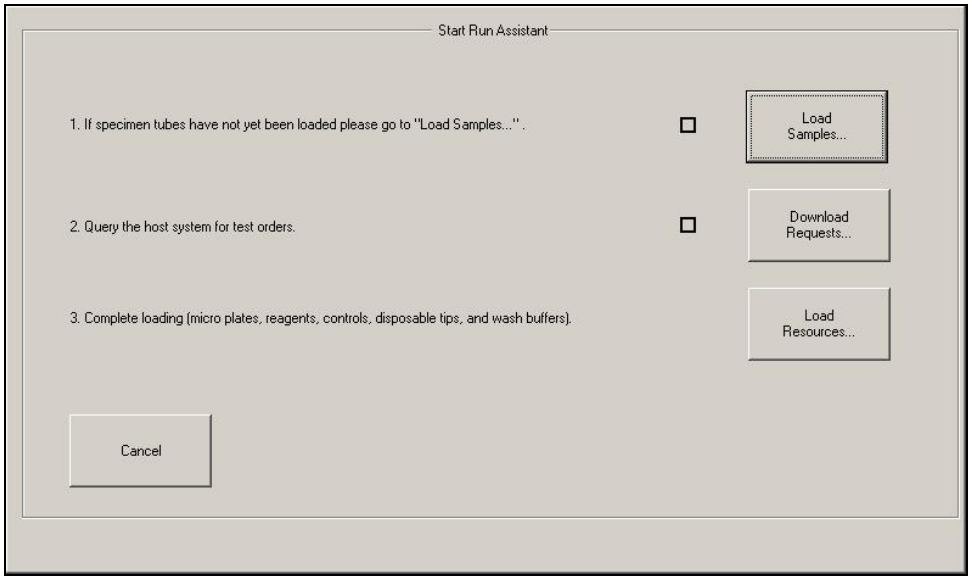
Note: During initialization, the system deletes all reagent and sample rack information. You must reload the racks before starting the next run.

Start Run Assistant

About the Start Run Assistant

The *Start Run Assistant* dialog provides an intuitive guide through the procedures necessary to start an assay run. Click the **Start Run Assistant** button.

The system displays the *Start Run Assistant* dialog.



The *Start Run Assistant* dialog presents you with three preparation stages:

Load samples.

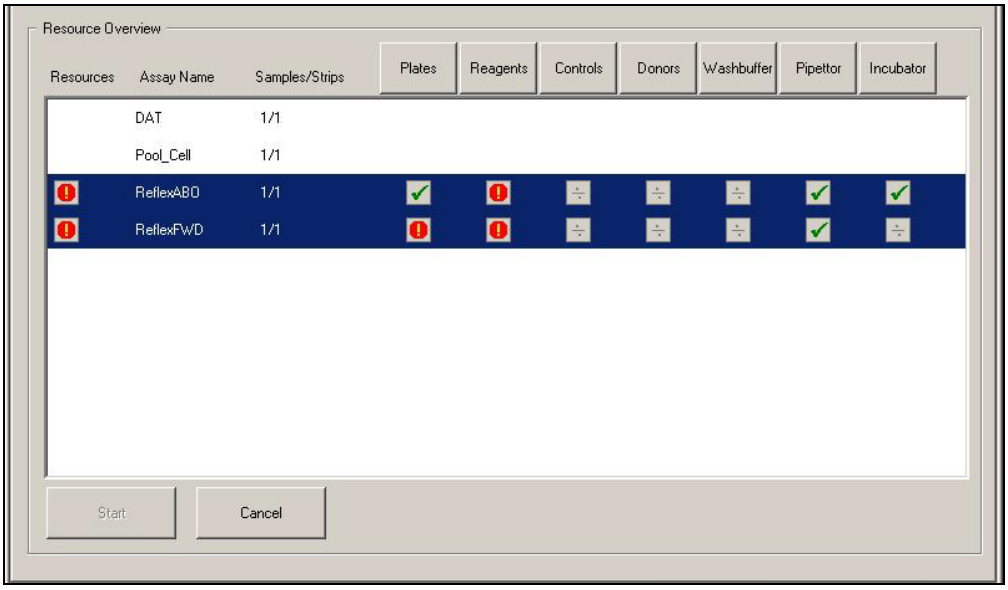
Download requests from the host Laboratory Information System (LIS).

Load Resources.

Refer to **Chapter 6 – Instrument Testing Operation** for more information about the Start Run Assistant.

Resource Overview Window

The *Resource Overview* window provides an overview of the consumables required to run all the assays requested for the samples loaded on the instrument. Click the **Load Resources...** button on the *Start Run Assistant* dialog to display the *Resource Overview* window.



How It Works

The system groups all test orders for the loaded samples onto plates. Each line in the dialog corresponds to one plate. Based on the Samples/Strips column, you can decide to start the plate or not.

To select a plate to be run, click in the corresponding line. The line highlights blue, and the system performs a resource check for all consumables needed to run that plate. If the system displays a red exclamation mark after selecting an assay, you can check the corresponding resource by clicking the button above each column. If you can use the resource loaded on the system, the system displays a green checkmark .

During scheduling, or if the resource is not used for the requested assay, the system displays a gray division sign in the column below the named resource.

Resource Overview Window Columns

The *Resource Overview* window displays a table with ten columns. When all Resources fields are either blank or have a green check mark displayed, you can click the Start button to start the run, otherwise the **Start** button is unavailable. The system generates a processing schedule (after start is selected) and a shopping list (if an item is deficient). Both are available to you.

The table below describes each of the columns in the *Resource Overview* window:

Column	Description
Resources	A summary of the resource check. If all required resources are present, the system displays a green checkmark  . If resources are missing or user maintenance is due, the system displays a red exclamation mark. 
Assay Name	The name of the assay to be run.
Samples/ Strips	The number of samples and strips assigned to that plate.
Plates	If the assay is sample driven, the system displays each sample request in this list. If there is no plate present, the system displays a red exclamation mark.  If a plate is present, the system displays a green checkmark  . If the assay is plate driven, every plate loaded in the loading tower generates a request for that plate. Clicking the **Plates** button at the top opens the **Loading Plate** dialog.
Reagents	If all reagents necessary for the assay are loaded, the system displays a green checkmark  . Clicking the button at the top accesses the 5-lane reagent loading bay.
Controls	If all controls are loaded, the system displays a green check mark.  Clicking the **Controls** button accesses the 14-lane loading bay.

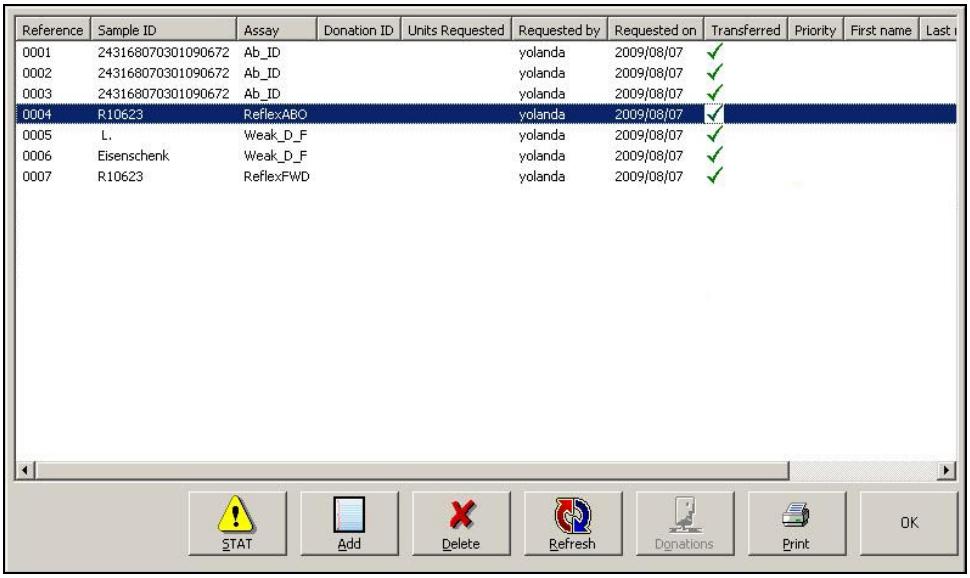
Column	Description
Donors	In all assays except the crossmatch and antigen screening assays, the system displays a gray division sign. If all requested donors are present for an assay, the system displays a green check mark.  Clicking the **Donors** button accesses the 14-lane loading bay.
Washbuffer	If the system displays a red exclamation mark  , you must check for the presence or absence of system liquid. You must also click the **Initial Prime** button on the **Wash Buffers** dialog for the specified buffer container.
Pipettor	If the system displays a red exclamation mark, the system liquid is empty or the waste is full.  In this case, refill the system liquid or empty the waste. Clicking the **Pipettor** button displays a more detailed description of what actually caused the error.
Incubator	If the system displays a red exclamation mark, the temperature in the incubator slots is out of range for the temperature zone required in this assay.  Clicking the **Incubator** button accesses the **Incubator** dialog.

Work List Editor

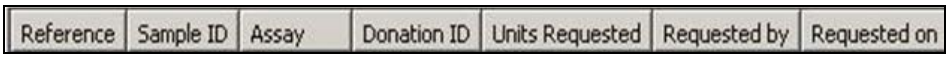
About the Work List Editor

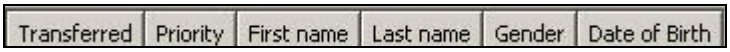
The *Work List* dialog allows you to manually view, edit, and request tests for samples in the software. Click the **Work List** button on the Main Menu Bar.

The system displays the *Work List* dialog.

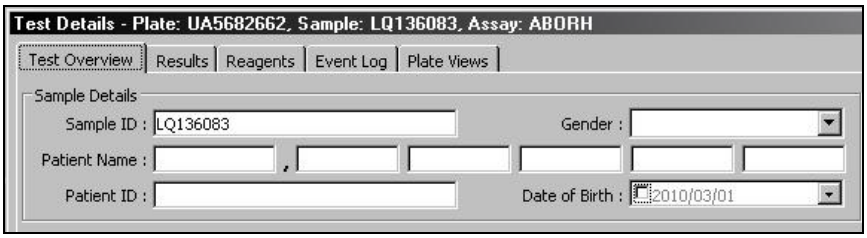


Column headers are displayed that describe various facets of the worklist entries. The column headers are shown below.





Patient demographic details will only be displayed under the relevant columns for a given sample if the patient already has one or more sample results stored on the computer hard drive and those demographic details have been manually entered on the *Test Overview* tab display of the sample result *Test Details* dialog for those previous sample(s). The **Gender** drop-down list allows for selection of *Male* or *Female*. The **Date of Birth** drop-down list allows for the selection of a date from a navigable calendar. The *Last name* of the patient name should be entered into the first field of **Patient Name** and the *First name* should be entered into the second field of **Patient Name**. Additional fields of **Patient Name** allow for the entry of middle names or other naming conventions.



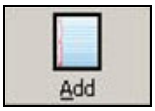
The window of the *Work List* dialog displays the work list entries. The order of these entries can be changed if one of the header descriptions is preferred as a sorting mechanism. For example, by pressing the **Sample ID** header, the order of all of the entries in the window will be rearranged according to alpha-numeric sample order.

The activity buttons are located at the bottom of the *Work List* dialog.

Note: The *OK* button is inactive when the *Refresh* button is pressed, and it remains inactive until the *Refresh* button task is completed.

Work List Editor Buttons

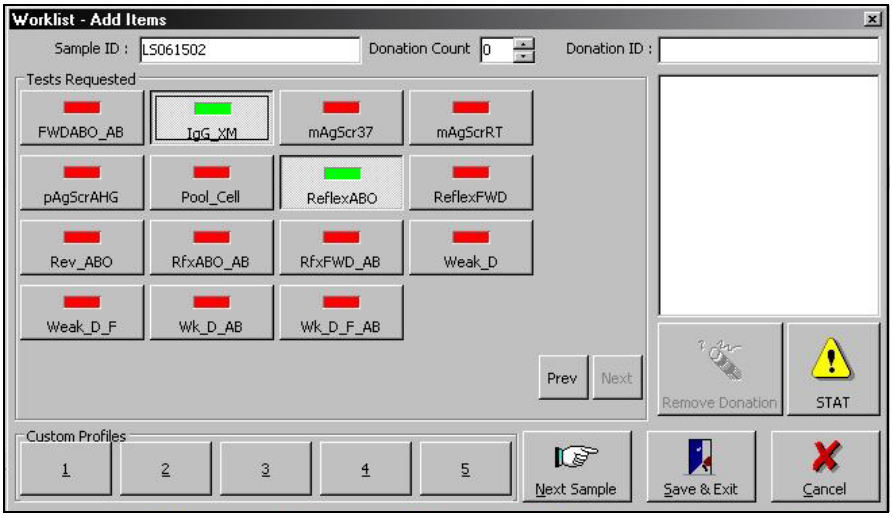
The table below describes the buttons in the *Work List Editor*.

Button	Option	Description
	STAT	Facilitates the ability to assign status of STAT to work list entries. A small version of the icon will be displayed under the *Priority* column if this status is applied to a specific sample or samples. **Note**: STAT priority cannot be removed using this button.
	Add	Display the *Worklist–Add Items* dialog.
	Delete	Delete a selected item. The system prompts you for confirmation. The default button in this dialog is the **No** button. Pressing the **Enter** or **Esc** key while in the dialog results in nothing being deleted. When no items are selected, the **Delete** button is unavailable. Pressing the **Delete** key on the keyboard has the same effect as pressing the **Delete** button.

	Refresh	Refresh the worklist. This has no effect on the automatic, timer operated refresh operations or their frequency. The **Refresh** button is always available.
	Donations	Add or delete donor IDs for crossmatch tests. This button is only available when you have selected a crossmatch test master entry, which specifies the sample ID and the number of donations. When you click the **Donations** button, the system displays the *Worklist–Add Items* dialog.
	Print	Print the contents of the worklist. The system displays the *Print* dialog. If you have selected lines, the system prints only those lines. If you have not selected any lines, the system prints the entire worklist. The **Print** button is always enabled.
	OK	Method to exit dialog back to the Machine Monitor.

Worklist-Add Items

The system displays the *Worklist–Add Items* dialog when you click the **Add** button from the worklist. Use this dialog to specify new worklist entries.



In the case of crossmatch and other similar assays, the system disables the Sample ID, test selection buttons, all **Custom Profiles** buttons, and the **Next Sample** button in the *Worklist–Add Items* dialog. Only Donation Count, Donation ID, donation list box, **Remove Donation**, **Save and Exit**, and **Cancel** are available. The title of the dialog becomes *Worklist–Add Donations* instead of the default *Worklist–Add Items*. The Donation ID is the first field with focus.

Worklist-Add Items fields and buttons

The table below describes the fields and buttons in the *Worklist – Add Items* screen.

Field	Description
Sample ID	Use the Sample ID field to identify the sample. The system automatically displays the cursor in this field. It contains the sample ID of the selected line from the *Worklist* dialog if any lines were selected when you clicked the **Add** button from the worklist. If no lines were selected, the input line for Sample ID is blank.
Donation Count	Use the Donation Count field to specify how many donors can be crossmatched. The default for this box is blank. The field has an up-down control with a range of 0 to 99. The control also works with the arrow cursor keys. This field is disabled if no crossmatch test is selected.

Field	Description
Donation ID	Use the Donation ID field for crossmatch testing by entering the donor unit identification numbers. Beneath the entry is a list box that contains the donation list. The list box is a multiple-selection type list box. This field is disabled if no crossmatch test is selected.
Enter	Press the Enter key from the Donation ID text box to perform the following sequence: 1. The system adds the item in the Donation ID field to the multiple-selection list box below it. If the entry already exists in the list box, the system does not add it again, but highlights the existing entry. 2. The system highlights the new item in the list box. 3. The system clears the Donation ID field. 4. The system places the text cursor in the Donation ID field. 5. If adding a donor causes the number of donors to exceed the donor count, the system displays a warning dialog box.
Remove Donation	Click the **Remove Donation** button to delete the selected entries. If the list box is empty, or no list item is selected, the **Remove Donation** button is unavailable.
STAT	Use this button to assign the status of STAT to the added entry.
Test Buttons	The *Worklist – Add Items* dialog contains a special button for each test. Each button contains the short name for the test and an indicator light. The light is red for unselected tests and green for selected tests. Additionally, the button is in a pressed state when selected and a raised state when not selected. All test buttons are initially red when the system opens the dialog. Pressing a button toggles it between selected and not selected.
Next/Prev	If there are more tests than can fit in the dialog, the **Next** and **Prev** buttons enable you to scroll through the complete set of available tests. The **Next** button is disabled when there are no more tests to display. The **Prev** button is disabled when there are no preceding tests to display.
Custom Profiles	The dialog contains **Custom Profiles** shortcut buttons that control which assays are selected. Click one of these buttons to select a particular profile of assays. When you click a custom profile button, the system selects every assay associated with that custom profile and excludes all other assays.

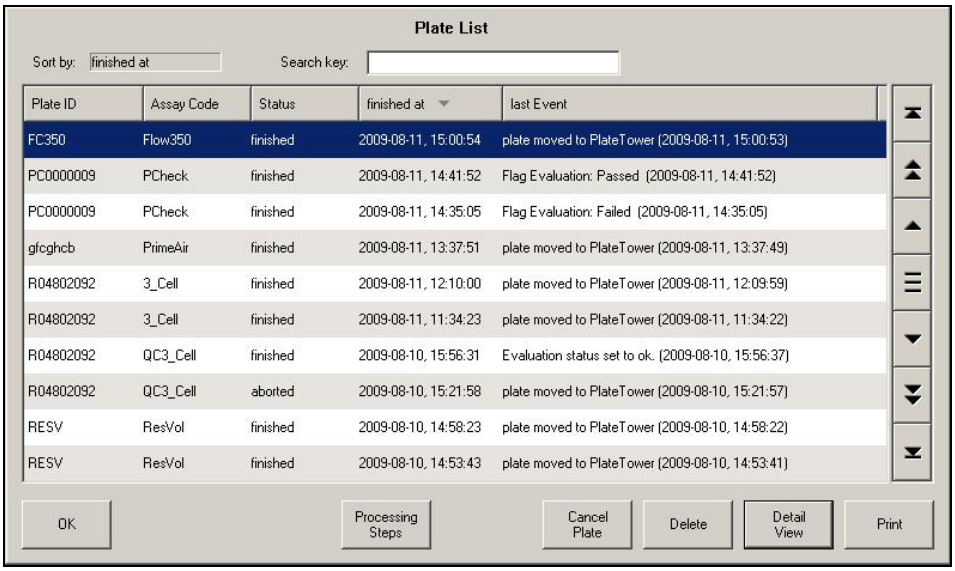
Field	Description
Next Sample	Click the **Next Sample** button in the Worklist–Add Item dialog to perform the following actions: 1. The system saves the current information to the worklist. 2. The system clears the Sample ID. 3. The system places the text cursor in the Sample ID field. 4. The system clears the Donor Count. 5. The system clears the Donor ID. 6. The system clears the Donations list box. 7. The system deselects all tests (red). The **Next Sample** button is unavailable whenever the Sample ID is blank or no tests are selected.
Save & Exit	Click the **Save & Exit** button to close the dialog, save the current changes, and add the request to the worklist. The **Save & Exit** button is unavailable if the Sample ID is blank or if no check boxes are selected.
Cancel	Click the **Cancel** button to close the dialog without saving the current changes. Pressing the **Esc** key has the same effect as pressing the **Cancel** button.

Plate List

About the Plate List

The *Plate List* dialog displays data about all plates that have been processed. You can also use this dialog to search for, view, and delete plate data. Click the **Plate List** button.

The system displays the *Plate List* dialog.



The *Plate List* dialog is divided into three areas:

Information area at the top

Plate status list in the middle

The buttons at the bottom

Information Area

The information area at the top of the dialog includes the **Sort by** field. The *Sort by* field displays the name of the column that the Plate List is currently sorted by. To change the content of the *Sort by* field, click on any of the column headers to sort the list by that column. The column header name appears in the *Sort by* field.

Plate Status List

The plate status list displays all plates that have been processed. The system database stores all plate data until the plates are deleted. The plate status list contains five columns:

Plate ID - displays the ID of the plate.

Assay Code - displays the assay code of the assay that the plate performs.

Status - displays the status of the plate, such as on board, active, and finished.

finished at - displays the time the system completed the results or when they are expected.

last Event - displays a short description of the last event that the plate has been put through.

Click the button at the top of each column to sort the list by that column. The Sort by field in the information area displays the name of the column that the list is currently sorted by.

There are seven navigation buttons on the right of the plate status list that can be used to move through the list. The following navigation buttons are available:

Button	Description
	Go to the beginning of the plate list.
	Go to the previous page of the plate list.
	Go to the previous entry in the plate list.
	Select this button to mark multiple entries. Using this button, you can print, cancel or delete all marked entries as a group.
	Go to the next entry in plate list.
	Go to the next page of the plate list.
	Go to the end of the plate list.

Buttons

In addition to the common **OK** button, the **Print**, **Processing Steps**, **Delete**, **Detail View** and **Cancel Plate** buttons are also available.

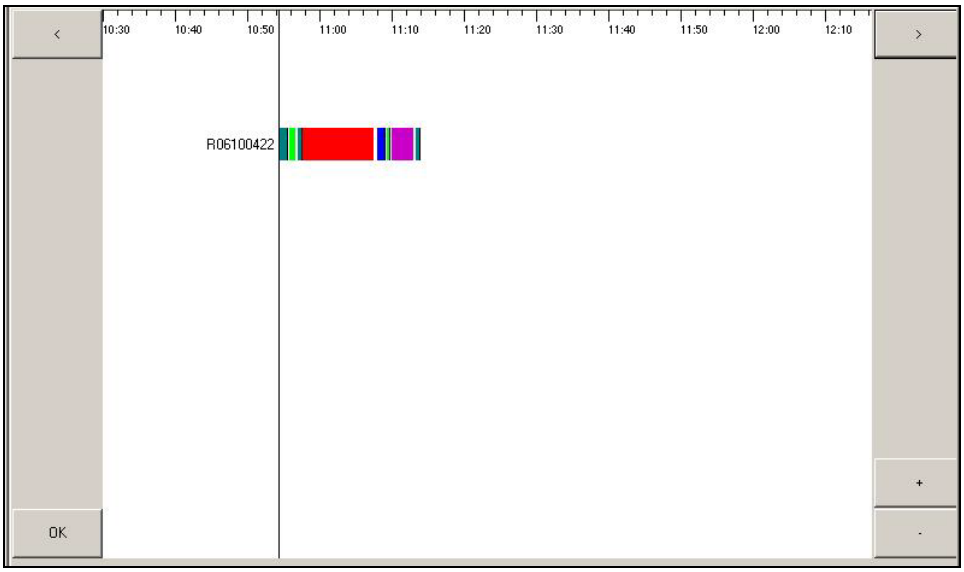
100000 access rights

Less than 100000 access rights

This **Print** button is only displayed and accessible if the user has 100000 security access rights. This **Print** button is not displayed if the user does not have 100000 security access rights.

This **Print** button is used to resend selected plate results to the data management software if the initial automated attempt at delivery failed. This failed delivery becomes apparent if the **Plate List** shows a given plate as finished without errors, but this plate does not display with results in the **Results** dialog. A printed copy of the results is generated when the selected plate results are resent using the **Print** button and a confirmation of the data being sent is added to the event log in the status bar (logged with the specific plate identification).

Processing Steps



Press the **Processing Steps** button to view a detailed graphical representation of the assays running on the instrument since the last initialization and that are scheduled for processing. The software displays each assay horizontally, with the plate name to the left of the multicolored bar. Each line corresponds to a slot in the plate loading tower. The time scale is represented using the sliding scale located at the top of the scheduler window. The current time is represented by the moving vertical line, moving from left to right horizontally.

The following buttons are also available:

Button	Description
<	Press this button to scroll left through the schedule.
>	Press this button to scroll right through the schedule.
+	Press this button to expand the scale displayed (more detail).
-	Press this button to reduce the scale displayed (less detail).
OK	Press the **OK** button to exit the scheduler, back to the *Plate List*.

The graphical representation uses different colors to symbolize different assay stations. The colors used are:

Color	Description
	(Charcoal gray) The start of plate processing is delayed before it was originally due to be picked up from the plate loading tower.
	Plate barcode scanning
	Transport
	Pipetting steps. The left and right pipettors use the same color.
	Incubation at room temperature
	Incubation at 37°C
	Plate washing step
	Centrifuging or shaking of a plate
	Camera reading

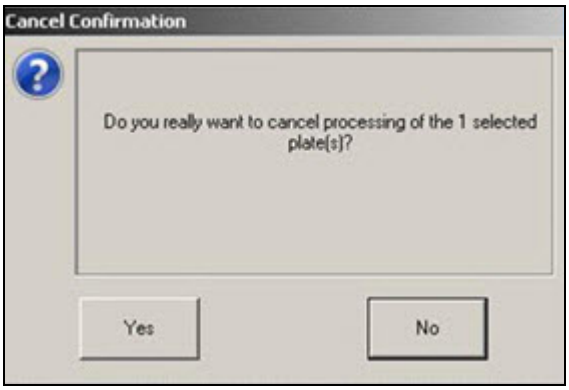
Delete

Press the **Delete** button to delete a plate and all of its results from the database. The information cannot be retrieved again.

Note: It is not possible to delete plates run as part of a maintenance task from the Plate List.

Cancel Plate

Press the **Cancel Plate** button to cancel a plate from the database. Select the plate(s) to be cancelled and then press the **Cancel Plate** button. A confirmation dialog will appear that must be acknowledged using the **Yes** or **No** button before the plate will be cancelled.


Cancel Confirmation
Do you really want to cancel processing of the 1 selected plate(s)?
Yes
No

Detail View

Press the **Detail View** button to display the *Detail* dialog. The *Detail* dialog displays more detailed information about the plate selected. The *Detail* dialog has six different tabs displaying different information details:

General Information

Assay Protocol

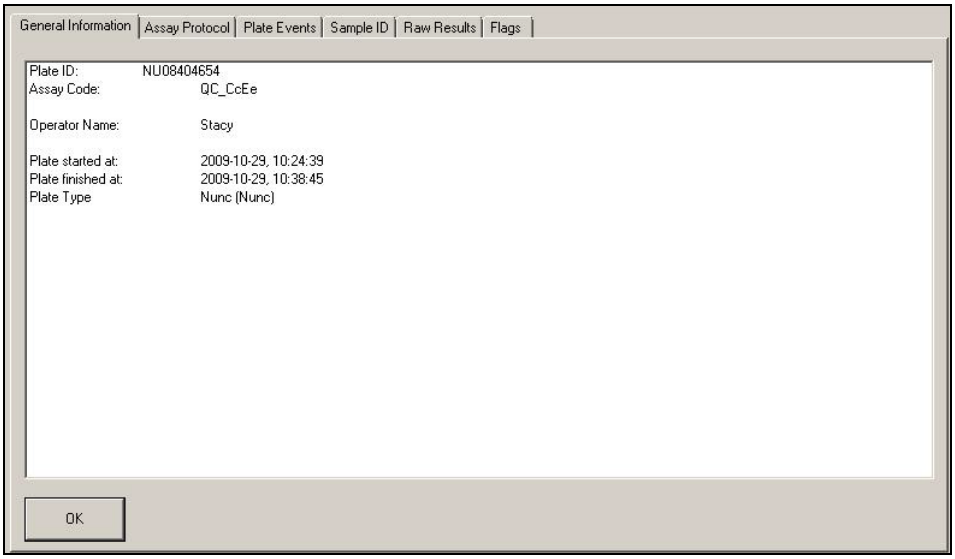
Plate Events

Sample ID

Raw Results

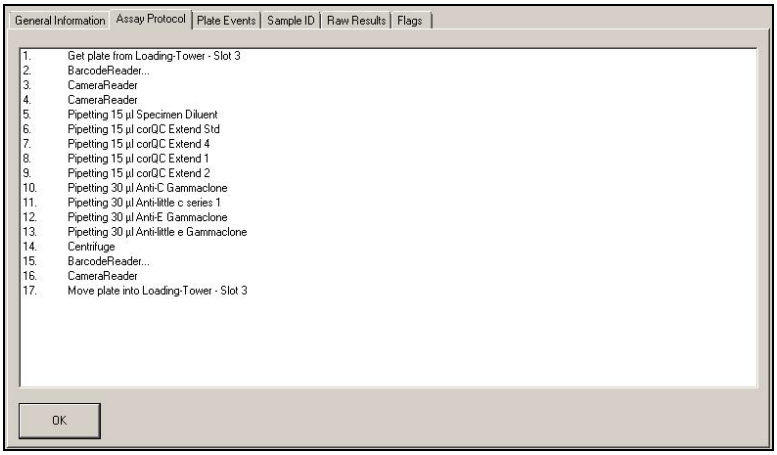
Flags

General Information Tab



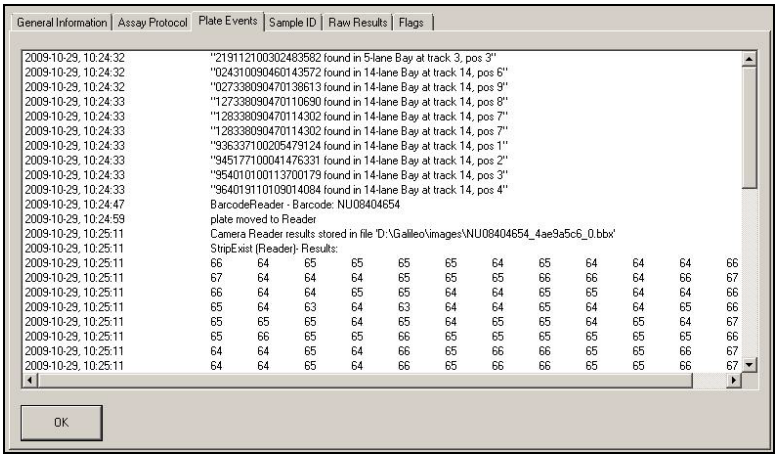
The *General Information* tab displays basic information about the plate. This information contains the plate ID, the assay code, the operator name, date and times when the plate is scheduled to start and finish, the type of the plate, and the manufacturer of the plate. Note that the times are not the times when the plate actually starts and is finished, but the times when it is scheduled to start and finish.

Assay Protocol Tab



The *Assay Protocol* tab displays the single steps of the assay in a concise form. The *Assay Protocol* tab serves as a short assay description and displays all of the protocol steps as defined when the assay was performed.

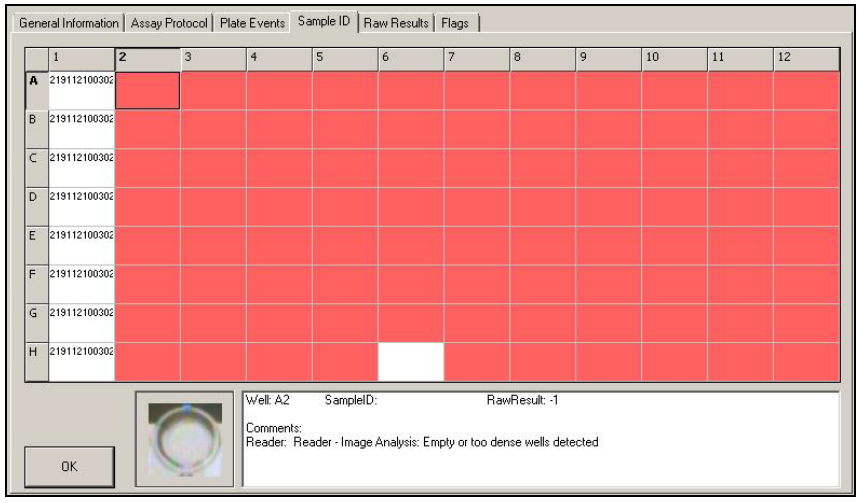
Plate Events Tab



The *Plate Events* tab displays a log of all events the plate has been through. The event log displays the time each event took place and specific information about the modules where the event took place, for example, ***Pipettor: Not enough Liquid LISS***. The plate events are not the planned or expected stations in the assay (as displayed under the *Assay Protocol* tab), but are recorded logs of what actually happened to the plate at a particular time.

Limitation: The timestamps for assay plate events that occur simultaneously with the end of Daylight Saving Time (DST) may not accurately reflect the actual time of those events, and it is not possible to predict what these timestamps will display due to their erratic nature. However, in this instance, the assay is successfully completed and the results are unaffected. These erratic timestamps are limited to the end of DST. By running the instrument initialization after the end of DST, the time stamping process is corrected. The timestamps for assay plate events that occur simultaneously with the beginning of DST are accurate and do not exhibit the same erratic features as the timestamps at the end of DST.

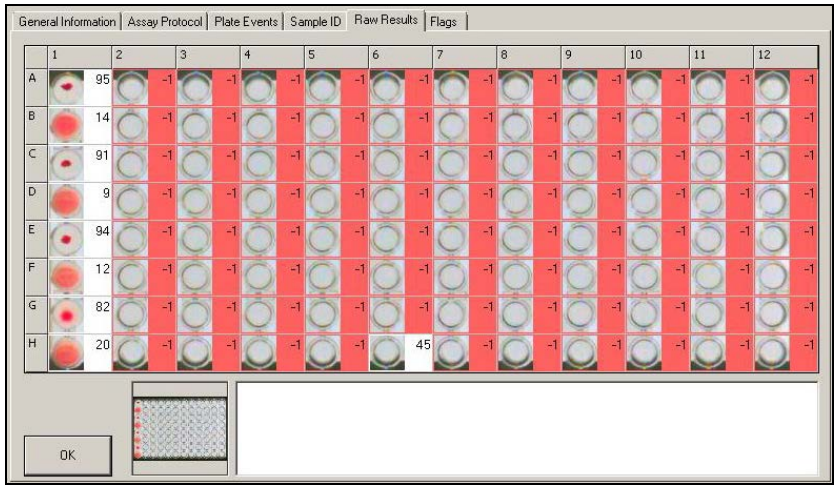
Sample ID Tab



The *Sample ID* tab displays a grid in which each cell represents a plate well; well A1 is in the top left-hand corner. The tab displays the ID of the sample pipetted into each well in the corresponding grid cell. If a well was used for a control or blank measurement, the system also displays it.

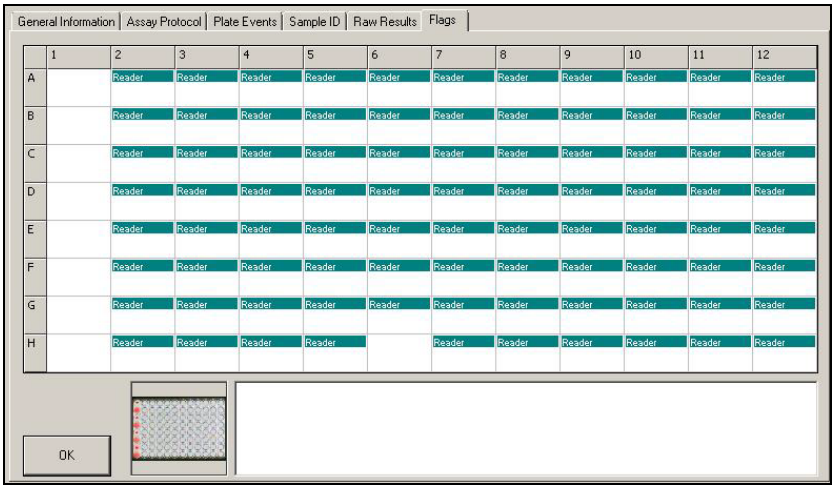
On this and other windows that display a grid, clicking on a cell displays more detailed information on that sample or control in the detail window to the right of the **OK** button. Details include well, sample ID, raw result, and any comments. To the right of the **OK** button is a small, complete image of the plate displayed.

Raw Results Tab



The *Raw Results* tab shows a grid in which each cell represents a plate well; well A1 is in the top left-hand corner. The tab displays the raw values from the analysis of the pictures made by the camera reader. The values vary between –2 and +100, where a negative value is an error code. A result marked in red is flagged. You can see the flag when you press on the results well image.

Flags Tab



The *Flags* tab displays a grid in which each cell represents a plate well; well A1 is in the top left-hand corner. The tab displays all flags assigned to the measured result in the corresponding grid cell. The tab displays a message in the large field at the bottom that explains the specific error message when you click the flag in the cell. This method explains all error flags.

Test Results

About Test Results

To view test results, click the **Results** button.

The system displays the *Results* screen, with the most recently used screen view (sample or plate).

From the *Results* screen, you can:

View Test Results in Sample View

View Test Results in Plate View

Refer to **Chapter 7 – Test Results** for more information regarding test results.

Before You Begin

Limitation: Validate Method is otherwise known as reflex testing. Reflex testing can only be ordered once per assay in response to results for a given sample number. The instrument WILL NOT order reflex testing again if that sample (with the same barcode) is repeated with the same assay on the instrument at a later phlebotomy date. This may cause incomplete test results to be indicated as final and made available for export.

For example, when a sample is run and assigned the result of A Pending, the reflex testing procedure orders the reflex assay of Weak_D. If the sample tests positive for Weak D, then the final result of A Weak D will be released. A few days later, another sample with the same barcode is tested on the instrument and the result of A Pending is assigned again. However, on this occasion, the instrument WILL NOT order the reflex assay of Weak_D, and this second result of A Pending will be the final result. The historic and latest final results are not identical.

This limitation also applies to the reflexive ordering of antibody ID testing for antibody screen positive samples. The consequence is that the second antibody identification test in the history of a given sample number will not be ordered for the second antibody screen positive sample, and so on for subsequent samples.

After the instrument database is archived and the data is removed from the database, the reflex testing procedure will again order a reflex assay on a given sample ID that requires it, because the current sample ID is again new to the instrument software.

Limitation: After the reflex testing procedure begins on a sample ID, the value of the result element not being resolved is not updated. For example, if a sample ID is run using the ReflexABO assay and is assigned the result of B NTD, the reflex testing procedure will order a repeat of the ReflexABO assay to resolve result element 2 (the Rh result). If the result from this repeated ReflexABO assay is O Rh Positive, the reflex testing procedure will continue and the current result would be B Rh Positive. The ABO result of O that was determined during the repeat testing is not considered for incorporation into the final result.

Note: You must review any test results that have an associated warning flag (⚠) through Results. This is to determine if any causes for the warning flag justify any instrument corrective actions. Consultation with Technical Support may be required.

Maintenance

About Maintenance

The *Maintenance* dialog allows you to view and activate automated maintenance actions. Click the **Maintenance** button.

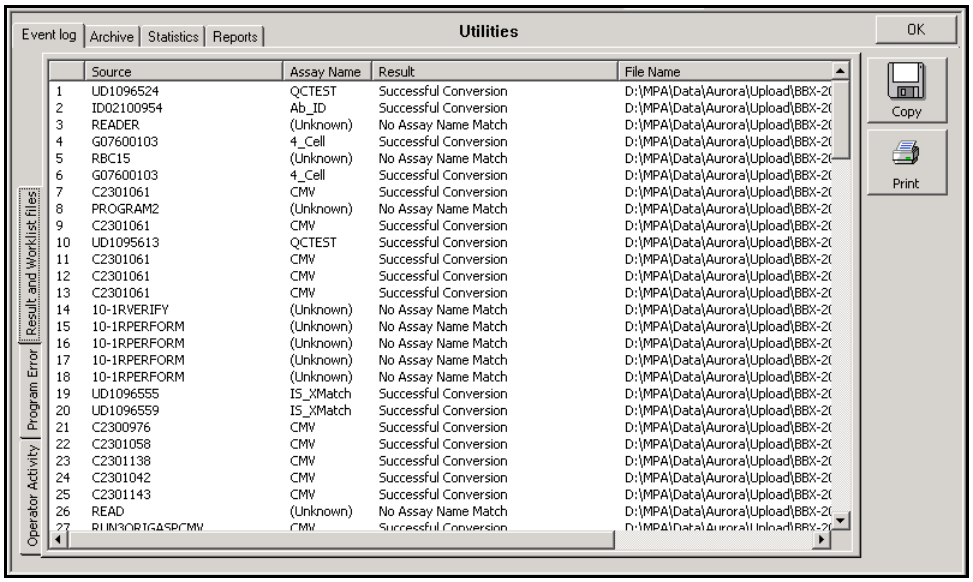
Refer to **Chapter 10 – Maintaining the NEO Iris** for more information regarding the *Maintenance* dialog.

Utilities

About Utilities

The *Utilities* dialog allows you to view event logs and statistics, as well as archive and print reports. Click the **Utilities** button.

The system displays the *Utilities* dialog.



The Utilities dialog is divided into four tabs:

Event Log

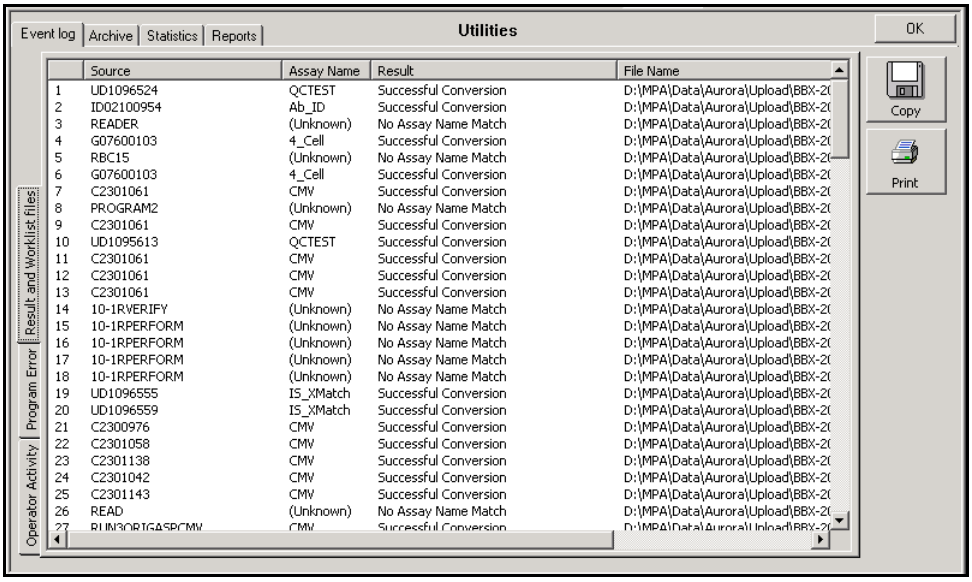
Archive

Statistics

Reports

Note: There may be a delay when entering the Utilities dialog before the screen is populated. This is related to the number of entries in the event log. Wait until the screen fully loads before selecting another tab.

Event Log tab



The *Event Log* allows you to view the event log, copy it to a disk, or print it.

The *Event Log* contains a list box with a separate vertical tab for each log (**Result and Worklist files**, **Program Error** and **Operator Activity**). The system populates the list box with the contents of the log you select. Initially, no lines are selected. If you click on a line to highlight it (blue) and then click **Copy** or **Print**, only the selected lines are copied or printed.

Column headers are displayed that describe various facets of the event log entries. The column headers are shown below.

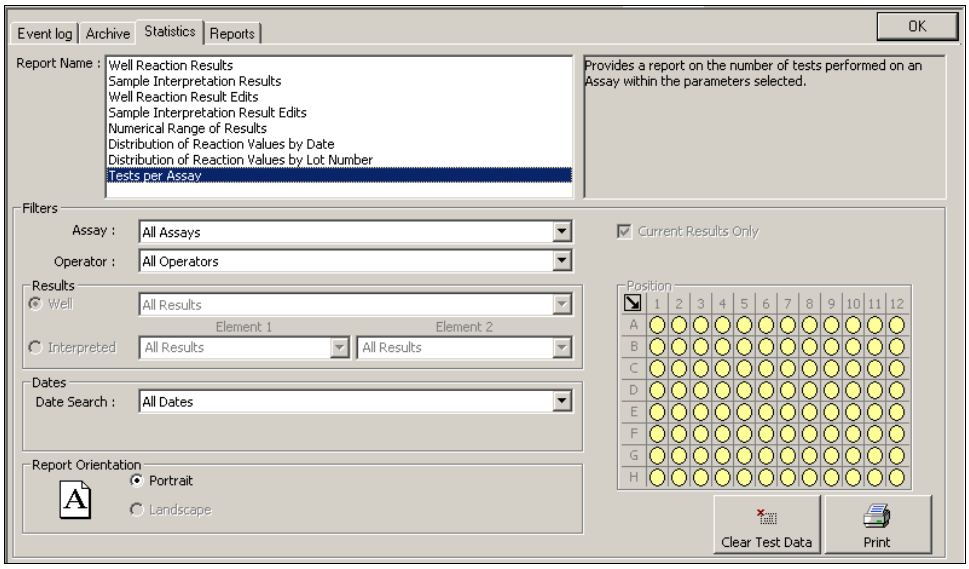
The window of the dialog displays the event log entries. The order of these entries can be changed if one of the header descriptions is preferred as a sorting mechanism. For example, by pressing the **Assay Name** header, the order of all of the entries in the window will be rearranged according to alpha-numeric assay name order.

Archive tab

Refer to **Chapter 10 – Maintaining the NEO Iris** for information regarding the creation of archives.

Limitation: In the event of an instrument computer hard drive crash, all data will be lost from the computer. Any data that was not previously archived will be lost.

Statistics tab



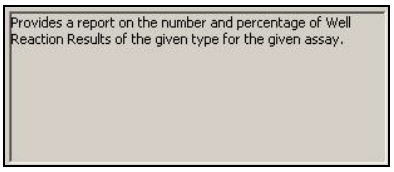
Limitation: Other than the Test per Assay Report, the outputs from the *Statistics* tab within the Utilities dialog must be verified on site by the end user. Immucor makes no claims as to the accuracy of those outputs.

The *Statistics* tab enables you to select from and customize the available statistical reports. You can customize the reports using the *Filters* options. Only data stored on the NEO Iris computer that remains after any previous archiving procedures can be used as a resource for generating statistical reports.

The **Report Name** list box contains the available statistical reports. The list includes **Tests per Assay** which prints a summary of the number of tests processed per assay. The list is:

- Well Reaction Results
- Sample Interpretation Results
- Well Reaction Result Edits
- Sample Interpretation Result Edits
- Numerical Range of Results
- Distribution of Reaction Values by Date
- Distribution of Reaction Values by Lot Number
- Tests per Assay

Whichever of the report names is selected from the *Report Name* list, a brief description of that report is displayed in an open area of text to the right of the report list and below the **OK** button. The example shown below is for the *Well Reaction Results* report.

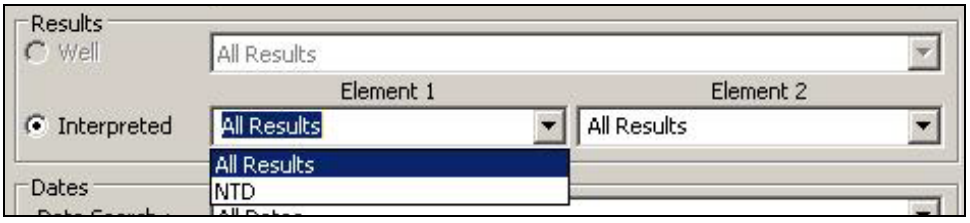


The **Assay** drop-down list contains each available assay name, including *All Assays*. You can indicate which assay type to include in the report. *All Assays* is the default.

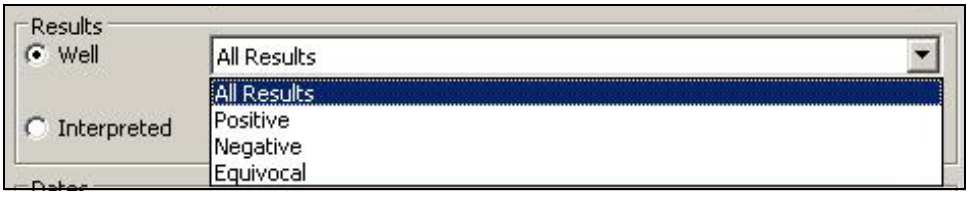
The **Operator** drop-down list contains each available operator ID, including *All Operators*, which is the default.

The **Results** area has two (2) options, *Well* and *Interpreted*. Each option is only available if an appropriate type of report is selected from the *Report Name* list. For example, if the *Well Reaction Results* report is selected, then both options are made available for use. If the *Sample Interpretation Result Edits* report is selected, then only the *Interpreted* option is made available for use. If the *Tests per Assay* report is selected, then neither option is available for use.

For each option, there is a drop-down list. *Interpreted* has two (2) drop-down lists, *Element 1* and *Element 2* that contain each pre defined result type, including *All Results*. This allows you to specify the types of results to include in the report. *All Results* is the default.



Well has one (1) drop-down list that contains defined well reaction categories, including *All Results*. This allows you to specify the types of well results to include in the report. *All Results* is the default.

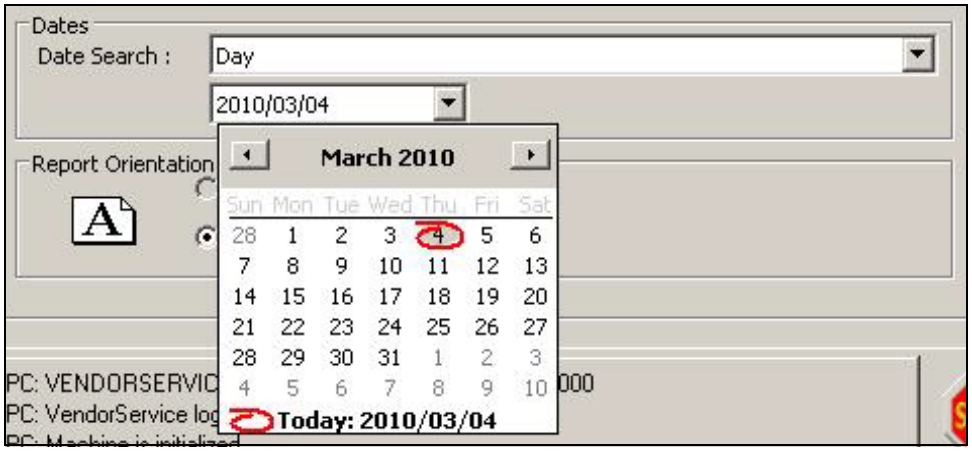


The **Position** area contains a plate map graphic. The system displays selected wells with a green background and a check mark and non-selected wells with a yellow background and no check mark. Click on a well to toggle it from available to unavailable. Click on a row letter or column number to toggle the entire row or column. Click the *Select All* indicator (◪) in the upper left of the plate graphic to select the entire plate. These settings indicate which wells to include in the report.

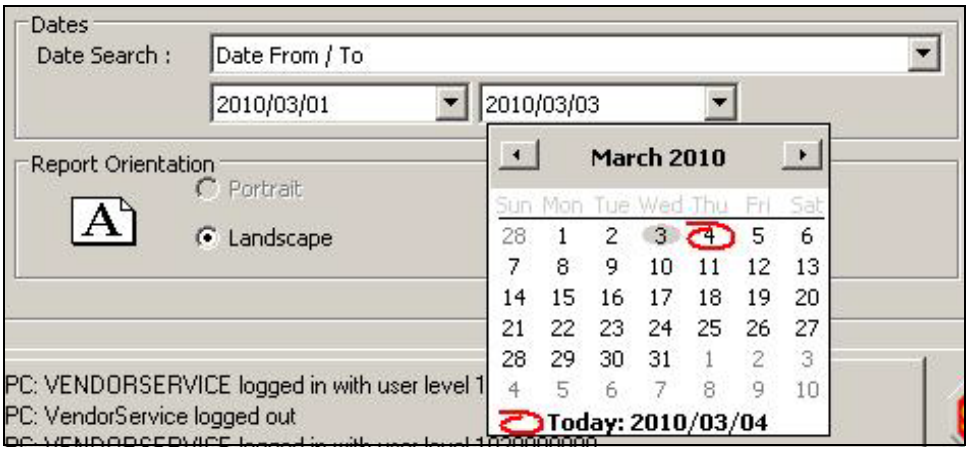
The **Date Search** drop-down list allows you to specify dates for data isolation. The default is *All Dates*. Other options are *Year*, *Month*, *Day*, *Year to Date* and *Date From/To*. Some options have additional date filtering mechanisms that appear in the *Dates* area. The *All Dates* and *Year to Date* options have no additional date filtering mechanisms. If you select the *Year* option, an additional list is made available to allow you to select a specific year.

If you select the *Month* option, an additional drop-down list is made available to allow you to select a specific month.

If you select the *Day* option, an additional calendar is made available to allow you to select a specific day.



If you select the *Date From/To* option, two (2) additional calendars are made available to allow you to set up a date range. If a *From* date is selected from the calendar on the left that occurs after a selected *To* date from the calendar on the right, then both dates are automatically adjusted to reflect a logical date range, which may not be the range you intended to use.



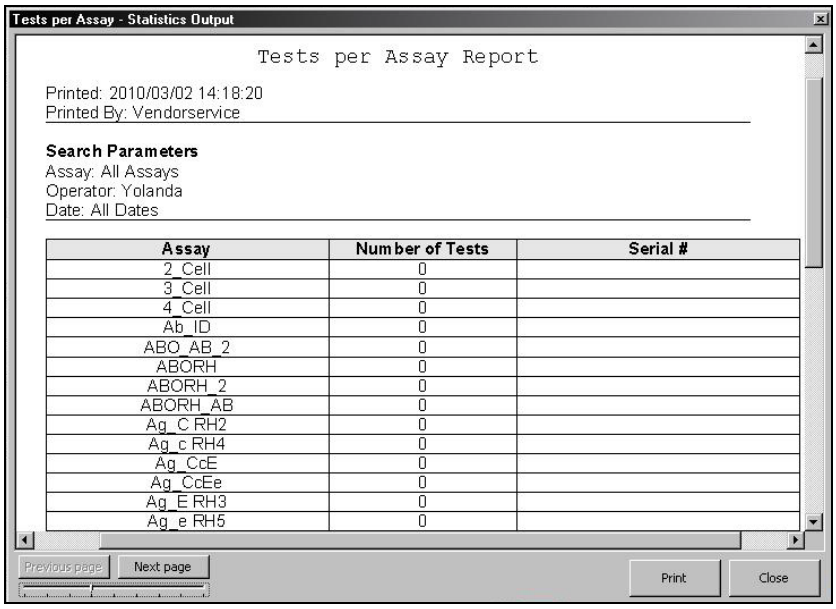
Report Orientation allows most statistical reports to be printed as either **Portrait** or **Landscape** format by selecting either of the two radio buttons. For some reports, one of the two radio buttons is preselected according to the report name chosen.

The **Current Results Only** checkbox determines if the report is only populated with current results. All report selections, with the exception of **Sample Interpretation Results**, have the checkbox configuration fixed. The **Current Results Only** checkbox for the **Sample Interpretation Results** option can be checked on or off.

The **Clear Test Data** button, located next to the **Print** button, is only visible and available when the **Tests per Assay** report is selected and if you have access to the button within your security setup.

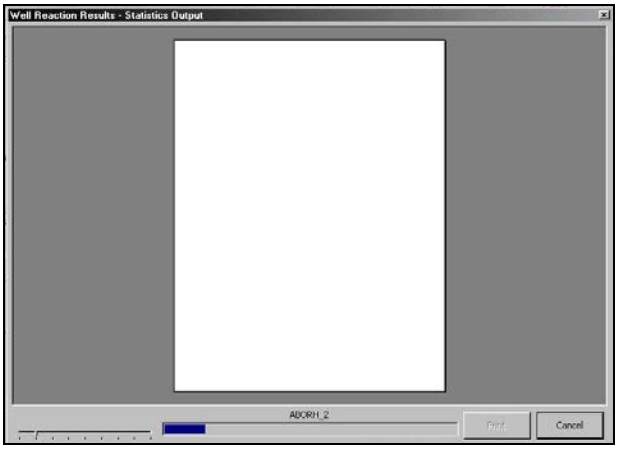
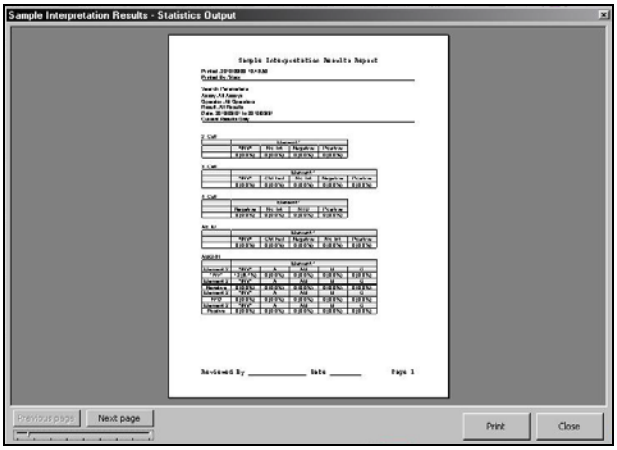
The **Clear Test Data** button is used to delete data because this database is not cleared during the archive process. Clearing the test data should be performed at a regular interval after the data has been analyzed. Refer to **Chapter 10 – Maintaining the NEO Iris** for details of this maintenance task.

The *Tests per Assay Report* prints a summary of the number of tests processed per assay based on the search range chosen. You can narrow the search by assay, operator and/or date range. This report prints a summary of the number of tests processed per assay. The database that contains these details is separate from the NEO Iris result databases and the data remains in the database after archiving. This enables the *Tests per Assay Report* statistics to be printed independent of the scheduled archiving tasks. A sample report is shown below.


Tests per Assay - Statistics Output
Tests per Assay Report
Printed: 2010/03/02 14:18:20
Printed By: Vendorservice
Search Parameters
Assay: All Assays
Operator: Yolanda
Date: All Dates
Assay
Number of Tests
Serial #
2_Cell 0
3_Cell 0
4_Cell 0
Ab_ID 0
ABO_AB_2 0
ABORH 0
ABORH_2 0
ABORH_AB 0
Ag_C RH2 0
Ag_c RH4 0
Ag_CcE 0
Ag_CcEe 0
Ag_E RH3 0
Ag_e RH5 0
Previous page
Next page
Print
Close

Printing Statistics

To print statistics:

Step	Action
1	After you select the report and filters, and then press the **Print** button, the system displays a preview window with a progress bar showing each assay, one after another. 
2	When the system completes the statistical report, you can view the report before printing.  With the slider bar in the bottom left corner you can enlarge or minimize the preview. Click **Print** to display the system print dialog and print the report.

Reports tab

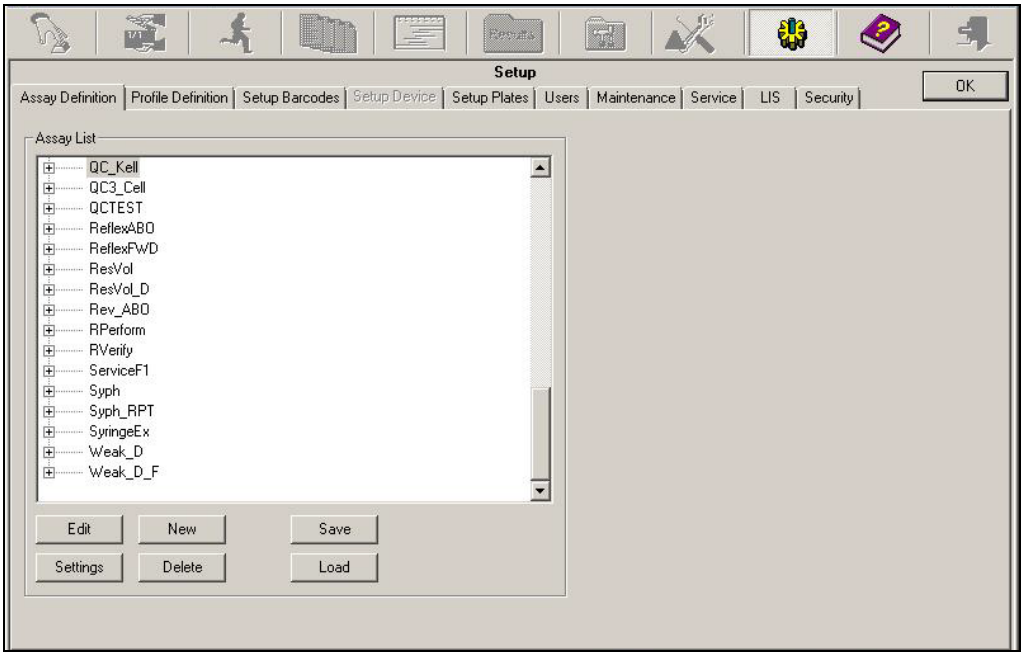
The **Reports** tab is an area to configure the upload pathways of instrument report formats. This area is only available with the correct user access rights. Refer to **Chapter 8 – NEO Iris Reports** for details of report formats.

Instrument Settings

About Instrument Settings

The *Instrument Settings* dialog allows you to program the system settings in order to configure the instrument to the individual needs of the laboratory. Press the **Settings** button.

The system displays the *Instrument Settings* dialog.



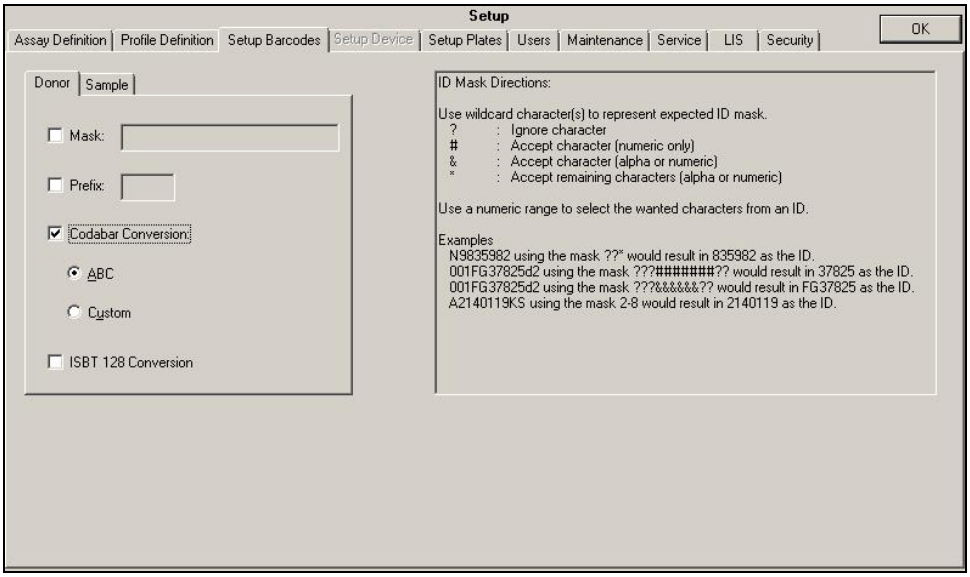
Note: The Settings button is not available for access when the instrument is actively processing samples and plates or is initializing, regardless of your security access level. This prevents the changing of settings during instrument activity.

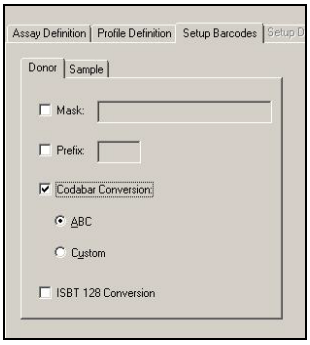
Access to different tabs is controlled by user access rights and some tabs are limited to Immucor personnel only. Operator accessible functions are described below.

From this dialog, you can program user names, passwords, and access rights. For complete instructions, refer to **Assigning Passwords and User Access Rights** in Chapter 4 - Security.

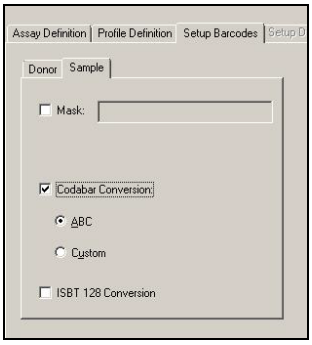
Barcode Settings Configuration

Under the Setup Barcodes tab of the Setup dialog, you can configure barcode features by checking or clearing check boxes or radio buttons for both Donor and Sample barcode information. By checking a box or selecting a radio button, you make that particular feature active.





Donor



Sample

Mask: Is used to define how a barcode is manipulated and is governed by how characters from the legend are combined. Masking is an alternative flexible method to manipulate the barcodes.

? means to Ignore a barcode character.

(Digit) means to use a barcode character if it is a digit.

& means to use Any character.

* means to use All remaining characters.

2–9 is an example of a numeric range that defines which characters are to be used. This number range can be customized.

The following ISBT 128 barcode data is an example of masking. If the mask was set at ?2-14, then the ISBT 128 barcode of =G07359931656200 would be masked to G073599316562. Additional examples are listed in the explanatory text displayed on the Setup Barcodes tab.

You can add a prefix to the barcode data by entering the desired prefix into the **Prefix:** field. The maximum number of characters that can be entered into the prefix field is five. **Prefix** is only available on the **Donor** tab.

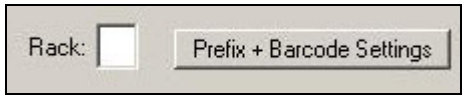
Note: Only one prefix per rack can be added at any one time.

Warning: You must be careful to make sure that the samples in one given rack are of a single prefix type. It is your responsibility to check this data. If you have mixed samples of different prefixes, all samples will have the same prefix added to that which you entered. Thereby, identification errors could occur if the operator fails in this tube data check.

The Codabar Conversion feature activates the alphanumeric conversion for Codabar barcodes. In the case of ABC conversion, the first two digits (of seven) of the barcode are replaced with designated alphas using a software embedded truth table. The Custom conversion is based on a site configurable software embedded truth table.

The ISBT 128 Conversion feature activates the stripping of the equal sign (=) at the beginning of the sixteen-character ISBT 128 blood unit identification barcodes and also the last two checksum digits, thereby leaving characters numbered between two and fourteen.

Even though settings can be configured, you can temporarily edit these settings on a rack-by-rack basis using the Prefix + Barcode Settings button on the *14-lane Bay* dialog.



When exiting and subsequently reentering the *14-lane Bay* dialog, the pre-configured settings will again be the default. The pre-configured settings cannot be changed by temporarily changing the settings on a rack-by-rack basis.

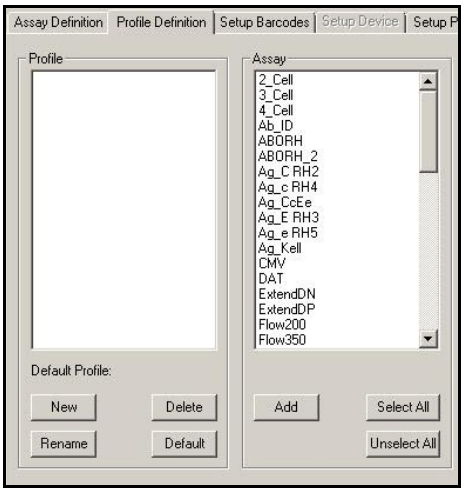
If a donor prefix is configured, it will be displayed as replacement text on the *14-lane Bay* dialog *Prefix + Barcode Settings* button. For example, if a donor prefix of *12345* is used, then it will display, as shown below, as replacement text on the button.

Refer to **Chapter 6 – Instrument Testing Operation** for more information regarding Barcode Settings.

You can close Setup by pressing the **OK** button at the top of the dialog to save the settings.

Creating Assay Profiles

You can use the *Profile Definition* tab to create assay profiles:



Step	Action
1	Press the **Settings** button from the Main Menu Bar.
2	Select the *Profile Definition* tab.
3	Press the **New** button from the Profile box.
4	Type a profile name into the open text box with the flashing cursor, for the new profile to be created. **Note**: Greater than twelve (12) characters can be typed into the open text box, however only a maximum of twelve (12) characters can be displayed on the assay profile button. If greater than twelve (12) characters are typed into the open text box, then the excess characters will not be visible on the profile button.
5	Select the assay to be included in the profile from the *Assay* box list.
6	Press the **Add** button from the Assay box. **Note**: The **Select All** and **Unselect All** buttons can be used to collect all assays into a profile or remove all assays from a profile respectively.

7	Repeat steps 5 and 6 for any additional assays to be added to the profile.  **Note**: If the newly created assay profile is required to be the default assay profile assigned to all samples tested on the instrument, then you must press the **Default** button after step 7 of this procedure. The system displays the assay profile name next to the *Default Profile:* text. You can remove the default assay profile status by pressing the **Default** button a second time, prior to step 8 of this procedure. You can only select one (1) assay profile as the default assay profile at any time.
8	Press the **OK** button on the *Setup* dialog when you are finished.
9	You will be asked to enter your login password in an Operation confirmation dialog. After your password entry, press the **OK** button of the Operation confirmation dialog.

The **Rename** button can be used to rename an existing profile name.

Help

About Help

The *Help* window displays the electronic NEO Iris Operator Manual on the NEO Iris PC monitor as well as providing access to the remote support functions and listing module version information.

Accessing Help

Press the **Help** button on the Main Menu Bar to display the *Help* window.

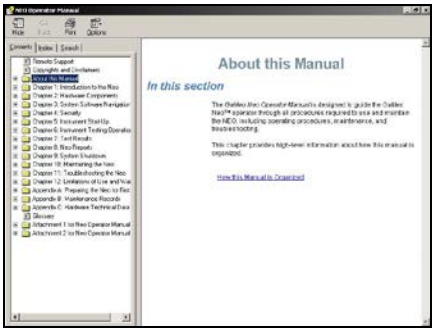
You must insert the current CD version of the electronic operator manual into the CD drive of the instrument PC tower to provide the files for the monitor display of the manual.

Note: Ensure that you have loaded the current CD version of the electronic NEO Iris Operator Manual into the CD drive of the instrument PC tower before pressing the Help button. If the CD drive is empty, or contains a wrong or damaged CD, the system displays an error message indicating that the CD of the manual must be loaded into the CD drive.

The system displays the *Help* window.

Extended Help

When you press the **Extended Help** button (only visible when the NEO Iris Operator Manual CD is loaded), the software displays the *NEO Iris Operator Manual* window at the **About this Manual** section.

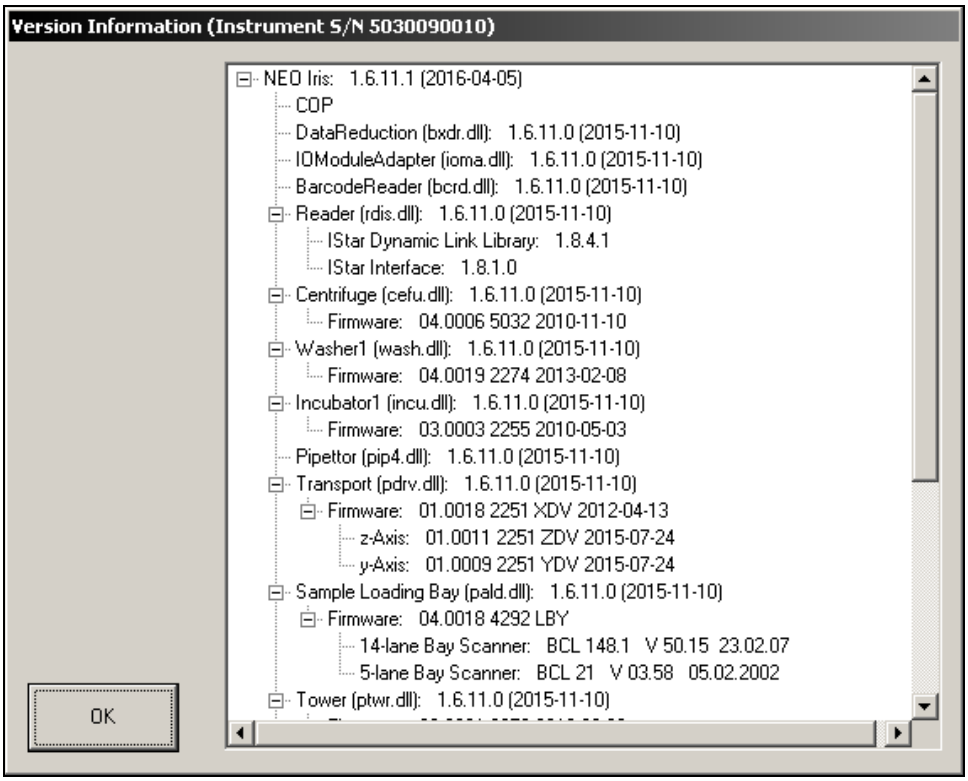


Press the hyperlinked text of a topic to access the selected topic. The display of the help content list is dependent on whether it was displayed when the file was last accessed on the PC. If the list was hidden on the most recent access, when the help display was closed at that time, then it will not display, or the list will be shown if it was displayed when on-line help was closed at that time. You can then press the *Hide* or *Show* buttons to toggle the display of the help contents. Pressing on any of the content topic links will display the selected topic in the help window.

Click the **X** button at the top right of the *NEO Iris Operator Manual* window to exit the Extended Help page and return to the Help window.

Version Information

Click the **Version Info** button. The *Version Information* dialog is displayed.

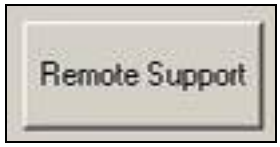


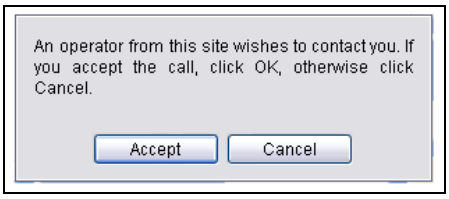
The *Version Information* dialog displays a list of the modules and software used on the instrument.

The dialog displays the information in a tree structure with modules at the roots and their dependent sub-modules as the branches. Press a plus sign (**+**) to expand the list and view more information under a topic. Press a minus sign (**–**) to collapse the list and hide information. Press the **OK** button to exit the *Version Information* dialog.

Access to Remote Support

Access to remote technical support using *blud_direct* is provided through the use of the **Remote Support** button in the help window:

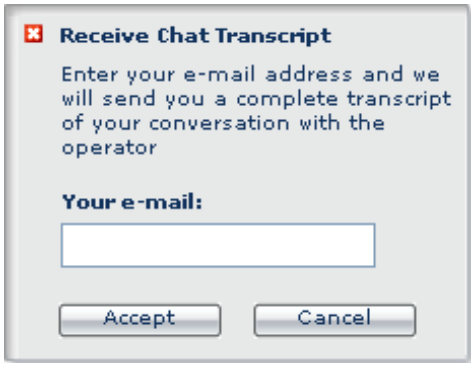
Step	Action
1	Press the **Help** button without the help CD being loaded into the PC disk drive.  **Result**: the following error message will be displayed:   **Note**: The error message will not be displayed if the help CD is loaded in the PC disk drive. In that instance, skip step 2 of this procedure and proceed to step 3.
2	Press the **OK** button of the error message.  Result: The error message disappears and the help window is displayed.
3	Press the **Remote Support** button.  Result: The blud_direct **Enter session:** page is displayed. 

4	You must then enter the correct session ID (provided by Immucor Technical Support over the phone) into the Enter session: field and then press the Send button within fifteen (15) minutes of assignment, otherwise it will expire and a new session ID will have to be assigned to you. The session ID is not case sensitive. When the session ID is confirmed, you will be presented with a message to accept contact by Immucor Technical Support (operator).
5	Click the **Accept** button to continue with the support session. 
6	The chat window of the blud_direct application will then display. You can then interact as necessary through the chat window which includes responding to any requests by Technical Support for remote control of your instrument computer. Remote access to your instrument computer is only provided when you accept a request to do so while in the current chat session.
	 **Note**: In addition to the chat window as a newly displayed window, the Help page will update with a button graphic. Do not press this button because doing so will create a new chat session.

blud_direct options

The table below describes the blud_direct options.

Option	Description
	The font of the text displayed within the chat can be increased, decreased, or reset by clicking the appropriate buttons shown.

Receive Chat Transcript	To receive a transcript of the details regarding your support session, click on the **Receive Chat Transcript** button. You will be prompted to enter where the transcript should be sent. Enter the e-mail address to which you would like to have the transcript sent and then click the **Accept** button.  **Note**: You may click on **Receive Chat Transcript** at any time during the chat session, but must do so before closing the chat window (i.e. before ending the session). It is important that a valid e-mail account is entered into the prompt. Please remember to check spelling, etc. of the address before clicking the **Accept** button.
Display chat window again	Should the chat window fall behind the instrument software, close the *Help* page and then reopen it. Press the **Display chat window again** link. This will allow the chat window to display again in front of the instrument software. Do not minimize the chat window. This will prevent the window from being able to be displayed again using the **Display chat window again** link.
	To end a remote control session without ending the chat session, you can press the **Terminate** button. To end the chat session, you can press the close icon in the upper right corner of the chat window. In closing the chat session, the remote control session will also be ended.

Shutdown

About Shutdown

The *Shutdown* dialog guides you through the procedure that you must perform before the system is shutdown. Press the **Shutdown** button.

The system displays the *Shutdown* dialog.

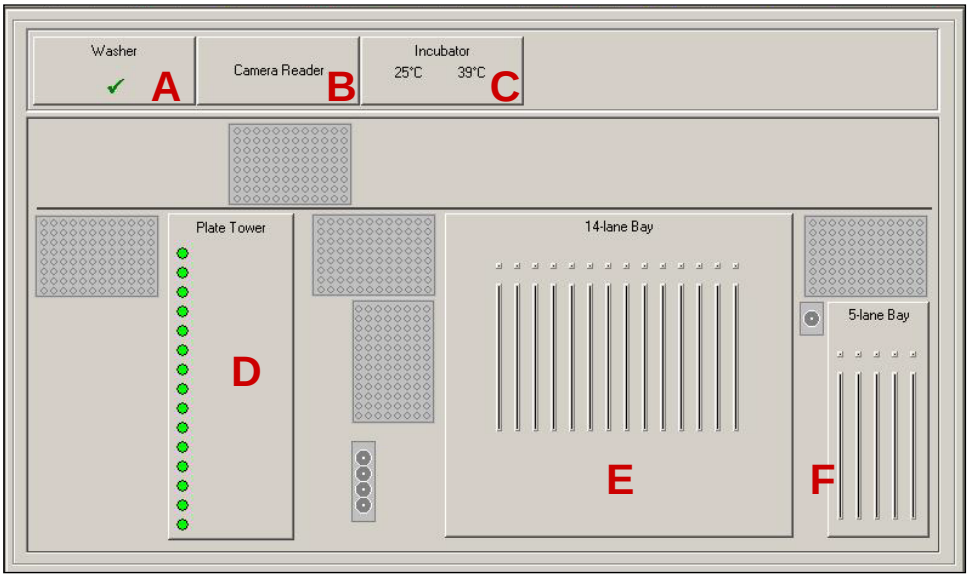
Refer to **Chapter 9 – System Shutdown** for information regarding system shutdown.

Machine Monitor

About the Machine Monitor

Parts of the Machine Monitor

The Machine Monitor is a graphical view of the instrument deck that displays the status of each of the system modules and provides access to the module dialogs. The instrument displays this screen when the system is in standby mode.



The table below describes the sections of the Machine Monitor.

Area	Name	Description
A	Washer	By pressing the button, the *Wash Buffers* dialog is displayed. This button also provides an overview of the system liquid on the instrument.
B	Camera Reader	By pressing the button, the most recent successfully captured image taken by the camera is displayed.
C	Incubator	By pressing the button, the *Incubator* dialog is displayed. This button also provides an overview of the incubator status.

D	Plate Tower	By pressing the button, the *Plate Loading Tower* dialog is displayed. This button also provides an overview of the plates in the loading tower.
E	14-lane Bay	By pressing the button, the *14-lane Bay* dialog is displayed. This button also provides an overview of the racks loaded in the 14-lane bay and the status of the module.
F	5-lane Bay	By pressing the button, the *5-lane Bay* dialog is displayed. This button also provides an overview of the racks loaded in the 5-lane bay and the status of the module.

Incubator

Incubator Dialog

The *Incubator* dialog provides an overview of the status of the incubator. Click the **Incubator** button in the Machine Monitor to display the *Incubator* dialog.

The *Incubator* dialog displays the Incubator Status List and the Environment area.

Incubator Status List - The incubator status list displays the status of the individual incubator positions. The State column (15–1) represents the positions in the incubator. If a plate is present in a position, it is indicated here. The Set Point column displays the temperature set for this incubator position, such as 39°C. The Actual temperature column displays the actual temperature of this incubator position. The acceptable range of a 39°C incubator position is 38°C to 40°C inclusive. Assay results are invalidated if the temperature falls outside of this range during the assay incubation.

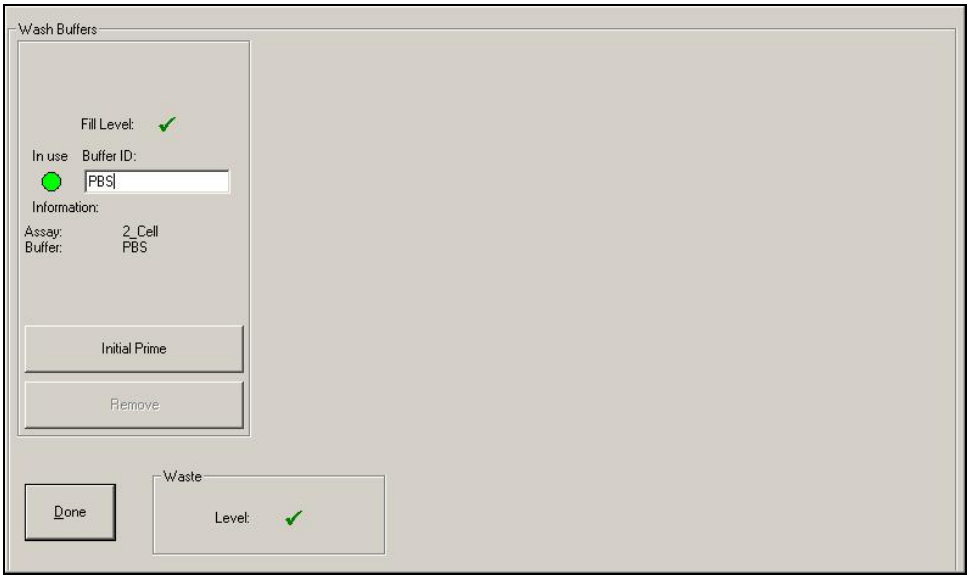
Environment Area - The Environment area in the lower right-hand corner of the *Incubator* dialog displays the actual ambient temperature measured inside the instrument.

Note: The thermodynamics of the incubator bays require an actual temperature of 39°C to yield a test well temperature of 37°C.

Wash Buffers

Wash Buffers Dialog

The *Wash Buffers* dialog provides an overview of the system liquid and the waste level status. Click the **Washer** button in the Machine Monitor to display this dialog. You can also access the *Wash Buffers* dialog from the *Resource Overview* window.



The Fill Level area displays a green check mark (√) if the liquid level is above the threshold level, or a red exclamation mark (**!**) if the liquid level is below the threshold level. The threshold is set in such a way that the remaining volume is sufficient for the completion of the plate currently in the washer.

If you use the **Initial Prime** button at the bottom of the wash buffer container area to request an extra prime for the system liquid, there is a delay of several seconds between pressing the **Initial Prime** button and pump activation.

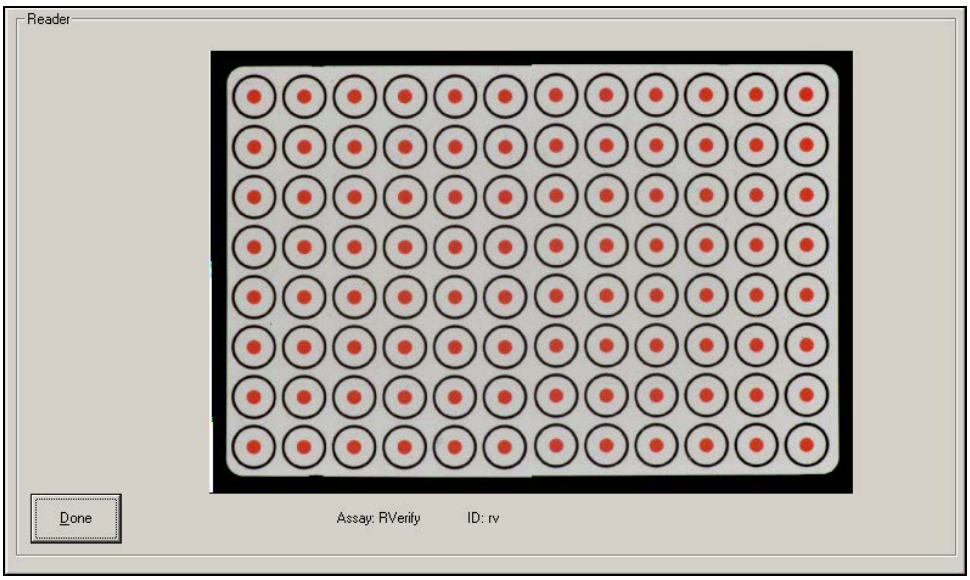
Refer to **Filling the System Liquid** in **Chapter 10 – Maintaining the NEO Iris** for more information regarding the Wash Buffers dialog.

Reader

Reader Dialog

Press the **Camera Reader** button to display the *Reader* dialog.

The *Camera Reader* dialog displays the most recent successfully captured image taken by the camera. The name of the **Assay** and **ID** associated with the plate are also displayed. Press the **Done** button of the *Reader* dialog to return to the *Machine Monitor*.

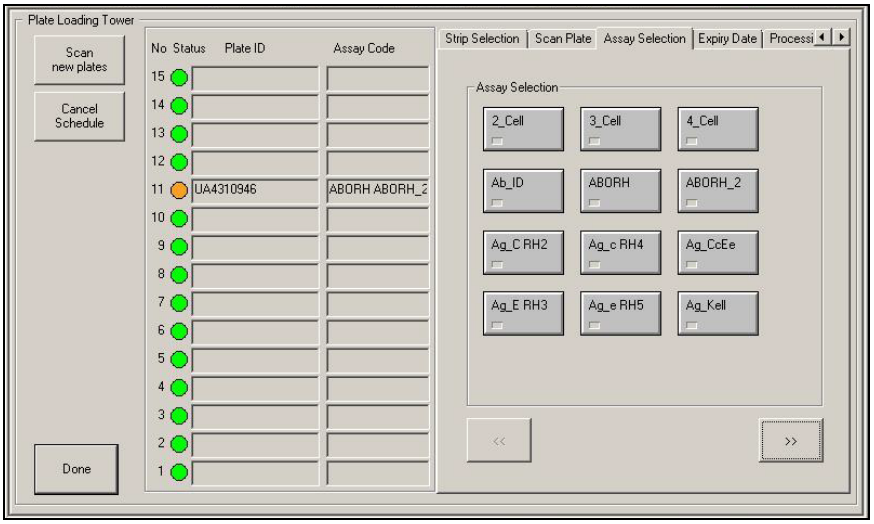


Note: The above image displays the Reader Verification Plate tool.

Plate Loading

Plate Loading Dialog

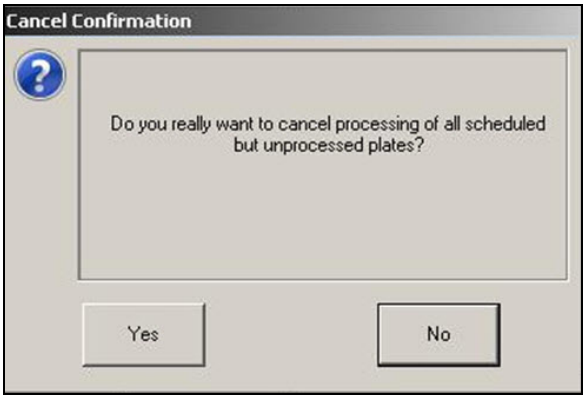
The *Plate Loading Tower* dialog provides an overview of the plates in the loading tower and prompts the operator when loading plates. Press the **Plate Tower** button in the Machine Monitor to display this dialog. You can also access the *Plate Loading Tower* dialog from the *Resource Overview* window.



Note: Use the left and right arrow buttons at the bottom of the *Assay Selection* tab to scroll through the available assays.

The *Plate Loading Tower* dialog is divided into two areas, the loading tower diagram on the left and the tabs on the right. There are several buttons in the *Plate Loading Tower* dialog that have functions described in the table below.

Button	Description
	Press these buttons to switch the display of tabs in the left or right direction.
	Press the **Scan new plates** button to initiate the barcode scanning of new plates.

Button	Description
Cancel Schedule	The **Cancel Schedule** button on the main *Plate Loading Tower* dialog is used to cancel all plates that have not begun processing. A *Cancel Confirmation* will appear that should be acknowledged using the **Yes** or **No** button before all plates that have not started processing will be cancelled. Only plates that have not started processing can be cancelled. Such cancelled plates retain the assays scheduled and will reappear in the Resource Overview window. If these plates are cancelled, any unused reagent will be electronically reassigned back to its vial. Such reagent reassignment is also activated if these plates are aborted during error recovery and troubleshooting. 
Done	Press the **Done** button to exit the *Plate loading Tower* dialog.

Loading Tower Diagram

The loading tower diagram displays the positions in the loading tower (15–1). For each position, the dialog displays the status, the plate ID (barcode), and the codes of the assays that can be performed with this plate. If the plate is already scheduled, the dialog displays only the assay that actually runs with this plate.

Tabs

Five tabs are available in the *Plate Loading Tower* dialog:

Strip Selection

Scan Plate

Assay Selection

Expiry Date

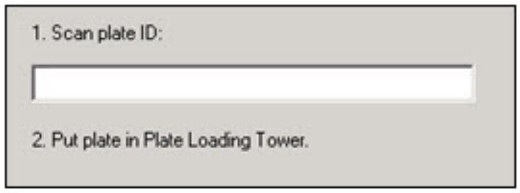
Processing Steps

Automatic Barcode Plate Identification

Place the plates into the loading tower with their barcodes facing to the left. For more information, refer to **Loading Plates** in **Chapter 6 – Instrument Testing Operation**. Close the plate tower door after the LED for that slot has changed to orange. Barcodes will be scanned automatically. If the automatic scanning process is not initiated because the plate tower dialog is not closed, press the **Scan new plates** button instead. The transport mechanism removes each new plate and presents its barcode to the laser scanner. The system updates the loading tower graphic to show the barcode of each plate and the assays that it may be used for.

Manual Plate Identification – Scan Plate Tab

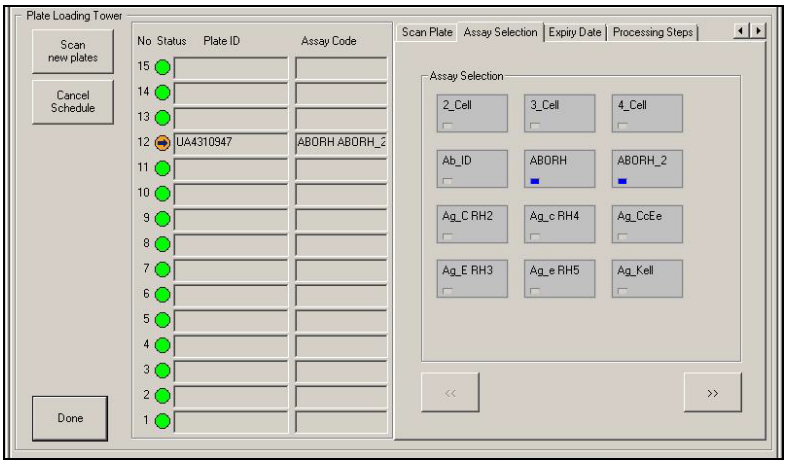
To load a plate with an unreadable barcode ID, you can type the barcode manually.

Step	Action
1	Click the *Scan Plate* tab.
2	The scan plate screen appears.  Type the barcode into the field either manually or using the hand-held barcode scanner. You must enter the plate lot number followed by the serial number if manual entry is used.
3	Load the plate into a free slot in the loading tower (indicated by a continuous green LED). The instrument allocates the barcode ID to the newly inserted plate. The system uses the plate as if the integrated barcode scanner had read the barcode.

Manual Plate Identification – Assay Selection Tab

You can also use the *Assay Selection* tab to manually type a barcode and assign an assay to a plate.

Step	Action
1	Click the *Assay Selection* tab to enter the plate details manually.
2	Insert the plate into an empty slot in the loading tower. The system updates the loading tower graphic.

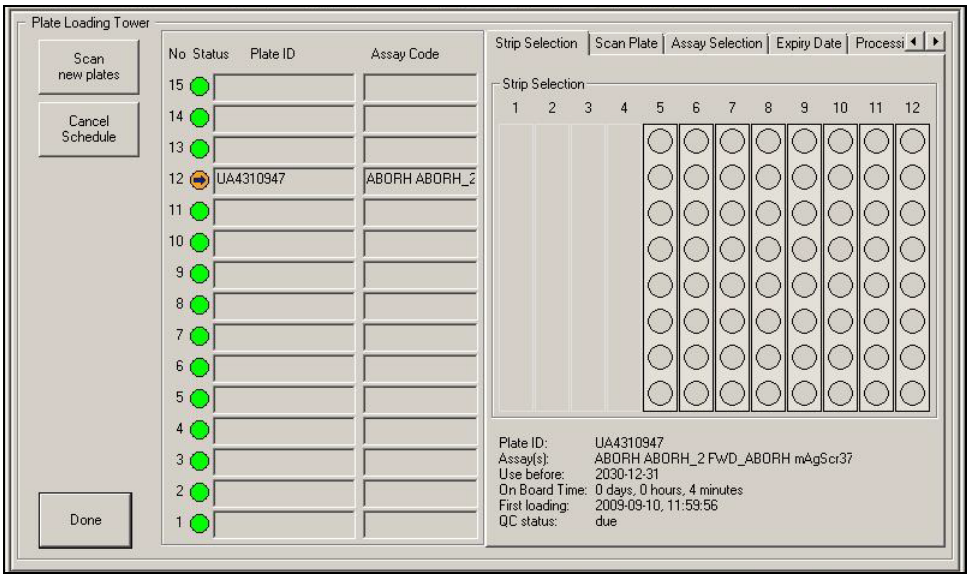
Step	Action
3	Type the plate ID in the respective position in the loading tower diagram (double-blind entry required). The corresponding assay assignment will automatically be populated if entering a plate barcode; if manually entering an id to run a maintenance task, click the assay button that should be run with that plate. 

De-selection of Absent Strips – Strip Selection Tab

The instrument supports de-selection of strips that are absent from the plate. This feature only works when an assay is already assigned to a plate. By default, the instrument assumes that when you insert a new plate, all strips are present on the plate. If this is not the case, you can deselect strips and make them unavailable for the instrument.

Limitation: The camera reader will verify the presence of clean and correctly positioned strips on a plate before starting an assay. If the reader detects the presence of strips that should have been deselected, such as wrong position of used strips, then the plate is aborted.

Select the *Strip Selection* tab and then select a plate.



By pressing on a vertical strip icon, you can toggle the strip on and off.

If the instrument has used up some but not all strips in an assay run, and the system brings the plate back to the loading tower, you can start the plate again. In this case, however, it is not possible to reuse already used strips for a second time.

Assigning Expiration Dates to Plates – Expiry Date Tab

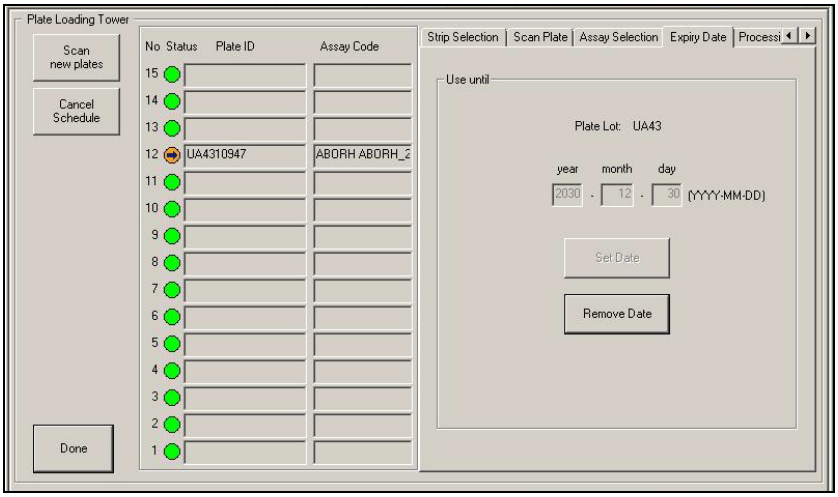
Manual expiry date entry is only required for *Scheme 1* plate frame barcodes and not for *Scheme 2*. If the *Scheme 2* lot number is unknown to the software, such as when the first plate of a new lot is loaded and scanned, the *Expiry Date* tab fields will automatically populate with date information when the plate frame barcode is scanned by the instrument.

When a *Scheme 2* plate barcode is assigned to a loading tower slot, the software disables editing of the plate *Expiry Date* tab.

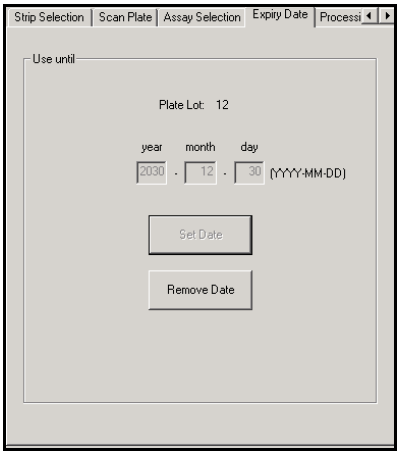
Refer to **Chapter 1 – Introduction to the NEO Iris** for more information regarding *Scheme 1* and *Scheme 2* plate frame barcodes.

You can assign an expiration date to *Scheme 1* plate frame barcodes. When the barcode scanner scans the plate frame, the barcode is interpreted. If the lot number is unknown to the software, such as when the first plate of a new lot is loaded and scanned, the system displays a message alerting you to enter the expiration date for this plate.

To enter the *Scheme 1* expiration date:

Step	Action
1	Select the *Expiry Date* tab and then select the plate with a left-trackball click or via the touch screen.  The system displays a new dialog where you can enter the expiration date for this plate lot.

Step	Action
2	Press the **Set Date** button. The system assigns this date as the expiration date to all plates of that lot on the system.



Limitation: If an incorrect, but valid, plate expiration date is entered and an assay using this plate lot is run, then the incorrect expiration date is stored for that lot in the software. If the incorrect date is then corrected in the software following this assay run, and this correct date is further into the future than the original incorrect date, the data management system cannot update the incorrect stored date. Consequently, if an assay is run using this plate lot again, at a date of testing between the original incorrect date and the corrected date, then these results will be displayed in the *Plate View* window with an associated warning message of **Plate failed criteria, please check Interpretation Failures**. The validity of these results is not compromised by this chain of events that generated this warning message, and these results can still be exported or printed.

Warning: If an incorrect plate expiration date is entered, which is beyond the actual expiration date of the plate, and an assay using this plate lot is run at a date after the actual expiration date, but before the erroneously entered software expiration date, then the validity of the results is compromised, even though the results will appear legitimate. It is the operator's responsibility to enter the correct plate expiration date into the software.

If you have access to change plate expiration dates and are logged into the software, you can clear the Set Date by pressing the **Remove Date** button. You can then set a different expiration date.

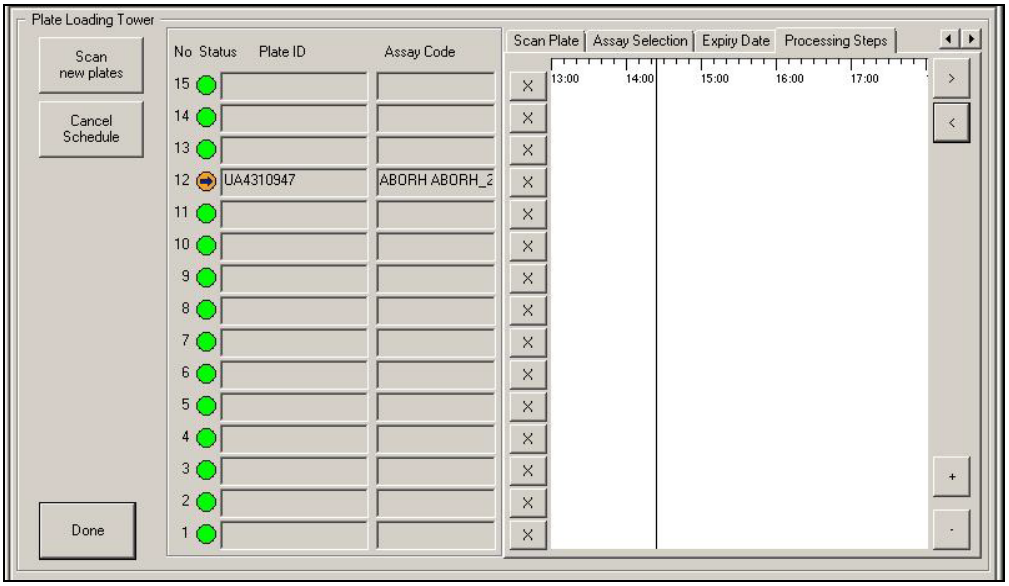
You cannot use a plate without an expiration date. If the expiration date on a plate is exceeded, you cannot use the plate.

Viewing Processing Steps – Processing Steps Tab

Select the *Processing Steps* tab to view a graphic of the current schedule.

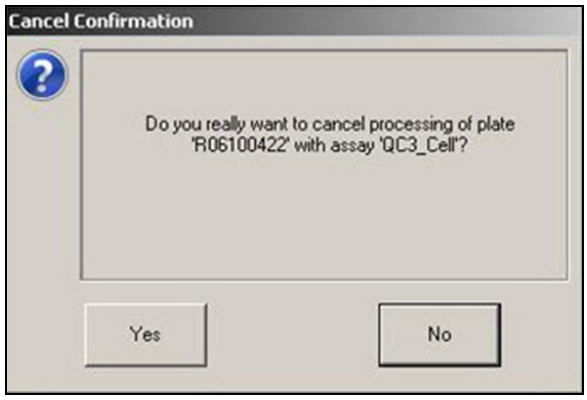
The scheduler axis line moves in real time from left to right to demonstrate time passing as the instrument operates.

Note: For more information on scheduling, refer to **Chapter 1 – Introduction to the NEO Iris**.



In addition to the buttons on the *Plate Loading Tower* dialog, the following navigation buttons are also available:

Button	Description
<	Press this button to scroll left through the schedule.
>	Press this button to scroll right through the schedule.
+	Press this button to expand the scheduler time scale displayed (more detail).
-	Press this button to reduce the scheduler time scale displayed (less detail).

Button	Description
	Each plate loading tower position on the scheduler has a cancel button, so that any individual plate being processed can be cancelled. Select the **X** that corresponds to the plate that should be cancelled/aborted. The specific **X** button corresponds to the chosen plate that is horizontally level with the button. A *Cancel Confirmation* will appear that should be acknowledged using the **Yes** or **No** button before the selected plate will be cancelled. Such a cancelled plate retains the assays scheduled and will reappear in the Resource Overview window. If the plate is cancelled before it has begun processing, any unused reagent will be electronically reassigned back to its vial. Such reagent reassignment is also activated if a plate is aborted during error recovery and troubleshooting.   **Note**: Cancelled plates are not lost to the system. Such cancelled plates are subsequently available after the STAT plate is started processing.

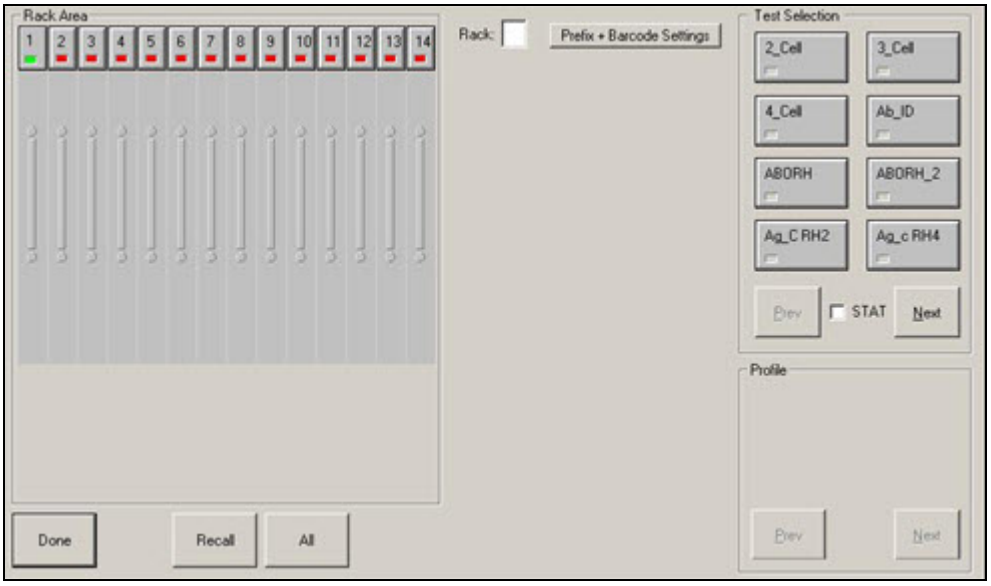
The scheduler graphical representation uses different colors to symbolize different assay stations. The colors used are:

Color	Description
	(Charcoal gray) The start of plate processing is delayed before it was originally due to be picked up from the plate loading tower.
	Plate barcode scanning
	Transport
	Pipetting steps. The left and right pipettors use the same color.
	Incubation at room temperature
	Incubation at 37°C
	Plate washing step
	Centrifuging or shaking of a plate
	Camera reading

14-lane Bay

Purpose

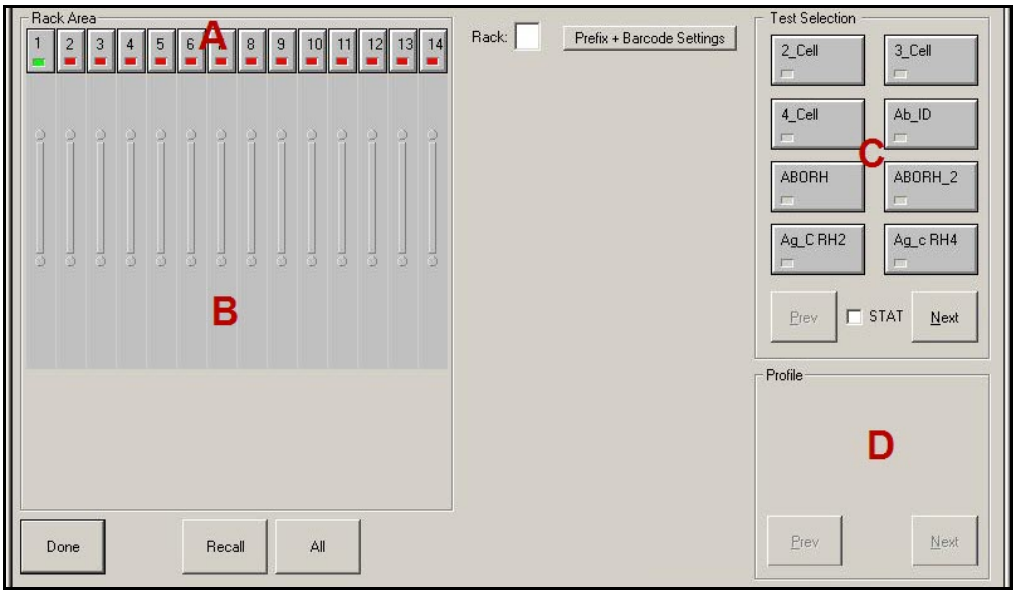
The **14-lane Bay** dialog provides an overview of the racks loaded on the 14-lane loading bay. In this dialog, you can view the status of the racks, the samples or reagents in each rack, and the assays requested for the samples. You can also use this dialog to enter a sample ID for a position in a rack and to manually request assays.



The system displays the 14 lanes of the loading bay. If a rack is in a lane, a rack is displayed in the lane on the icon. The system displays a green check mark (√) at the bottom of the rack on the Machine Monitor if the rack type is recognized. The system displays a red question mark (?) at the bottom of the rack on the Machine Monitor if the rack type is not recognized. The five-lane reagent loading bay exhibits the same features.

Parts of the 14-lane Bay

Press the **14-lane Bay** button in the Machine Monitor to display this dialog. You can also access the *14-lane Bay* dialog from the *Resource Overview* window.



A: Lane button

B: Lane

C: Assay button

D: Profile area

The *14-lane Bay* dialog is divided into three areas: the Rack Area, the Identifiers area, and the Test Selection area.

Rack Area

The *Rack Area* displays a graphical, aerial view of the sample loading bay and the **Recall** and **All** buttons. The 14-lane bay graphic displays each of the 14 lanes of the bay with a corresponding button above. If a rack is present in a lane, the dialog displays a graphic of a rack in the lane. Click a rack to select it. A dark gray bar highlights the currently selected rack.

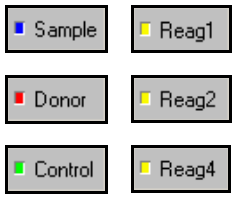
Use a lane selection button (1–14) to focus the barcode reader on the desired lane. The colored bar in the button displays the status of the lane in accordance with the consistent color codes. The color displayed here is the same as that of the lane LED on the instrument.

If a sample rack is loaded and one or more barcodes on that rack is/are unreadable, you can correct the unread barcode. Click the **Recall** button to manually enter unreadable barcodes. Refer to **Chapter 6 – Instrument Testing Operation** for more information regarding how to rescan unread barcodes.

Identifiers Area

The *Identifiers* area displays the details of the selected rack of the 14-lane bay graphic. The system displays the rack type in the Rack type field at the top of the Identifiers area, and sample information in the list below.

The first column of the list displays the position in the rack. The second column contains tags that are used to select the type of material in the container. The following options are available:



The Sample tag indicates that sample material is loaded. The Donor and Control tags indicate that donor or control material is in this position. Reag1, Reag2, and Reag4 indicate that reagents are loaded in this position. The number states the number of probes of the 4-probe arm that can access the vial simultaneously. The tags are not strict. The material in a vial labeled Sample can also serve as a donor. Controls can also be labeled as reagents. The tags are set by default when you insert a rack. To change them manually, you must activate the ID field, and then press the button to change the tag.

If the rack contains samples with barcodes, the system displays these in the text box of the third column. If a sample does not have a barcode, or the instrument is unable to read the barcode, you can enter the ID manually. Refer to **Chapter 6 – Instrument Testing Operation** for information regarding the input of barcodes that are not initially scanned by the instrument.

The **Prefix + Barcode Settings** button can be used if barcodes require any data conversion or manipulations. Refer to **Chapter 6 – Instrument testing Operation** for information regarding the use of this button.

Test Selection Area

The *Test Selection* area contains two sets of buttons. At the top are buttons for all assays available on the system. At the bottom are buttons for all of the profiles (predefined combinations of assays) defined on the system. Use these buttons to manually assign an assay or profile to a sample.

To assign an assay or profile, click a sample ID in the *Identifiers* area and then click an assay or profile button. If the system does not display an assay or profile button in the Test Selection area, use the **Previous** and **Next** buttons to scroll through the pages of the assay list.

The **STAT** check box can be used if samples must be tested urgently. Refer to **Chapter 6 – Instrument Testing Operation** for information regarding the use of the **STAT** feature.

If a reagent rack is loaded or selected for display, the software operates as described in *5-lane Bay* below.

5-lane Bay

Purpose

The **5-lane Bay** dialog provides an overview of the racks loaded in the 5-lane bay. This bay is designed for the use of reagents only. In this dialog, you can view the status of the racks and the reagents in each rack.

Parts of the 5-lane Bay

Both the *14-lane Bay* and the *5-lane Bay* dialogs display reagent information when a reagent rack or position is selected. In the *5-lane Bay* dialog, you can view the status of the racks, the reagents in each rack, and the remaining volumes of the reagents. You can also use this dialog to manually enter a reagent ID and volume for a position in a rack. Click the **5-lane Bay** button in the Machine Monitor to display this dialog. You can also access the *5-lane Bay* dialog from the *Resource Overview* window.

The tool tip (D, below) displays the *Use before* date. This indicates the first day which you can no longer use a particular reagent. The *Use before* date is the day immediately following the expiration date.

A: Lane button

B: Empty lane

C: Rack in lane

D: Tool tip – information about the reagent

The *5-lane Bay* dialog is divided into three areas:

Rack

Reagent IDs

Reagent Properties

Rack Area

The Rack Area displays a graphical, aerial view of the 5-lane bay and the **Recall** button. The 5-lane bay graphic displays each of the 5 lanes with a corresponding button above. If a rack is present in a lane, the dialog displays a graphic of a rack in the lane. Click a rack to select it. A gray bar highlights the currently selected rack.

Use the lane selection buttons (1–5) to focus the barcode reader on the desired lane. When activated, the barcode scanner is focused on this lane and the instrument does not perform any operations on this lane. The colored bar in the button displays the status of the lane in accordance with the consistent color codes. The color displayed is the same as that of the lane LED on the instrument.

Click the **Recall** button to manually enter unreadable barcodes. If a reagent rack is loaded and one or more barcodes on that rack is/are unreadable, you can input the unread barcode. Refer to **Chapter 6 – Instrument Testing Operation** for more information regarding how to rescan unread barcodes.

Reagent IDs Area

The Reagent IDs area displays details of the selected rack of the reagent loading bay graphic. The system displays the rack type in the Rack type field at the top of the Reagent IDs area, and reagent information in the list below.

The column contains tags that are used to select the type of material in the container.

The following options are available:

The software displays the reagent barcodes in the field of the Reagent IDs area. If the instrument is unable to read the reagent vial barcode, you can enter the ID manually. Refer to **Chapter 6 – Instrument Testing Operation** for information regarding the manual entry of unread reagent barcode data.

Reagent Properties Area

The Reagent Properties area lists the description of the reagent and also its remaining volume. By selecting the reagent description button, the tool-tip information about that reagent is displayed. The tool-tip lists the name, lot number, use before date, first on board, date and on-board time left, and QC status.

Status Bar

Using the Status Bar

Status Bar Buttons

The Machine Monitor contains a Status Bar at the bottom of the screen. The system **Emergency Stop** button, in the middle of the status bar, stops all actions on the instrument at any time.

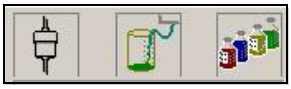
After you press the **Emergency Stop** button, the software requests confirmation. You must either press the **Yes** button to stop the system or the **No** button to continue NEO Iris operation. The NEO Iris will need to be initialized after the **Yes** button is pressed, and everything in process will be lost.

Limitation: Stopping the system with the **Emergency Stop** button interrupts instrument sampling.

The Status Bar also contains the three system status indicators that display the overall status for the instrument's connection to the PC, the level of the liquid waste in the common waste container, and the level of the available system liquid in the system liquid container.

Indicator	Description
	Connection of the PC to the instrument
	Level of the liquid waste collection
	Level of available system liquid

A status indicator has a gray background when the item has an acceptable normal state.



A status indicator has a yellow background when the item is reaching the point where action is recommended to either fill the system liquid because it is getting low or when the common waste container is nearing full and emptying the waste is recommended. The waste status indicator graphic also changes by showing the level of green liquid to have increased.

The system liquid indicator graphic also changes by showing the level of liquid in the bottles to have decreased to a very low level and a question mark is added to the graphic.

A status indicator has a red background when the item has reached a critical status point. For example:

The NEO Iris is switched off and the PC that is still switched on cannot connect to the NEO Iris.

The common waste container is full and must be emptied.

The system liquid is insufficient and must be replenished.

Words Indicating State of NEO Iris

The wording located between the Emergency Stop button and the three system status indicators describes the overall state of the NEO Iris. Wording options include *Not initialized*, *Initializing*, *Ready*, *Active*, *Halted*, *Starting Up* and *Login*. These states are described in the table below.

Wording	Description
	**Not Initialized**: The NEO Iris is not initialized. No sample processing is permitted.
	**Initializing**: The NEO Iris is in the process of initializing.
	**Ready**: The NEO Iris is initialized and is ready for use, but it is not currently active.  **Note**: Scheduled maintenance may still be due.
	**Active**: The NEO Iris is initialized and is actively performing tasks such as processing samples, performing maintenance or scanning plate barcodes.
	**Halted**: The NEO Iris has been halted due to an unexpected event such as error recovery.

	**Starting Up**: This wording is only visible for a few seconds when the PC is initially powered off and is then powered on, but the database is not yet completely loaded. Once the database is completely loaded, a *Login* dialog is displayed and the **Login** wording is displayed, which replaces the **Starting Up** wording.  The **Login** dialog and wording is no longer displayed after the operator logs in and the software display is completely established. Other wording is then displayed, depending on the status of the NEO Iris.
	 **Note**: This **Login** wording is only displayed under the scenario described here. When operators routinely log into and out of the NEO Iris software, while the NEO Iris software is displayed, then some wording other than **Login** is displayed, depending on the status of the NEO Iris.

 **Note**: Another wording option is **Completing Run**. This wording option is only displayed when a software error occurs at the same time as when samples are being processed on the NEO Iris. That current run of sample processing is allowed to finish, however the starting of new processing runs is not permitted. The operator must shut down and then restart the software after that current run is finished.

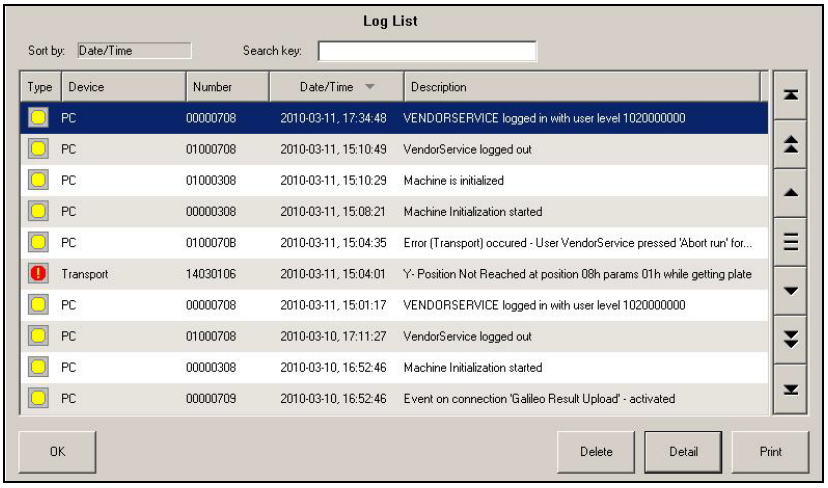
Log List

The *Log List* dialog displays a list of messages that have been issued since the last database clean up. You can also use this dialog to delete alarms or print a report of the message list.

Viewing Messages

To view messages:

Step	Action
1	Press the **Log List** button (to the left of the **Emergency Stop** button) in the status bar. 

2	The *Log List* dialog appears. 

Sections of the Log List

The *Log List* dialog is divided into three areas:

Information area at the top

Log list in the middle

The buttons at the bottom

Information Area

The information area at the top of the dialog comprises the **Sort by** and **Search key** fields. The Sort by field displays the name of the column that the event list is currently sorted by. To change the content of the Sort by entry, click on any of the field headers to sort the list by that field. The header of the field appears in the Sort by field. In the Search key field, you can enter search criteria for searching the log list.

Log List

The Log List displays events and alarms that have occurred since the system was powered on. The system database stores entries until they are deleted. The log list contains five columns:

Type - displays an icon for the types of messages issued.

Device - displays the name of the system module that issued the message, for example, the PC.

Number - displays the message number, which is used to identify the entry.

Date/Time - displays the date and time the message was issued.

Description - displays a short description of the event that led to the message being issued.

Press the button at the head of each column to sort the list by that column. The Sort by field in the information area displays the name of the column that the list is currently sorted by.

Message Types

The following message types are available:

Type	Description
	General Message (event or warning)
	Fatal Device Message
	Critical Device Message
	Database
	Operating System
	Communication
	Other

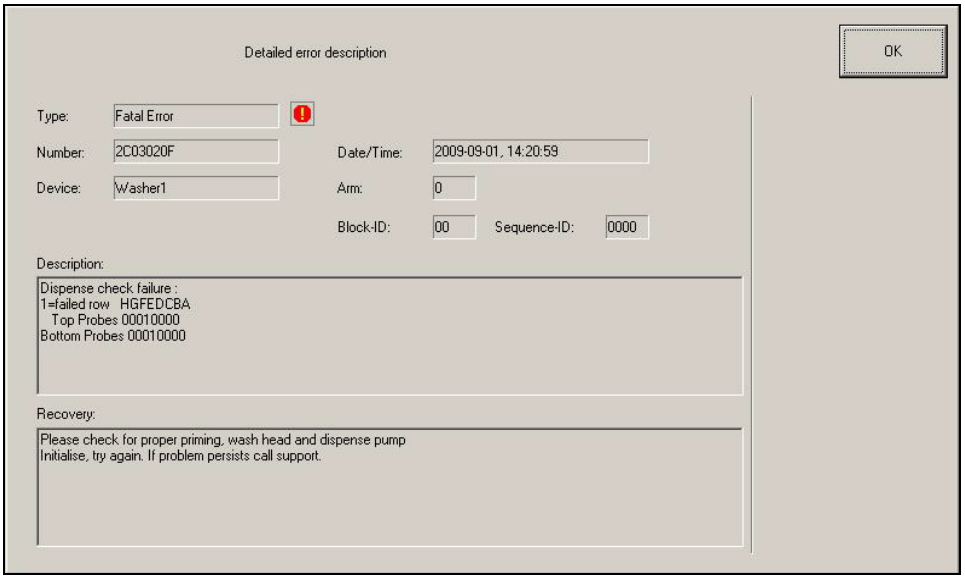
Log List Navigation

On the right side of the dialog are seven navigation buttons that you can use to browse through the list. The following navigation buttons are available:

Button	Description
	Go to the beginning of the log list.
	Go to the previous page of the log list.
	Go to the previous entry in the log list.
	Select this button to mark multiple entries. Using this button, you can print or delete all marked entries as a group.
	Go to the next entry in log list.
	Go to the next page of the log list.
	Go to the end of the log list.

Log List Buttons

In addition to the common **OK** and **Print** buttons, the **Delete** and **Detail** buttons are also available. Press **Delete** to delete the entry selected in the log list. Press **Detail** to display the *Details* dialog.

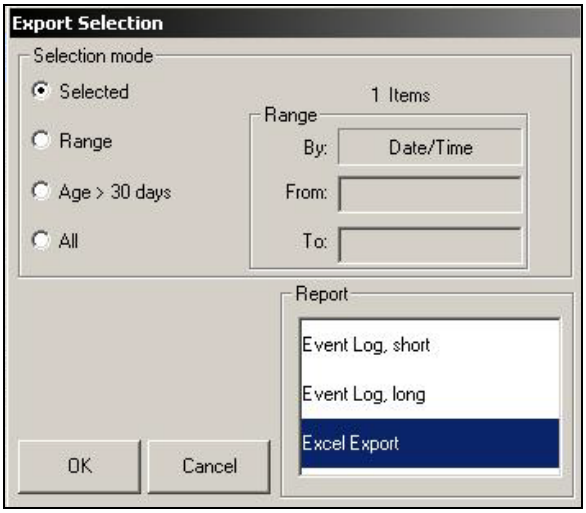


The *Details* dialog displays more detailed information about the selected entry.

Press the **Print** button to display the *Export Selection* dialog.

Export Selection Dialog

When one or more log list entries are selected and then the **Print** button is pressed, the **Export Selection** dialog is displayed. The *Selection mode* area allows filtering of the log list entries prior to export. One of the three (3) report options is *Excel Export*.

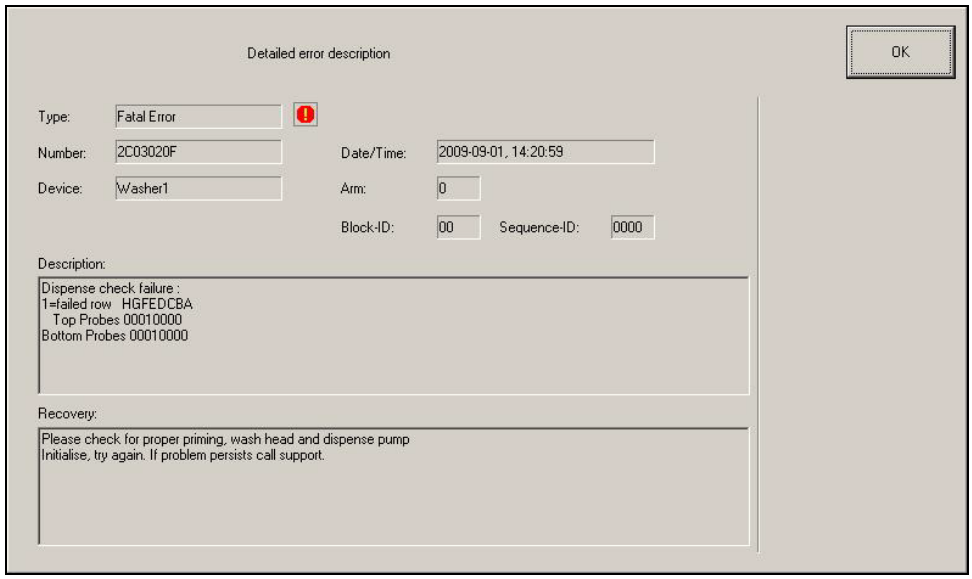


Note: This export process results in the selected log items being exported to the hard drive of the PC, and not to an external hard drive, memory stick or laboratory information system. The purpose of this localized export process is as a troubleshooting tool in the event that valuable information is saved in the event log lists. Such information can be then accessed remotely by Technical Support and used as part of the troubleshooting diagnostic effort.

Press the **OK** button to complete the selected export process or press the **Cancel** button to cancel the selected export process.

Details Dialog

The *Details* dialog provides detailed information about the entry selected in the Log List dialog. Press the **Detail** button on the *Log List* dialog to display the *Details* dialog.



The detail screen displays the **Type** of message, the unique identifying **Number** of each error message, the **Device** involved, the **Date/Time** when the event occurred, and the **Arm**, **Block-ID**, and **Sequence-ID** indicating whether the pipettor was involved. The **Description** field contains a description of the event.

Press the **OK** button to exit the *Details* dialog.

Chapter 4: Security

In This Chapter

This chapter describes the procedures required to maintain NEO Iris users.

Assigning Passwords and User Access Rights

Purpose

The NEO Iris system uses user names and passwords to track which user is currently operating the system and to restrict access to areas of the system by unauthorized operators.

Each operator has a unique user name and password with corresponding access rights. This section describes defining users with associated access rights, including adding a new operator and editing and deleting current operators.

Note: Even though the *Settings* dialog responds to touch-screen, Immucor recommends that you use the keyboard and trackball-mouse when using this dialog.

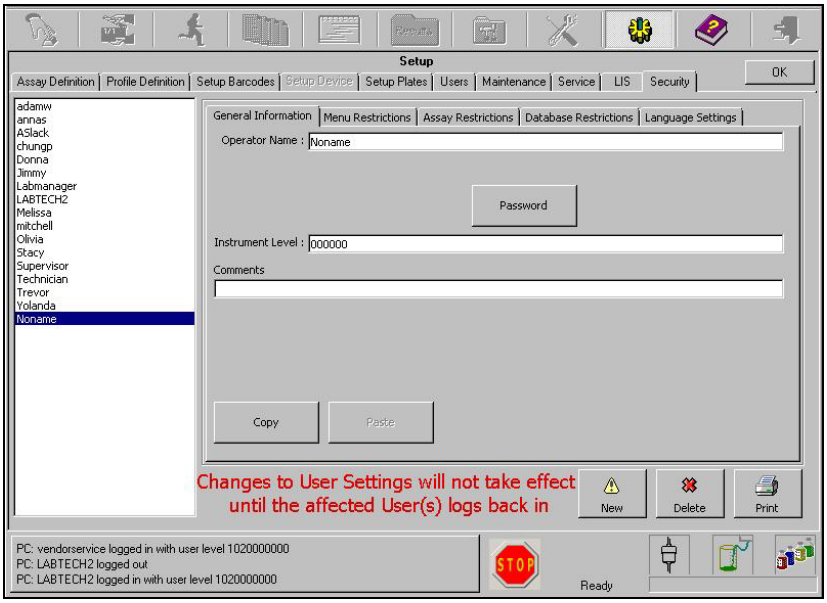
Where to Do This

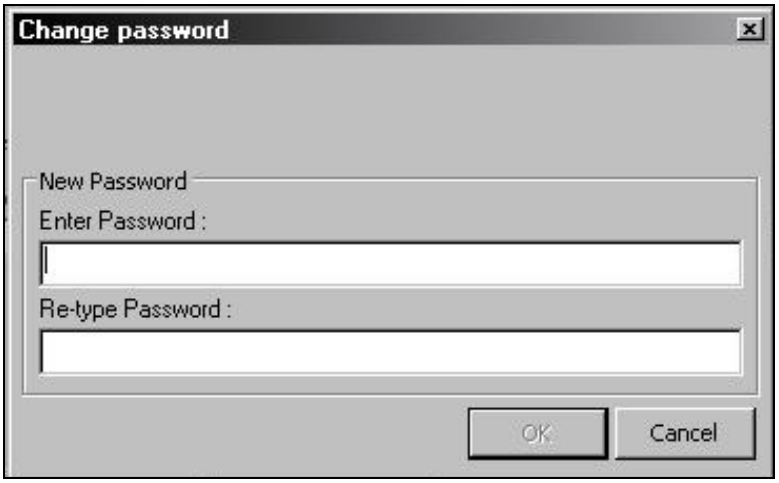
You administer user names, passwords, and access rights from the *Security* tab of the *Settings* dialog.

Note: Permission to use the *Security* tab is given by Immucor personnel to site operators on a case-by-case basis by configuring the site operator's user access rights.

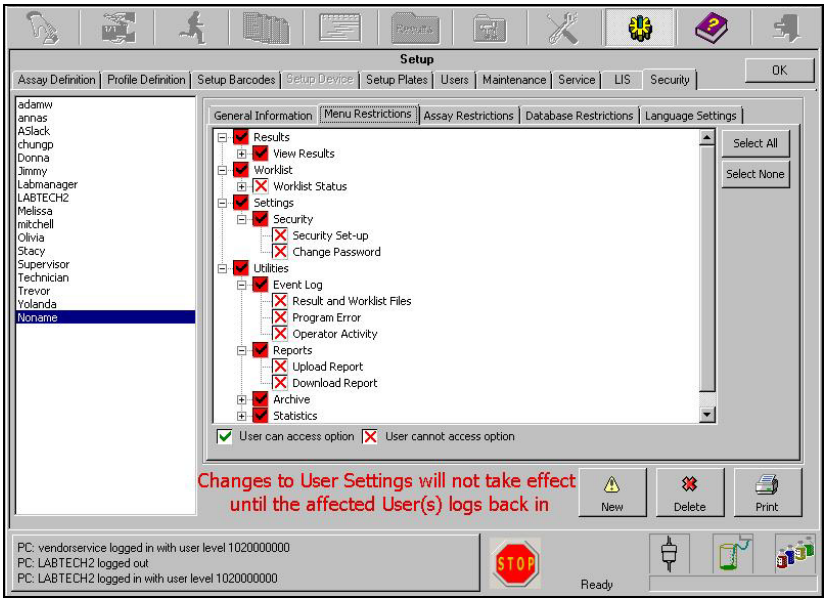
Adding a User

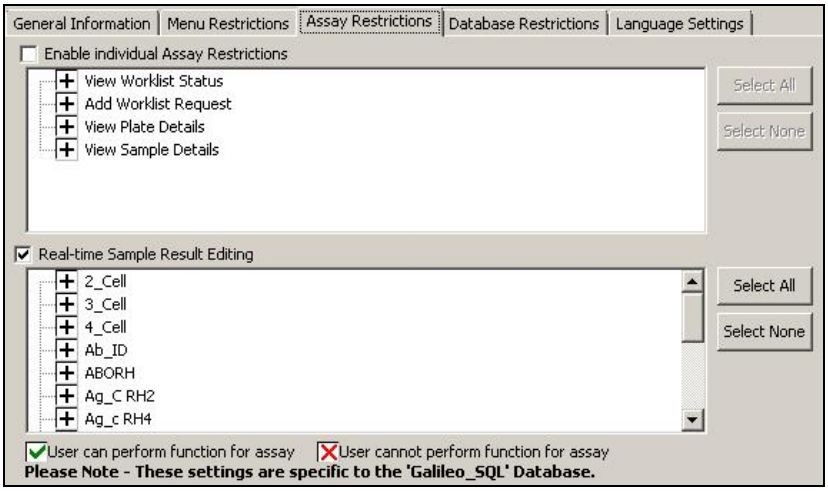
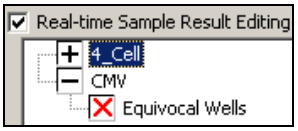
To add a new user:

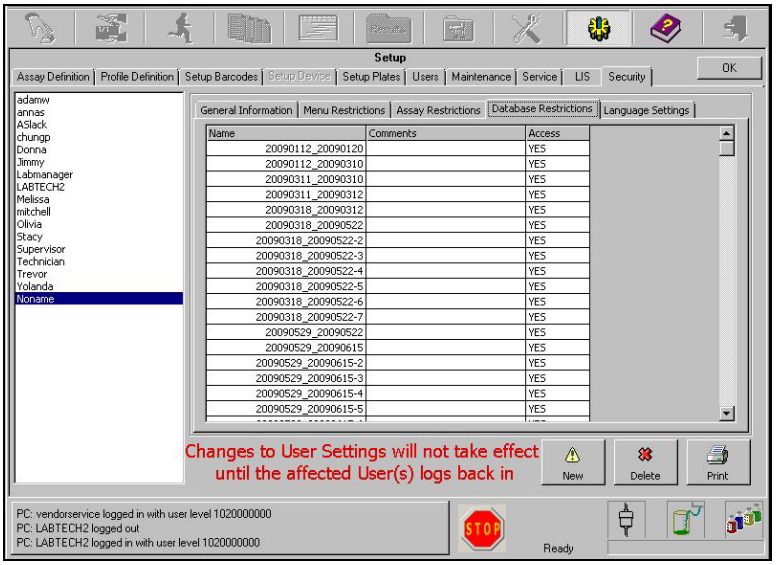
Step	Action
1	Press the **Settings** button on the Main Menu Bar. 
2	The system displays the *Settings* dialog. Press the *Security* tab.
3	The *General Information* tab is displayed as the default.  Press the **New** button.
4	In the *Operator Name* field, type the new operator name. **Note**: This field is not case sensitive.

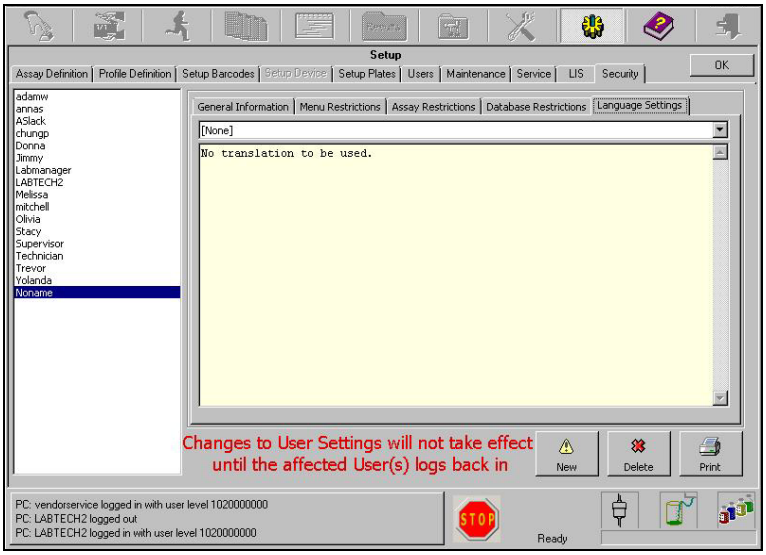
Step	Action
5	Press the **Password** button to open the *Change password* dialog. 
6	Type the user password into the *Enter Password* field. **Note**: This field is case sensitive.
7	Re-type the user password into the *Re-type Password* field to confirm. **Note**: This field is case sensitive.
8	Press the **OK** button to accept the password entries. Both entries must be identical to proceed. Alternatively, press the **Cancel** button to cancel. **Note**: Passwords must be between a minimum of five and a maximum of thirty alphanumeric characters in length. Because manual entry of passwords in login dialogs is case sensitive, passwords must be entered exactly as set up for successful entry into the NEO Iris software.
9	In the *Instrument Level* field, type the operator's instrument access level number. The access level number determines the access rights that are assigned to each operator. These access rights determine the functions of the software that the operator is authorized to access.

Step	Action
	Note: The description and numeric assignments of the different access levels are as follows: • Low (20000) • Medium (30000) • High (100000)
9 (*cont.*)	For access rights, see the section **Default Access Rights** in this chapter. **Limitation**: It is not possible to: • Assign to a new user higher user rights than the current user. • Edit the user rights or change the password of a user with higher user rights than the current user. • Add a user who is already present on the user list. It is important to consider the needs of each operator when assigning access rights. Setting access rights too low may prevent an operator from performing job activities. Setting access rights too high may permit an operator to gain access to portions of the instrument software he or she is unfamiliar with. Incorrectly assigning access rights can result in operator software changes that could negatively impact the performance of the NEO Iris.
10	Press the *Menu Restrictions* tab.

Step	Action
11	The *Menu Restrictions* tab appears.  Press **Select All** to select all options. You can then selectively deny access to some specific functions by clicking to insert a red **X** next to the functions.
12	Press the *Assay Restrictions* tab.

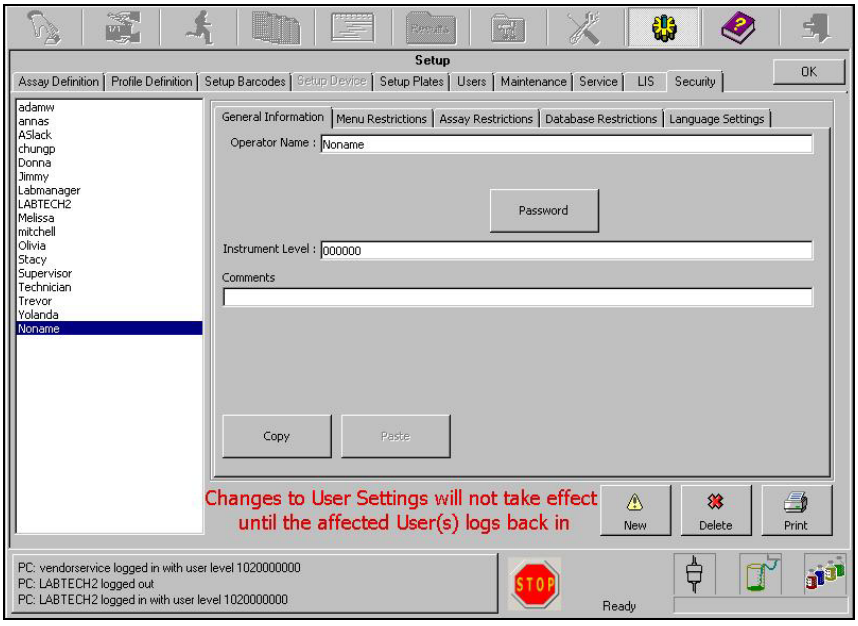
Step	Action
13	The *Assay Restrictions* tab appears.  Two windows related to assay restrictions and result editing are accessible for configuring a user's assay ability. Each window has an associated check box. If the box is checked, then the contents of the associated window are editable with the correct security level. This activates the associated **Select All** and **Select None** buttons. If the box is not checked, then the contents of the associated window are not editable and the **Select All** and **Select None** buttons are inactivated. *Real-time Sample Result Editing* is used to configure the rights for real-time result editing of equivocal well results for certain assays. It is not possible for an operator to edit the final interpreted result of a sample. An example of not being able to edit an assay equivocal is shown below.  Press **Select All** to select all options. You can then selectively deny access to some specific functions. Press the **Select None** button to remove all selections.
14	Press the *Database Restrictions* tab.

Step	Action
15	The *Database Restrictions* tab appears.  Press **Select All** to select all options. You can then selectively deny access to some specific functions.
16	Press the *Language Settings* tab.

Step	Action
17	The *Language Settings* tab appears.  Configure the user's language settings as required using the drop-down list to display the language options. For example, if Spanish is configured for a specific user, then each time this particular user is logged in, the system displays all data management software in Spanish. This tab cannot be used to configure the language for the NEO Iris operating program screens.
18	Press the **OK** button to exit. All data entered is automatically saved.

Editing a User

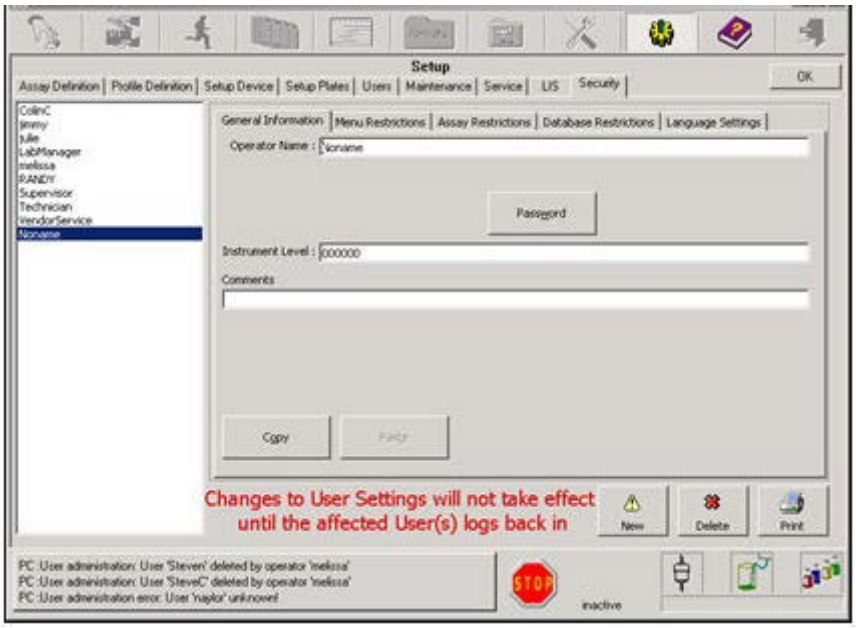
To edit a user:

Step	Action
1	Press the **Settings** button on the Main Menu Bar. 
2	The system displays the *Settings* dialog. Press the *Security* tab.
3	The *General Information* tab is displayed as the default.  Press the user name that you want to edit from the user list. The system displays the data for that user in the fields of the General Information box.
4	Edit the password and settings for the selected user using the relevant tabs: • General Information • Menu Restrictions • Assay Restrictions • Database Restrictions • Language Settings

5	Press the **OK** button to exit. All data entered is automatically saved.

Deleting a User

To delete a user:

Step	Action
1	Press the **Settings** button on the Main Menu Bar. 
2	The system displays the *Settings* dialog. Press the *Security* tab.
3	The *General Information* tab is displayed as the default.  Select the user name that you want to edit from the user list. The system displays the data for that user in the fields of the General Information box.
4	Press the **Delete** button. The system displays the *User Warning* dialog that specifies the name of the user and asks "Are you sure?"
5	Press the **No** button to cancel or press the **Yes** button to confirm. If you press the **Yes** button to confirm, the deleted user name disappears from the user list. A printer prompt appears with options to **Print** or **Cancel**. Printing will provide a log of the user being deleted.
6	Press the **OK** button to exit.

Default Access Rights

The table below lists the Default access rights for the 20000 (Low), 30000 (Medium) and 100000 (High) User Levels.

The rights are as follows:

✓ Access Granted

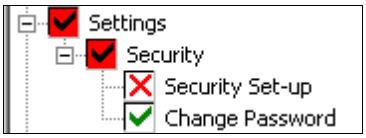
⊗ Access Denied

Function	**Low (20000)**	**Medium (30000)**	**High (100000)**
Toolbar			
Login/Logout	✓	✓	✓
Initialize Instrument	✓	✓	✓
Start Run	✓	✓	✓
Worklist	✓	✓	✓
Plate Lists	✓	✓	✓
Results	✓	✓	✓
Maintenance	✓	✓	✓
Utilities	⊗	✓	✓
Settings	✓	✓	✓
Help	✓	✓	✓
Exit	✓	✓	✓
Module Dialogs			
Washer	✓	✓	✓
Incubator	✓	✓	✓
Reader	✓	✓	✓
Loading Tower	✓	✓	✓
14-lane and 5-lane Bays	✓	✓	✓
14-lane Bay barcode configuration	⊗	✓	✓

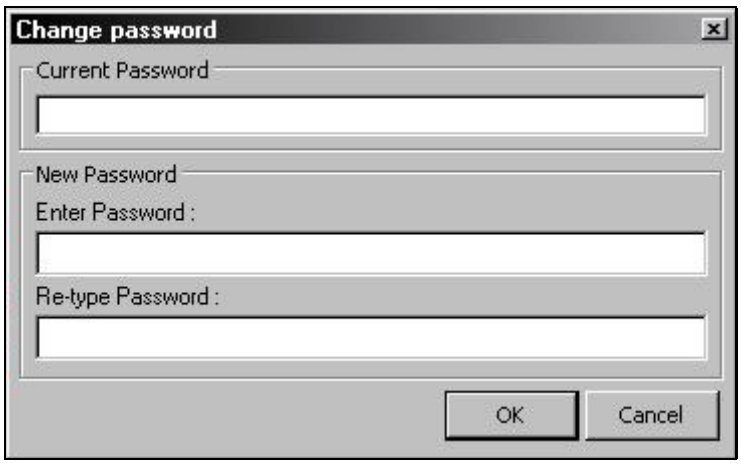
Function	Low (20000)	Medium (30000)	High (100000)
Start Run			
Sample Loading	✓	✓	✓
Resource Loading	✓	✓	✓
Plate List			
Processing Steps	✓	✓	✓
Delete	⊗	⊗	⊗
Detail View	✓	✓	✓
Print	⊗	⊗	✓
Settings			
Assay Definition	⊗	⊗	⊗
Profile Definition	⊗	⊗	✓
Setup Barcodes	⊗	✓	✓
Setup Device	⊗	⊗	⊗
Setup Microplates	⊗	⊗	⊗
Users	⊗	⊗	⊗
Maintenance	⊗	⊗	⊗
Service	⊗	⊗	⊗
Plate Loading Tower			
Strip Selection	✓	✓	✓
Scan Plate	✓	✓	✓
Assay Selection	✓	✓	✓
Plate Expiry Entry	✓	✓	✓
Plate Expiry Removal	⊗	⊗	✓
Processing Steps	✓	✓	✓

Changing a Password

You can change your password without having full access to the security configuration as long as your access has been set up by another operator with appropriate access rights of their own. Your access rights must be configured to *Change Password*.



To change your password, without rights to changing access rights:

Step	Action
1	Press the **Settings** button on the Main Menu Bar.  The *Security* tab will open as the default and the **Change password** dialog automatically displays. No additional operator set up options will be available. 
2	Enter your current password into the **Current Password** field followed by two (2) identical entries in the two (2) fields in the *New Password* area (**Enter Password** and **Re-type Password**).

3	Press the **Cancel** button to cancel your entries, or press the **OK** button to register your new password. The **Change password** window will close and the blank security tab will be displayed indicating that no options are available to you.  **Note**: You will have to use your new password when you log on next time.

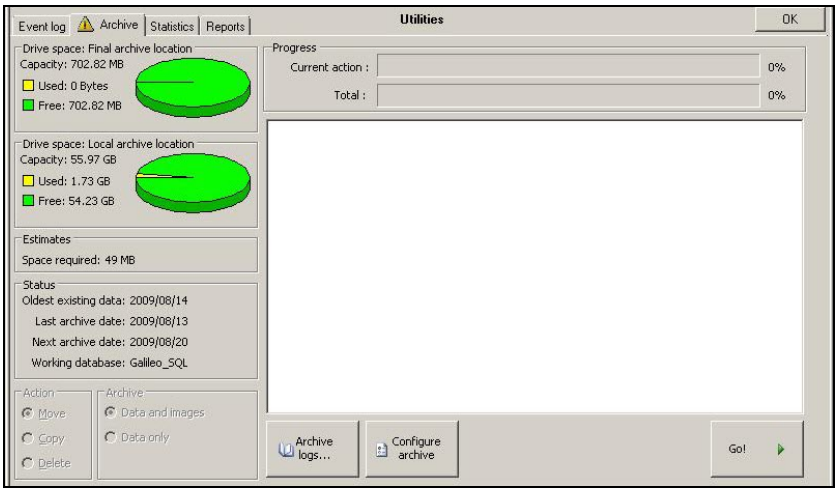
Archive Configuration

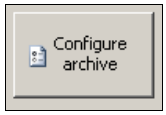
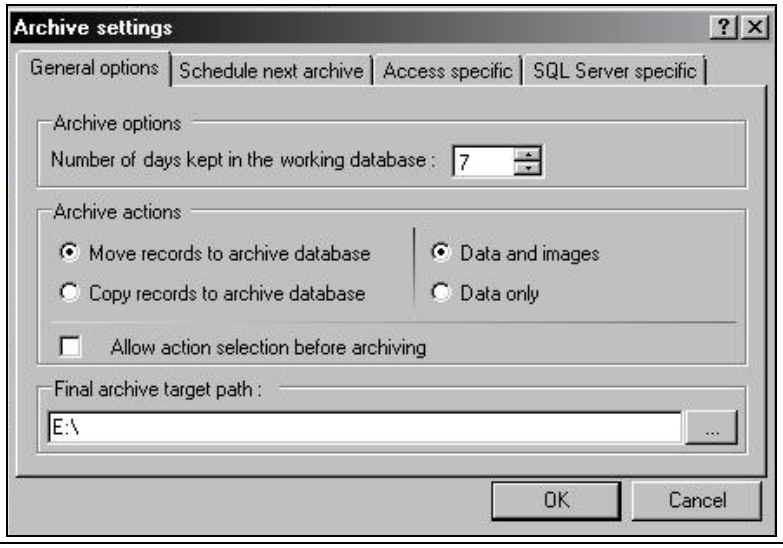
This section describes how to configure the archive process and view archive logs.

Note: The purpose of describing the archive configuration is to inform you of the configurations available. An Immucor employee with sufficiently high security access rights is required to configure the available options. You will not be able to access these configurations.

Configuring the Archive Process

To configure the Archive process:

Step	Action
1	The **Utilities** dialog allows you to view event logs and statistics, as well as archive and print reports. Select the **Utilities** button to access the **Archive** tab.  **Utilities** button 

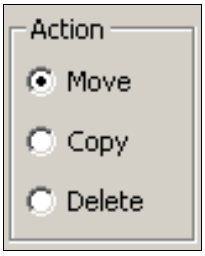
Step	Action
2	The **Configure archive** button is only available on the **Archive** tab if the Immucor employee security configuration allows access.  **Configure archive** button  **Security access permissions** for archiving configuration **Note**: The Action and Archive boxes are not normally accessible on the Archive tab, but show what has been selected on the configuration screen. Access to these boxes can be activated from the **General options** tab as described later.
3	The **Archive settings** dialog is displayed when the **Configure archive** button is selected. 

The **Archive settings** dialog has four tabs:

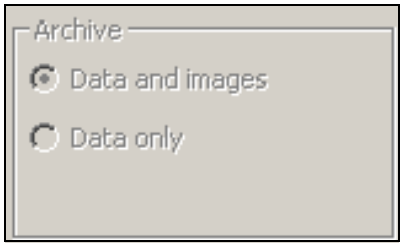
- General options
- Schedule next archive
- Access specific
- SQL Server specific

General options tab

A number of configurations can be set up through the general options tab. The number of day's worth of data that should remain in the working database after an archive, assuming records have been moved (copy and deleted), can be set using the **Number of days kept in the working database:** numeric selection box. Seven (**7**) days is the maximum number of day's worth of data that can be kept. Zero (**0**) is the minimum number of day's worth of data that can be kept. You can select whether to copy or move (copy and delete) records to the archive database. You can configure whether the move/copy data to the archive database can be selected on the main archive dialog using the check box for **Allow action selection before archiving**. If selected, the **Action** and **Archive** boxes are displayed on the main archive window.



Action box



Archive box

The **Move** action is defined as copy and delete. The **Copy** action is defined as copy without delete. The **Delete** action is defined as delete without copy.

Note: The **Delete** option of the **Action** box is only active if a copy action has been performed.

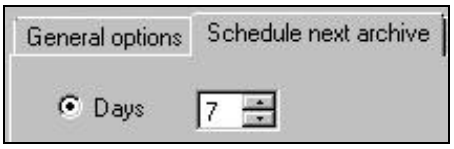
You can select whether to archive **Data and images** or **Data only**. If the selection is **Data only** and the action is to move (archive) data, any associated image files within the corresponding date range will be deleted.

You can define the final archive target path, e.g. another area of the hard disk, network or removable media. The correct target is **E:₩**.

The Immucor employee can accept the required configurations by selecting the **OK** button or reject any changes by selecting the **Cancel** button.

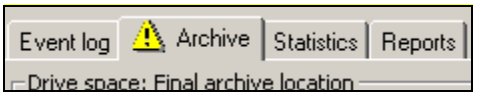
Schedule next archive tab

The **Schedule next archive** tab allows the archive interval to be defined. The default and maximum allowable schedule time is **7** days. Archiving can be performed more frequently than 7 days if needed or preferred. The allowable numeric range for the number of days selection is between one (1) and seven (7) days inclusive. Zero (0) days and greater than seven (7) days cannot be selected.



Schedule next archive tab

The instrument will not prevent you from running assays if this scheduled time is exceeded. However, there will be a warning flag generated on the Archive tab within the Utilities dialog and also on the Utilities button.



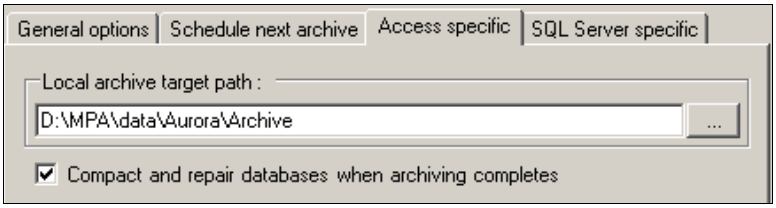
Refer to **Chapter 10 – Maintaining the NEO Iris** for more information regarding the incorporated archive warning system.

The Immucor employee can accept the required configurations by selecting the **OK** button or reject any changes by selecting the **Cancel** button.

Access specific tab

The **Access specific** tab is not needed for routine archive configuration. The entries in this tab should not be modified without consulting Immucor.

The **Access specific** tab allows definition of a local archive path. The default value is **D:₩MPA₩data₩Aurora₩Archive**. The check box is used to configure **Compact and repair databases when archiving completes**.



Access specific tab

The Immucor employee can accept the required configurations by selecting the **OK** button or reject any changes by selecting the **Cancel** button.

SQL Server specific tab

The **SQL Server specific** tab is not needed for routine archive configuration. The entries in this tab should not be modified without consulting Immucor.

The **SQL Server specific** tab allows definition of a server name for archiving. The drop down list finds and lists any servers present. Once the server is selected, a **Verify server** button will become active with a warning symbol. When selected, the software will verify that the server name entered exists and that it is configured for remote access. If successful, the warning symbol will then be removed.

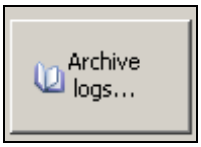
SQL Server specific tab

A check box for **Shrink/truncate databases when archiving completes** is located on this SQL Server specific tab.

The Immucor employee can accept the required configurations by selecting the **OK** button or reject any changes by selecting the **Cancel** button.

Viewing the Archive Logs

A list of archive activity can be viewed using the archive logs. The **Archive Logs** are accessed by pressing the **Archive logs** button on the main *Archive* dialog.

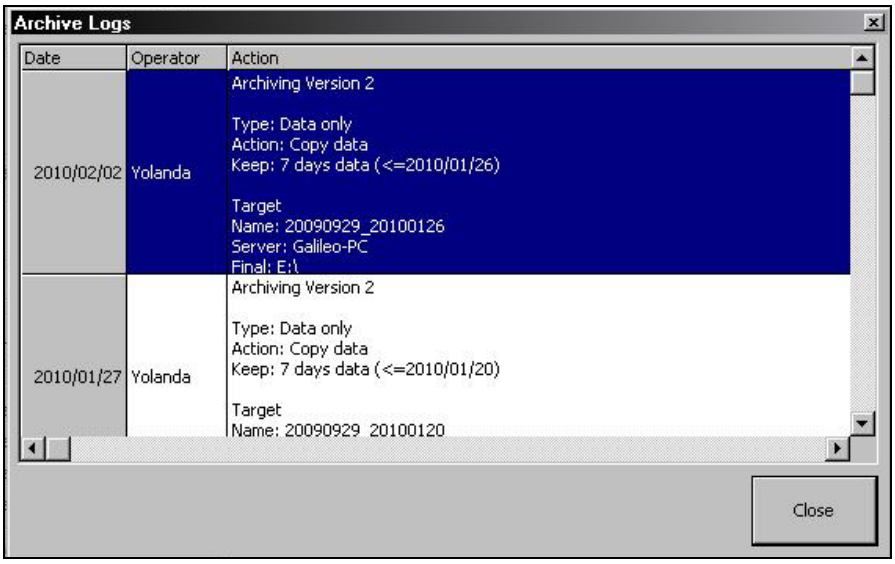


Archive logs button

The **Archive Logs** dialog has three columns:

- Date
- Operator
- Action

The *Date* column documents the date when the archive activity took place. The *Operator* column documents the identification of the operator who performed the archive. The *Action* column describes the details of the archive activity.



When large quantities of entries are listed, horizontal and vertical scroll bars can be used to navigate the **Archive Logs** dialog. Press the **Close** button of the **Archive Logs** dialog to exit the dialog.

Chapter 5: Instrument Start-Up

In This Chapter

This chapter describes how to start up the instrument.

Starting Up

Purpose

To use the instrument, you must turn on the NEO Iris PC and the NEO Iris module.

Note: The centrifuge module should already be switched on unless it was switched off during some troubleshooting process.

These steps should be followed when the NEO Iris instrument is needed for test processing or to perform the daily shutdown/startup of the instrument.

Procedure

To start the NEO Iris:

Step	Action
1	Turn ON the computer. **Note**: Open the right door of the cabinet to locate the computer.
2	Turn ON the monitor.
3	Turn ON the NEO Iris instrument. **Note**: The power switch is located next to the monitor pole. **Note**: Although the centrifuge module is not typically powered off, it may be necessary to turn ON if the module was turned off during the shutdown procedure. The power switch is located at the rear of the module.
4	The Camera Reader lamp and instrument overhead lights will be illuminated when the NEO Iris is powered ON. **Limitation**: The instrument must be switched on at least thirty (30) minutes prior to the first plate read to allow the reader lamp to warm up. Reading of plates prior to completion of this warming period can cause incorrect negative reading of weakly positive reactions.
5	Log into the NEO Iris software. Refer to **Logging In and Initialization** published in this chapter for detailed information.

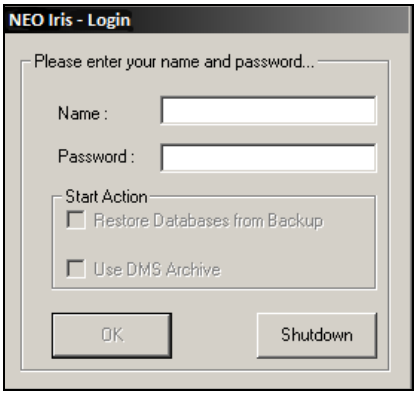
Logging In and Initialization

Purpose

To access the instrument software, you must enter a valid operator ID and password. For more information about operator IDs and passwords, refer to **Assigning Passwords and User Access Rights** in Chapter 4 - Security.

Note: The instrument software is password protected to prevent unauthorized operator access to the computer operating system and also prevents configuration changes by unauthorized personnel.

Procedure

Step	Action
1	The **Login** dialog will be displayed either automatically at startup or by selecting the Login button on the Main Menu Bar. 
2	In the Name field, type your operator name. **Note**: This field is not case sensitive.
3	In the Password field, type your password. **Note**: This field is case sensitive.

Step	Action
4	If you have sufficient user rights, you can select the **Use DMS Archive** check box.  **Limitation**: The **Use DMS Archive** check box control option allows you to view archived results that are saved on a disk or another Archive medium using the DMS. You can only view archived results through the DMS with the Archive medium attached to the computer or by inserting the disk into the drive of the computer.
5	Click **OK** to complete the **Login** process. The system automatically performs an initialization routine that includes removing any plates that may have been left on the instrument and returns them to the Plate Loading Tower.  **Attention**: If the instrument displays a Centrifuge: Rotor error message during initialization, the centrifuge module is not powered on.  **Limitation**: The COP: Serial Buffer Deleted error message may appear during initialization. In this case click the **OK** button. However, if this error occurs in other situations it is recommended to complete the current run(s) but do not start any new plates. Initialize the instrument using the Initialize button before starting new plates.
6	The instrument is now ready to perform system maintenance and sample processing.

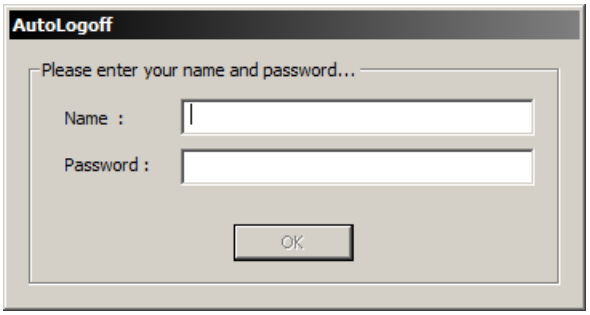
Auto Logoff

Purpose

If the automatic Logoff function is configured, the system will activate a locking screen after a certain period of inactivity. You must enter a valid operator ID and password to access again the instrument software.

Note: The optional Auto Logoff function is only available with Instrument Control Software version 1.8 and higher.

Procedure

Step	Action
1	The **AutoLogoff** dialog will be displayed automatically after the configured duration of the inactivity period will elapse. 
2	In the Name field, type your operator name. **Note**: This field is not case sensitive.
3	In the Password field, type your password. **Note**: This field is case sensitive.

Step	Action
4	 **Limitation**: Once the Auto Logoff has occurred, only users with equal or higher access rights than the user that was logged in when the Auto Logoff was triggered are able to access the system.
5	Click **OK** to unlock the system. The instrument software is again accessible.

Chapter 6: Instrument Testing Operation

In This Chapter

This chapter describes the detailed operating procedures required to process samples.

Using the Start Run Assistant

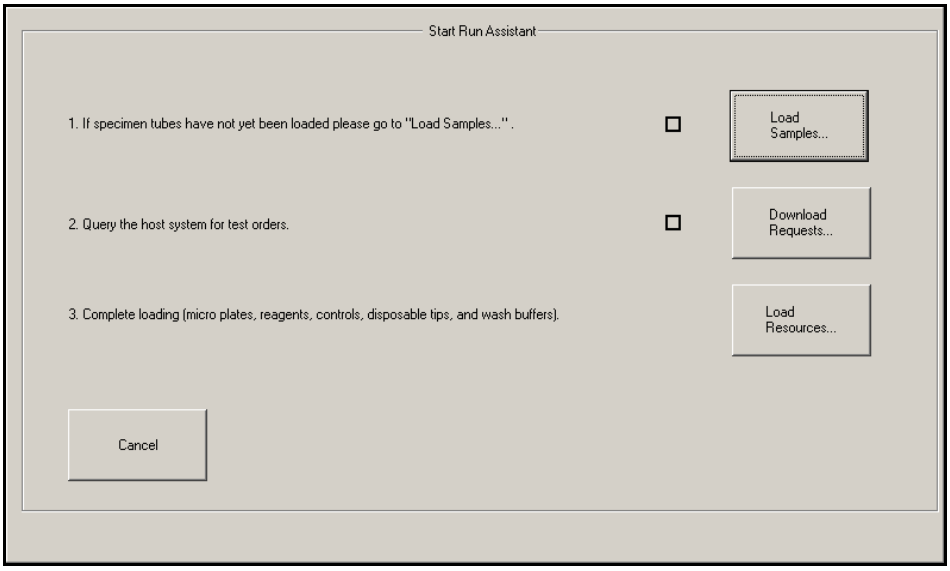
Before You Begin

You must prepare all of the necessary reagents and samples according to the reagent package insert requirements before running assays. The *Start Run Assistant* dialog provides an intuitive guide to starting assay runs.

About the Start Run Assistant

Click the **Start Run Assistant** button on the Main Menu Bar.

The instrument displays the *Start Run Assistant* dialog.



Start Run Assistant Steps

The following steps must be completed:

1. Load Samples
2. Download Requests from LIS (optional)
3. Complete the Sample Loading Process
4. Load Reagents and Controls
5. Load Plates
6. Start Processing

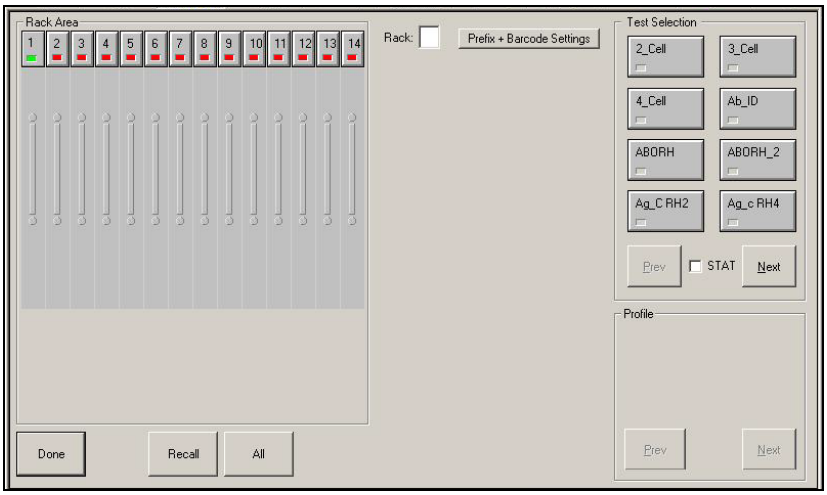
Loading Samples

Sample Requirements

Refer to **Attachment 1 for Neo Iris Operator Manual** for details regarding sample requirements.

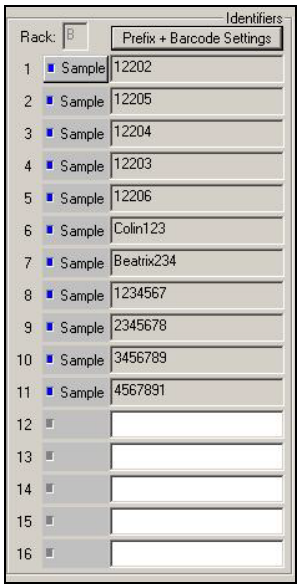
Procedure

To load samples:

Step	Action
1	Click the **Load Samples** button on the *Start Run Assistant* dialog. The instrument displays the *14-lane Bay* dialog. 
2	Ensure that the sample tubes are seated in the appropriate rack and the barcode labels can be seen through the gap on the right of the sample rack. **Note**: Correct position requires that the tubes fit securely, with the barcode positioned between 20 mm and 105 mm (0.8 and 4.1 inches) from the bottom of the tube.

Step	Action
	
3	Slide the sample racks into the sample loading bay one at a time. Use the lane with the continuous green indicator LED.  **Note**: The far left lane will be the default lane. You must wait for that lane LED and on-screen indicator to be continuous green before loading a rack. A different lane can be selected if needed.

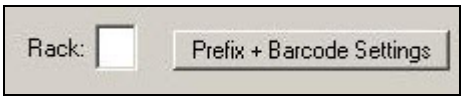
Step	Action
4	Verify that all the barcodes have been scanned successfully. Successfully scanned barcodes appear in the fields of the Identifiers area of the *14-lane Bay* dialog.



If...	Then...
All barcodes have been scanned successfully	Load further racks of samples as necessary.
A barcode has not been scanned successfully	Follow the procedure to **Rescan Unread Sample Barcodes**.

Barcode Settings

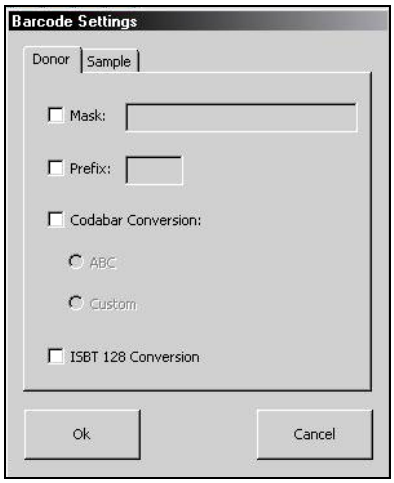
The *Barcode Settings* dialog can be used if sample barcodes require any data conversion or manipulations on a rack-by-rack basis. This dialog is accessed by pressing the **Prefix + Barcode Settings** button located top center of the sample loading dialog.



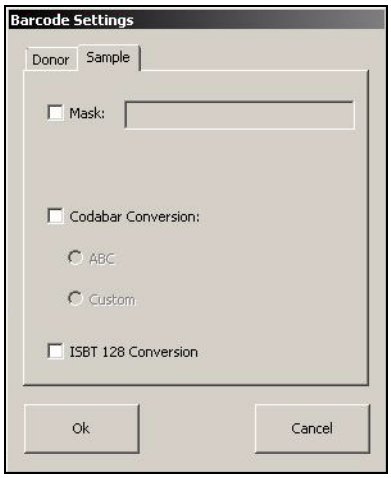
- Sample tubes requiring barcode conversion should be loaded into racks with tubes of like barcode properties
- Configurations defined via this dialog will remain active until the 14-lane bay is exited or the settings are modified again

- If racks that require different barcode conversions, the Prefix + Barcode Settings dialog must be opened to modify the current conversion scheme before loading a rack with a different conversion requirement
- To cancel the current conversion, the dialog can either be opened and conversion de-selected or exit the 14-lane bay to revert back to any default barcode settings.

The *Barcode Settings* dialog has two tabs (Donor and Sample).



Barcode Settings>Donor tab



Barcode Settings>Sample tab

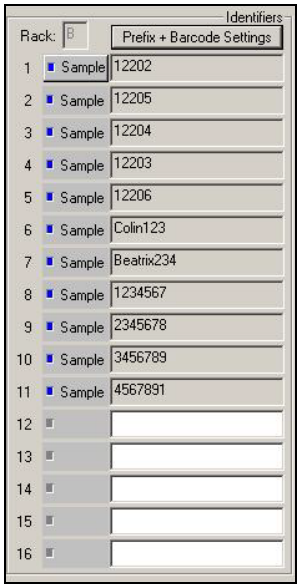
The Donor and Sample tabs have the same features for being able to set a barcode mask, converting Codabar (ABC or Custom) and ISBT 128 conversion. The Donor tab has the additional feature of being able to assign a designated prefix to all samples on a given donor rack. Separate prefixes cannot be assigned to different samples in the same donor rack. The maximum number of characters that can be entered into the Prefix field is five. The tabs will populate with the pre-configured settings that were previously inputted into the *Setup Barcodes* tab of the *Setup* screen, however this default can be changed by you on a rack-by-rack basis.

If a donor prefix is configured, it will be displayed as replacement text on the *14-lane Bay* dialog *Prefix + Barcode Settings* button. For example, if a donor prefix of *12345* is used, then it will display, as shown below, as replacement text on the button.

Press the **Cancel** button of the *Barcode Settings* dialog to cancel any selected options and close the dialog. Press the **OK** button of the *Barcode Settings* dialog to accept any selected options and close the dialog. Refer to **Chapter 3 – System Software Navigation** for details regarding customized Codabar conversion and masking.

Rescanning Unread Sample Barcodes

To rescan unread sample barcodes:

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Remove the rack with the unread barcode and check that the barcode is correctly aligned.</td></tr>
<tr><td>2</td><td>Slide the rack back into the loading bay. Use the lane with the continuous green indicator LED.</td></tr>
<tr><td>3</td><td>Verify that all the barcodes have been scanned successfully. Successfully scanned barcodes appear in the fields of the Identifiers area of the Loading Bay dialog.
 

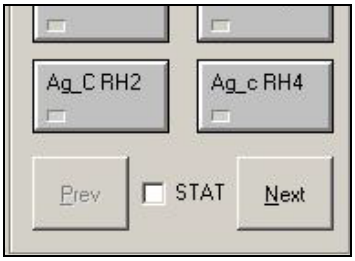
<table>
<tr><th>If...</th><th>Then...</th></tr>
<tr><td>All barcodes have been scanned successfully</td><td>Assign required assays.</td></tr>
<tr><td>A barcode has not been scanned successfully</td><td>Go to step 4.</td></tr>
</table></td></tr>
</table>

4	a. Remove the rack and select the **Recall** button to display the sample IDs on the screen for the last rack removed. b. Hand-scan or type any missing / unread barcodes into the relevant field (double data entry is required) c. Reinsert the rack in the lane with the continuous green LED  **Note**: You can make assay assignments at this time if you are assigning assays manually (within the 14-lane Bay dialog). If you have requested the assays through a LIS, close the 14-lane Bay dialog and proceed to **Downloading Requests from LIS**. If the assays have been requested using the Worklist facility, then the assays will be automatically assigned when the samples are loaded.

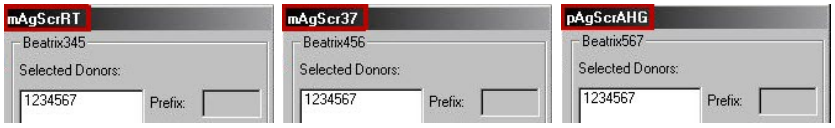
Manually Selecting the Assays Required

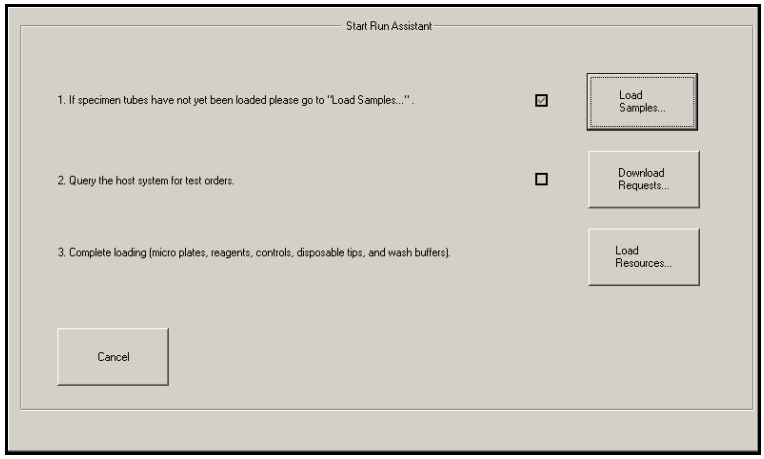
To manually select the assays required:

Step	Action
1	Select the rack to receive assay assignments within the *14-lane Bay* dialog.
2	Select a sample ID to choose a specific sample. The field is highlighted in blue. For STAT samples, proceed to step 3. For non-STAT samples, proceed to step 4.

Step	Action
3	When loading samples, testing can be ordered as STAT by using the **STAT** check box of the *Test Selection* area.  Load the STAT sample(s) into the loading bay, select the sample(s) on the screen, and then: a. Check the box for **STAT**. b. Assign the necessary assay to the sample(s). The word STAT is displayed on the assay button if STAT is assigned to the assay correctly. STAT can be used when selecting profiles, but the STAT assay button indication will only be displayed on the individual buttons for the assays in the profile and not on the profile button itself.  The STAT assignment for a given assay assignment will also be indicated in the *Resource Overview* window in the *Samples/Strips* column. Only assays that contain STAT samples will be displayed in the window. Only after the STAT assays are started can the other non-STAT assays be started. STAT test processing, when in conjunction with non-STAT test processing, is described in the *Completing the Sample Loading Process* section of this chapter. You must de-select the STAT box before ordering normal priority assays. If there are non-STAT samples loaded for an assay being run with STAT samples they will all be run on the same plate if space permits. Use of plate resources can be optimized for STAT samples using the **Cancel Plate** button on the *Plate List*, as described in **Chapter 3: System Software Navigation**.

Step	Action
4	For non-STAT samples, press an assay button or assay profile button in the Test Selection area to select an assay or assay profile. **Note**: If a crossmatch assay is selected, then an additional input window is displayed (titled with the name of the assay) after the assignment of that assay to a specific sample. The ID of the specifically selected sample is displayed just below the name of the assay.  This window allows the operator to input the specific donor unit segment IDs that are to be crossmatched with that specific sample. The operator must hand scan or manually enter the donor ID(s) information into the **New Donor** field: a. Hand-scanning will automatically add the Donor ID to the Selected Donors dialog; manual entry of id must be followed by pressing the **Enter** key on the keyboard to add the Donor ID to the Selected Donors dialog. b. After all donors are in the Selected Donors box, select **OK** and then load the donor rack onto the instrument and move onto the next step. **Note**: The *Prefix* field is populated by the configured value from the *Setup Barcodes* tab of the *Setup* screen. As barcode data is entered into the *Selected Donors* field, the prefix is automatically assigned to the ID in the list.

Step	Action
	Use the **Delete** button of the input window to remove specifically highlighted donors ID(s) from the *Selected Donors* list. Press the **Cancel** button of the input window to cancel the current donor assignments. Press the **OK** button of the input window to accept the donor assignments. If crossmatches have been previously assigned and accepted by pressing **OK**, and you wish to subsequently remove them, you can reenter the crossmatch input window and press the **No X-match** button to inactivate the assignments. **Note**: You must press the **OK** button to close the dialog before loading the donor rack into the bay, otherwise the tests will not be ordered correctly.
4 (*cont.*)	Other assays, such as red blood cell antigen screening assays, utilize equivalent data entry windows with the same kind of functionality. The data entry window is titled with the name of the assay. Examples are shown below: 
5	Repeat steps 1–4 for all samples requiring that assays be manually assigned. **Note**: To apply the same assay selection to all samples in a rack, place the curser in the first position and then select the All button. The first position can be empty. If you select a position other than the first position and click **All**, the assay will NOT be ordered for all samples. Refer to **Attachment 1 for Neo Iris Operator Manual** for a full list of assays and their respective assay button abbreviations. Profile buttons are site-customized buttons that can be built to combine two or more assays. Profiles are a group of assays that can be selected together and therefore make assay selection easier.

Step	Action
6	You must click **Done** on the *14-lane Bay* dialog when sample loading and assay assignment is finished. The system redisplays the *Start Run Assistant* dialog.  **Note**: The selected check box to the left of the **Load Samples** button indicates that this stage has been completed.

Downloading Requests from LIS

Purpose

You can download all test requests for samples from the LIS if a suitable interface is active.

The configuration of the LIS interface may require manual query for assay assignments using the procedure below or the assay assignments may be received by the instrument in real-time and therefore immediately appear when the sample is loaded on the instrument.

Note: You must validate the interface communication between the LIS and the instrument software prior to use. It is your responsibility to perform this validation. For more information on the configuration requirements, refer to **Attachment 2 for Neo Iris Operator Manual**.

Procedure

To download Assay Selections from the LIS:

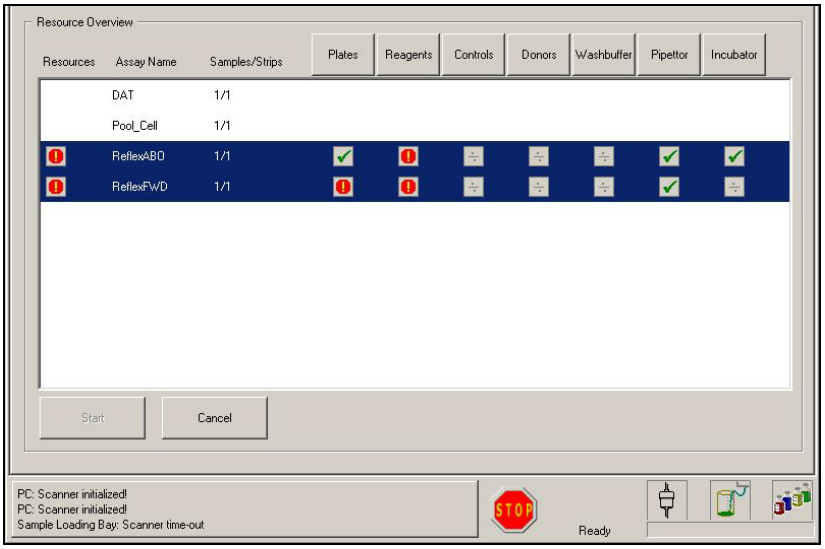
Step	Action
1	Click **Download Requests** on the *Start Run Assistant* dialog.
2	The instrument queries the LIS for assay requests for the samples loaded and then downloads these requests from the LIS.
3	When it has finished, the system redisplays the *Start Run Assistant* dialog.

4	If the instrument is currently running assays, Open and close the *Loading Bay* dialog (via **Load Samples** of the *Start Run Assistant*) **AFTER** the LIS worklist orders have been received but **BEFORE** the *Resource Overview* window is opened. If no assays are currently running, skip to *Completing the Sample Loading Process* section.  **Note**: The selected check box to the left of the **Download Requests** button indicates this stage has been completed.  **Limitation**: When a sample is actively being tested by an assay and the same assay is requested again for that same sample from the LIS, a second request is added. This will cause the sample to appear in the *Resource Overview* window for a duplicate test. To avoid this, open and close the *Loading Bay* dialog (via **Load Samples** of the *Start Run Assistant*) **AFTER** the LIS worklist orders have been received but **BEFORE** the *Resource Overview* window is opened.

Completing the Sample Loading Process

Procedure

To complete the sample loading process:

Step	Action
1	Click **Load Resources** on the *Start Run Assistant* dialog. The system displays the *Resource Overview* window.  The *Resource Overview* window presents a list of plates (with the assay name and number of samples on each) that need to be processed to fulfill the assays ordered for the samples currently loaded onto the instrument. For information regarding STAT test processing, see below. To continue to the next step in this procedure, see the next page.

STAT Test Processing

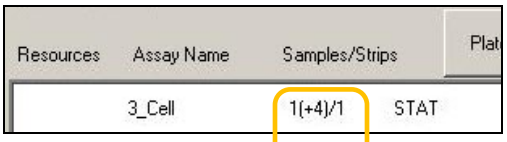
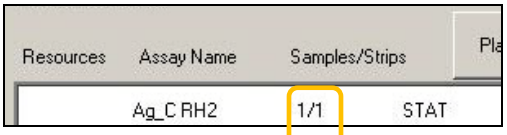
The Resource Overview window preferentially displays STAT test orders before routine test orders. Existing routine test orders do not display until STAT tests start. After STAT tests start, routine test orders reappear in the window and their tests can be started.

- When other normal priority samples on the instrument require the same test as the STAT sample, the instrument uses the remaining positions on the plate for those samples.
- The Resource Overview window's *Samples/Strips* column displays:

o **X(+Y)/Z** where:

- X is the number of STAT tests ordered
- Y is the number of normal priority tests ordered
- Z is the number of strips required or loaded to run the STAT tests

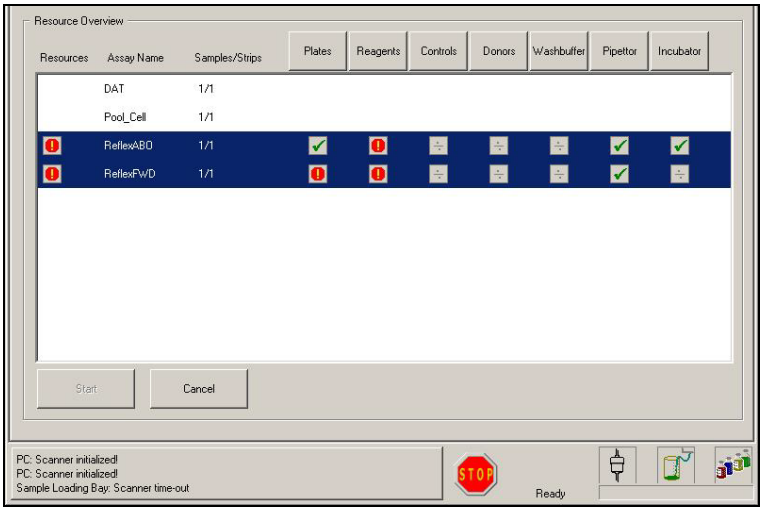
- After you select a Resources Overview window line, the software checks available resources (including plates) and if STAT samples are included, it recalculates how it will use them. The *Samples/Strips* display changes, based on strip availability and resources needed. The number of normal priority samples displayed (Y) can decrease, based on the remaining capacity of the strip wells available after STAT samples are accommodated.

Samples/Strips Display Examples After STAT Tests Ordered	**Number of Strips Loaded**	**Status Examples**
 **X(+Y)/Z = 1(+4)/1** X = 1 STAT Y = 4 normal priority samples Z = 1 strip required for the 1 STAT	None	Assay cannot be started because no strips are available. If one strip is loaded, it will be used to run the STAT sample and as many of the normal priority samples as can be accommodated, based on the remaining strip capacity.
 **X(+Y)/Z = 1(+0)/1 = 1/1** X = 1 STAT Y = no normal priority samples Z = 1 strip required for the 1 STAT	None	Assay cannot be started because no strips are available. When one strip is loaded, it will be used to run the STAT sample only.
 **X(+Y)/Z = 1(+1)/1** X = 1 STAT	1 strip	Assay can be started. The one strip will be used to run the STAT sample and include one normal priority sample.

Y = 1 normal priority sample Z = 1 strip loaded for the 1 STAT		

Procedure (continued)

Step	Action
2	To select a plate to be run, click anywhere in the line of the screen where the plate is displayed. The system calculates and displays the status of the consumables (plates, reagents, controls, and wash buffer) for that plate. If the system displays a green check mark (✔) in the column of a consumable, this indicates that sufficient resource is available to perform the assays on the selected plate.  If the system displays a red exclamation symbol (❗) in one of the columns for a consumable, you must load that consumable.
3	Open the *Loading* dialog for the missing resources directly from the *Resource Overview* window by clicking on the appropriate button above the column with the exclamation mark: • Plates • Reagents • Controls • Donors • Washbuffer • Pipettor • Incubator
4	Resolve the resource issue using the missing list provided by the software.

Step	Action
5	Close the resource dialog. The system redisplays the *Resource Overview* window.  You cannot adjust the number of strips on a plate in the plate loading dialog, if you have already selected that plate through the *Resource Overview* window. You must deselect the plate in the *Resource Overview* window before you can change the number of strips on the plate. **Note**: You should not remove sample or reagent vial racks while the *Resource Overview* window is currently being displayed. If a rack is removed, a message will appear and Cancel must be selected to start the loading process again.

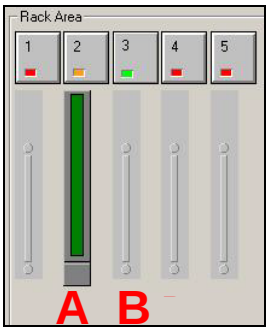
Loading Reagents and Controls

Procedure

To load Reagents and Controls:

Step	Action
1	Load the reagents and controls required for the planned assays into the instrument reagent racks. Reagent rack details are listed in **Appendix A – Preparing the NEO Iris for First Use**.  **Note**: The vials of cellular reagents should be gently mixed by hand, before removing the dropper assembly or cap, to completely resuspend the cellular contents (prior to adding the stirball in step 3 below).

Step	Action
2	Check the position of the vials in the reagent rack to make sure that the NEO Iris designated vial barcodes on the vial label are facing towards the opening in the right hand side of the rack.  **Limitation**: Excluding QC assays, some assays will not be processed under the following conditions: A corQC EXTEND Standard vial loaded in the 5-lane bay will be recognized; however this reagent will be listed as missing in the *Resource Overview* window due to the risk of a probe arm crash. When running a DAT assay, a DAT Positive Control Cell vial loaded in the 5-lane bay will be recognized; however this reagent will be listed as missing in the *Resource Overview* window due to the risk of a probe arm crash. Under both of these scenarios, the assays will not be able to be scheduled until the necessary reagent is loaded into the 14-lane bay.  **Warning**: Inspect all reagents and controls for the presence of foam before placing on the instrument. Do not vigorously agitate blood grouping anti-sera or controls. Shaking will produce foam in the vial that can cause the Liquid Level Detection (LLD) feature of the pipetting system to aspirate foam and/or air rather than reagent. This will produce incorrect results or an error.  **Warning**: Before placing reagents on the instrument, you must remove the bottle caps. You are advised to remove and discard the dropper by pulling the dropper from the bulb. When you remove the reagents from the instrument for storage, you must place the caps back on the bottles. To avoid cross contamination of reagents, it is important that you place the caps on the correct bottles. Mixing caps can result in erroneous test results. Immucor-approved disposable vial caps can alternatively be used instead of replacing the saved original vial caps. Contact Technical Support for information regarding these caps.

Step	Action
3	Add one stirball into each vial containing cellular reagents, such as Referencells, Capture Indicator Cells, and quality control cells. A stirball is not required if one has already previously been added to a given vial prior to previous usage. **Note**: The stirballs are used to keep cellular reagents in suspension during testing. **Warning**: If you do not add the stirballs to the cell suspensions, the results may be invalid or incorrect. Do not touch the stirballs. You should add them directly to the cellular reagent vials using the dispenser provided. Contamination and neutralization of cellular reagents can occur if the stirballs are touched. You must only add one stirball per vial of cellular reagent. Do not add more than one stirball per vial.
4	Depending on the reagent rack size being used, open the *14-lane Bay* by selecting the Controls button at the top of the *Resource* Overview window or open the *5-lane Bay* dialog selecting the **Reagents** button at the top of the *Resource Overview* window.  **A**: Lane containing rack **B**: Empty lane

Step	Action
5	Load the reagent racks into appropriate slots following the indicator lights. You can introduce racks into the loading bay when the indicator light is continuous green. You can place non-cellular reagents and controls in any lane.  **Note**: You should place racks that are accessed using the single probe arm to the right hand side of the loading bay; for example, a reagent rack. You should place a rack that is accessed only by the 4-probe arm on the left-hand side of the bay; for example, a sample rack. This practice optimizes the instrument's operational efficiency. You must place racks that contain cellular reagents in the lanes that have stirrer mechanisms (two positions on the right-hand side of the 14-lane Bay).
6	You can change the lane that is activated for insertion of a rack by clicking one of the indicator buttons at the top of the lane as represented on the *14-lane* or *5-lane Bay* dialog. The button above the selected lane changes to continuous green color, indicating that the barcode scanner is activated for this lane.

Step	Action
7	Wait for the indicator light (LED) at the front of the lane itself to change to continuous green before inserting a rack. This may take a few seconds.  **Limitation**: When you insert a rack into the activated lane, the system scans the barcodes. The system displays the barcode data and interpretation (reagent name, lot number, expiration date) on the right-hand side of the on-screen dialog. The system also displays the volume remaining in each container. In the case of Immucor lot numbered reagent vials, the volume is based on the full volume of the container (for new vials) or the remaining volume (if the vial was previously used on the instrument). If the actual volume is less than that displayed (for example, if the reagent vial has also been used for manual testing), you may enter a reduced volume. It is not possible to enter an increased volume for the bottle.  **Warning**: If you are using two or more instruments, then the specific reagent vials for each instrument must be dedicated for use on that single instrument to ensure correct reagent volume tracking. If the actual reagent volume (less than the software numeric volume) is not sufficient for the number of tests scheduled, the instrument will produce invalid results and samples will need to be rescheduled for testing.
8	Verify that the instrument has read all barcodes. If a barcode is not read, you may remove the rack, press the **Recall** button, hand scan the necessary barcode into the correct field (double entry required), and reinsert the rack.
9	If the entries are inconsistent, the system displays a **Warning** message and you must re-enter the duplicate entries.  **Note**: This method uses the **Recall** button. After removing the reagent rack, click the **Recall** button to display the reagent IDs on the screen of the last set of barcodes read. You can then scan any missing unread barcodes into the relevant field with the hand held scanner.  **Note**: If an assay consumes large volumes of a reagent (for example, Capture LISS), you can load several vials of the same reagent. The instrument will automatically use another vial when the first is empty.

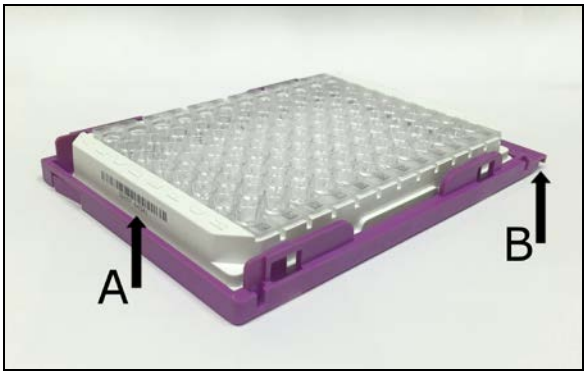
Step	Action
10	When you have finished loading reagents, click **Done** to exit the *Loading Bay* dialog.  **Limitation**: If a reagent expires during a testing process, the results will not be flagged. For example, a reagent that will expire after midnight is loaded onto the instrument and scheduled to an assay before midnight of the expiration date. However, the test will not be completed until after midnight when that vial has expired. The instrument prevents any test runs with this vial in the future.

Loading Plates

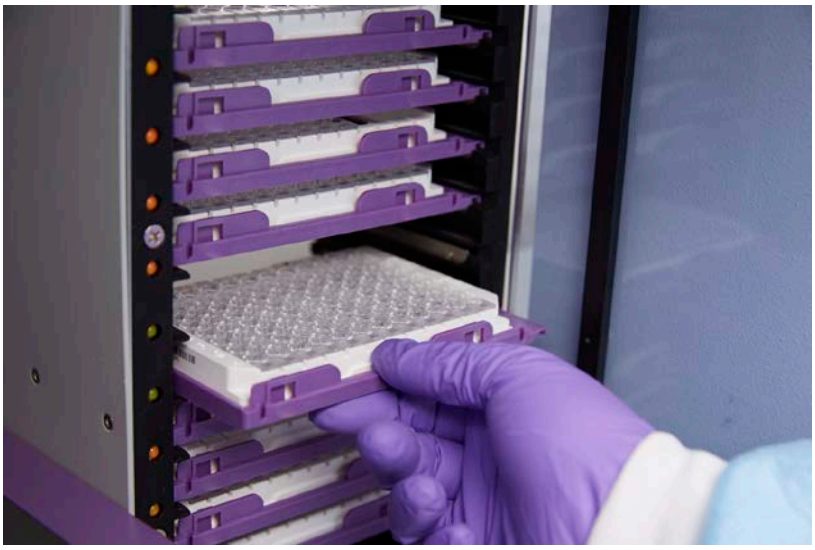
Procedure

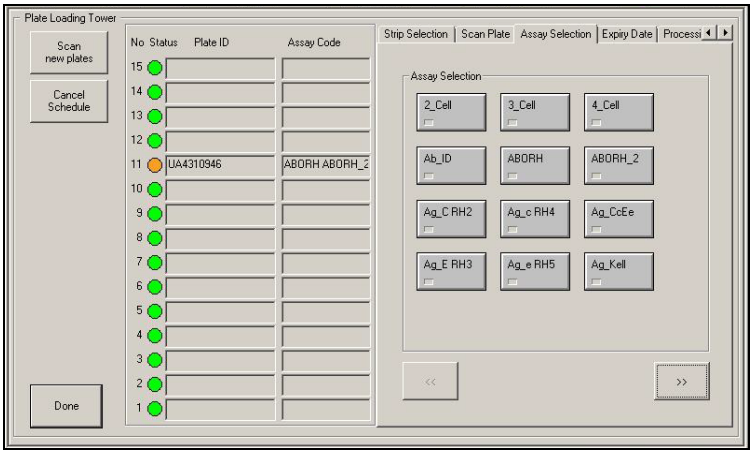
To load plates:

Step	Action
1	Insert each plate into its own transport frame with well A1 at the top left corner. **Note**: The transport frame has A1 imprinted onto the upper left corner to indicate the correct placement of a plate (as shown in the photograph below).  **Note**: When using solid phase red cell adherence plates, verify that the plate is within its expiration date imprinted on the storage pouch and that the colored humidity indicator inside the storage pouch indicates that the plate has remained free from humidity.

Step	Action
2	Position the frame so that the guiding groove is on the right and the plate is inserted into the frame upright with well A1 at the top left corner. The barcode must be on the left edge of the plate. This image illustrates how the plate must be positioned in the transport frame.  Correct positioning of a plate in a transport frame **A**: Plate barcode **B**: Guiding groove
3	Make sure that the plate is correctly seated in the transport carrier depression and that it is not partially raised away from the bed of the transport frame. **Warning**: Incorrectly placing a plate in a transport frame may cause damage to the pipetting system and other modules on the instrument in addition to wasted resources.

Step	Action
4	Make sure that the required numbers of strips are inserted into the white plate frame, and that all strips are inserted in the correct orientation and pressed fully into position in the white frame.  **Warning**: Loading a plate with an incorrect strip orientation results in invalid results and can create a biohazardous spill on the instrument. Incorrect orientation includes strips inserted upside-down in a white plate frame. **Warning**: Loading incorrect strips in a white plate frame can produce incorrect sample results without **Warning**. For example, loading Capture-R Ready-Screen strips in a barcoded Capture-R Select white frame is incorrect. **Warning**: When using Capture-R Ready-Screen or Ready-ID strips, load only the number of strips that are required for testing, as indicated in the *Resource Overview* window. Do not use Capture-R Ready-Screen or Ready-ID strips for testing that have previously traveled though the NEO Iris system on a plate frame, but were not used for testing. **Note**: The *Resource Overview* window displayed during the resource loading process confirms the number of strips needed, and the reader verifies the presence of the necessary number of strips before testing.
5	Open the *Plate Loading Tower* dialog by selecting the **Plates** button at the top of the *Resource Overview* window.

Step	Action
6	Open the door of the plate loading tower.
7	Insert each of the required plates on its transport frame into a vacant slot in the loading tower. Continuously illuminated green indicator lights indicate a vacant slot. 
8	Ensure that the frame is inserted fully towards the back of the loading tower.
9	If there are no free slots, you may remove the plates in any slot with flashing green indicator lights. The light next to a free slot changes to continuous green to indicate that a new plate may be inserted at this position.

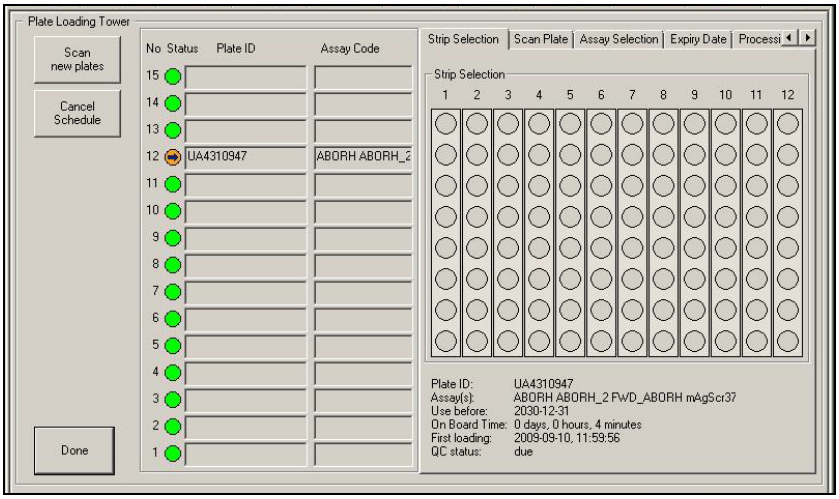
Step	Action
10	When you have loaded all required plates, close the loading tower door or press the **Scan new plates** button to initiate the plate barcode reading process. When the plate transport system is available, it takes each new plate from the loading tower and presents it to the barcode scanner for identification, then returns it to the same position in the tower. **Warning**: You must not place new plates into the tower while the transport system is accessing that module. Wait a few seconds after the transport has left the module, and then insert the new plates. **Note**: The plate barcode indicates the type of plate (such as blood grouping). This barcode determines the assays for which the plate may be used. The system displays these assays alongside the barcode information as shown below.  **Attention**: The plate tower door should be closed at all times, except when you are loading or unloading plates. This ensures that the plates are not accidentally disturbed. **Note**: The **Cancel Schedule** button can be used as a STAT resource interruption tool. If you have a STAT sample that you wish to begin immediately, but there are plates in the plate tower that are scanned and assigned into the system for other assays, but not yet started, you can remove all of the plates from the schedule using the **Cancel Schedule** button. This will allow more timely scheduling of the plate to be used for the STAT sample.
11	After loading a plate, make sure that the strip pattern in the **Plate Loading Tower** dialog (*Strip Selection* tab) corresponds to the strips loaded in the plate.

Checking the Plate On Board Time

Although the NEO Iris provides no alerts if the on-board storage times for Capture strips are exceeded, there are tools available on the instrument to assist you in tracking this information.

Warning: You can load and store Capture strips (excluding Capture-R Ready-Screen and Ready-ID) on the instrument, outside of the storage pouch, according to the time **Limitations** printed in the relevant package inserts. However, it is the operator's responsibility to keep track of the on-board Capture strip storage time. The instrument will provide no alerts if the on-board storage time is exceeded and will not flag results generated from such strips.

To check the amount of time that the white plate frame has been on the instrument and when the white plate frame was first loaded:

Step	Action
1	Press the **Plate Loading** button on the Machine Monitor to access the Plate Loading dialog.
2	Select the plate ID that you are interested in by touching the Plate ID position on the **Plate ID** position on the dialog.
3	Select the **Strip Selection** tab. The Plate ID, Assay(s) to be run with this plate, the Use before date, the On Board Time, and the date and time that the plate was first loaded (First loading) are displayed at the bottom right of the screen. 

Background Information

- Strips that have been removed from the pouch and placed on the NEO Iris, but not used, should not be returned to the storage pouch.
- The On Board Time provided by the NEO Iris stops accumulating time once a plate is removed from the loading tower. When the plate is returned to the tower and the barcode is scanned, the time is not reset and the timer will resume counting. The time displayed represents the total "on-board" time.
- It is your responsibility to ensure that plates are not used beyond their approved on-board storage time. Each facility should implement procedures to ensure that this requirement is met.

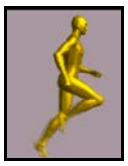
Starting Processing

When You Can Start Processing

You can start an assay run when all designated consumables for a given assay name on the *Resource Overview* window have green check marks.

Procedure

To start processing samples via the Resource Overview window:

Step	Action
1	Confirm that the consumable items designated for processing are selected and highlight the plate(s) that should be started.
2	Press the **Start** button.  The software displays a running man animation on the screen while the tests are programmed into the schedule.  The instrument begins processing. The system displays the *Schedule (Processing Steps)* dialog on the screen.  **Note**: Refer to **Chapter 3 – System Software Navigation** for more information about the *Schedule* dialog.  **Limitation**: When running the Crossmatch assay, if there are not sufficient wells remaining on a plate to accommodate the scheduled number of crossmatch tests for a given sample such as a sample to be crossmatched with three donor units and only one well remains on a plate, then the three tests will be batched on the next plate, leaving the remaining well on the first plate unused. If subsequent samples are scheduled for crossmatch assay, then the instrument cannot backtrack to the unused well(s) on the previous plate such as the one unused well in this example. Under these circumstances, such wells will remain unused.

Continuous Loading During Operation

Purpose

To maintain high throughput, you can access the instrument at any time to continuously load samples, replenish reagent, or empty waste while the instrument is processing.

Warning: Removing racks while the probes are accessing the tubes or vials from those rack results in damage to the probes and invalidated results. Wait until the LED for the rack is blinking green before removing.

Loading Additional Samples or Requesting Additional Assays

You can load more samples if there are available loading positions, or you can request additional tests at any time on samples that are already loaded.

When all the samples in a rack have been pipetted and the LED for the rack is blinking green, you can remove the rack and insert a new one.

To load additional samples:

Step	Action
1	Open the *Start Run Assistant* by pressing the **Start** button on the Main Menu Bar.  The system displays the *Start Run Assistant* dialog.
2	Click the **Load Samples** button to activate the *Loading Bay* dialog.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>3</td><td>You can remove a rack if the instrument has completed sampling the rack. These racks are marked by a flashing green LED in the loading bay lane.

  <u>Warning</u>: The operator must first open the loading bay dialog in order to remove sample and reagent racks.

A continuous orange LED indicates that the samples are not required for the current processing. However, continuous orange can also indicate that outstanding tests remain for at least one sample in the rack that is not scheduled as part of the current processing.

  <u>Warning</u>: Prematurely removing a sample or reagent rack will invalidate results.</td></tr>
<tr><td>4</td><td>Load new samples and, if necessary, request that the assay be performed as described in Loading the Samples in this chapter.</td></tr>
<tr><td>5</td><td>Click Done to close the 14-lane Bay dialog. The system redisplays the Start Run Assistant.</td></tr>
<tr><td>6</td><td>If required, click the Download Requests button to obtain requested assays from the LIS.</td></tr>
<tr><td>7</td><td>Click the Load Resources button. The system displays the Resource Overview window.</td></tr>
<tr><td>8</td><td>Verify that you have loaded sufficient consumables onto the NEO Iris to complete the assays for the samples as described in Completing the Sample Loading Process in this chapter.</td></tr>
<tr><td></td><td>
<table>
<tr><th>If...</th><th>Then...</th></tr>
<tr><td>Sufficient consumables are available</td><td>Go to step 9.</td></tr>
<tr><td>Insufficient consumables are available</td><td>Replenish the necessary resource, and then go to step 9.</td></tr>
</table>
</td></tr>
<tr><td>9</td><td>Press the Start button.

The system generates a new schedule incorporating the new samples and assays.</td></tr>
<tr><td></td><td></td></tr>
</table>

Reloading Plates

After the system has completely used a plate, remove the plate from the instrument and insert a new one as needed.

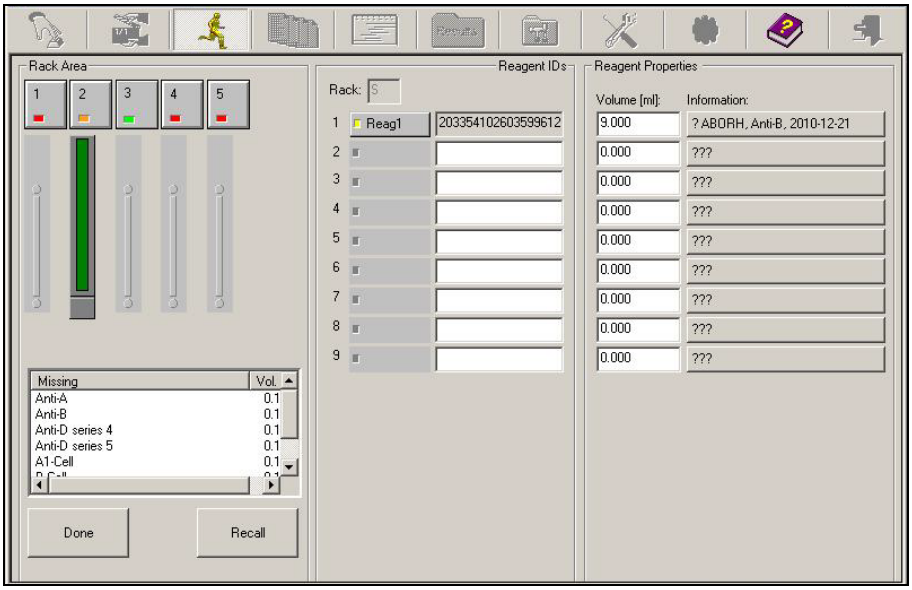
To replace a plate:

Step	Action
1	Remove the completed plates from the loading tower as indicated by the flashing green LEDs.
2	Dispose of the used plates following standard laboratory practice.  **Warning**: Used plates contain potentially biohazardous material. Wear protective gloves and clothing at all times when handling used plates. If any liquid is spilled, clean it up immediately following standard laboratory practice.
3	Insert new plates into the Loading Tower as described in **Loading Plates** in this chapter.

Replenishing Reagents and Controls

Follow the procedure for **Loading Reagents and Controls** in this chapter.

The system displays a list of **Missing** (but necessary) reagents (refer to screen below).



Replenishing System Liquid

To replenish the System Liquid, follow the procedure for **Filling the System Liquid** in **Chapter 10 - Maintaining the NEO Iris**.

Removing Liquid Waste

When the common waste container becomes full, the Waste icon in the Status Bar turns red and an audible alarm sounds.

A number of further pipetting and washer operations can occur (after the system displays the red waste icon) before the instrument stops pipetting and flags the results as invalid.

All liquid waste is collected in the common waste container. You can empty the liquid waste container at any time by draining the contents of the container into the shuttle container.

Limitation: If the common waste container is full and the waste icon turns red during sample processing, you will lose the interrupted testing run only if critical processing points exceed acceptable time limits because of excessive time removing the waste.

Examples of exceeding critical acceptable limits are:

- Too much time has elapsed between ABORh plate shaking and reading.
- A Capture-R Ready-Screen plate is incubated beyond the programmed time limit.

To drain the common waste container, follow the procedure for **Emptying the Common Waste Container** in **Chapter 10 - Maintaining the NEO Iris**.

Chapter 7: Test Results

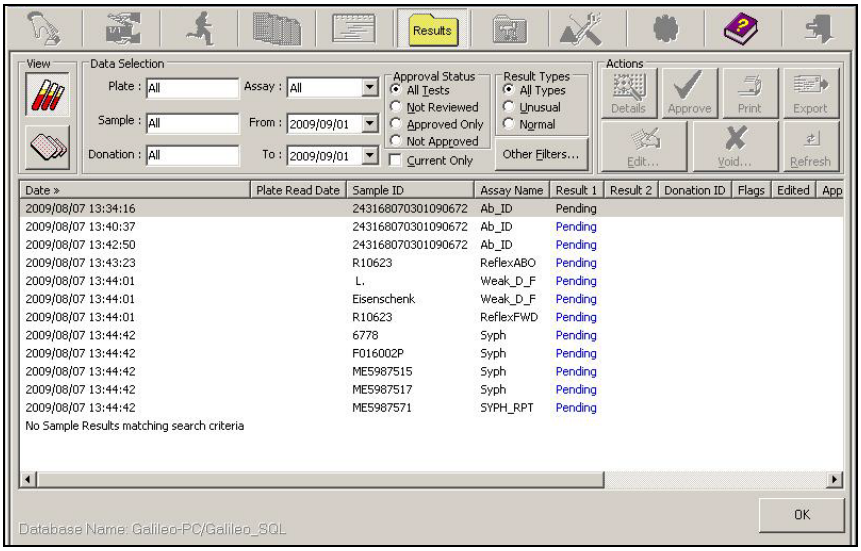
In This Chapter

This chapter describes the methods for viewing, approving and exporting test results.

Accessing the Results Screen

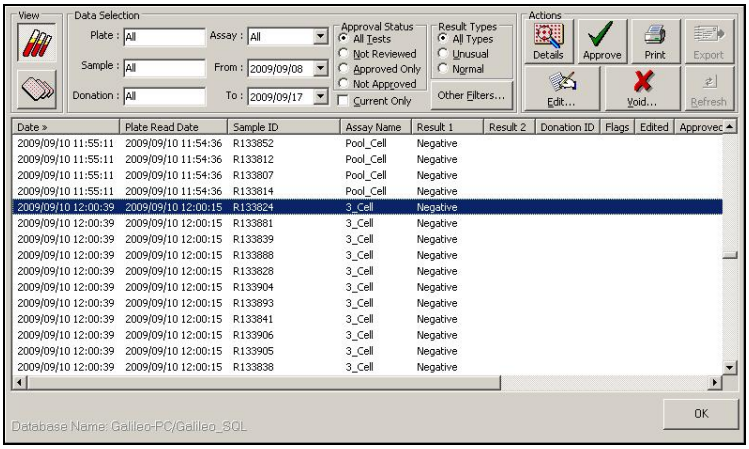
The Results screen is where test results can be viewed.

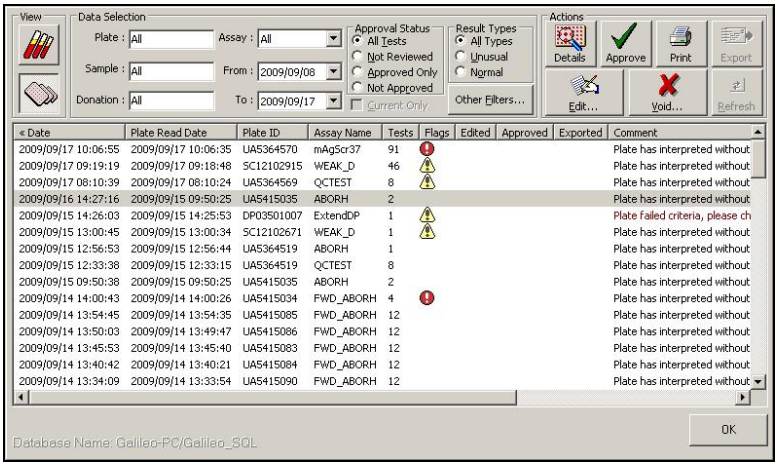
To access the Results screen:

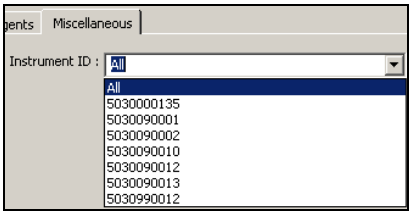
Step	Action
1	Click the **Results** button on the Main Menu Bar of the Machine Monitor. 
2	The *Results* screen with the most recently used screen view (sample or microplate) appears. 

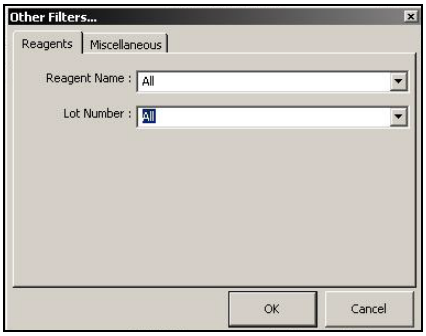
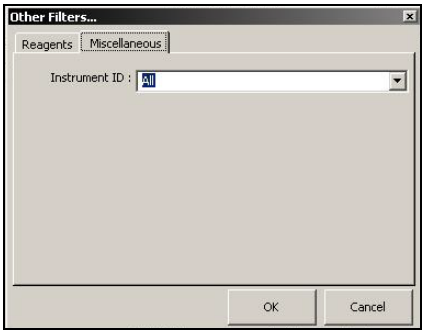
Viewing Results

To view results:

Step	Action
1	Click the **Sample View** button in the View area of the window.  - Sample View (see step 2)  - Plate View (see step 3) You can only select one of these buttons at a time. The selected button exhibits a "pressed" appearance. The Results area defaults to the most recently used of these two views when first selected.
2	The *Sample View Results* screen appears.  The Data Selection controls affect which records are displayed in the list.

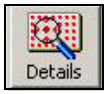
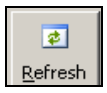
Step	Action
3	The *Plate View Results* screen appears.  The Data Selection controls affect which records are displayed in the list.

Step	Action
4	For both the Sample and Plate Views, enter any of the following criteria: • In the Plate field, type a plate ID. This field defaults to **All**. • In the Sample field, type a Sample ID. This field defaults to **All**. • In the Donations field, type a Donation ID. This field defaults to **All**. • From the Assay drop-down list, select the assay from the list of available assays. You can select **All** from the list to include all assays. • Select the From and To date drop-down lists to select a different from or to date. Select a date from the displayed calendar box. • From the Approval Status area, select an approval status. This area defaults to **All Tests**. Other options are **Not Reviewed**, **Approved Only** and **Not Approved**. • From the Result Types area, select a result type. This area defaults to **All Types**. Other options are **Unusual** and **Normal**. If you change any of the data selection controls, the list updates immediately. The **Other Filters** button is used to access the Other Filters dialog. This dialog allows additional criteria for filtering results listed on the results screen. Two (2) tabs are available, **Reagents** and **Miscellaneous**. The Reagents tab allows filtering via **Reagent Name** and/or **Lot Number**. A drop down list is used for both, where selections can be made. The Miscellaneous tab allows filtering via **Instrument ID**. A drop down list is used to make a selection. Selecting the Miscellaneous tab allows an instrument identification to be selected from a list of identifications saved in the database. The default selection for all of the drop down boxes is **All**.  Use the **Cancel** button of the Other Filters dialog to cancel the selections made or use the **OK** button to apply the filtering selections made. If you change the other filters criteria and apply them using the **OK** button, then the result list updates immediately. 

Step	Action
	  Data identifier columns on both the plate view and sample main view results display have adjustable widths.

Sample View and Plate View Icons and Symbols

The table below contains descriptions of the icons/symbols used in the *Sample View* and *Plate View* windows:

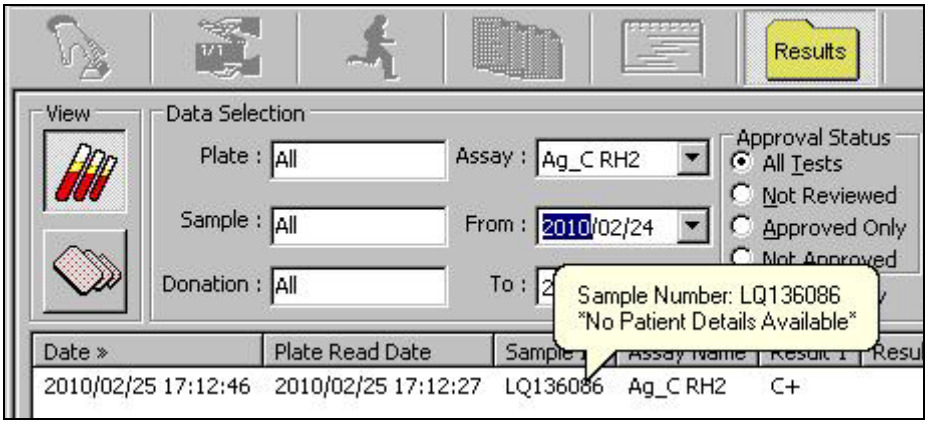
Icon/Symbol	Description
	The **Details** button displays the *Test Details* dialog which contains information for the item that was selected in the main *Results* screen.
	The **Approve** button displays the *Approval* dialog which contains approval information for the item that was selected in the main *Results* screen.
	The **Print** button displays the print dialog. This enables you to print results. Refer to **Chapter 8 – NEO Iris Reports** for details on how to print reports.
	The **Export** button displays a dialog that has a list box containing the currently approved, but not exported, tests. This enables you to export results if a functioning interface is set up. Refer to **Attachment 2** for the interface configuration requirements.
	The **Edit** button displays the *Test Details* dialog. Refer to **Chapter 8 – NEO Iris Reports** for a list of assays with equivocal reactions that cannot be edited.
	The **Void** button displays a confirmation dialog that displays a message signaling that continuing will void a chosen test result. Pressing the **Delete** key on the keyboard has the same effect as the **Void** button. A voided test will not appear in later search results.
	The **Refresh** button allows you to update the list of results on the screen while the instrument is running, and without the need to exit and then reenter the *Results* screen. This button becomes active when new results become available.
	In the Flags column, the system displays the warning symbol if the sample has any associated warnings. You must review any test results that have an associated warning flag.

Icon/Symbol	Description
	The system displays the error symbol if the sample has any associated errors. The system also displays this icon to indicate non-critical process incidents that occurred during sample processing that do not affect the sample result.
	In the Edited column, the system displays the edited symbol if any results for that test have been edited.
	The software has built-in parameters to automatically designate a result for further testing. This function is called Validate Method. It is represented by the **Validate** icon. An example of this designation is qualifying all initially Rh (D) negative tests as Weak D Pending. Weak D testing subsequently resolves the sample result. These parameters are configurable on an instrument-by-instrument basis.
	In the Approved column, the system displays the green check mark symbol if the test has been approved. The system displays the red **X** symbol if the test has been unapproved. The system displays no symbol if the test has not yet been approved. In the Exported column, the system displays the green check mark symbol if the test has been exported. The system displays no symbol if the test has not yet been exported.

Using Tool Tips

When you leave the mouse cursor stationary over a line, error symbol, or warning symbol for one-half second or more, the system displays a tool tip. If the cursor is held over the sample ID, then the patient information tool tip appears. If the cursor is held over an error/warning symbol, then the ID and error information appear.

The screen image below displays an example of the tool tip.

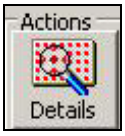
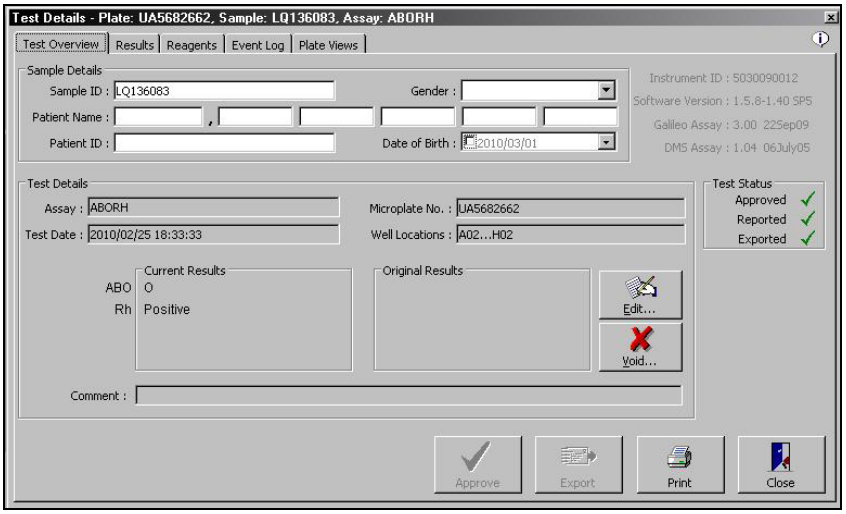


A flashing screen can be displayed if the cursor is held over a symbol that has an excessive amount data linked with it. The tool tip associated with that particular symbol cannot be displayed because the size of the tool tip, determined by the amount of data linked with it, exceeds the size of the screen display.

Viewing Test Details

Procedure

To view test details:

Step	Action
1	Click the **Details** button in the *Actions* area when in the *Sample View* mode. 
2	The system displays the *Test Details* dialog, which contains the *Test Overview* tab for the first test that was selected when you clicked the **Details** button. The completion of the *Test Overview* tab fields is optional. Alternatively, double-clicking a line in the list window box will also display the *Test Details* dialog.  This screen consists of 4 additional tabs: • Results • Reagents • Event Log • Plate Views  **Note**: If the Plate View mode is used, then the default tab that the *Test Details* dialog displays is *Plate Views*.

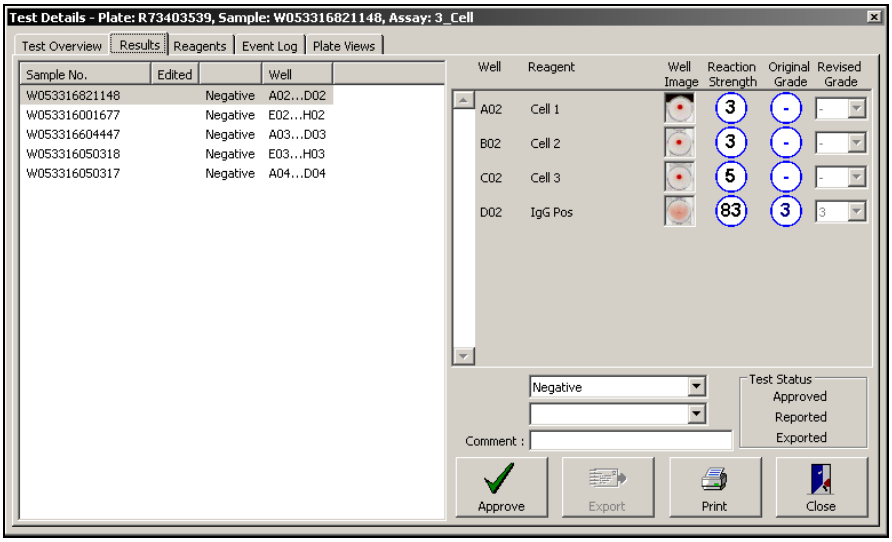
Results Tab

The left side of the dialog, below the *Results* tab, is a list box that displays all samples for the selected plate. From this list box you can select the particular sample that you want to view.

The right side of the dialog displays test details for the selected sample. On the far right-hand side of the dialog, you can make edits to the results.

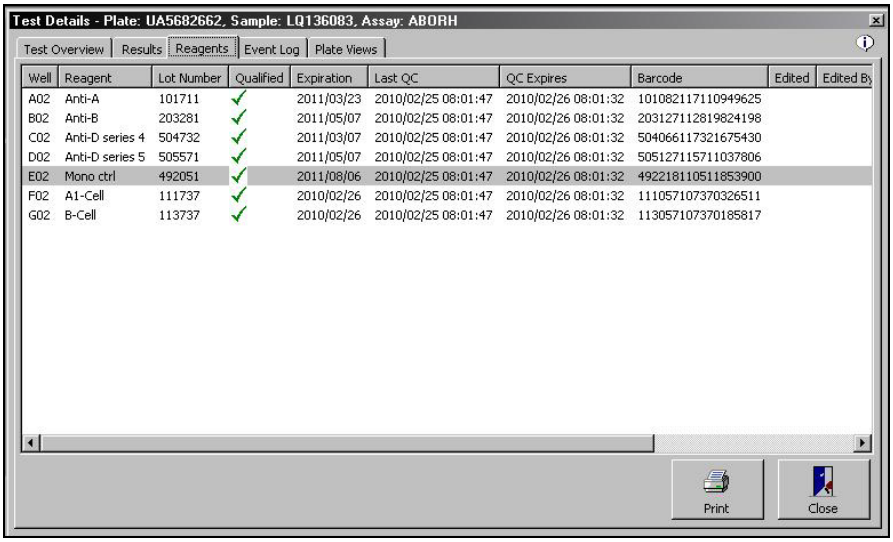
To edit a well reaction, choose one of the available results from the *Revised Grade* drop-down menu.

Warning: Refer to **Attachment 1 for NEO Iris Operator Manual** for a list of assays with equivocal reactions that cannot be edited.



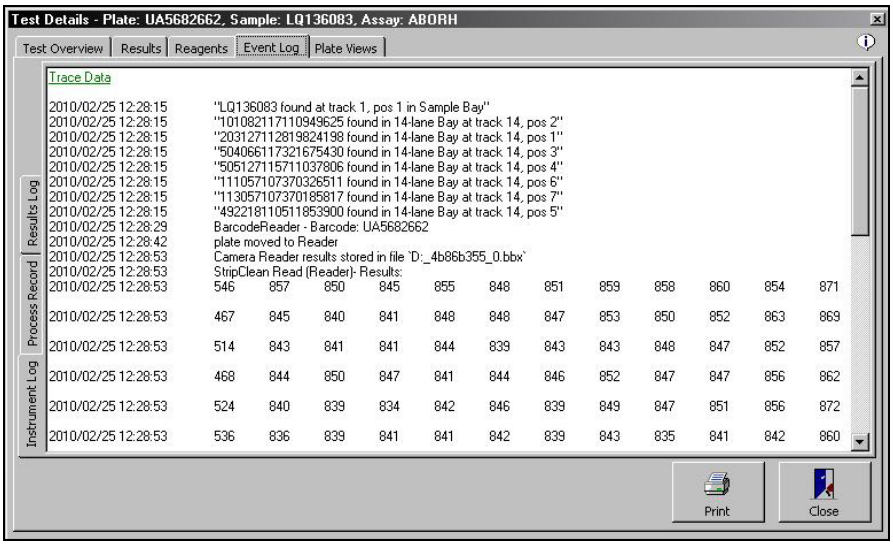
Reagents Tab

The *Reagents* tab displays details for all reagents that were used for the currently selected results.



Event Log Tab

The *Event Log* tab displays the detailed list of events that occurred for testing of a given sample or plate. If the plate has been used for more than one run, the event log lists the events for the run currently being viewed.



When viewing a plate that has failed controls and has not been saved, it is still possible to view the **Event Log** and **Plate Views** tabs. However, in this instance, the **Test Overview**, **Results** and **Reagents** tabs cannot be accessed and the tabs will be grayed out, as shown in the image below.

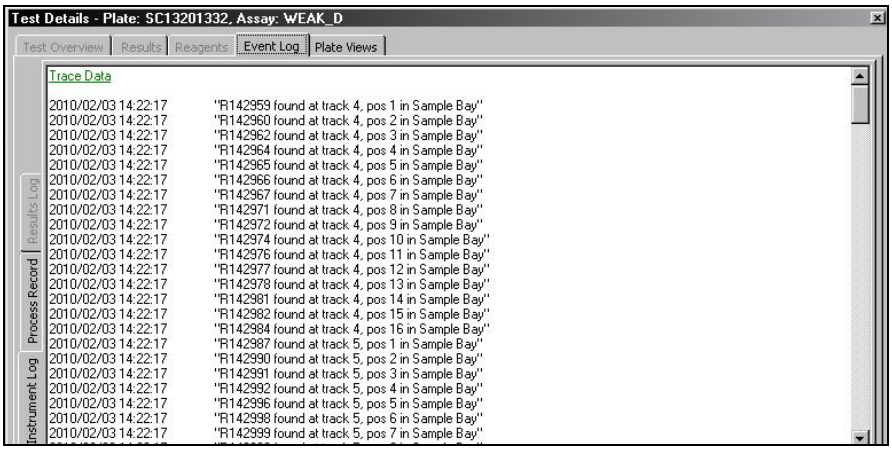
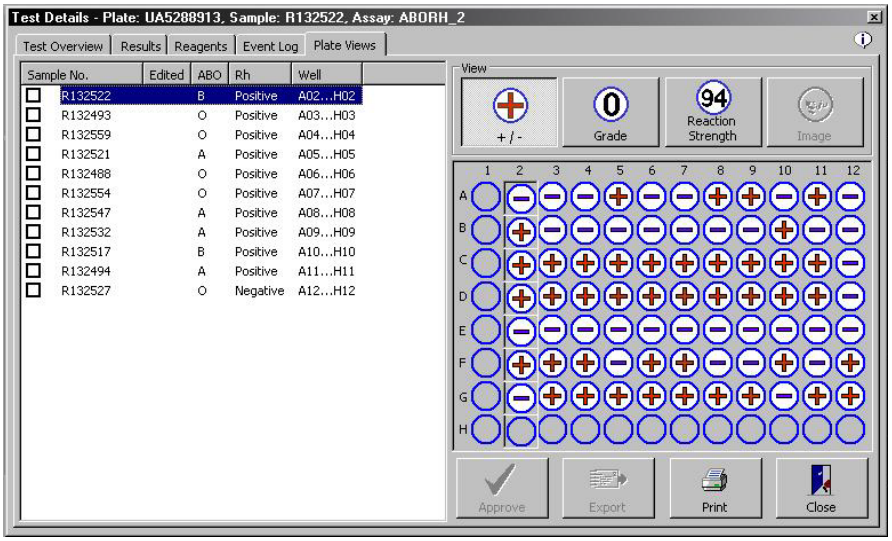
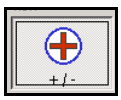


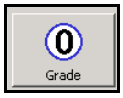
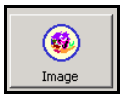
Plate Views Tab

The *Plate Views* tab displays several options to view plate information.



To view Plate Views from this tab:

Step	Action
1	Click the plate view **+/–** button.  The system expresses the results in plate wells as **+** or **–**. 

Step	Action
2	Click the **Grade** view button to display the same plate with results expressed as a graded numeric value for each reaction. 
3	Click the **Reaction Strength** view button to display the same plate with results expressed numerically.  Any value over 99 will be displayed as 99. All numbers are rounded so it is possible to see the same value classified as positive and negative.
4	Click the **Image** view button to display the same plate with the well images shown photographically. 

Manually edited wells will be flagged with an edited symbol  .

Some icons/symbols are common to most Plate Views, with the single exception of the **Image** icon.

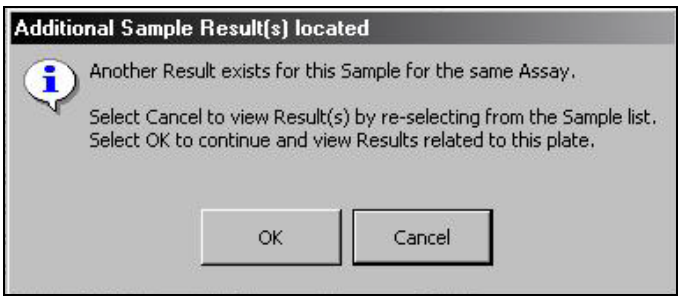
The table below contains descriptions of these common symbols.

Symbol	Description
	The Equivocal symbol indicates an equivocal result for a given well.
	The Invalid Well symbol indicates an error status for a given well, such as quantity not sufficient (QNS) or other error.
	The Blank symbol indicates wells that are not occupied.

Viewing Additional Sample Results

If a sample entry is highlighted in the Sample View window and a previous result exists for that same sample with the same assay (such as a previous blood group NTD now resulting with a defined blood group), and you press the **Details** button, the system displays a dialog warning you that other results

exist. The *Additional Sample Result(s) located* dialog offers you the option to proceed if you press the **OK** button. Press the **Cancel** button to cancel.



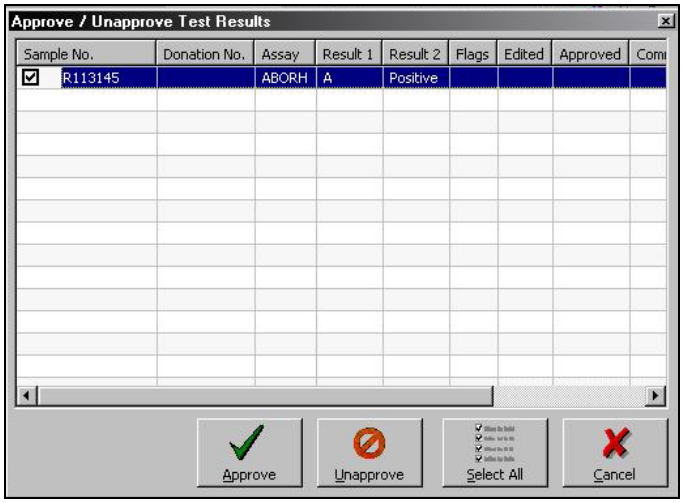
Exiting Test Details

When you are finished, click the **Close** button of the *Test Details* dialog.

The system returns to the *Results* screen.

Approving Test Results

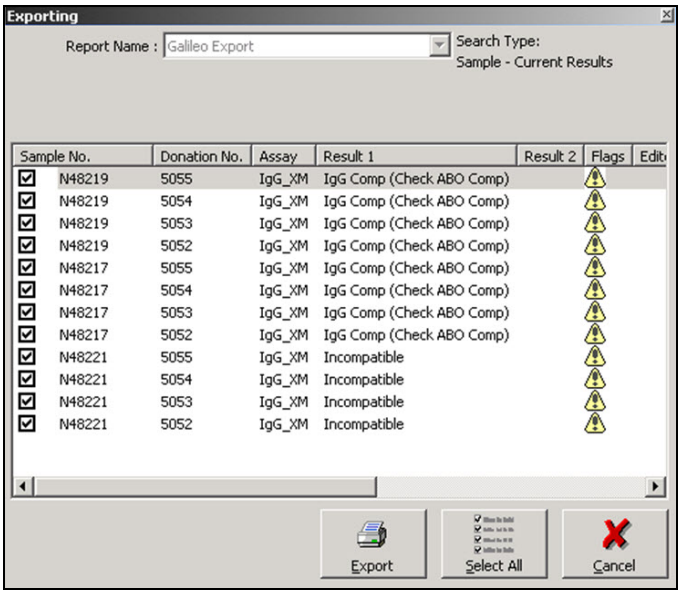
To approve test results:

Step	Action
1	Select the plate or sample results that you would like to approve in the main *Results* screen. Click the **Approve** button in the *Actions* area of the screen. 
	Note: The *Approve* dialog can also be selected while in the *Test Details* dialog of a result.
2	The system displays the *Approve* dialog.  Select the individual results to be approved using the line check boxes or select all results using the **Select All** button of the *Approve* dialog. Press the **Cancel** button to cancel the approval process if required.
3	Click the **Approve** button in the *Approve* dialog to approve all tests where check boxes are checked.

Exporting Test Results

To export test results:

Step	Action
1	The system displays a *Result Approval* dialog after a result is approved. This dialog gives you the option to export the approved results to the LIS.  Press the **Cancel** button of the *Result Approval* dialog to cancel the approval process.  **Note**: By pressing the **No** button, the results are approved but not exported, and are then subsequently available for export, if required, from the main results screen. In this instance, the approved results can be exported by selecting the **Export** button from the *Action*s area of the main results screen when those results are selected.  Before approval, the **Export** button is not available for use when unapproved results are selected in the main results screen. 

Step	Action
2	Press the **Yes** button of the *Result Approval* dialog to export. The system displays the *Exporting* dialog with the correct report configured and the selected samples or plates listed. 
3	Select the individual results to be exported using the line check boxes or select all results using the **Select All** button of the *Exporting* dialog. Press the **Cancel** button to cancel the export process if required. **Note**: Verify that all samples to be exported have been selected on the *Exporting* dialog after using the line check boxes or selecting all results by pressing the *Select All* button.
4	Press the **Export** button of the *Exporting* dialog to export. The monitor display returns to the previous screen that was used before the *Exporting* dialog, following the result export.

Exiting Test Results

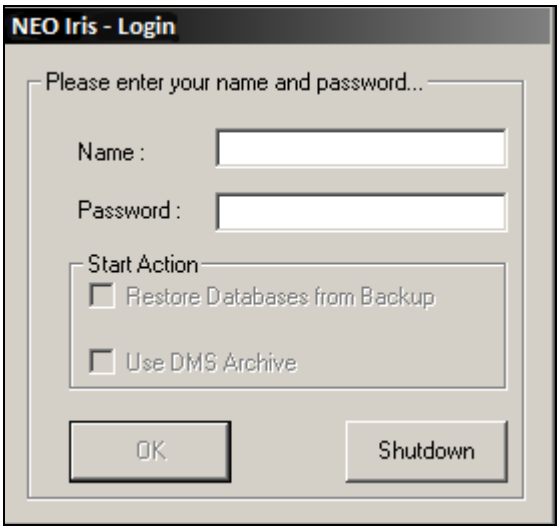
To exit *Test Results*, press the **OK** button. The monitor display will return to the Machine Monitor screen.

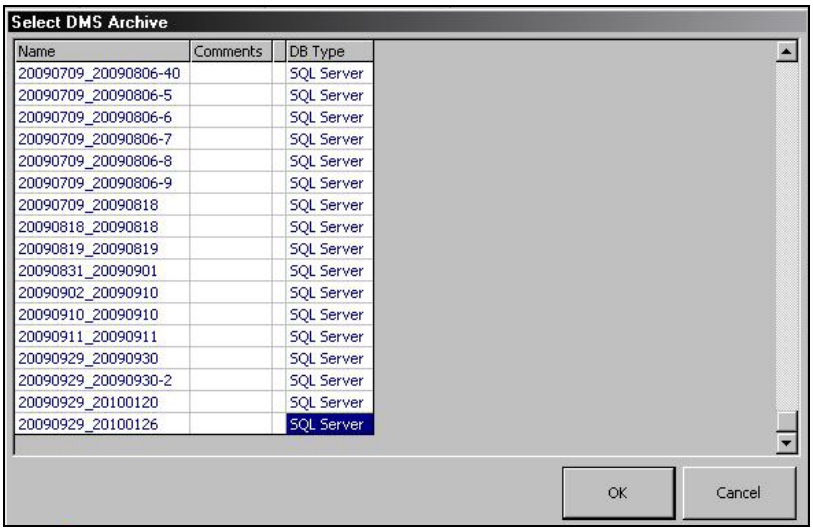
Viewing Archives

This section describes how to view archives.

Procedure

To view archives:

Step	Action
1	If result archives are stored on disks, insert a previously archived DVD+R disk into the disk drive.
2	Select the **Login** button on the main menu bar to display the **Login** dialog. 
3	Enter your **Name** and **Password** into the **Login** dialog. Select the checkbox for **Use DMS Archive** and then press the **OK** button of the **Login** dialog.  The list of all archives performed on the instrument will then be displayed on the **Select DMS Archive** dialog.  **Note**: The **Select DMS Archive** dialog will display all archives ever performed on the particular instrument. The most recent archive will be at the bottom of the list.

Step	Action
4	Select the archive you would like to view from the displayed list of all archives performed on the instrument. The selected archive must match the archive stored on the archive medium attached to the PC (or DVD+R disk inserted into the drive in step 1 above).  Press the **OK** button and allow the software to retrieve the archive files selected and do not press any keys during this process.  **Note**: When the archive is viewed, the software will first create a copy of the archive on the hard drive. The local copy will be opened for viewing; the archive on the disk is never opened. This reduces the potential for corrupting the archive.
5	Select the **Results** button on the Main Menu Bar to display the archived results on the results screen.   **Note**: You can customize your viewed result data, for example by date range, by using the methods described in this chapter.
6	Press the **OK** button of the results screen to close the screen after you have finished viewing the archived results.
7	To target the instrument software back to the list of current results, select the **Login** button on the Main Menu Bar to display the **Login** dialog. 

Step	Action
8	Enter your **Name** and **Password** into the **Login** dialog. Do not select the checkbox for **Use DMS Archive** and then press the **OK** button of the **Login** dialog to open the working database.
9	If the archive was viewed from a disk, remove it from the PC disk drive and store it in a safe place, according to the recommended storage conditions of the disk manufacturer.

Chapter 8: NEO Iris Reports

In This Chapter

This chapter describes the NEO Iris reports.

Reports Overview

Result Report Types

NEO Iris reports follow a general formatting scheme that is described by the following three main types. Each result report is assay specific and the different assay reports vary in the format details.

So that you can obtain all necessary printed information, the three main types of result report are:

Type of Report	Description
Plate Based	This type of report is plate based, and can only report sample results generated on a single plate run. This report type displays samples in the order they appear on the plate and includes control information. Plate based reports are the only method to print control results.
Sample Based	This type of report type displays the sample(s) selected. Samples from different plate runs can be printed on one page as a batch report. Samples are printed in alphanumeric order according to their plate ID. Only sample interpretations are printed on this report; there are no well results printed. If you select samples from an assay that is not the same as the selected report assay type, the report displays blank lines where these samples would have been reported.
Current Result	This type of report displays only the most current results for a sample. This type of report includes red blood cell antibody identification assay reports. Only one sample is listed per page along with the reagents used (not including the control information). This type of report includes Group and Screen reports.

Note: The report templates used in this chapter are examples chosen to illustrate the various report types and their respective design. Please, contact your local Immucor Representative to get more information about the reports that are available.

Generating Reports

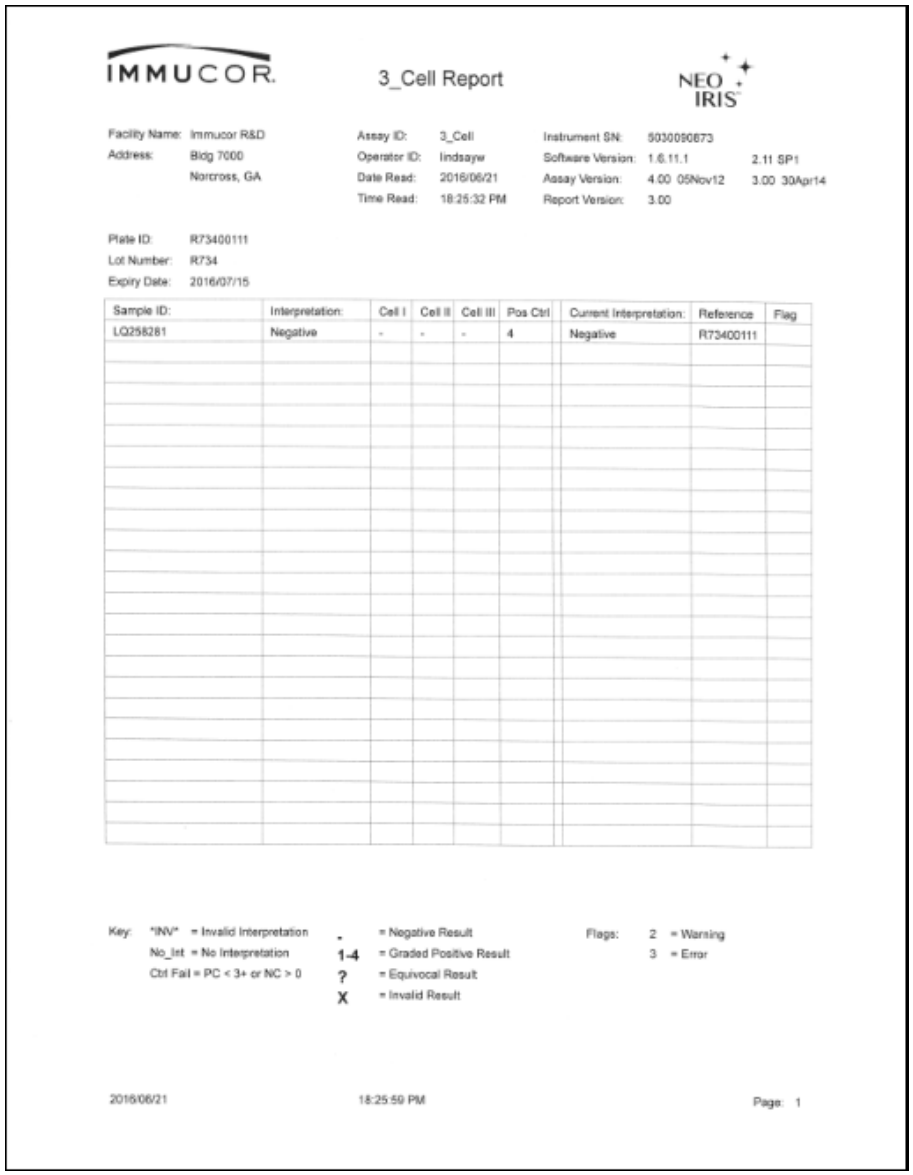
A maximum of two reports can be configured to automatically output when the system interprets the result file. Immucor configures this for printed reports or an export file to the LIS. The export file to the LIS is defined as a report output.

You can also manually print reports in the results section of the software.

Parts of the Report

Example of a Report

This example of a report exhibits features common to all reports and is described area-by-area in this chapter.



IMMUCOR

3_Cell Report

NEO IRIS

Facility Name: Immucor R&D
Address: Bldg 7000
Norcross, GA

Assay ID: 3_Cell
Operator ID: lindsayw
Date Read: 2016/06/21
Time Read: 18:25:32 PM

Instrument SN: 5030090873
Software Version: 1.6.11.1 2.11 SP1
Assay Version: 4.00 05Nov12 3.00 30Apr14
Report Version: 3.00

Plate ID: R73400111
Lot Number: R734
Expiry Date: 2016/07/15

Sample ID:	Interpretation:	Cell I	Cell II	Cell III	Pos Ctrl	Current Interpretation:	Reference	Flag
LQ258281	Negative	-	-	-	4	Negative	R73400111	

Key: "INV" = Invalid Interpretation
No_Int = No Interpretation
Ctrl Fail = PC < 3+ or NC > 0

\- = Negative Result
1-4 = Graded Positive Result
? = Equivocal Result
X = Invalid Result

Flags: 2 = Warning
3 = Error

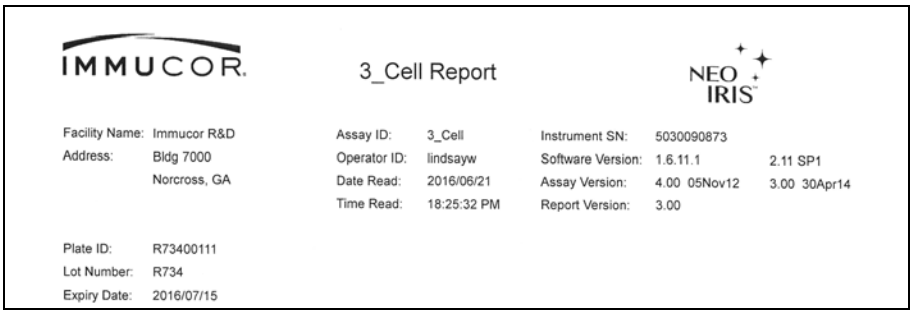
2016/06/21 18:25:59 PM Page: 1

The report consists of three (3) sections:

- Report Header
- Report Body
- Report Footer

Report Header

The following is an example of a report header.



The report header consists of the following:

Graphic	Name	Description
IMMUCOR	Immucor Logo	The Immucor logo is located in the top left corner of all NEO Iris reports.
Facility Name: Immucor R&D Address: Bldg 7000 Norcross, GA	Facility	The blood testing facility from which you generate reports and its address are located immediately below the Immucor logo.
	Report Title	The report title is located at the top center of all reports. This title identifies the type of report and what it represents.
Assay ID: 3_Cell Operator ID: lindsayw Date Read: 2016/06/21 Time Read: 18:25:32 PM	Details	The specific run details for the reported results are located under the report name, which includes the instrument plate read date and time. This corresponds to the information in the *Plate Read Date* column of the results display. **Note**: Group and screen reports do not list any information in this area. Reagent reports do not list the Operator ID.
NEO IRIS	NEO Iris Logo	The NEO Iris logo is located in the top right corner of all reports.

Instrument SN: 5030090873 Software Version: 1.6.11.1 Assay Version: 4.00 05Nov12	Instrument Serial Number, Software Version, Assay Version	The instrument serial number, software versions, and assay versions related to the reported results are located under the NEO Iris logo. If the report lists results for multiple assays, the report identifies assay versions for each assay. If it is a Reagent Report, no assay version is included.
Report Version: 3.00	Report Version Number	The report version number is located directly below the software and assay version numbers, at the right hand side of the report header.

Report Body

The report body contains the reported results and Plate details.

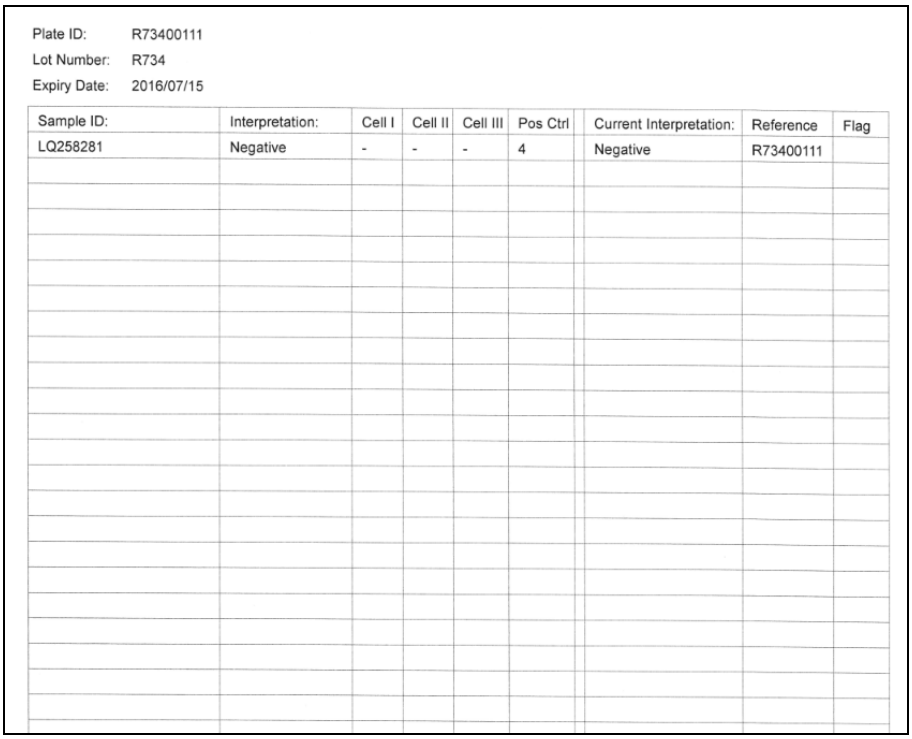
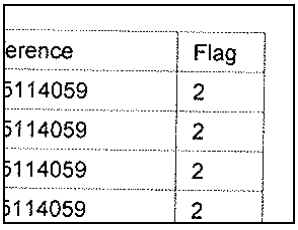


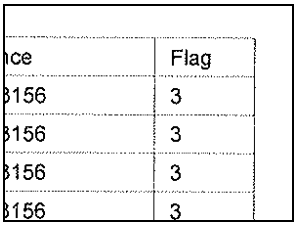
Plate ID: R73400111
Lot Number: R734
Expiry Date: 2016/07/15

Sample ID:	Interpretation:	Cell I	Cell II	Cell III	Pos Ctrl	Current Interpretation:	Reference	Flag
LQ258281	Negative	-	-	-	4	Negative	R73400111	

Each report includes a processing **Flag** column within the report result grid. This column is either left blank or is populated with a 2 or a 3. The key states that 2 indicates a **Warning** and 3 indicates an **Error**. A blank table cell indicates no associated flags. Examples are shown below.



erence	Flag
5114059	2
5114059	2
5114059	2
5114059	2



ıce	Flag
3156	3
3156	3
3156	3
3156	3

Note: **Warning** (2) flags do not require you to review any associated test results. There are three scenarios that generate a 2 flag. These scenarios are described in the table below:

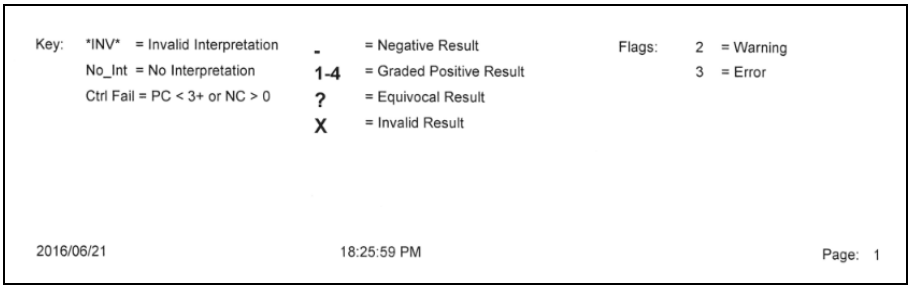
Warning Text	Interpretation	Potential Issue
ID entered manually	A reagent, sample or plate ID was entered manually.	Loading bay or plate barcode scanner cannot read a barcode. Reagent, sample, or plate barcodes cannot be read due to poor quality of barcode.
No barcode read	The plate barcode scanner was unable to read the barcode on the plate during assay processing.	Plate barcode scanner does not read.
Warning in device	This is the warning assigned to any result where plate jam errors were recovered from successfully. If error recovery was unsuccessful or untimely, then associated results will be invalidated.	Error recovery after plate jam.

Error (3) flags are either associated with results where the interpretation is invalid or with unused wells. Neither situation requires you to review any associated test results.

Other report features are discussed later in this chapter.

Report Footer

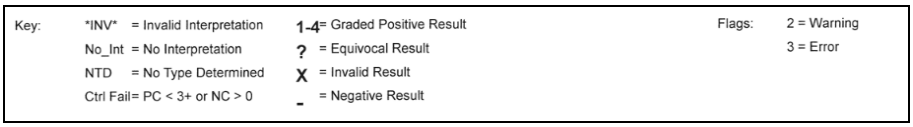
The following is an example of the report footer.



Reagent information is listed in a separate grid for some reports.

Assay Name:	Reagent Name:	Lot Number:	Lot Expiry:
ABORH	Mono ctrl (10ml)	492241	2018/03/01
ABORH	A1-Cell (10ml)	111083	2016/07/08
ABORH	Anti-A (10ml)	101746	2017/09/01
ABORH	B-Cell (10ml)	113083	2016/07/08
ABORH	Anti-B (10ml)	203620	2017/10/20
ABORH	Anti-D series 4 (10ml)	504715	2018/03/03
ABORH	Anti-D series 5 (10ml)	505741	2017/08/11
3_Cell	LISS (10ml)	211750	2017/03/29
3_Cell	Cap-R Ind Cells (10ml)	221650	2016/07/07

At the bottom of most reports is a key with symbols to assist you in interpreting the reports. An example is shown below. The key is populated with information pertinent to the report upon which it is printed. Therefore different types of reports will be printed with different keys. For example, the crossmatch assay includes **Comp = Compatibility** in the key. This item in the key is only found for crossmatch assay. Quality control reports do not print with a key included.



The date and time that the report is generated, as well as the page number, are also located at the bottom of the page. An example is shown below.

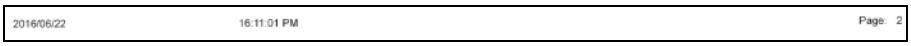
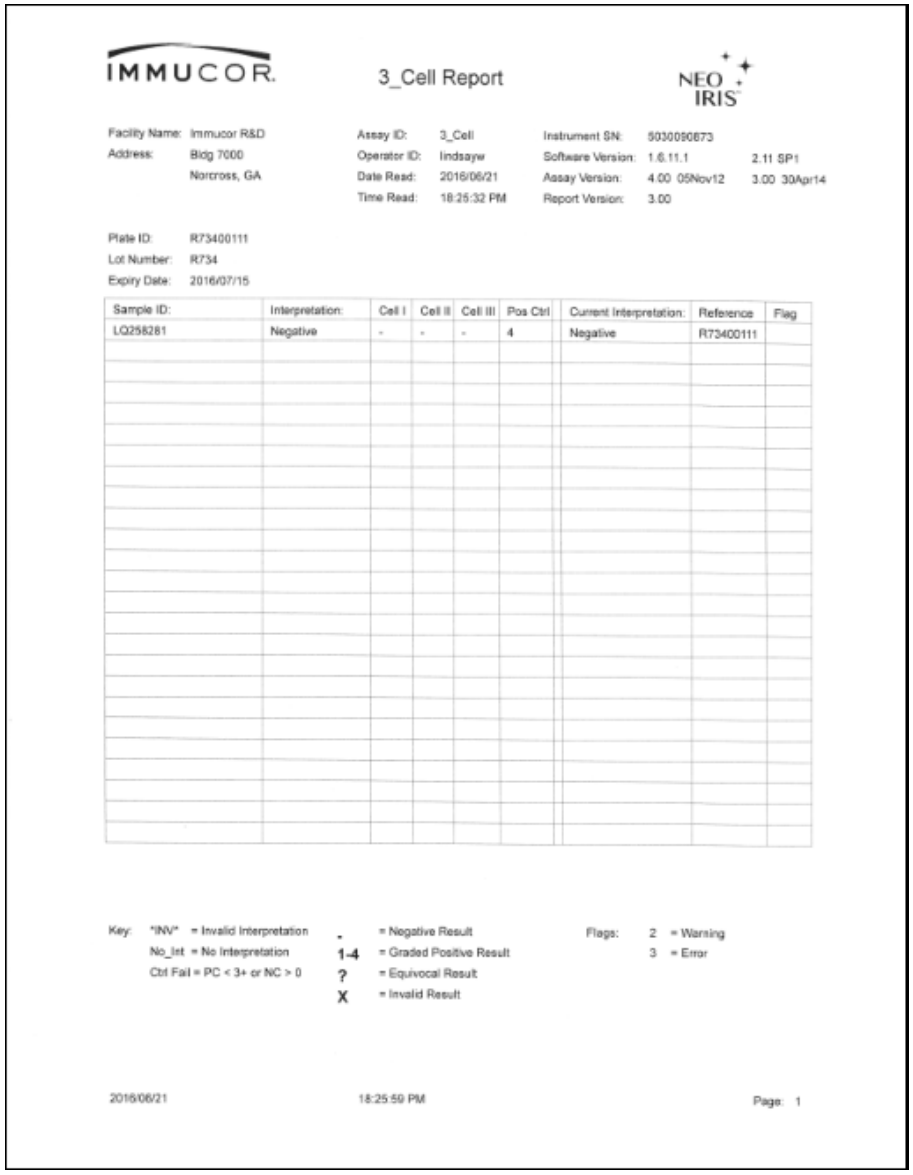


Plate Based Reports

Report Details

The details of the plate used to determine the reported results are located on the left side of the report, above the results grid. The results grid is in the center of the report. The column titles vary slightly, depending on the assay reported.



IMMUCOR

3_Cell Report

NEO IRIS

Facility Name: Immucor R&D
Address: Bldg 7000
Norcross, GA

Assay ID: 3_Cell
Operator ID: lindsayw
Date Read: 2016/06/21
Time Read: 18:25:32 PM

Instrument SN: 5030090873
Software Version: 1.6.11.1 2.11 SP1
Assay Version: 4.00 05Nov12 3.00 30Apr14
Report Version: 3.00

Plate ID: R73400111
Lot Number: R734
Expiry Date: 2016/07/15

Sample ID:	Interpretation:	Cell I	Cell II	Cell III	Pos Ctrl	Current Interpretation:	Reference	Flag
LQ258281	Negative	-	-	-	4	Negative	R73400111	

Key: "INV" = Invalid Interpretation
No_Int = No Interpretation
Ctrl Fail = PC < 3+ or NC > 0

\- = Negative Result
1-4 = Graded Positive Result
? = Equivocal Result
X = Invalid Result

Flags: 2 = Warning
3 = Error

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Note: The printed plate based report option lists the sample IDs in the pipetted plate order. It is important to note that the pipetted plate order is not the same as the sample order in the 14-lane Bay or the order the samples were pipetted to the plate. This pipetting

technique optimizes the pipetting procedure and overall workflow. The controls are listed on the plate reports. When printing from plate view, only plate-based reports are available.

Report Columns

The table below describes the Plate Based Report columns.

Column	Description
Sample ID	The patient identification barcode information as it appears on the tube.
Interpretation	The instrument interpretation from the original results created on this plate run.
Result text	The result text column(s) represent each test well (with a description of the well, such as Cell I or Anti-A) and the result that the system used to determine the interpretation.
Current Interpretation	This interpretation may be the same as the original interpretation. If you repeated the sample with the same assay and had a different result, edited the sample, or the sample was run with the validate method, this interpretation is different than the original interpretation.
Reference	This column indicates where the current interpretation is from. If you have not adjusted the interpretation from further testing (such as VALIDATE), this ID is the original plate ID. Otherwise, it represents the plate that the current interpretation was generated from (such as a second run of the same sample with the same assay). If the current interpretation is from an edit, the report displays 'Manual Edit' in this column. If the current interpretation is from the result of a validate method, the report displays 'VALIDATE' in this column.
Flag	This processing flag column is either left blank or is populated with a 2 or a 3. The key states that 2 indicates a **Warning** and 3 indicates an **Error**. A blank table cell indicates no associated flags.

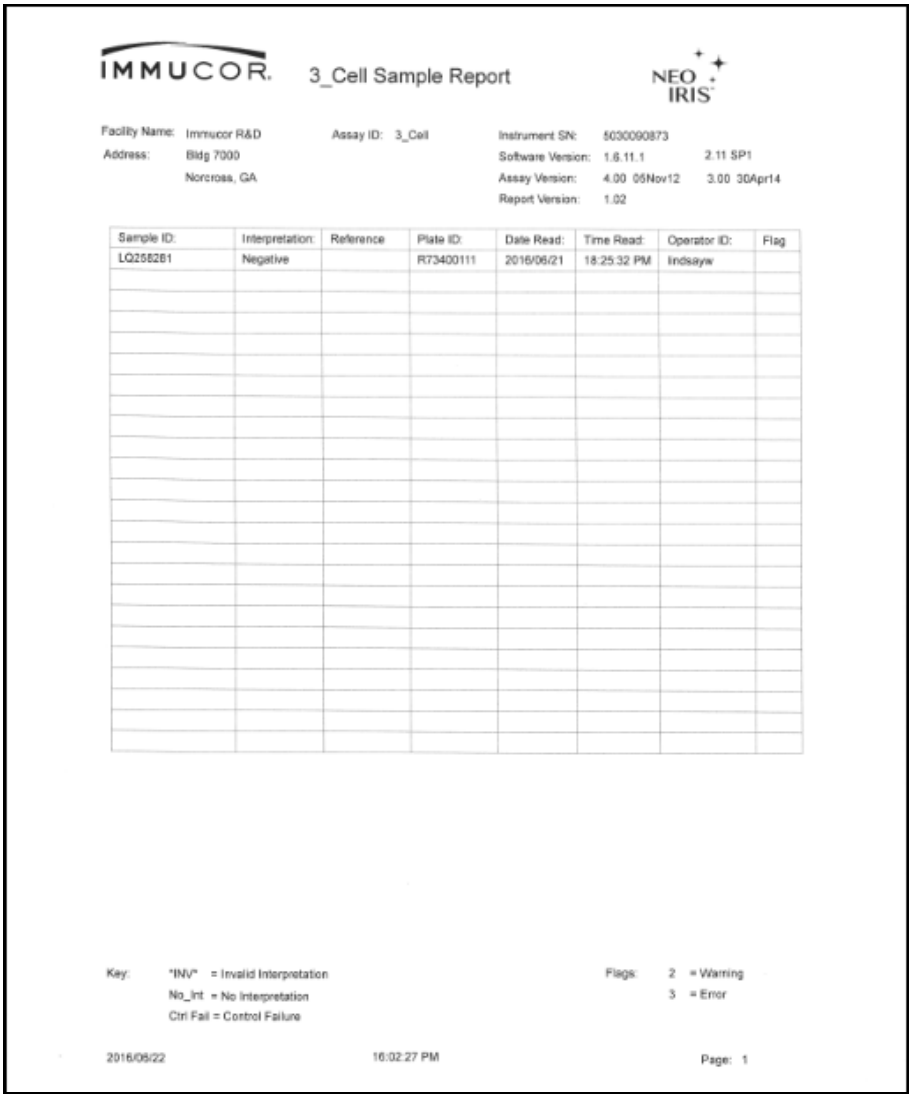
Sample Based Reports

Sample Based Report Types

Sample based reports include reports for samples tested by a single assay.

Sample Based Report Details

The sample based report lists all highlighted samples for one assay. This repeat can print samples run on different plates and will report the samples in alphanumeric order. Refer to **Reagent Reports** later in this chapter for information regarding reagent reports.



IMMUCOR 3_Cell Sample Report NEO IRIS

Facility Name: Immucor R&D
Address: Bldg 7000
Norcross, GA

Assay ID: 3_Cell

Instrument SN: 5030090873
Software Version: 1.6.11.1 2.11 SP1
Assay Version: 4.00 05Nov12 3.00 30Apr14
Report Version: 1.02

Sample ID:	Interpretation:	Reference	Plate ID:	Date Read:	Time Read:	Operator ID:	Flag
LQ2582B1	Negative		R73400111	2016/05/21	18:25:32 PM	lindsayw	

Key: "INV" = Invalid Interpretation
No_Int = No Interpretation
Ctrl Fail = Control Failure

Flags: 2 = Warning
3 = Error

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Single Assay Sample Based Report Columns

The table below describes the Sample Report columns.

Column	Description
Sample ID	The patient identification barcode information as it appears on the tube.
Interpretation	The most current interpretation for the sample. ABO and Rh columns report separate interpretations for the blood type.
Reference	If the current interpretation is from an edit, the report displays 'Manual Edit' in this column. If the current interpretation is from the result of a validate method, the report displays 'VALIDATE' in this column.
Plate ID	The plate ID from the location from which the sample results were generated.
Date Read	The date the NEO Iris reader read the plate.
Time Read	The time the NEO Iris reader read the plate.
Operator ID	The ID of the operator logged in when the sample results were generated. If the results were edited or run with a validate method, the report displays the ID of the user who was logged in at the time of the edit or running of the validate method.
Flag	This processing flag table cell is either left blank or is populated with a 2 or a 3. The key states that 2 indicates a **Warning** and 3 indicates an **Error**. A blank cell indicates no associated flags.

Current Reports

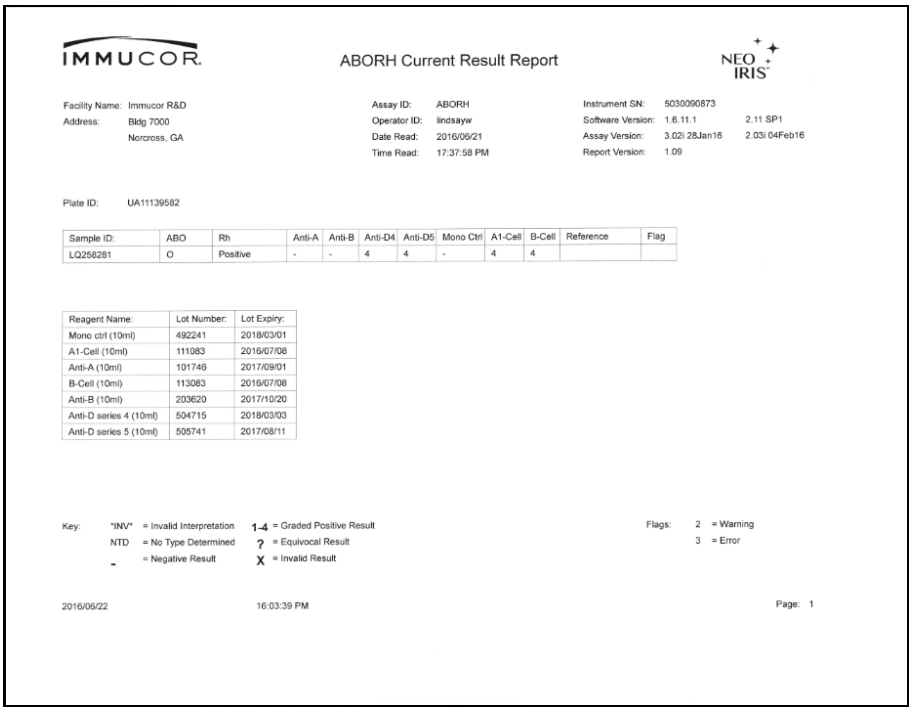
Current Report Types

Current reports are a variation of sample based reports and are accessed as such. Current reports cannot be accessed through the plate based method of printing reports. Only one sample is listed per page along with the reagents used (not including the control information). Plate based reports are the only method to print control results. The result printed on the current report is the most current result. The three (3) broad categories of current reports are:

- Non-antibody identification reports
- Antibody identification reports
- Group and screen reports

Non-antibody Identification Current Report Details

This sample based report lists one sample per page, along with the reagents used (not including the plate control information). The assay name is displayed in the report header.



IMMUCOR

ABORH Current Result Report

NEO IRIS

Facility Name: Immucor R&D
Address: Bldg 7000
Norcross, GA

Assay ID: ABORH
Operator ID: lindsayw
Date Read: 2016/06/21
Time Read: 17:37:58 PM

Instrument SN: 5030090873
Software Version: 1.6.11.1 2.11 SP1
Assay Version: 3.02i 28Jan16 2.03i 04Feb16
Report Version: 1.09

Plate ID: UA11139582

Sample ID:	ABO	Rh	Anti-A	Anti-B	Anti-D4	Anti-D5	Mono Ctrl	A1-Cell	B-Cell	Reference	Flag
LQ258281	O	Positive	-	-	4	4	-	4	4		

Reagent Name:	Lot Number:	Lot Expiry:
Mono ctrl (10ml)	492241	2018/03/01
A1-Cell (10ml)	111083	2016/07/08
Anti-A (10ml)	101746	2017/09/01
B-Cell (10ml)	113083	2016/07/08
Anti-B (10ml)	203620	2017/10/20
Anti-D series 4 (10ml)	504715	2018/03/03
Anti-D series 5 (10ml)	505741	2017/08/11

Key: "INV" = Invalid Interpretation
NTD = No Type Determined
- = Negative Result
1-4 = Graded Positive Result
? = Equivocal Result
X = Invalid Result

Flags: 2 = Warning
3 = Error

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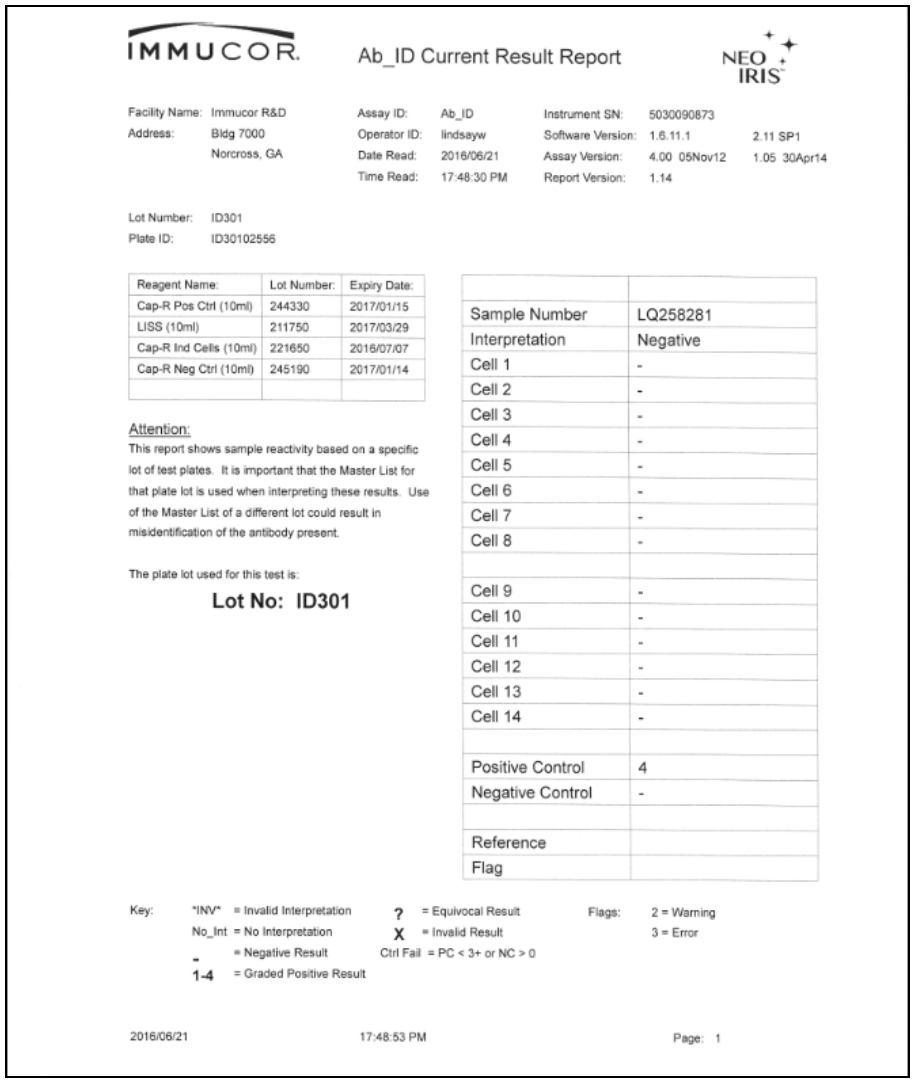
Antibody Identification Report Details

The antibody identification reports have a unique format to better align with Masterlists. The plate ID that sample was run with is located on the left side of the report directly above the results grid. Only one sample is listed per page along with the reagents used.



IMMUCOR

Ab_ID Current Result Report

NEO IRIS

Facility Name: Immucor R&D
Address: Bldg 7000
Norcross, GA

Assay ID: Ab_ID
Operator ID: lindsayw
Date Read: 2016/06/21
Time Read: 17:48:30 PM

Instrument SN: 5030090873
Software Version: 1.6.11.1 2.11 SP1
Assay Version: 4.00 05Nov12 1.05 30Apr14
Report Version: 1.14

Lot Number: ID301
Plate ID: ID30102556

Reagent Name:	Lot Number:	Expiry Date:
Cap-R Pos Ctrl (10ml)	244330	2017/01/15
LISS (10ml)	211750	2017/03/29
Cap-R Ind Cells (10ml)	221650	2016/07/07
Cap-R Neg Ctrl (10ml)	245190	2017/01/14

Attention:
This report shows sample reactivity based on a specific lot of test plates. It is important that the Master List for that plate lot is used when interpreting these results. Use of the Master List of a different lot could result in misidentification of the antibody present.

The plate lot used for this test is:

Lot No: ID301

Sample Number	LQ258281
Interpretation	Negative
Cell 1	-
Cell 2	-
Cell 3	-
Cell 4	-
Cell 5	-
Cell 6	-
Cell 7	-
Cell 8	-
Cell 9	-
Cell 10	-
Cell 11	-
Cell 12	-
Cell 13	-
Cell 14	-
Positive Control	4
Negative Control	-
Reference	
Flag	

Key: *INV* = Invalid Interpretation
No_Int = No Interpretation
- = Negative Result
1-4 = Graded Positive Result
? = Equivocal Result
X = Invalid Result
Ctrl Fail = PC < 3+ or NC > 0

Flags: 2 = Warning
3 = Error

2016/06/21 17:48:53 PM Page: 1

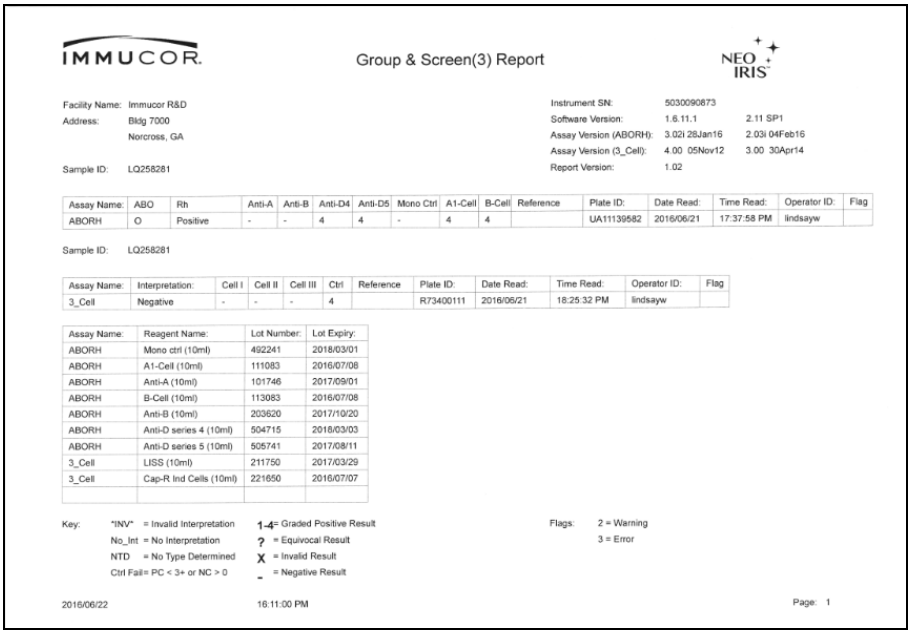
Antibody Identification Report Columns and Features

The table below describes the antibody identification report columns and features.

Column or feature	Description
Reagent Name:, Lot Number: and Expiry Date	A reagent details grid lists the name lot number and expiry date used in the assay.
Sample Number	The patient identification barcode information as it appears on the tube.
Interpretation	The most current interpretation for this sample, run with this assay.
Result text	The result text grid lists each test well and the result that was assigned by the software. Each test well is described, e.g. Cell 13.
Reference	If the current interpretation is from an edit, the report displays 'Manual Edit'. If the current interpretation from the result of a validate method, the report displays 'VALIDATE'.
Flag	This processing flag table cell is either left blank or is populated with a 2 or a 3. The key states that 2 indicates a **Warning** and 3 indicates an **Error**. A blank cell indicates no associated flags.
Ctrl Fail = PC < 3+ or NC > 0	Some current reports have criteria set for qualifying the control results. These criteria are listed in the footer key. If actual results fall outside of the criteria, then the controls are deemed to have failed and are invalid.
Attention:	As an example, red blood cell antibody identification reports include an attention that gives guidance on the use of the report. It states: "This report shows sample reactivity based on a specific lot of test plates. It is important that the Master List for that plate lot is used when interpreting these results. Use of the Master List of a different lot could result in misidentification of the antibody present."
Plate lot number	The plate lot number is reiterated in large bold text to stress this information.

Group and Screen Sample Based Report Details

The Group and Screen report combines sample results from two assays onto one page. The sample ID for which the instrument generates results is located on the left side of the group and screen report, directly above the results grid. This report lists results for sample runs with the ABORH or the ReflexABO assay combined with a screen assay (Pool_Cell, 2_Cell, or 3_Cell). If results exist for only one of the assays, the other grid table cells remain blank (refer to the example report shown below). This report lists one sample per page, along with the reagents used (not including the control information) for both assays.



IMMUCOR

Group & Screen(3) Report

NEO IRIS

Facility Name: Immucor R&D
Address: Bldg 7000
Norcross, GA

Instrument SN: 5030090873
Software Version: 1.6.11.1 2.11 SP1
Assay Version (ABORH): 3.02i 28Jan16 2.03i 04Feb16
Assay Version (3_Cell): 4.00 05Nov12 3.00 30Apr14
Report Version: 1.02

Sample ID: LQ258281

Assay Name:	ABO	Rh	Anti-A	Anti-B	Anti-D4	Anti-D5	Mono Ctrl	A1-Cell	B-Cell	Reference	Plate ID:	Date Read:	Time Read:	Operator ID:	Flag
ABORH	O	Positive	-	-	4	4	-	4	4		UA11139582	2016/06/21	17:37:58 PM	lindsayw	

Sample ID: LQ258281

Assay Name:	Interpretation:	Cell I	Cell II	Cell III	Ctrl	Reference	Plate ID:	Date Read:	Time Read:	Operator ID:	Flag
3_Cell	Negative	-	-	-	4		R73400111	2016/06/21	18:25:32 PM	lindsayw	

Assay Name:	Reagent Name:	Lot Number:	Lot Expiry:
ABORH	Mono ctrl (10ml)	492241	2018/03/01
ABORH	A1-Cell (10ml)	111083	2016/07/08
ABORH	Anti-A (10ml)	101746	2017/09/01
ABORH	B-Cell (10ml)	113083	2016/07/08
ABORH	Anti-B (10ml)	203620	2017/10/20
ABORH	Anti-D series 4 (10ml)	504715	2018/03/03
ABORH	Anti-D series 5 (10ml)	505741	2017/08/11
3_Cell	LISS (10ml)	211750	2017/03/29
3_Cell	Cap-R Ind Cells (10ml)	221650	2016/07/07

Key: "INV" = Invalid Interpretation
No_Int = No Interpretation
NTD = No Type Determined
Ctrl Fail= PC < 3+ or NC > 0

1-4= Graded Positive Result
? = Equivocal Result
X = Invalid Result
- = Negative Result

Flags: 2 = Warning
3 = Error

2016/06/22 16:11:00 PM Page: 1

Group and Screen Sample Based Report Columns

The table below describes the Group and Screen Report columns.

Column	Description
Assay Name	The assay name for the results generated.
Interpretation	The most current interpretation for this sample run with this assay. ABO and Rh columns report separate interpretations for the blood type.
Result Text	The result text column(s) represent each test well (with a description of the well, such as Anti-A) and the result that the system used to determine the interpretation.

Column	Description
Reference	If the current interpretation is from an edit, the report displays 'Manual Edit' in this column. If the current interpretation is from the result of a validate method, the report displays 'VALIDATE' in this column.
Plate ID	The plate ID from the location from which the sample results were generated.
Date Read	The date the NEO Iris reader read the plate.
Time Read	The time the NEO Iris reader read the plate.
Operator ID	The ID of the operator logged in when the sample results were generated. If the results were edited or run with a validate method, the report displays the ID of the user who was logged in at the time of the edit or running of the validate method.
Flag	This processing flag table cell is either left blank or is populated with a 2 or a 3. The key states that 2 indicates a **Warning** and 3 indicates an **Error**. A blank cell indicates no associated flags.

Quality Control Reports

Report Details

Quality Control (QC) reports are only available as plate based reports and not through sample based report printing methods. The plate ID for which the quality control (QC) results are generated is located on the left side of the QC report, directly above the result grid. The result grid identifies the reagents in each test well, the result generated with this run, and the expected result.

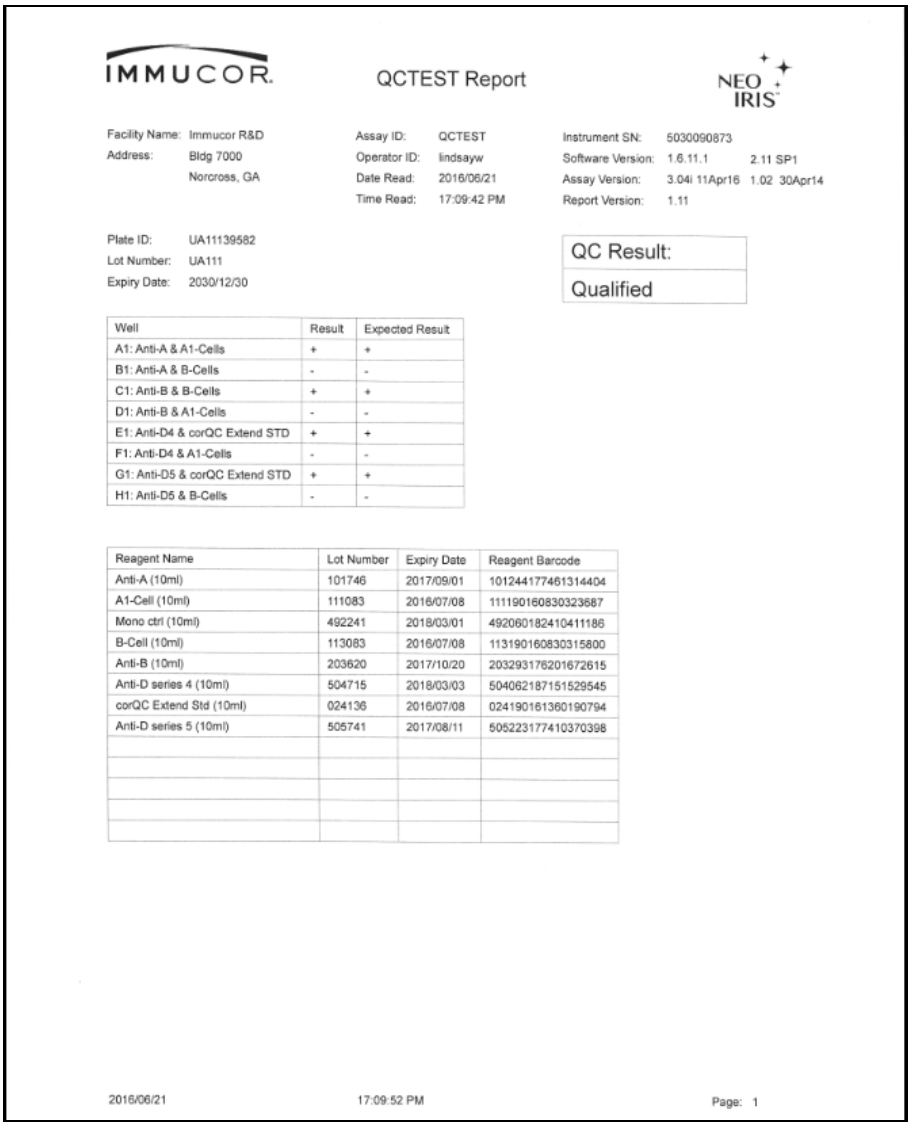
The reagent details grid is located directly below the result grid. This report lists the reagents used for this QC with their lot number, expiry date and reagent barcode information. The **QC Result** column lists either 'Qualified' or 'Failed' as a summary, depending on the outcome of the individual results and if those individual results match the expected results.

There are multiple QC assays dependent upon the selected reagents being used for different blood group purposes. Refer to **Attachment 1 for NEO Iris Operator Manual** for a detailed list of the QC assays and their applications.

In cases where multiple vials of the same lot of reagent are loaded and used in single quality control test assays such as QCTEST, then the report supports the documentation of multiple vials.

The entire barcode information of the used reagent vials is documented on all quality control reports along with the lot number and expiry date of those same vials.

Below are two (2) examples of QC reports.



IMMUCOR

QCTEST Report

NEO IRIS

Facility Name: Immucor R&D
Address: Bldg 7000
Norcross, GA

Assay ID: QCTEST
Operator ID: lindsayw
Date Read: 2016/06/21
Time Read: 17:09:42 PM

Instrument SN: 5030090873
Software Version: 1.6.11.1 2.11 SP1
Assay Version: 3.04i 11Apr16 1.02 30Apr14
Report Version: 1.11

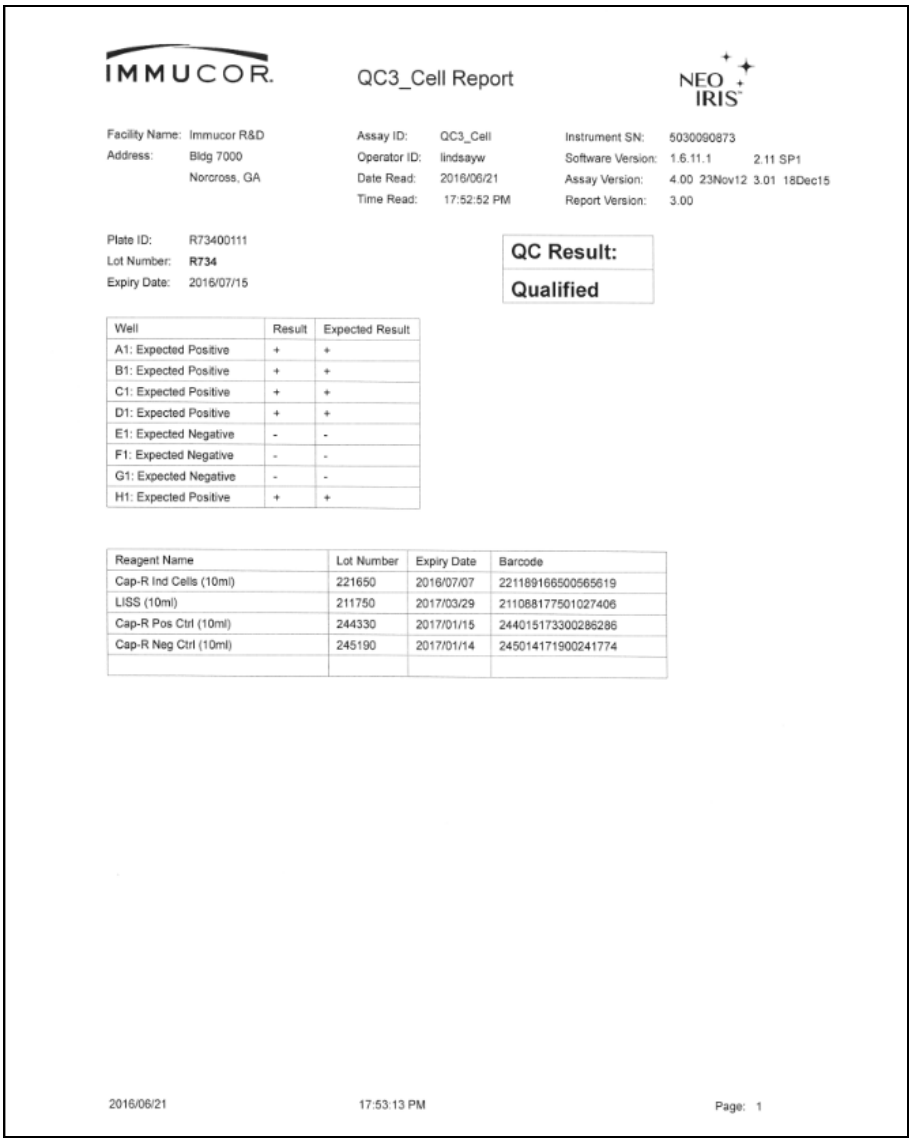
Plate ID: UA11139582
Lot Number: UA111
Expiry Date: 2030/12/30

QC Result:
Qualified

Well	Result	Expected Result
A1: Anti-A & A1-Cells	+	+
B1: Anti-A & B-Cells	-	-
C1: Anti-B & B-Cells	+	+
D1: Anti-B & A1-Cells	-	-
E1: Anti-D4 & corQC Extend STD	+	+
F1: Anti-D4 & A1-Cells	-	-
G1: Anti-D5 & corQC Extend STD	+	+
H1: Anti-D5 & B-Cells	-	-

Reagent Name	Lot Number	Expiry Date	Reagent Barcode
Anti-A (10ml)	101746	2017/09/01	10124417746131 4404
A1-Cell (10ml)	111083	2016/07/08	111190160830323687
Mono ctrl (10ml)	492241	2018/03/01	492060182410411186
B-Cell (10ml)	113083	2016/07/08	113190160830315800
Anti-B (10ml)	203620	2017/10/20	203293176201672615
Anti-D series 4 (10ml)	504715	2018/03/03	504062187151529545
corQC Extend Std (10ml)	024136	2016/07/08	024190161360190794
Anti-D series 5 (10ml)	505741	2017/08/11	505223177410370398

2016/06/21 17:09:52 PM Page: 1



IMMUCOR

QC3_Cell Report

NEO IRIS

Facility Name:	Immucor R&D	Assay ID:	QC3_Cell	Instrument SN:	5030090873
Address:	Bldg 7000	Operator ID:	lindsayw	Software Version:	1.6.11.1 2.11 SP1
	Norcross, GA	Date Read:	2016/06/21	Assay Version:	4.00 23Nov12 3.01 18Dec15
		Time Read:	17:52:52 PM	Report Version:	3.00

Plate ID: R73400111
Lot Number: **R734**
Expiry Date: 2016/07/15

QC Result:
Qualified

Well	Result	Expected Result
A1: Expected Positive	+	+
B1: Expected Positive	+	+
C1: Expected Positive	+	+
D1: Expected Positive	+	+
E1: Expected Negative	-	-
F1: Expected Negative	-	-
G1: Expected Negative	-	-
H1: Expected Positive	+	+

Reagent Name	Lot Number	Expiry Date	Barcode
Cap-R Ind Cells (10ml)	221650	2016/07/07	22118916650056561 9
LISS (10ml)	211750	2017/03/29	21108817750102740 6
Cap-R Pos Ctrl (10ml)	244330	2017/01/15	24401517330028628 6
Cap-R Neg Ctrl (10ml)	245190	2017/01/14	24501417190024177 4

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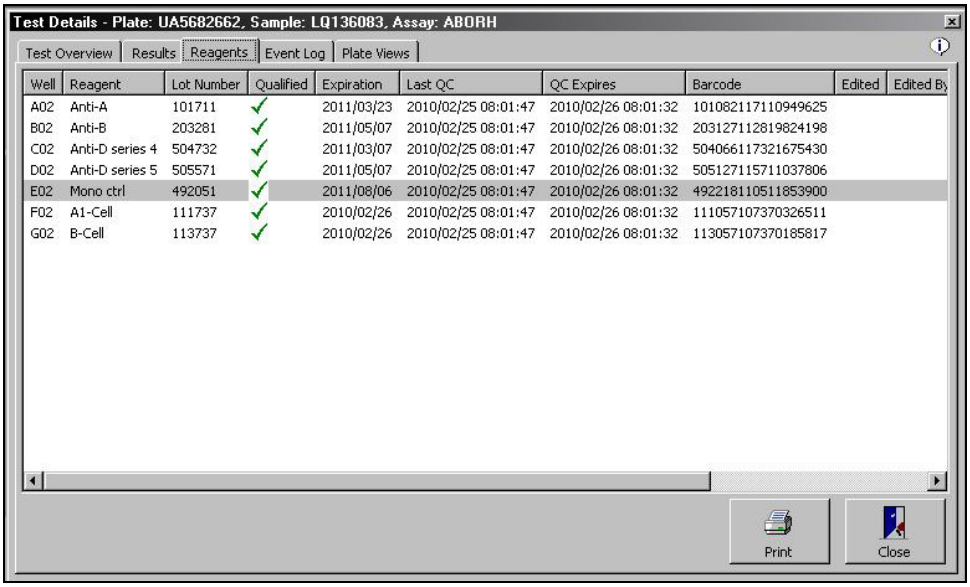
Reagent Reports

There are two (2) versions of reports that list reagent details. One version of reagent report is derived from plate based reports and is not accessible through the sample based methods of reporting. This version uses the *Reporting* dialog. The other version of reagent report is derived from both sample and plate based methods of reporting using the **Details** button.

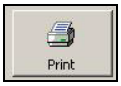
Using the Details Button

You can access one version of **Reagents** reports by selecting the *Reagents* tab of the *Test Details* dialog, via the **Details** button, for a chosen sample or plate item on the main *Results* screen.

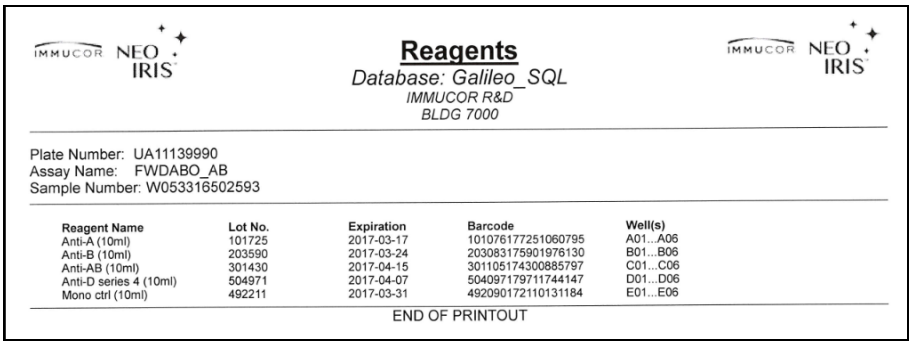


Well	Reagent	Lot Number	Qualified	Expiration	Last QC	QC Expires	Barcode	Edited	Edited By
A02	Anti-A	101711	✓	2011/03/23	2010/02/25 08:01:47	2010/02/26 08:01:32	101082117110949625		
B02	Anti-B	203281	✓	2011/05/07	2010/02/25 08:01:47	2010/02/26 08:01:32	203127112819824198		
C02	Anti-D series 4	504732	✓	2011/03/07	2010/02/25 08:01:47	2010/02/26 08:01:32	504066117321675430		
D02	Anti-D series 5	505571	✓	2011/05/07	2010/02/25 08:01:47	2010/02/26 08:01:32	505127115711037806		
E02	Mono ctrl	492051	✓	2011/08/06	2010/02/25 08:01:47	2010/02/26 08:01:32	492218110511853900		
F02	A1-Cell	111737	✓	2010/02/26	2010/02/25 08:01:47	2010/02/26 08:01:32	111057107370326511		
G02	B-Cell	113737	✓	2010/02/26	2010/02/25 08:01:47	2010/02/26 08:01:32	113057107370185817		

Press the **Print** button to print the **Reagents** report.



An example of a **Reagents** report derived from the *Reagents* tab is shown below. This version of reagent report lists the reagents used with a given sample or plate. The sample number field displays the sample identification that is currently selected or is defaulted to the top sample in any sample list if a specific sample is not selected, such as in the case of plate based reports. In the case of quality control assays, the sample number field displays the barcoded identification information of one of the reagents undergoing quality control on that quality control plate.



IMMUCOR NEO IRIS

Reagents

Database: Galileo_SQL
IMMUCOR R&D
BLDG 7000

IMMUCOR NEO IRIS

Plate Number: UA11139990
Assay Name: FWDABO_AB
Sample Number: W053316502593

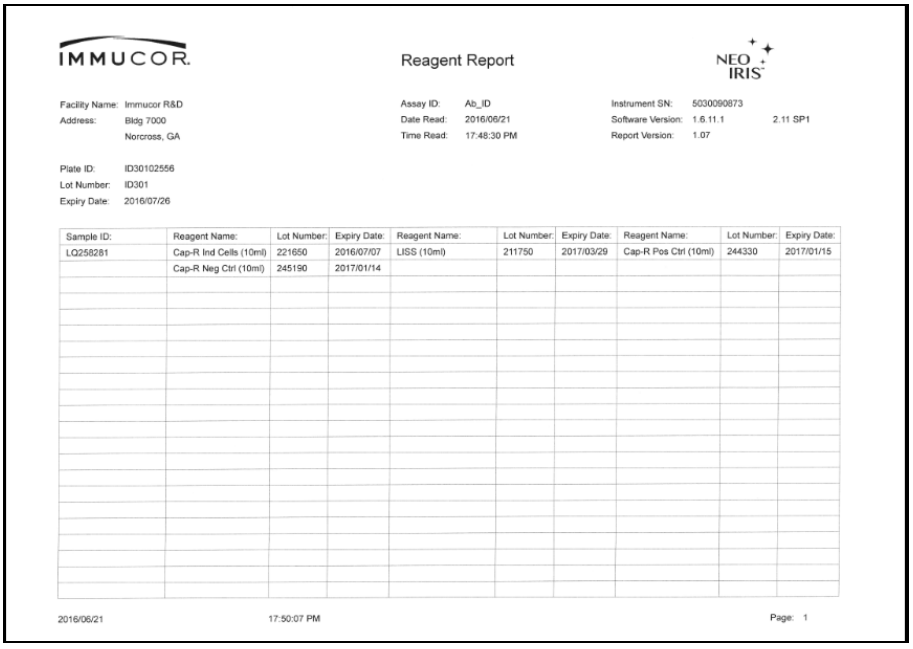
Reagent Name	Lot No.	Expiration	Barcode	Well(s)
Anti-A (10ml)	101725	2017-03-17	101076177251060795	A01...A06
Anti-B (10ml)	203590	2017-03-24	203083175901976130	B01...B06
Anti-AB (10ml)	301430	2017-04-15	301105174300885797	C01...C06
Anti-D series 4 (10ml)	504971	2017-04-07	504097179711744147	D01...D06
Mono ctrl (10ml)	492211	2017-03-31	492090172110131184	E01...E06

END OF PRINTOUT

Refer to the **Printing Reagents Report from Test Details** section of this chapter for details of this method of printing.

Using the Reporting Dialog

The second version of a report listing reagents (the **Reagent Report**) is available using the *Reporting* dialog, as described in the **Printing Reports** section of this chapter. This version of **Reagent Report** lists the reagents used on a given plate on a sample-by-sample basis for all of the sample identifications included on that plate. This version of the report is not accessible through the sample based methods of reporting.



IMMUCOR

Reagent Report

NEO IRIS

Facility Name: Immucor R&D
Address: Bldg 7000
Norcross, GA

Assay ID: Ab_ID
Date Read: 2016/06/21
Time Read: 17:48:30 PM

Instrument SN: 5030090873
Software Version: 1.6.11.1 2.11 SP1
Report Version: 1.07

Plate ID: ID30102556
Lot Number: ID301
Expiry Date: 2016/07/26

Sample ID:	Reagent Name:	Lot Number:	Expiry Date:	Reagent Name:	Lot Number:	Expiry Date:	Reagent Name:	Lot Number:	Expiry Date:
LQ258281	Cap-R Ind Cells (10ml)	221650	2016/07/07	LISS (10ml)	211750	2017/03/29	Cap-R Pos Ctrl (10ml)	244330	2017/01/15
	Cap-R Neg Ctrl (10ml)	245190	2017/01/14						

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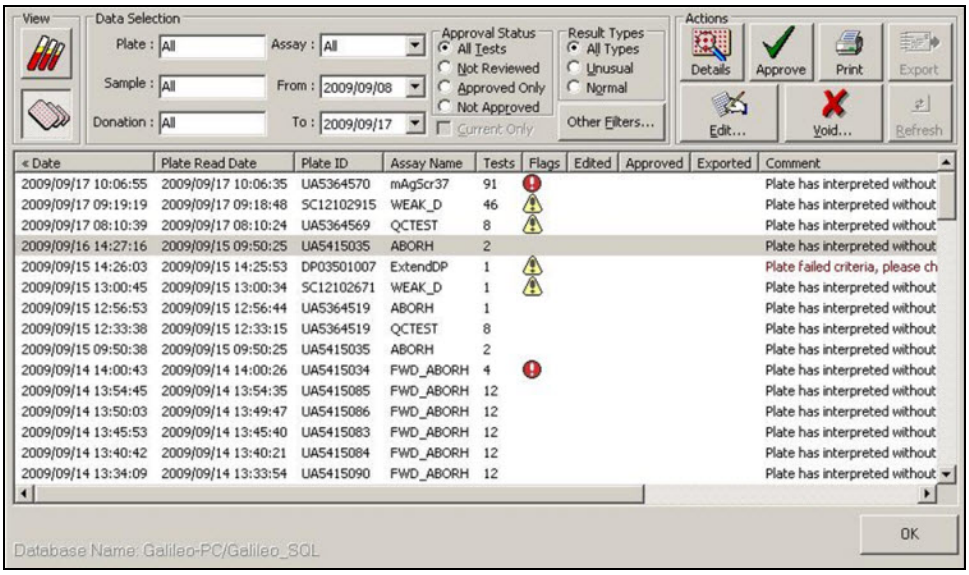
Refer to the **Printing Reports** section of this chapter for details of this method of printing.

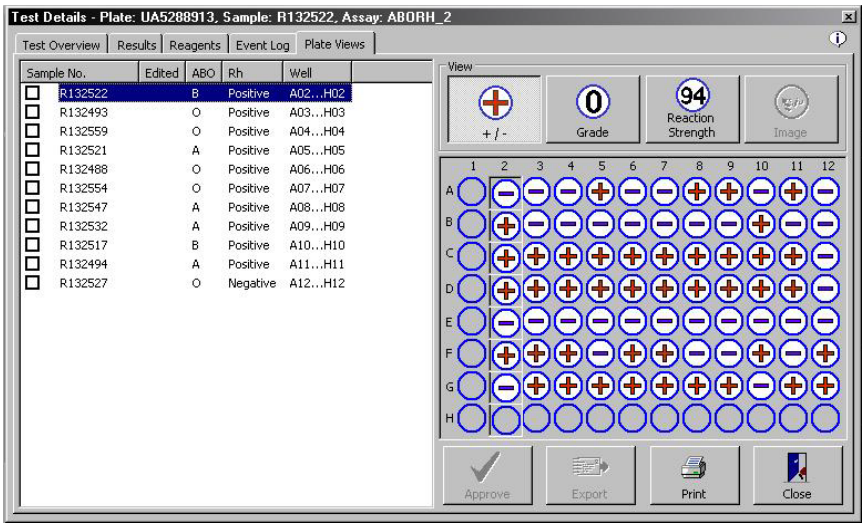
Accessing Plate Based Reports

You can access plate based reports by setting the results view to plate, selecting the plate entries to be reported, and pressing the **Print** button in the upper right corner.



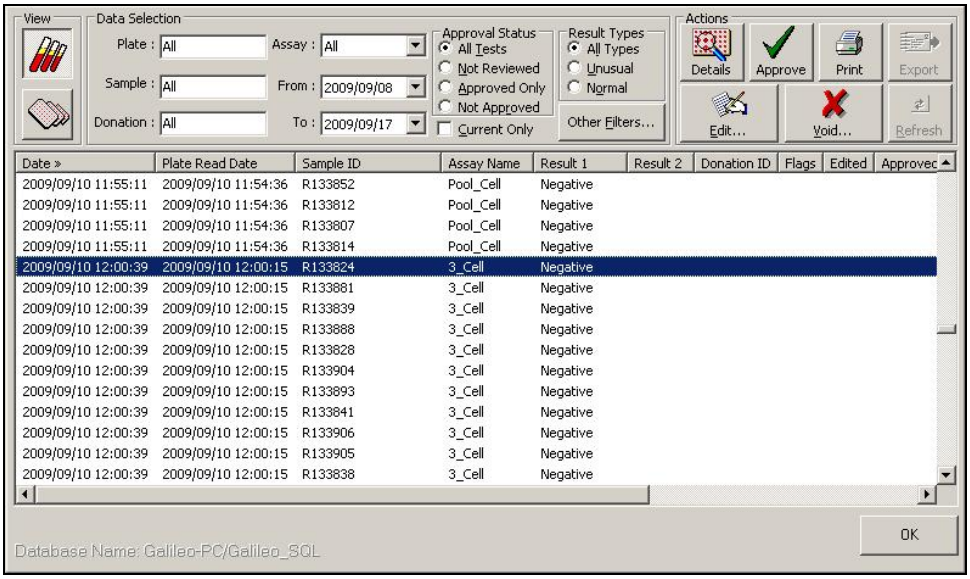
Note: You must select at least one plate entry before pressing the **Print** button.

You can also access plate based reports by selecting the **Print** button in the *Plate Views* tab of the *Test Details* dialog of a plate. You can access *Test Details* by pressing the **Details** button.


Test Details - Plate: UA5288913, Sample: R132522, Assay: ABORH_2
Test Overview
Results
Reagents
Event Log
Plate Views
Sample No.
Edited
ABO
Rh
Well
R132522 B Positive A02...H02
R132493 O Positive A03...H03
R132559 O Positive A04...H04
R132521 A Positive A05...H05
R132488 O Positive A06...H06
R132554 O Positive A07...H07
R132547 A Positive A08...H08
R132532 A Positive A09...H09
R132517 B Positive A10...H10
R132494 A Positive A11...H11
R132527 O Negative A12...H12
View
+ / -
Grade
Reaction Strength
Image
1 2 3 4 5 6 7 8 9 10 11 12
A
B
C
D
E
F
G
H
Approve
Export
Print
Close

Accessing Sample Based Reports

You can access sample based reports by setting the results view to sample, selecting the sample entries to be reported, and pressing the **Print** button in the upper right corner.

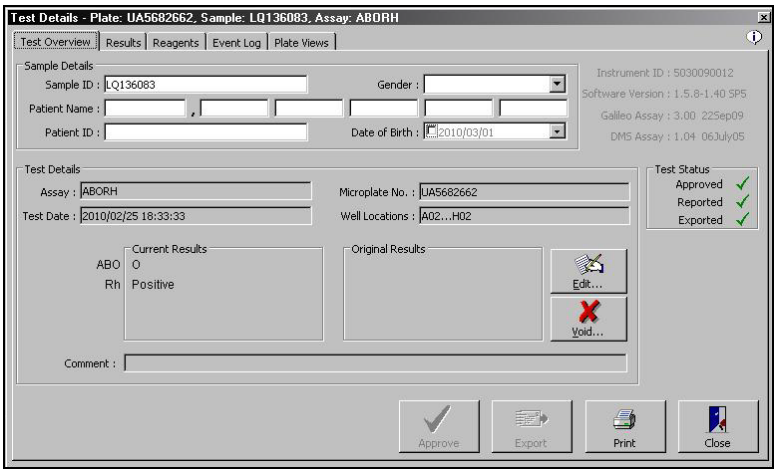


Note: You must select at least one sample entry before pressing the **Print** button.

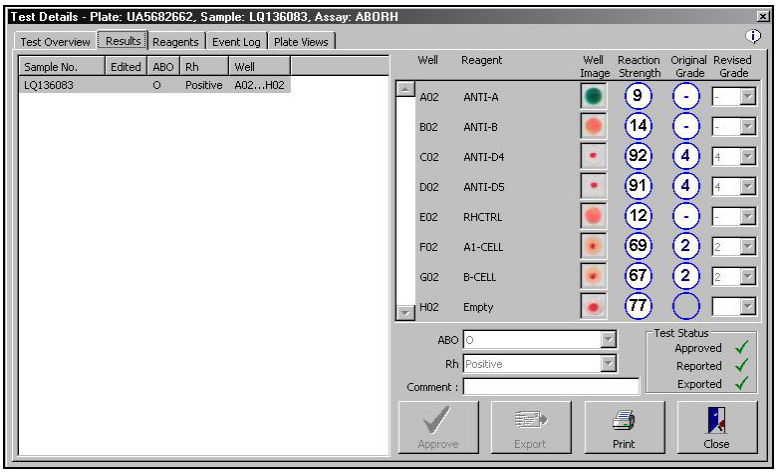
You can also access sample based reports, such as Group and Screen reports, by using the **Print** button in the *Test Overview* tab or the *Results* tab of the *Test Details* dialog.

Note: Group and Screen reports can only be accessed using the sample based report methods and not by using the plate based report methods.

You can access the *Test Details* dialog by pressing the **Details** button in the *Actions* area of the main *Results* screen. You must select one sample entry before pressing the **Details** button.



Test Details dialog>Test Overview tab



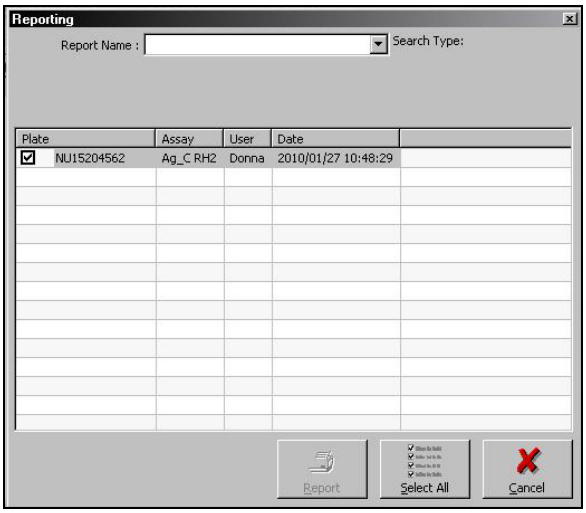
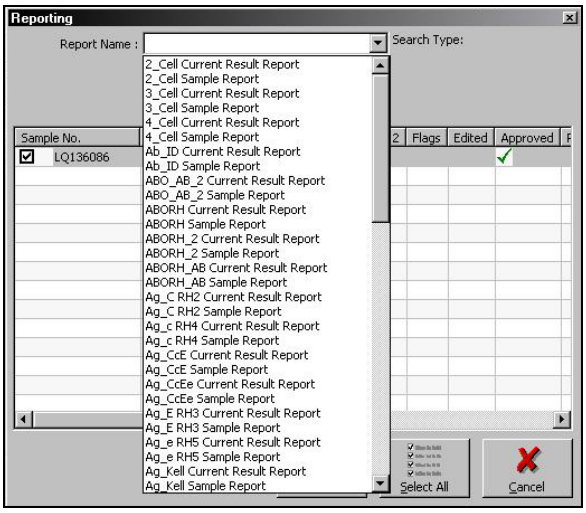
Test Details dialog>Results tab

Printing Reports

Printing Reports Using the Print Button

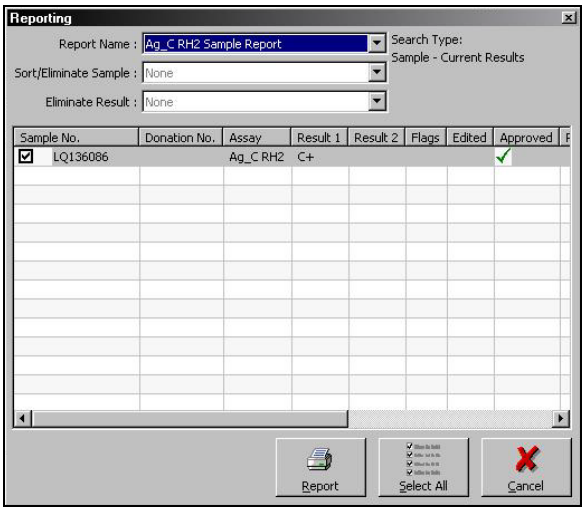
You can print reports by doing the following:

Step	Action
1	**Sample Based Reporting Options:** If you would like to print one of the following reports: • Sample based report • Antibody Identification report • Group and Screen report The Print button should be selected from one of the following screens: • Sample View Main Results screen • Test Details → Test Overview tab • Test Details → Results tab **Plate Based Reporting Options:** If you would like to print one of the following reports: • Plate based report • Reagent report • Quality Control report The Print button should be selected from one of the following screens: • Plate View Main Results screen • Test Details → Plate View tab

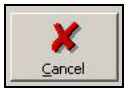
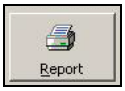
Step	Action
2	The system displays the *Reporting* dialog with the check box for the selected entry already checked.  From the Report Name drop-down list, select the appropriate report.  You can only print one report type at a time; therefore it is important to select a *Report Name* that corresponds to the assay name of the selected plate(s) or sample(s).

Step	Action
3	The sample results to be printed will be indicated by the box checked in front of the ID.

The *Reporting* dialog is displayed.



From this screen you can do the following:

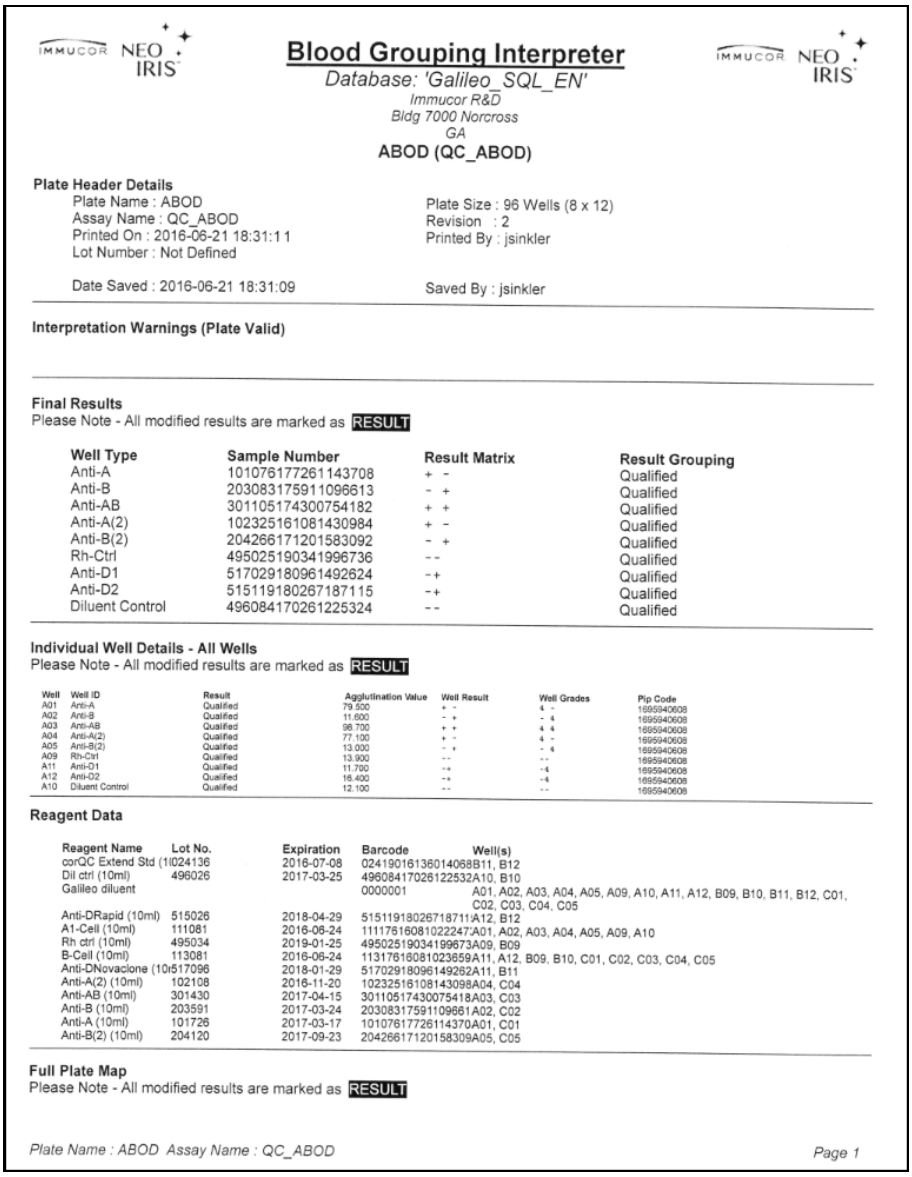
To....	...press...	Button
Select all sample IDs	**Select All**	
Cancel the selection	**Cancel**. This action closes the *Reporting* dialog.	
Print the report	**Report** from the *Reporting* dialog after selecting the *Report Name*.	

Automatic Printing of Failed Plate Reports

A printed report is automatically generated when an assay with plate controls yields a control failed criteria. The automatically printed report indicates that the plate failed, what Control caused the failed status, and the list of the samples that were on the plate.

Note: The value listed in the **Well** column is the first well that the sample or control is found in. It is not necessarily the well that failed. Determination of which well failed can be made by examining the results on the NEO Iris.

Note: **Well ID** is the control material or the sample ID.



IMMUCOR NEO IRIS

Blood Grouping Interpreter

Database: 'Galileo_SQL_EN'
Immucor R&D
Bldg 7000 Norcross
GA

ABOD (QC_ABOD)

IMMUCOR NEO IRIS

Plate Header Details

Plate Name : ABOD
Assay Name : QC_ABOD
Printed On : 2016-06-21 18:31:11
Lot Number : Not Defined

Plate Size : 96 Wells (8 x 12)
Revision : 2
Printed By : jsinkler

Date Saved : 2016-06-21 18:31:09
Saved By : jsinkler

Interpretation Warnings (Plate Valid)

Final Results
Please Note - All modified results are marked as RESULT

Well Type	Sample Number	Result Matrix	Result Grouping
Anti-A	101076177261143708	+ -	Qualified
Anti-B	203083175911096613	- +	Qualified
Anti-AB	301105174300754182	+ +	Qualified
Anti-A(2)	102325161081430984	+ -	Qualified
Anti-B(2)	204266171201583092	- +	Qualified
Rh-Ctrl	495025190341996736	- -	Qualified
Anti-D1	517029180961492624	-+	Qualified
Anti-D2	515119180267187115	-+	Qualified
Diluent Control	496084170261225324	- -	Qualified

Individual Well Details - All Wells
Please Note - All modified results are marked as RESULT

Well	Well ID	Result	Agglutination Value	Well Result	Well Grades	Pip Code
A01	Anti-A	Qualified	79.500	+ -	4 -	1695940608
A02	Anti-B	Qualified	11.600	- +	- 4	1695940608
A03	Anti-AB	Qualified	98.700	+ +	4 4	1695940608
A04	Anti-A(2)	Qualified	77.100	+ -	4 -	1695940608
A05	Anti-B(2)	Qualified	13.000	- +	- 4	1695940608
A09	Rh-Ctrl	Qualified	13.900	- -	- -	1695940608
A11	Anti-D1	Qualified	11.700	-+	-4	1695940608
A12	Anti-D2	Qualified	16.400	-+	-4	1695940608
A10	Diluent Control	Qualified	12.100	- -	- -	1695940608

Reagent Data

Reagent Name	Lot No.	Expiration	Barcode	Well(s)
corQC Extend Std (10	024136	2016-07-08	02419016136014068	B11, B12
Dil ctrl (10ml)	496026	2017-03-25	49608417026122532	A10, B10
Galileo diluent			0000001	A01, A02, A03, A04, A05, A09, A10, A11, A12, B09, B10, B11, B12, C01, C02, C03, C04, C05
Anti-DRapid (10ml)	515026	2018-04-29	51511918026718711	A12, B12
A1-Cell (10ml)	111081	2016-08-24	11117616081022247	A01, A02, A03, A04, A05, A09, A10
Rh ctrl (10ml)	495034	2019-01-25	49502519034199673	A09, B09
B-Cell (10ml)	113081	2016-06-24	11317616081023659	A11, A12, B09, B10, C01, C02, C03, C04, C05
Anti-DNovaclone (10r	517096	2018-01-29	51702918096149262	A11, B11
Anti-A(2) (10ml)	102108	2016-11-20	10232516108143098	A04, C04
Anti-AB (10ml)	301430	2017-04-15	30110517430075418	A03, C03
Anti-B (10ml)	203591	2017-03-24	20308317591109661	A02, C02
Anti-A (10ml)	101726	2017-03-17	10107617726114370	A01, C01
Anti-B(2) (10ml)	204120	2017-09-23	20426617120158309	A05, C05

Full Plate Map
Please Note - All modified results are marked as RESULT

Plate Name : ABOD Assay Name : QC_ABOD *Page 1*

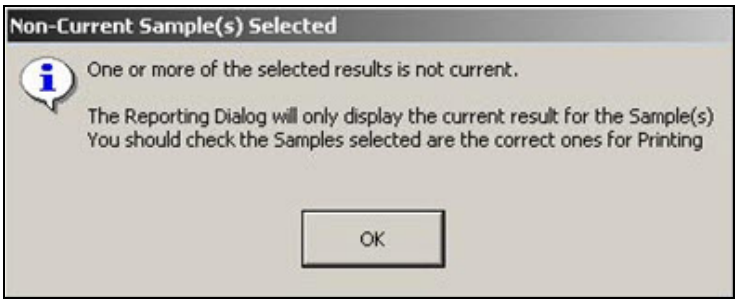
Report Naming Conventions and General Features

In the case of current and sample based reports such as antibody identification and Group and Screen reports respectively, if the assay name selected from the Report Name drop-down list does not match the assay name for which selections are checked in the body of the *Reporting* dialog then a blank grid will be printed on the report.

In the case of plate based reports, if the assay name selected from the Report Name drop down list does not match the assay name for which selections are checked in the body of the *Reporting* dialog then incorrectly formatted data will be printed on the report.

All plates or samples in the *Reporting* dialog are extracted from the filtered list in the main results section and listed in descending chronological order. This allows you to select multiple plates or samples for reporting by clicking the box to the left of the plate/sample ID.

When non-current and current results are selectively combined and printing is attempted, the software displays the *Non-Current Sample(s) Selected* dialog. You must press the **OK** button of the dialog to acknowledge the message.



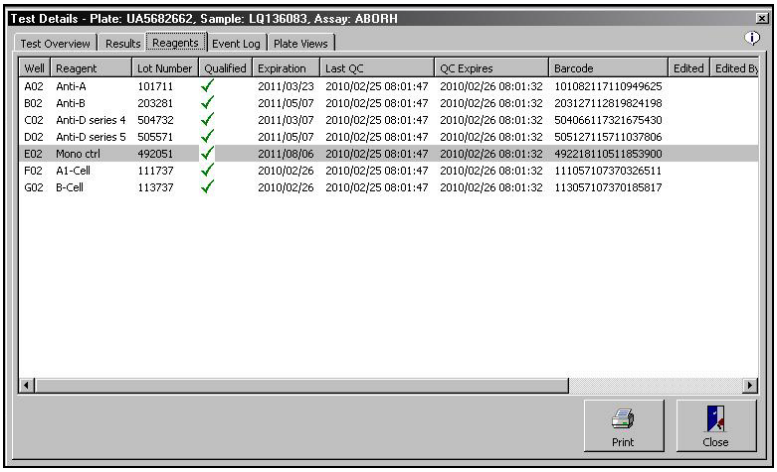
Selecting a Large Group of Continuous Entries

To select a large group of continuous entries from the main results screen:

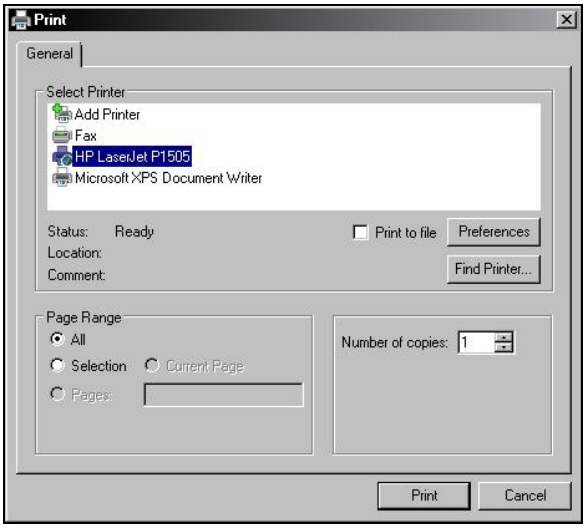
Step	Action
1	Select a plate or sample at one end of the desired group.
2	Press and hold the **Shift** key on the keyboard.
3	Select the plate or sample at the other end of the desired group.
4	Press the **Print** button on the software screen.

Printing Reagents Report from Test Details

To print Reagents reports from Test Details:

Step	Action
1	Press the **Details** button, for a chosen sample or plate item on the main *Results* screen under sample or plate view respectively.   **Note**: The *Reagents* report is available using both the sample and plate based results views. Select the *Reagents* tab of the *Test Details* dialog.  **Note**: This version of reagent report lists the reagents used for a given sample or plate. The sample number field displays the sample identification that is currently selected or is defaulted to the top sample in any sample list if a specific sample is not selected, such as in the case of plate based reports. In the case of quality control assays, the sample number field displays the barcoded identification information of one of the reagents undergoing quality control on that quality control plate. 

Well	Reagent	Lot Number	Qualified	Expiration	Last QC	QC Expires	Barcode	Edited	Edited By
A02	Anti-A	101711	✓	2011/03/23	2010/02/25 08:01:47	2010/02/26 08:01:32	10108211711094962 5		
B02	Anti-B	203281	✓	2011/05/07	2010/02/25 08:01:47	2010/02/26 08:01:32	20312711281982419 8		
C02	Anti-D series 4	504732	✓	2011/03/07	2010/02/25 08:01:47	2010/02/26 08:01:32	50406611732167543 0		
D02	Anti-D series 5	505571	✓	2011/05/07	2010/02/25 08:01:47	2010/02/26 08:01:32	50512711571103780 6		
E02	Mono ctrl	492051	✓	2011/08/06	2010/02/25 08:01:47	2010/02/26 08:01:32	49221811051185390 0		
F02	A1-Cell	111737	✓	2010/02/26	2010/02/25 08:01:47	2010/02/26 08:01:32	11105710737032651 1		
G02	B-Cell	113737	✓	2010/02/26	2010/02/25 08:01:47	2010/02/26 08:01:32	11305710737018581 7		

Step	Action
2	Press the **Print** button of the *Print* dialog to print the Reagents report. Press the **Cancel** button to close the *Print* dialog. The **Number of copies** can be selected. 

Test Results and Interpretation

For information about Test Results and Interpretation, refer to **Attachment 1 for NEO Iris Operator Manual**.

Chapter 9: System Shutdown

In This Chapter

This chapter provides a summary of the procedures required to shut down the NEO Iris.

Logging Out

To log out of the NEO Iris:

Step	Action
1	Click the **Login** button on the Main Menu Bar to log out. 
2	The system displays the *Login* dialog. You are now logged out. The screen remains available for the next user to log in.

Shutting Down the NEO Iris After Operation

Purpose

The NEO Iris module and the computer must be completely shut down every day to prevent potential long-term memory leakage and modular drift. Refer to **Chapter 10 – Maintaining the NEO Iris** for information regarding this maintenance task.

Note: The maximum duration of the NEO Iris instrument shutdown must be limited to thirty (30) seconds so that the reader lamp and incubators will maintain warmth.

If the NEO Iris remains inactive for a short period (such as overnight), remove all samples, reagents, and unused plates, and store them according to the relevant reagent package inserts.

Because of the washer auto-flush feature, you do not need to perform a full shutdown. The auto-flush feature is the programmed flushing of the washer manifold with 5 ml of system liquid every 30 minutes when the NEO Iris is inactive.

Note: If the NEO Iris is in use, auto-flush is not triggered. Therefore, it is important that you monitor the system liquid volume to ensure that sufficient system liquid volume is present, so that the container will not run dry over extended periods of inactivity. Inactivity triggers auto-flush. System liquid monitoring is incorporated into the NEO Iris daily maintenance.

Note: You must perform a full system shutdown if you are switching off the NEO Iris instrument power for a prolonged time period (auto-flush will be inactive). Shutdown incorporates flushing of pumps, manifold, and tubing with deionized water to prevent potential salt crystallization build up and blockages. Shutdown also allows you to back up software.

Summary of Shutdown Strategies

The table below describes the suggested hierarchy of NEO Iris shutdown procedures related to projected time periods of instrument inactivity.

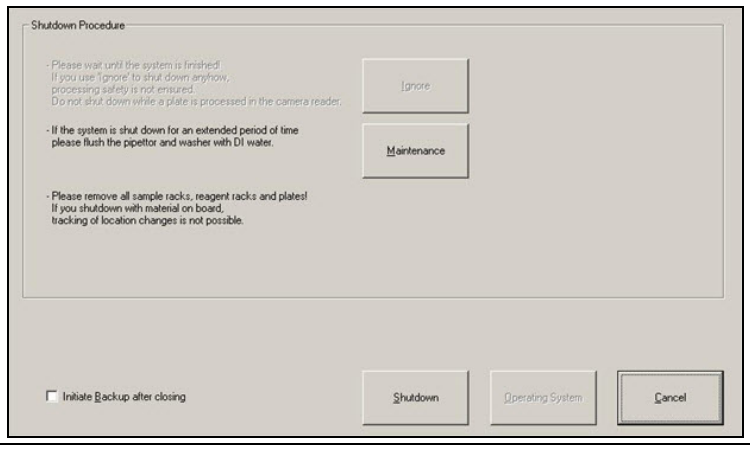
If your goal is to shut down the NEO Iris…	**You should…**
to perform the daily maintenance shutdown task.	perform the shutdown procedure, but do not include the Flush System Liquid action (by excluding step 3 of the procedure below).
for a period of time when use of the NEO Iris	perform the shutdown procedure and include the Flush

for testing is not expected in the very near future, but is anticipated to be further in the future (e.g. greater than four days).	System Liquid action that leaves deionized water in the tubing. Make a note indicating there is deionized water in the tubing to prevent accidental running of the instrument before switching the liquid over to PBS.
for a prolonged period (such as taking the NEO Iris out of service and putting it into storage).	perform the extended shutdown procedure which includes decontamination and flushing the system with air.

Procedure

To shut down the NEO Iris:

Step	Action
1	Press the **Shutdown** button on the Main Menu Bar of the Machine Monitor dialog.  The shutdown procedure is guided by the *Shutdown* dialog. Pressing the **Shutdown** button on the Main Menu Bar displays the *Shutdown* dialog.

Step	Action
2	If the NEO Iris is active then the **Shutdown** dialog will display with the **Ignore** button as available, and the running man icon visible. Pressing the **Ignore** button can have unwanted consequences, as detailed on the dialog. By pressing the **Ignore** button, the **Shutdown** and **Maintenance** buttons will become available.  If the NEO Iris is not active then the **Shutdown** dialog will display with the **Ignore** button not available, and the running man icon will not be visible. The **Maintenance**, **Shutdown** and **Cancel** buttons will be available. **Note:** The **Operating System** button is only available to Immucor personnel. You can select the **Cancel** button if you decide to terminate the Shutdown procedure. 
3	To run the Flush Liquid System maintenance task: **Note**: Do not include this step 3 if performing daily maintenance shutdown.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td></td><td>
<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Select the Maintenance button. This will direct you to the Maintenance screen.</td></tr>
<tr><td>2</td><td>Select the Flush System Liquid maintenance action from the maintenance list. Refer to Flushing the System Liquid in Chapter 10 – Maintaining the NEO Iris for details of this procedure.</td></tr>
</table>

<u>Note:</u> Running the Flush System Liquid maintenance task is optional. You should only perform this action if your intention is to leave the shutdown NEO Iris liquid system filled with deionized water. If your intention is to leave the shutdown NEO Iris liquid system filled with PBS, then you should skip the Maintenance button and proceed to remove all sample racks, reagent racks and microplates, and then select the Shutdown button.
</td></tr>
<tr><td>4</td><td>To remove all sample racks, reagent racks and microplates:
<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Remove all samples from the loading bay and store them according to standard laboratory practices.</td></tr>
<tr><td>2</td><td>Remove all reagents from the loading bay and store them according to the relevant reagent package inserts.</td></tr>
<tr><td>3</td><td>Remove all plates from the loading tower and discard all consumed test wells.</td></tr>
</table>
</td></tr>
<tr><td>5</td><td>To use the Shutdown button:
<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Select the Shutdown button. The NEO Iris software completely shuts down.</td></tr>
</table>
</td></tr>
</table>

Step	Action	
	2	Switch off the NEO Iris module using the power switch on the bottom right side of the NEO Iris module. 

Extended Shutdown of the NEO Iris

Purpose

If the NEO Iris is to be taken out of service for an extended period of time, it is recommended that the system be decontaminated, flushed with deionized water, and then primed with air to clear all liquid from the system.

Note: If the NEO Iris will be out of service for a short period of time, it is recommended to leave the NEO Iris powered on to allow the auto-flush feature to periodically prime the washer manifold. A sufficient volume of system liquid must be maintained in the system liquid container to prevent the washer manifold from running dry.

Procedure

To perform extended shutdown:

Step	Action
1	Perform the decontamination procedure as outlined in **Chapter 10 - Maintaining the NEO Iris**.
2	Perform the Flush System Liquid procedure as outlined in **Chapter 10 - Maintaining the NEO Iris**.
3	To prime the system with air:

Step	Action
1	After completing the Flush System Liquid procedure, disconnect the system liquid tubing connections, including the washer liquid line, from the 20 L system liquid container lid. Rest the ends of the tubing on an absorbent material (e.g. paper towel).
2	Run the **ClearTube** assay. This will prime the system with air to remove all liquid in preparation for storage.
3	Once the assay is complete, remove both system liquid containers and discard the deionized water. Return the empty containers to their proper position on the cabinet drawer.

	4 | Reconnect the system liquid and washer tubing to the empty 20 L system liquid container lid.
4	Enter the Shutdown dialog as described in this chapter. Select the **Shutdown** button. The NEO Iris software completely shuts down. Switch off both the NEO Iris instrument and the centrifuge module using the on/off switches for both systems. **Note**: When bringing the NEO Iris back into service following an extended shutdown, perform the decontamination procedure as outlined in **Chapter 10 - Maintaining the NEO Iris**.

Chapter 10: Maintaining the NEO Iris

In This Chapter

This chapter describes the detailed procedures for maintaining the NEO Iris.

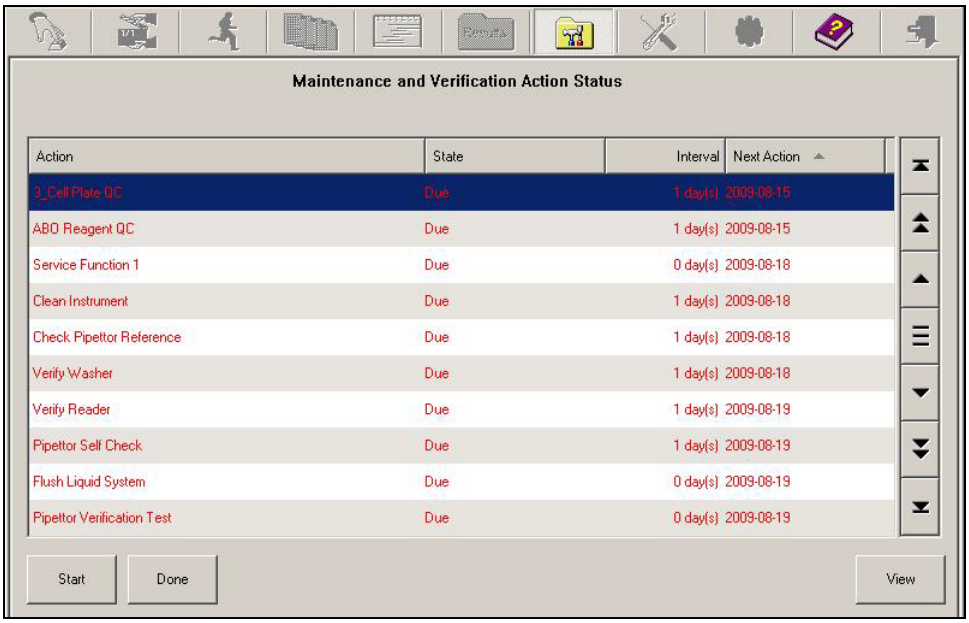
Maintenance Overview

Maintenance and Verification Action Status Screen

The *Maintenance and Verification Action Status* screen lists all of the maintenance actions that are available on the NEO Iris, along with the current state, the required interval, and the date the next action must be performed. You can highlight and perform multiple actions at one time.

To access the *Maintenance and Verification Action Status* screen, click the **Maintenance** button.

The **Maintenance and Verification Action Status** screen lists all of the software driven maintenance actions that are available on the NEO Iris, along with the current state, the required interval, and the date the next action must be performed. You can highlight and perform multiple actions at one time.

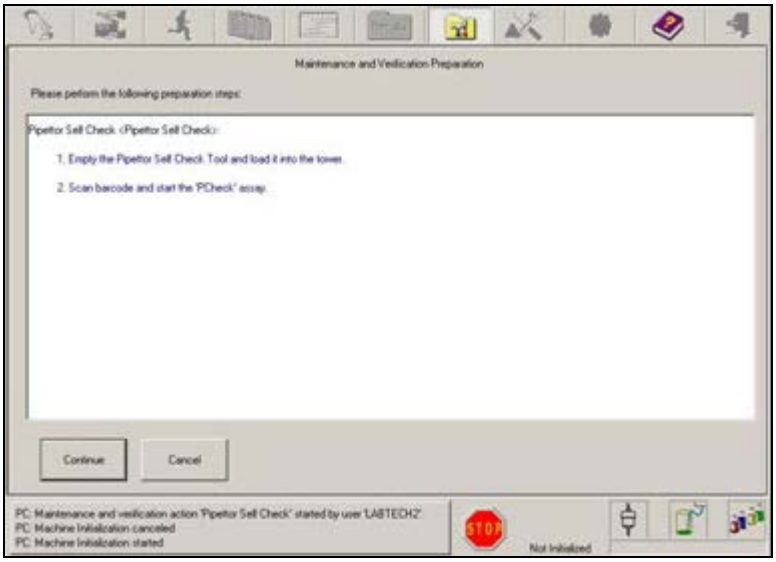


The NEO Iris software defines monthly as 30 days. You can successfully perform any maintenance action **before** the required time interval date. If you do, the next required time interval date for that action remains automatically calculated from that last action date. For example, if you performed a 7-day action after only 4 days, the next required date is calculated as 7 days from this latest action date. **Daily** is defined as a 24-hour period, such as 9 AM to 9 AM.

The system lists the state of maintenance actions as **OK**, **Due**, or **Pending**. **OK** means no action is required. The next action for that item is designated for the future. **Due** means that this action must be taken now and the required date is overdue. The text for a **Due** item is in **red** font. Actions with an interval of 0 days do not prevent assays from being run, and it is not necessary to perform these actions

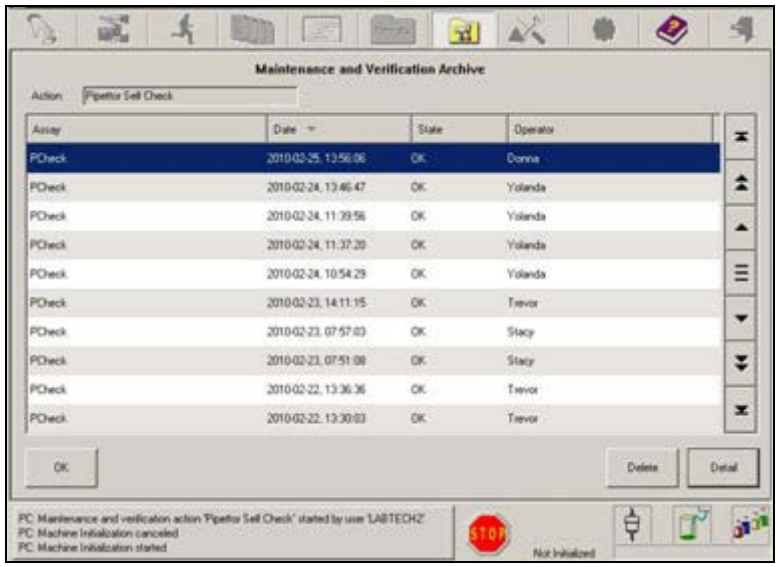
when their state is **Due**. **Pending** means that this action is in process and awaiting completion. Once an action is completed, the status changes from **Due** to **OK**. A status of **Not Passed** can be associated with a task if that given task failed. An example of such a task is **Pipettor Self Check**.

To run a particular maintenance action, you can select (highlight) the given action and then press the **Start** button on the **Maintenance and Verification Action Status** screen. The on-screen instructions will then be displayed for that action. Press the **Done** button to exit the **Maintenance and Verification Action Status** screen.

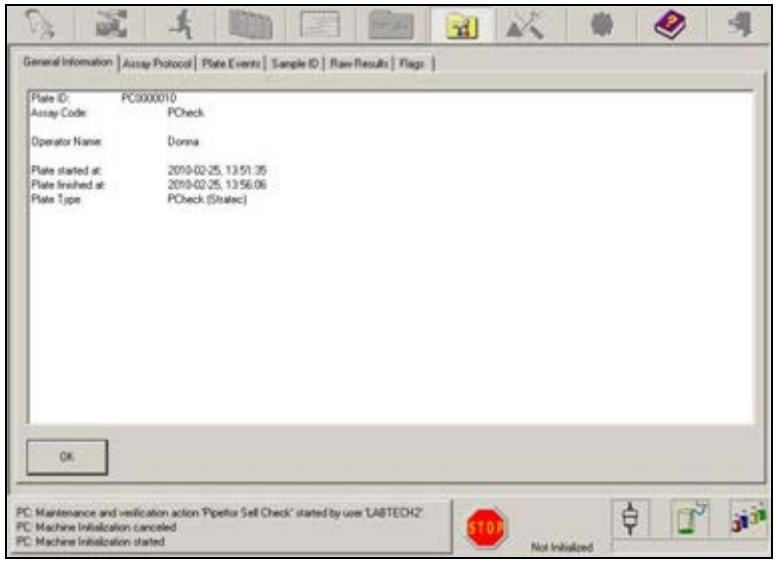


Press the **Continue** button of the **Maintenance and Verification Preparation** screen to begin the maintenance action, or press the **Cancel** button to abort the action.

You can view an archive list of a given software driven maintenance action by selecting the required action on the **Maintenance and Verification Action Status** screen and then selecting the **View** button. The **Maintenance and Verification Archive** screen is then displayed for that required action which lists each chronological event.



You can view the event details by selecting a particular event from the **Maintenance and Verification Archive** screen and then pressing the **Detail** button. The event detail screen is then displayed. You can delete an archived log entry by highlighting a particular entry on the archive screen and pressing the **Delete** button, but you must have the necessary security level to be able to delete.



Various aspects of an event detail, other than **General Information**, can be viewed by selecting the other associated tabs (**Assay Protocol**, **Plate Events**, **Sample ID**, **Raw Results** and **Flags**).

Press the **OK** button of the event detail screen to return to the **Maintenance and Verification Archive** screen. Press the **OK** button of the **Maintenance and Verification Archive** screen to return to the **Maintenance and Verification Action Status** screen.

Limitation: Maintenance actions for the NEO Iris verify that specific modules of the instrument are functioning at the required specifications. The actions described are critical to the NEO Iris assay performance.

If a maintenance item is not successfully performed for a module within the required time interval, then any assays that use that module will not run. For example, all assays use the reader. If you do not perform the daily **Pipettor Self Check** task then all assays are locked down and no assays can run.

Limitation: Before using any cleaning or decontamination methods except those recommended by the manufacturer, users should check with the manufacturer that the proposed method will not damage the equipment.

Warning: If a maintenance action requires the manual entry of a plate ID, **do not** input an ID with 2 digits of alpha characters followed by numeric characters. Because the software may recognize this ID scheme as that of a sample testing plate, entry of a plate expiration date will be required. Entry of a plate expiration date is not part of the instructions for maintenance actions.

You can log documentation of maintenance actions onto the four maintenance forms: NEO Iris Daily Maintenance Record, NEO Iris Weekly Maintenance Record, NEO Iris Monthly Maintenance Record, and PipTest Chart. Master copies of these four record sheets are located in **Appendix B – Maintenance Records**.

Daily Maintenance Tasks

Daily Tasks

The following tasks are to be completed each day:

- Perform a NEO Iris module and PC shutdown
- Filling the system liquid
- Emptying the common waste container
- Clean the instrument
- Check Pipettor Reference
- Complete Reagent Quality Control (QC)
- Complete QC3_Cell Quality Control (QC)
- Pipettor Self Check

PC and NEO Iris Module Shutdown

Purpose

The purpose of shutting down, and immediately powering up, the NEO Iris module and PC is to reset all volatile module memory and prevent potential long-term computer memory leakage.

Procedure

To shut down and power up the NEO Iris module and PC:

Step	Action
1	Shut down the PC according to the daily routine procedure described in **Chapter 9 – System Shutdown**.
2	Power off the NEO Iris module.
3	After step 2 above is completed, immediately power on the NEO Iris module and PC according to the procedures described in the starting up section of **Chapter 5 –Instrument Start-Up**.

Automatic Deletion of Outdated Plates

At the beginning of full initialization, the following outdated information is automatically deleted from the database:

- plates from the plate list, greater than forty eight (48) hours old
- plates from maintenance actions with greater than two (2) plates per assay (leaving 2 plates in the database after the automatic deletion), and
- event log entries, greater than ninety (90) days old.

As a result, the manual deletion of historic sample and maintenance plate entries is not required on the part of the operator.

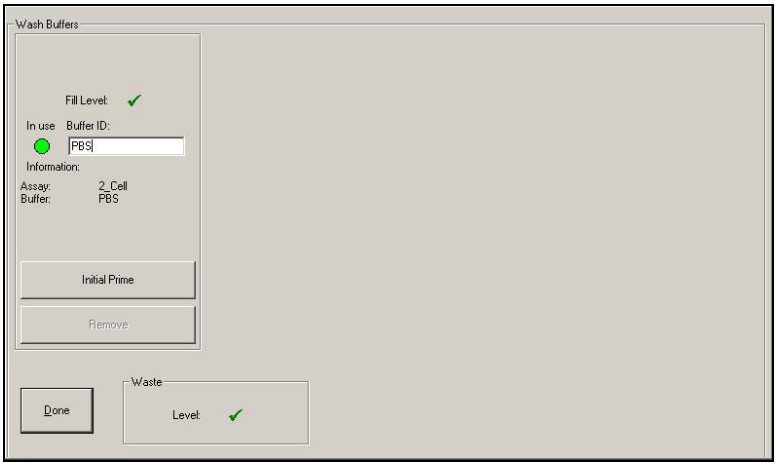
Filling the System Liquid

Both of the system liquid containers are mounted inside the cabinet on a sliding drawer that allows easy access to the liquid containers and connections when pulled forward. This section describes how to check the 10-liter refill system liquid container and fill it with system liquid.

Procedure

To fill the 10-liter System Liquid Container:

Step	Action
1	Open the cabinet doors and pull out the drawer to access both of the system liquid containers.
2	Check the system fluid level of the 20-liter system liquid container. If required, follow the procedure below to refill the container with system liquid.
3	Remove the cap of the 10-liter refill system liquid container and fill it with system liquid. A funnel can be used. Alternatively, the 10-liter refill container can be disconnected and filled off-line. Reconnect the 10-liter refill container after filling this container off-line. Allow approximately five (5) minutes for gravitational equilibration of liquid levels into the 20-liter container.  Left: 20-liter system liquid container. Right: 10-liter refill container.

Step	Action
4	Replace the cap of the 10-liter refill system liquid container, to prevent contamination. **Warning:** Results can be adversely affected if the system liquid container is filled with anything other than PBS (e.g. de-ionized water).
5	Click the **Washer** button on the Machine Monitor. The system displays the **Wash Buffers** dialog.  The **Buffer ID** name will automatically be displayed as PBS.
6	The green **Fill Level** check mark (✔) appears in the pump area of the **Wash Buffers** dialog when the system liquid container has adequate fluid. This must be the case in order to prime the pump. **Note:** The pump will automatically prime itself if Initialization is run. If needed, press the **Initial Prime** button. This primes the pump with PBS. The **In use** circle turns **red**. **Note:** If the 20-liter container is filled, but the **Initial Prime** button is not available, click in the **Buffer ID** field for the pump. This activates the **Initial Prime** button.
7	Click **Done** to leave the dialog.

Step	Action
8	When you have completed steps 1–7, ensure that the sliding drawer is fully pushed back into the cabinet and close the doors.  **Warning:** Filling the container with the incorrect fluid adversely affects Solid Phase Red Cell Adherence reactions.

Limitation: Immucor requires the use of phosphate buffered (approximately 15mM) isotonic saline, pH 6.5-7.5 (PBS), on the NEO Iris system. Reactions between an antibody and its antigen may be weakened if acidic or unbuffered saline is used.

Using saline and/or deionized water in PBS preparation from sources with systems in place to control proliferation of microbes helps to reduce the chance for microbial bioburden on the system. Excessive microbial bioburden can cause degradation of system or assay performance.

Use of Cubed Saline

As an alternative method of filling, a commercially obtained cube of unbuffered saline (that must be buffered prior to its use as per limitation above) can be directly connected (using the supplied in-line connector) to the 20-liter container, instead of using the 10-liter refill container. In this instance, the commercially obtained cube of PBS must be elevated on the drawer to at least the same level as the 10-liter refill container so that passive gravitational draining equilibration can take place. The cube must be located in the space on the drawer to the left of the common waste container and requires an extended length of tubing to connect the cube to the detachable in-line connector.

Emptying the Common Waste Container

The purpose of emptying the common waste container is to maintain empty space in the waste container for the collection of waste fluids (into the waste container).

You must perform this task at least every day or when the common waste container is full. The waste container status indicator, located on the bottom of the screen, monitors the liquid level in the container. It is normally displayed with a yellow background. When the waste container is full, the status indicator is displayed with red background.

Waste container status indicator in a capacity-for-waste condition

Required Tool(s)

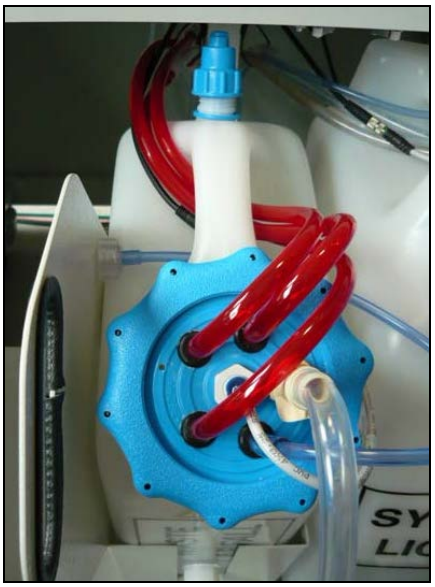
The following tool(s) are required to complete this task:

- Waste shuttle container

Procedure

To empty the common waste container:

Step	Action
1	Obtain the empty waste shuttle container before starting this procedure.
2	Open the cabinet doors and pull out the drawer to access the common waste container.

Step	Action
3	Disconnect the female quick-connector of the draining tube from the lid of the common waste container. 
4	Connect the female quick-connector at the end of the draining tube to the male quick-connector on the waste shuttle container cap. You will hear a "click" when the connection is made.  Female quick-connector connected to the waste shuttle container cap The liquid waste drains into the waste shuttle container.

Step	Action
5	When the waste transfer is complete or the shuttle container is full, disconnect the draining tube from the waste shuttle container cap.
6	Reconnect the draining tube to the male quick-connector on the lid of the common waste container. You will hear a "click" when the connection is made.
7	Push the drawer back into the cabinet and close the doors.
8	Dispose of the waste liquid following your standard laboratory practice.  **Warning:** Blood samples, liquid waste, used micro-well strips, and consumed liquid reagent vials contain potentially bio-hazardous material. Always wear protective gloves and clothing when handling blood samples, liquid waste, micro-well strips, or liquid reagent vials. All blood samples, liquid waste, micro-well strips, and liquid reagent vials must be discarded following the standard practice of the laboratory. All blood products must be treated as potentially infectious. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

Cleaning the Instrument

Purpose

The purpose of cleaning the instrument is to remove biohazardous contamination on the NEO Iris caused by spills or debris from reagents or samples.

NEO Iris initialization is included as part of the cleaning process.

Required Tool(s)

The following tool(s) are required to complete this task:

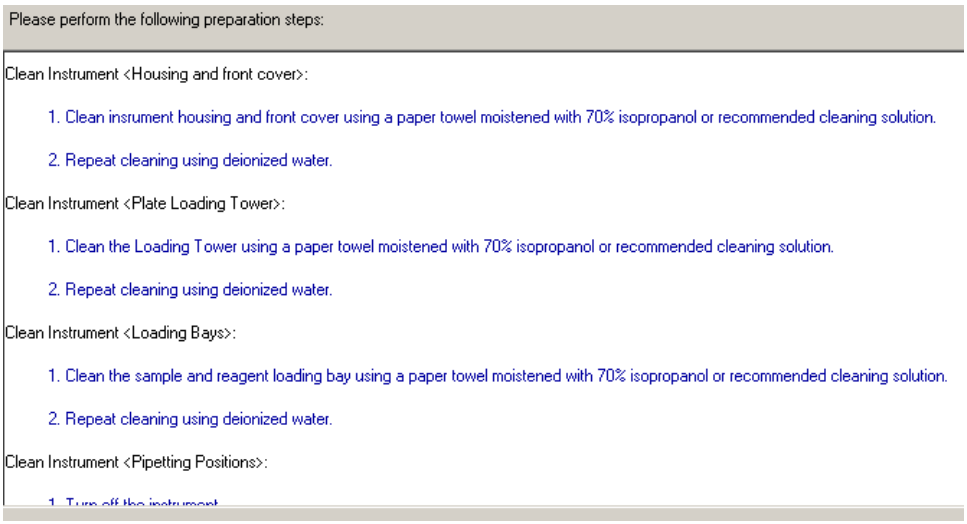
- Alcohol wipes or 0.25% sodium hypochlorite (NaClO) as the recommended cleaning solution

  Refer to Monthly Maintenance- Decontaminate Tubings for the specifications and preparation of 0.25% NaClO

Procedure

To clean the instrument:

Step	Action
1	Press the **Maintenance** button on the Main Menu Bar. 
2	Select **Clean Instrument** from the action list.
3	Press the **Start** button.

4	Follow the on-screen instructions. 
5	Press the **Continue** button below the instruction screen after the NEO Iris initialization is completed.

Checking Pipettor Reference

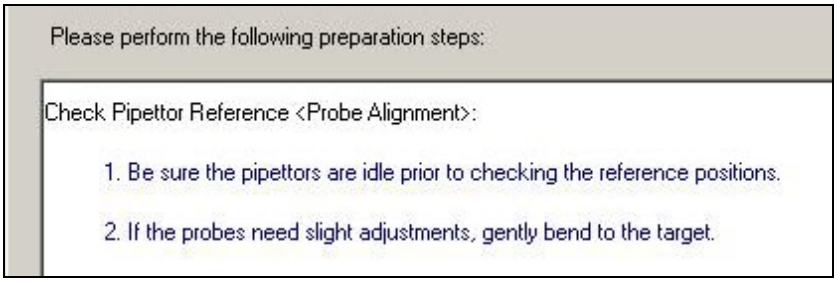
Purpose

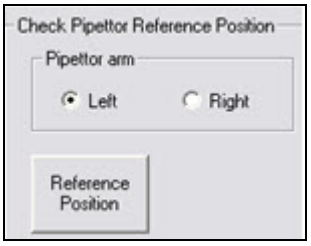
The purpose of checking the pipettor reference is to

- Verify that pipettor alignment is correct prior to running assays.
- Correct pipettor alignment after a probe has been bent. You should first straighten the probe.
- Confirm that alignment is acceptable after probe exchange.

Procedure

To check pipettor reference:

Step	Action
1	Press the **Maintenance** button on the Main Menu Bar. 
2	Select **Check Pipettor Reference** from the action list.
3	Press the **Start** button.
4	Follow the on-screen instructions.   **Warning:** This maintenance task can only be performed when the NEO Iris is not active. You should only use this function for minor corrections. If a probe is badly bent, you should straighten it or replace it. Resetting a badly bent probe can result in crashes as the hardware tries to move to positions outside of the mechanical boundaries of its reach.  **Warning:** You can open the instrument hood during this maintenance action to access the probes. When accessing the instrument deck, you must not move the pipetting turntable. Moving the turntable results in an instrument crash.

Step	Action
5	Press the **Check Reference** button.
6	Select the **Reference Position** button. The instrument defaults to checking the left arm first.  The left Pipettor arm moves to the reference position target and all four probes will move to their previous Z-position. **Note:** Corrections are not necessary if the probe tip is within the inner circle of the reference target.
7	If corrections are required for the left arm in the X (left-right) or Y (front-back) direction, gently bend the probe(s) to the target.
8	All probes must be centered approximately 0.75 mm above the target surface and all must be horizontally even. The probes must not touch the target. If up-down adjustments are necessary, you must contact Technical Support to determine further action.
9	After the probes are aligned correctly, click the **Position OK** button. You can now check the right arm.
10	If there was a problem aligning the left arm, you should click the **Position Wrong** button. By clicking the **Position Wrong** button, the process will be returned to step 6 above.
11	Select the **Right** arm and click **Reference Position**. The right arm moves to the reference position target and the probe will move to the previous Z-position. **Note:** Corrections are not necessary if the probe tip is within the inner circle of the reference target.
12	If corrections are required for the right arm in the X (left-right) or Y (front-back) direction, gently bend the probe to the target.

Step	Action
13	Inspect the probe. The probe must be centered approximately 0.75 mm above the target surface. The probe must not touch the target. If up-down adjustments are necessary, you must contact Technical Support to determine further action.
14	After you have correctly aligned the probe, click the **Position OK** button.
15	If there was a problem aligning the right arm, you should click the **Position Wrong** button. By clicking the **Position Wrong** button, the process will be returned to step 11 above.
16	The **Close** button should now be selected. This will initialize both arms and return you to the instruction screen. **Continue** should be selected to complete the task and return to the *Maintenance* screen.

Completing Reagent Quality Control (QC)

Purpose

The purpose of completing the reagent QC is to:

- Verify that the agglutination reagents are reacting appropriately.
- Verify that the centrifuge shake sequence is performed correctly.

You must perform this action every day, or prior to the use of all agglutination reagents.

If the agglutination reagents are not used for one or more days, then it is not necessary to perform the reagent QC until just prior to when those reagents are required for blood sample testing. In this instance, the reagent QC maintenance action will be listed on the Maintenance and Verification Action Status screen as **Due** until the QC is performed.

Warning: Immucor requires that the quality control (QC) assay for agglutination tests is performed on the system every day, or prior to the use of agglutination reagents. The primary objective of QC is to ensure that the loaded reagents are satisfactory.

Warning: Repeated QC failures in absence of a reagent related cause can be an indication of conditions that have impacted instrument system performance (i.e. pipetting, centrifugation, incubation, etc), or that an incorrect system liquid (deionized water rather than PBS) may have been loaded.

Note: The procedure described in this section is provided as a standard method which fits with most of the local QC requirements. However, if this Reagents QC is not appropriate for your region, please contact your local Immucor Representative to accommodate the QC procedure to your local requirements and regulation needs.

Reagents

Refer to the NEO Iris **Assay Reagent Component Grid** of Attachment 1 for NEO Iris Operator Manual for the list of reagents used with reagent QC.

The reagent QC assay includes agglutination reagents for ABO- and Rhesus D-typing and for Rh- and Kell- phenotyping.

Procedure

To complete the reagent QC check:

Step	Action
1	Load an unused ABO plate by the methods described in **Chapter 6 – Instrument Testing Operation**.
2	Load all of the necessary reagents for the **QC** assay, as listed in **Attachment 1 for NEO Iris Operator Manual**, by the methods described in **Chapter 6 – Instrument Testing Operation**.
3	Press the **Maintenance** button on the **Main Menu Bar**.
4	Select the **Reagent QC** item on the **Maintenance and Verification Action Status** screen, and then press the **Start** button. This will take you to the **Maintenance and Verification Preparation** instructions for **Reagent QC**.
5	Press the **Continue** button on the **Maintenance and Verification Preparation** screen to access the **Resource Overview** window.
6	Select the **QC** line on the **Resource Overview** window to determine if any additional resources are required. Load any additional resources required.
7	Press the **Start** button of the **Resource Overview** window to begin the **QC** assay when all resource requirements are satisfied.
8	Once **QC** is complete, remove the plate from the Plate Loading Tower and discard it.

Completing QC3_Cell Quality Control (QC)

Purpose

The purpose of completing QC3_Cell is to:

- Verify that the 3_Cell reagents are reacting appropriately.
- Verify that centrifugation of 3_Cell assays is performed correctly.

Required Interval

You must perform this action every day, or prior to the use of 3_Cell reagents.

If 3_Cell reagents are not used for one or more days, then it is not necessary to perform the QC3_Cell QC until just prior to when those reagents are required for blood sample testing. In this instance, the **3_Cell Plate QC** maintenance action will be listed on the **Maintenance and Verification Action Status** screen as **Due** until the QC is performed.

Note: Immucor provides a QC for the 3_Cell reagents only. Other Capture screening methods (using 2_Cell, 4_Cell or Pool_Cell reagents) always use an internal Negative control and an internal Positive control (containing a mixture of antibodies) with each run. Therefore an additional daily QC is not required for those as it is built into the test system. Please contact your local Immucor Representative if you need more details and/or if you want to discuss the possibility of using other external QC material on a daily basis with the 2_Cell, 4_Cell or Pool_Cell screen assays.

Reagents

Refer to the NEO Iris **Assay Reagent Component Grid** of Attachment 1 for NEO Iris Operator Manual for the list of reagents used with QC3_Cell.

Procedure

To complete the QC3_Cell quality control:

Step	Action

Step	Action
1	Load an unused Capture-R® Ready-Screen® (3) strip into a Capture-R® Ready-Screen® (3) white frame at strip position one (1). Load the prepared plate by the methods described in **Chapter 6 – Instrument Testing Operation**.  **Warning:** For the QC3_Cell assay, the correct position for the Capture-R® Ready-Screen® (3) strip in a Capture-R® Ready-Screen® (3) white plate frame is at strip position one (1). The instrument will not check for the correct placement of the Capture-R® Ready-Screen® (3) strip in the white plate frame. You must make sure of the correct placement of this strip yourself. Incorrect placement of this single strip can result in test material being pipetted onto the pipetting station surface, an overflow error in the washer, and a failed quality control. Unused Capture-R® Ready-Screen® (3) strips should not be present in any of the other positions of the plate. It is not required that strip positions two (2) to twelve (12) of the white plate frame be occupied by any strips at all. Those positions can be left empty, but all strip positions should be activated in the software. The Strip Selection tab in the Plate Loading Tower dialog must indicate that all twelve (12) strips are available even though only the strip at position (1) is present.
2	Load all of the necessary reagents for the **QC3_Cell** assay, as listed in **Attachment 1 for NEO Iris Operator Manual**, by the methods described in **Chapter 6 – Instrument Testing Operation**.
3	Press the **Maintenance** button on the **Main Menu Bar**.
4	Select the **3_Cell Plate QC** item on the **Maintenance and Verification Action Status** screen, and then press the **Start** button. This will take you to the instructions for **3_Cell Plate QC**.
5	Press the **Continue** button on the **Maintenance and Verification Preparation** screen to access the **Resource Overview** window.
6	Select the **QC3_Cell** line on the **Resource Overview** window to determine if any additional resources are required. Load any additional resources required.
7	Press the **Start** button of the **Resource Overview** window to begin the **QC3_Cell** assay when all resource requirements are satisfied.
8	Once **QC3_Cell** is complete, discard the used Capture-R® Ready-Screen® (3) strip, but save the white frame for future use.

Performing the Pipettor Self Check

Purpose

The purpose of performing the pipettor self check is to verify that the probe wash tower rinse pumps are functioning correctly and that the probes are aspirating and dispensing fluid correctly. Both the four probe arm and the single probe arm are verified.

Required Tool(s)

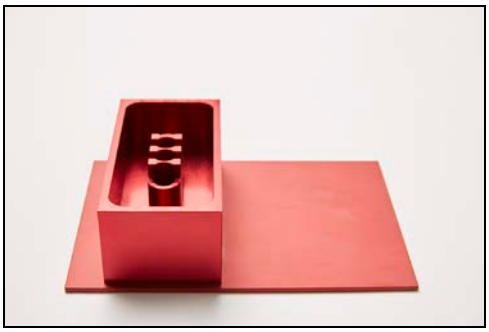
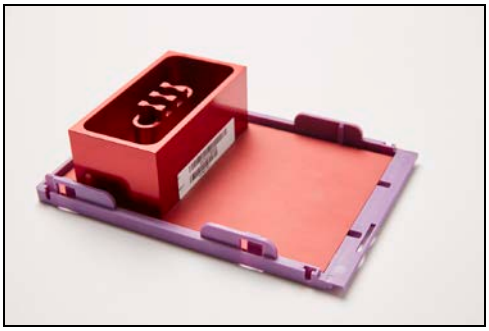
The following tool(s) are required to complete this task:

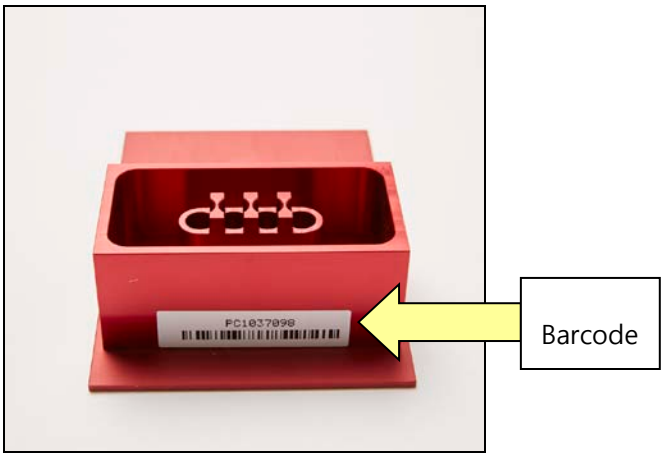
- Pipettor self check tool

Procedure

To perform the pipettor self check:

Step	Action
1	Select the **Pipettor Self Check** action from the **Maintenance and Verification Action Status** list and then press the **Start** button.

Step	Action
2	Make sure that the pipettor self check tool is clean, and insert it into a plate carrier as shown in the photographs below.  Pipettor self check tool not inserted into plate carrier  Pipettor self check tool inserted into plate carrier
3	Load the pipettor self check tool (in the plate carrier) into the plate loading tower. The red tower of the tool should be orientated to the left side of the plate carrier when inserted onto the plate loading tower.  **Note:** The pipettor self check tool occupies two (2) plate loading tower slots.

Step	Action
4	Close the door of the Plate Loading Tower to initiate an automatic reading of the tool barcode. **Note:** The tool will be taken to the plate barcode scanner by the transport so that the barcode can be read. The tool will then be returned to its assigned position in the Plate Loading Tower. Wait until the tool has been returned to the Plate Loading Tower before proceeding to step **5**. 
5	Press the **Continue** button on the *Pipettor Self Check* instruction screen. **Note:** Allow step **4** to complete before performing this step **5**.
6	Select the **PCheck** assay on the *Resource Overview* window.
7	Press the **Start** button on the *Resource Overview* window to begin the PCheck assay. The software analyzes the results and sets a pass or fail status. Refer to **Chapter 11 – Troubleshooting the NEO Iris** for details regarding information about the fail status. **Note:** No Liquid/Not enough liquid flags are generated and appear in the Log List during processing. This is expected and necessary.
8	After completion of the PCheck assay, remove the pipettor self check tool from the plate loading tower and then also from the plate carrier.

Step	Action
9	Rinse the cavities only of pipettor self check tool with tap water and then immediately dry all of its surfaces carefully with a paper towel.  **Note:** Make sure not to damage the barcode affixed to the tool.
10	Store the pipettor self check tool in a dry secure place.

Weekly Maintenance Tasks

Weekly Tasks

The following tasks are to be completed weekly:

- Cleaning the Reader Mirror and Renewing Flatfield Images
- Creating Archives
- Cleaning the Pipettor Wash Towers
- Cleaning the Common Waste Container
- Inspecting the Syringes

Cleaning the Reader Mirror and Renewing Flatfield Images

Purpose

The purpose of cleaning the mirror and renewing flatfield images is to:

- To remove spills or dirt on the mirror hampering the reader functionality.
- Take background images to eliminate dust and debris from interfering with the interpretations.

Required Tool(s)

The following tool(s) are required to complete this task:

- Alcohol wipes
- Clean dry absorbent laboratory disposable wipes
- Flashlight

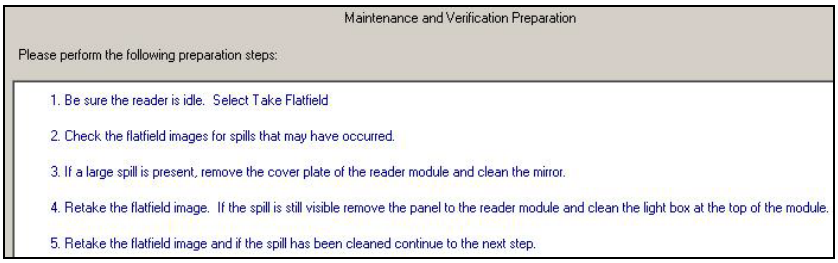
Procedure

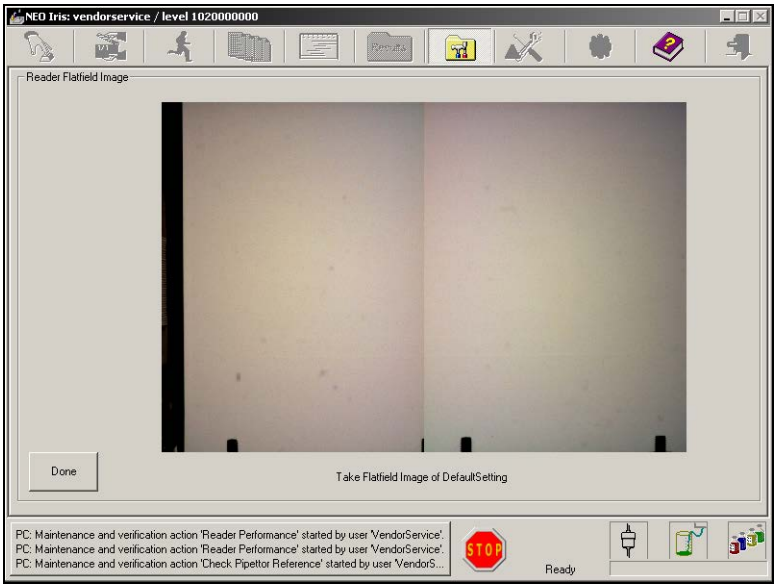
To clean the reader mirror:

Step	Action
1	Power off the NEO Iris module.
2	Refer to the instructions provided to clean the mirror in the **As Needed Maintenance Tasks** section of this chapter.

To renew flatfield images:

Step	Action
1	Power on the NEO Iris module.  **Limitation:** The instrument must be switched on for at least thirty (30) minutes prior to take flatfield images so that the reader lamp can warm up.
2	Press the **Maintenance** button on the Main Menu Bar. 

Step	Action
3	Select **Take Flatfield Images** from the action list.
4	Press the **Start** button.
5	Follow the on-screen instructions for taking the Flatfield Image.   **Warning:** You should not initiate this maintenance function if an assay is scheduled to use the reader. Leaving a microplate in the reader during this action affects the analysis of results.
6	Press the **Take flatfield** button after confirming that a plate is not in the reader.  The system takes one flatfield image for "Default Setting" analysis used on the NEO Iris. While the system takes the image, look for any large spills that may have occurred on the mirror or the light diffuser.

Step	Action
7	Once the system has finished taking the flatfield image, the system makes the **Done** button available in the *Reader Flatfield Image* window. Press the **Done** button.  If there are any significant spills, the mirror and the light diffuser need to be cleaned. Refer to the instructions provided for these tasks in the **As Needed Maintenance Tasks** section of this chapter.
8	Repeat steps 5 and 6 to verify that the spill is completely cleaned.

Creating Archives

Purpose

The purpose of creating archives is to reduce the physical size of the database and to preserve historical results in an electronic format. Additionally, during the archive process, excess space created by the process of deleting and modifying data is removed. Performing this maintenance task can minimize software errors caused by database corruption and data fragmentation.

The Incorporated Warning System

A yellow warning triangle will be displayed on the **Utilities** button of the Main Menu Bar if the configured required time interval for the scheduled next archive of results has been exceeded.

Pressing the **Utilities** button (with the warning displayed) gives access to the **Utilities** window. A second yellow warning triangle is subsequently associated with the **Archive** tab of the **Utilities** window.

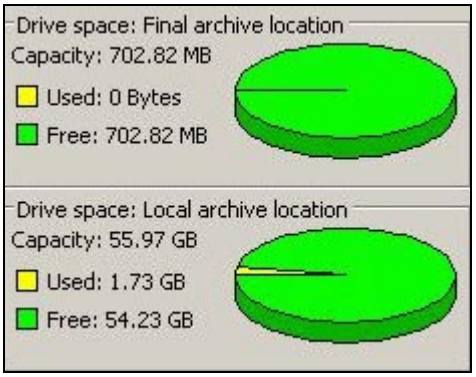
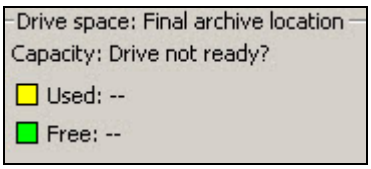
The yellow warning triangle is removed after the required archiving is completed which then subsequently restarts the configured required time interval. Refer to **Chapter 4 – Security** for details regarding **Archive Configuration**.

Warning: Failure to archive results according to the configured time schedule interval, at a minimum, can result in the accumulation of excessive result data on the instrument computer which can lead to the slowing down of the speed of the computer processing and activity.

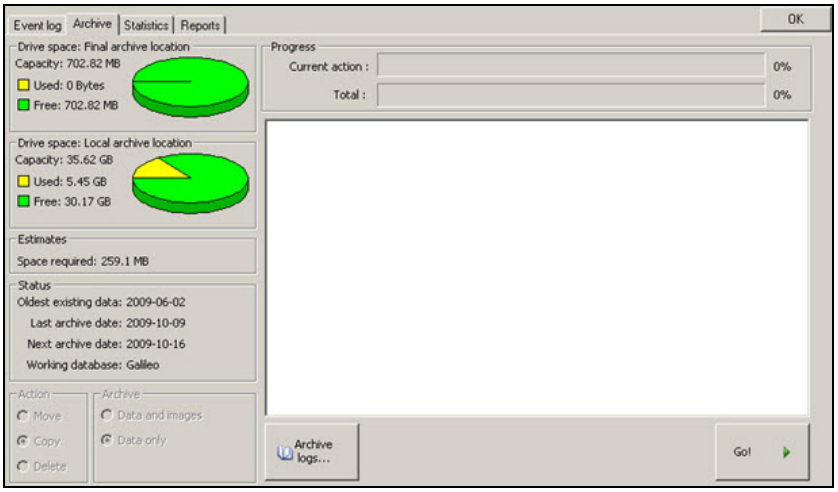
Warning: You must not enter the *Archive* tab of the *Utilities* window while the NEO Iris is processing, otherwise there is a risk that conversion of results could be interrupted and that results could need to be re-sent.

Procedure

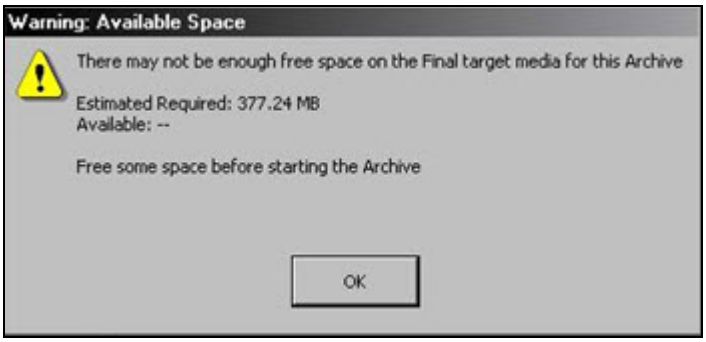
To create archives:

Step	Action
1	Make sure that the selected backup medium is attached to the PC (i.e. external USB drive) or insert a DVD+R disk into the disk drive. If DVD disk is used, wait until the LED on the drive is no longer illuminated before moving to step 2. **Note:** Do not use CD or DVD-R disks. **Note:** Only one archive is allowed per disk.
2	Select the **Utilities** dialog from the Main Menu Bar. 
3	Select the *Archive* tab of the Utilities window.
4	Verify that the space estimate required for this archive is less than the Free space in both the Final archive location and the Local archive location.  If the Final archive location does not recognize the media loaded, or if no media is loaded, the software will indicate the drive is not ready for archiving. Check that a disk is loaded in the correct drive and that it is the correct media type. 

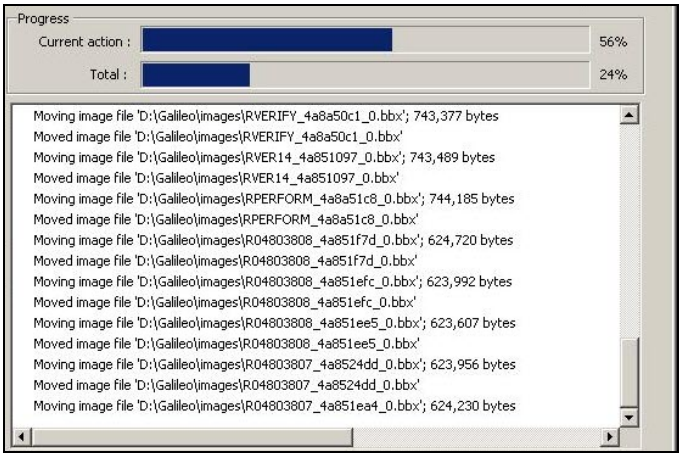
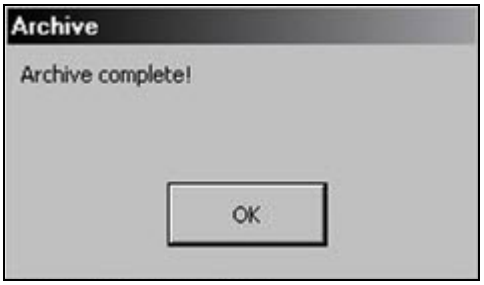
5 Press the **Go!** button to begin the archive.



Note: Before performing the archive process, the instrument calculates the amount of space required to archive the data and the amount of space available on the archive media and on the local drive. If there is less space on the archive media or on the local drive than is needed for the archive, the instrument will alert you with the following dialog. The dialog will indicate if the drive that has insufficient space is the final archive media or the local temporary folder. In this instance, the archive will not be performed. Clear the dialog by pressing the **OK** button and verify the proper media is in the drive. If the message persists, contact Immucor Technical Support.



Note: The software will automatically name the archive according to the date range to be archived. The yyyymmdd_YYYYMMDD format is used where yyyymmdd is the date corresponding to the oldest data being archived and YYYYMMDD is the date corresponding to the most recent data being archived according to the number of days kept in the working database (i.e. current date – number of days configured to be kept). In cases where more than one archive is created with the same date range a "_N" will be appended to differentiate them (where N = incrementing number).

6	The **Progress** of the archive is displayed as it proceeds. Once complete, the scroll bar can be used to go back and view the full sequence. **Note:** Do not attempt to stop the archive or turn off the PC while the archive is in progress. This may result in data corruption or data loss.  **Note:** If there is a problem with the burning of the archive to the disk, the software permits one (1) retry attempt before the archive is written to the harddrive. This single available retry attempt is indicated by a pop-up dialog that includes a warning message. If the archive is written to the harddrive, this triggers the re-write process. Refer to the **Rewriting Archives** section below for more information.
7	When the archive process is completed, a confirmation dialog is displayed stating **Archive complete!** Press the **OK** button of the **Archive complete!** message. Do not remove the archive media from the drive at this time. 
8	Press the **OK** button to close the Utilities dialog.

9	If a DVD was used, remove the archive disk from the PC disk drive and store it in a safe place, according to the recommended storage conditions of the disk manufacturer.  **Note:** It is recommended that the disk is removed only when the disk drive LED is no longer illuminated following the display of the message. This ensures that the process has gone to completion.

Rewriting Archives

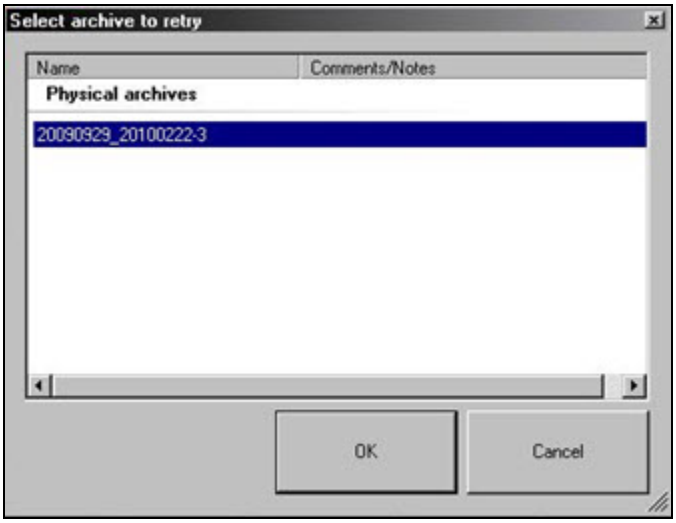
The rewriting of archives to a disk is triggered if there is a problem with the burning of an archive to a disk and the one (1) permitted retry attempt fails. A backup copy of the archive is stored on the harddrive of the PC in such cases.

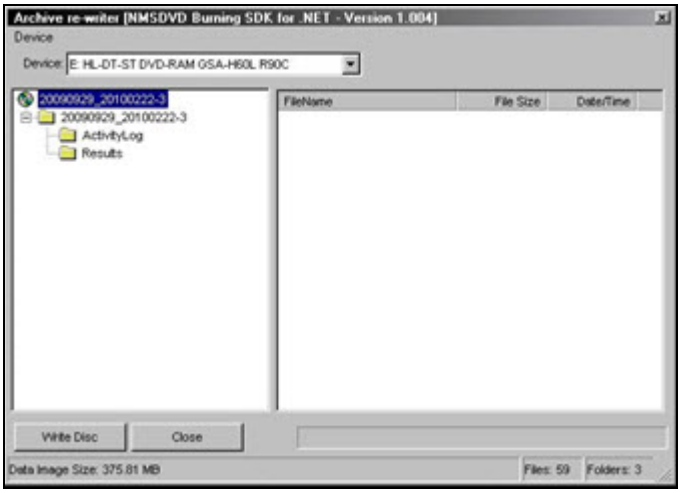
The re-write process has no limits on the number of times that it can be executed.

To rewrite archives:

Step	Action
1	Make sure that a DVD+R disk is in the disk drive. Wait until the LED on the drive is no longer illuminated before moving to step 2.  **Note:** Do not use CD or DVD-R disks.  **Note:** Only one archive is allowed per disk.

Step	Action
2	If any archives already exist on the hard drive, then when you select the *Archive* tab, the **Unburnt archives located!** dialog is displayed.  Press the **Re-write archive** button to display a list of all backed up archives on the **Select archive to retry** dialog.  **Note:** If the **Re-write later** button is pressed, the **Unburnt archives located!** dialog is closed and the **Archive** dialog is then displayed. In this case, a **Re-write Archive** button will be displayed on the **Archive** dialog where you can attempt the re-write at anytime.  When all harddrive stored backups have been copied to disk sucessfully, the **Re-write Archive** button will no longer be displayed on the **Archive** dialog. 

Step	Action
3	Select the archive to be written to disk from the list and then press the **OK** button.  The **Archive re-writer** dialog is displayed after the **OK** button is pressed. Alternatively, press the **Cancel** button to cancel the archive rewrite process.

Step	Action
4	Press the **Write Disc** button on the **Archive re-writer** dialog to start the writing of the selected harddrive archive to the disk. Alternatively, press the **Close** button to close the **Archive re-writer** dialog.  After pressing the **Write Disc** button and the process subsequently completes, a message is displayed indicating that the process is complete and the selected backup copy on the hard drive is removed.  Press the **OK** button of the *Write and Verify Complete!* message.
5	Remove the archive disk from the PC disk drive and store it in a safe place, according to the recommended storage conditions of the disk manufacturer. **Note:** It is recommended that the disk is removed only when the disk drive LED is no longer illuminated following the display of the completion message. This ensures that the process has gone to completion.

Cleaning the Pipettor Wash Towers

Purpose

The purpose of cleaning the pipettor wash towers is to reduce tower contamination.

Note: The NEO Iris must be switched OFF.

Required Tool(s)

The following tool(s) are required to complete this task:

- 0.25% sodium hypochlorite (NaClO) as the recommended cleaning solution

  Refer to Monthly Maintenance- Decontaminate Tubings for the specifications and preparation of 0.25% NaClO

Procedure

To clean the pipettor wash towers:

Step	Action
1	Prepare a concentration of 0.25% NaClO working solution.  **Note:** Approximately 50 to 60 mL of solution is required for this weekly task. This task can be performed at the same time as the weekly decontamination of the waste container and the monthly decontaminate tubings task, if convenient.
2	Manually move the pipettor arms away from both probe wash towers and reposition them over a loading bay by either moving both arms over the 14-lane Bay, or by moving the left arm over the 14-lane Bay and the right arm over the 5-lane Bay.
3	Dispense the working solution of the recommended cleaning solution into the probe tip rinse cup of both towers and allow it to drain, or be added directly into the surrounding waste cup until filled. The solution should not be added to the overflow trough and tubing. The volume of solution required to completely fill each tower can range between 25 to 30 mL (approximately 50 to 60 mL in total).

4	Allow the pipettor wash towers to be exposed to the cleaning solution for a contact time of 10 minutes before powering on the NEO Iris. The solution will then automatically drain when the NEO Iris is powered on.  **Note:** After powering on the NEO Iris, the reader lamp must be allowed to warm up for at least thirty (30) minutes.

Images

The following images illustrate this task:

Cleaning the Common Waste Container

Purpose

The purpose of cleaning the common waste container is to reduce gross contamination in the container.

Required Tool(s)

The following tool(s) are required to complete this task:

- 0.25% sodium hypochlorite (NaClO) as the recommended cleaning solution

  Refer to Monthly Maintenance- Decontaminate Tubings for the specifications and preparation of 0.25% NaClO

- Alcohol wipes, if available

Procedure

Note: Only follow this procedure when the NEO Iris is **switched off**.

To clean the common waste container:

Step	Action
1	Prepare a concentration of 0.25% NaClO working solution.
2	Empty the common waste container.
3	Vigorously rinse the common waste container with the working solution of the recommended cleaning solution. Allow the common waste container to be exposed to the cleaning solution for a contact time of 10 minutes.
4	Use the alcohol wipes or the recommended cleaning solution to clean the inside of the common waste container lid. Allow the container lid to air dry after using the alcohol wipes, or wipe the container lid with deionized water following use of the recommended cleaning solution.
5	Empty the recommended cleaning solution out of the common waste container after the 10 minute contact time has expired.
6	Rinse the common waste container with deionized water.
7	Empty the deionized water out of the common waste container.

8	Reconnect the common waste container back onto the instrument.

Inspecting the Syringes

Purpose

The purpose of inspecting the syringes is to determine if any of the syringes are too loose and/or are leaking.

Procedure

Note: Only follow this procedure when the NEO Iris is **switched off**.

To inspect the syringes:

Step	Action
1	Inspect the syringes for leakage. Syringes must not be leaking.
2	Check the barrels of the syringes to determine if they are finger tight by grasping the knurled screw and twisting gently clockwise. You must never use tools for this procedure. Syringes must be finger-tight secured to the bottom of the 3-way valve.  Close-up of knurled securing screw at top of syringe connected to 3-way valve **Note:** If you determine that, for whatever reason, a syringe must be replaced, you r follow the **Removing and Replacing a Syringe** procedure described later in this ch perform the necessary follow-up maintenance tasks as described in that procedure.

Monthly Maintenance Tasks

Monthly Tasks

The following tasks are to be completed on a monthly basis:

- Clearing Test Data
- Decontaminate Tubings

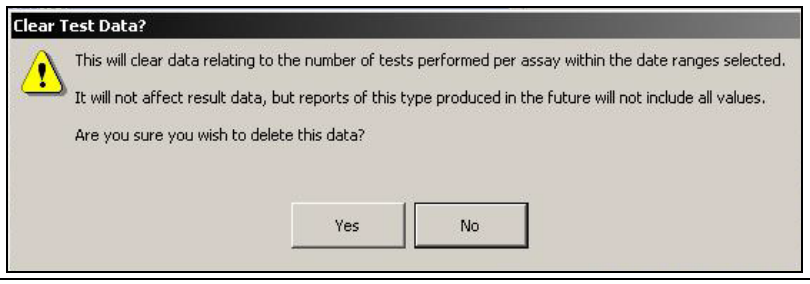
Clearing Test Data

Purpose

The purpose of deleting statistical test data via the Utilities>Statistics tab is to delete data that is not deleted using the archive method. If such data is allowed to build up, this could impact the PC performance. The statistical data is related to the Tests per Assay report. This clearing task should be performed monthly, but not until after your site statistical analysis period has ended. If your analysis period is greater than a month, then the frequency of this task will be dictated by that analysis period schedule. Once data is cleared, it will no longer be available for inclusion in a future Test per Assay report. Data conservation should be based on your analysis period schedule. If this data is not required to be analyzed by your site at any time, then this clearing task should be performed monthly.

Procedure

To clear test data:

Step	Action
1	Press the **Utilities** button on the Main Menu Bar. 
2	Select the **Statistics** tab.
3	Select the **Tests per Assay** report name. The **Clear Test Data** button will then be displayed.
4	Press the **Clear Test Data** button. A confirmation dialog will then be displayed. 
5	Press the **Yes** button of the confirmation dialog to proceed or the **No** button to cancel the task. 

Step	Action
6	Press the **OK** button of the **Test data cleared** message to acknowledge the completion of the task.
7	Record completion of the task on the monthly maintenance record.  **Note:** If the data is not cleared on a monthly basis, based on the requirements of y statistical analysis period, then record N/A (or whatever equivalent nomenclature yo documentation requires) on the monthly maintenance record to indicate that it was performed within a given month. However, you may perform this task on a subsequ month, as defined by your analysis period. N/A = Not Applicable.

Decontaminate Tubings

Purpose

The purpose of decontaminating tubings is to meet biohazard regulations.

Required Tool(s)

The following tool(s) are required to complete this task:

- 0.25% sodium hypochlorite (NaClO) as the recommended cleaning solution
- PBS
- 1L container
- Alcohol wipes, if available
- WipeAll or paper towels

Note: You must still keep your original NEO Iris 10 L system liquid container available, even If you use cubed saline as your system liquid reservoir, because that original NEO container will be required for the decontamination procedure.

Specifications for Sodium Hypochlorite (NaClO)

NaClO sourced for use in the decontamination protocol should be aligned to the following specifications:

CAS Number:	Sodium hypochlorite: 7681-52-9
Grade	Commercial
Concentrations	Sodium hypochlorite: Variable

Warning: Common household bleach or sodium hypochlorite with detergent additives should not be used as these could affect the performance of the system.

Preparation of 0.25% Sodium Hypochlorite (NaClO) Solution

- 2 L of 0.25% NaClO is required for monthly maintenance
- The dilution is prepared using deionized water

- The concentration for the purchased NaClO solution should be verified on the certificate of analysis (CoA) for the lot used
- To determine the volume of NaClO required based on the concentration in the CoA, use the formula (V1) = (C2)(V2)/(C1) where
    - V1 = volume of undiluted NaClO required
    - C2 = concentration of NaClO desired (0.25%)
    - V2 = volume of 0.25% NaClO desired (2000mL)
    - C1 = concentration of NaClO indicated on the CoA
    - Otherwise, V1(mL) = 500/C1

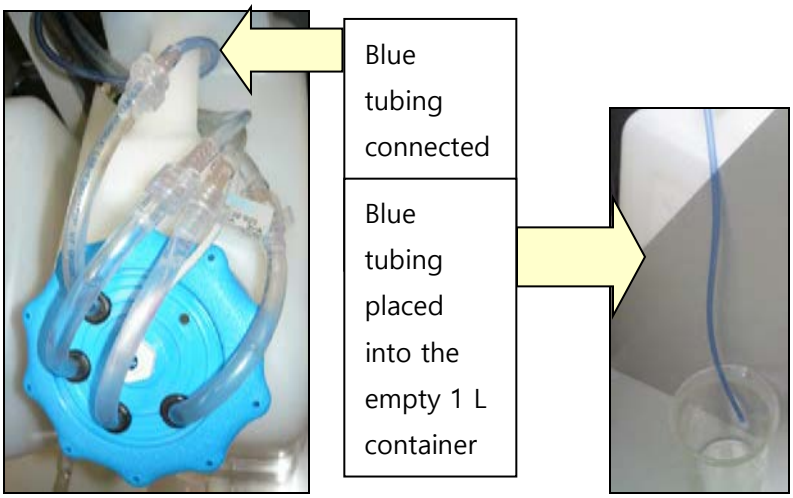
Volumes required for typical NaClO			
C1 **NaClO Concentration**	**DiH2O**	**V1** **Volume Undiluted NaClO**	**Final Volume of Prepared Solution**
8.27%	1940 mL	60 mL	2L
12.0%	1958mL	42mL	
14.0%	1965mL	35mL	

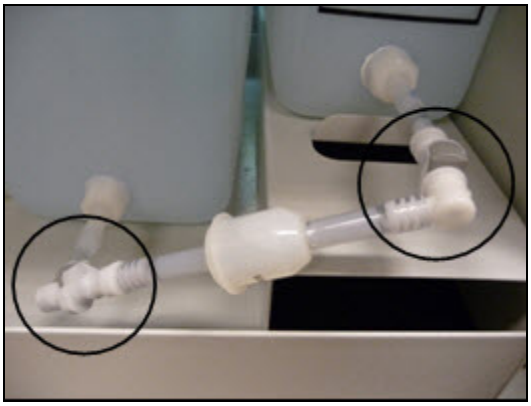
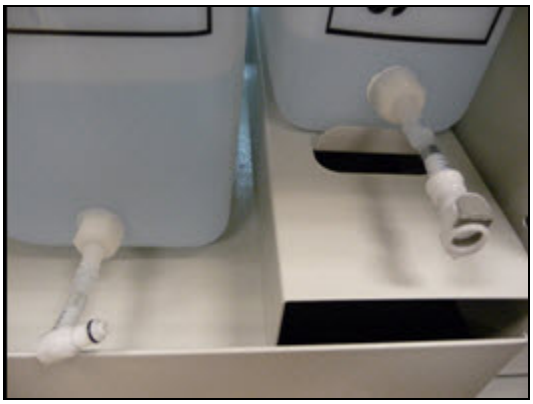
Warning: Washer dispense check failures may occur during decontamination maintenance checks. If the ion concentration of a solution is too low, the liquid level detection sensors may fail to detect the presence of decontamination solution used on the instrument. Should you observe repeated washer dispense check failures after verifying the NaClO dilution, and have ruled out other mechanical related causes for the error, it may be necessary to perform dilution of the NaClO using phosphate-buffered saline (PBS) instead of DI water.

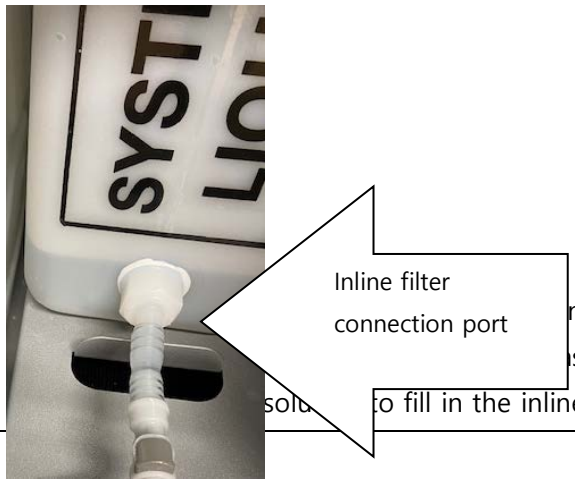
Procedure

To decontaminate the tubings:

Step	Action

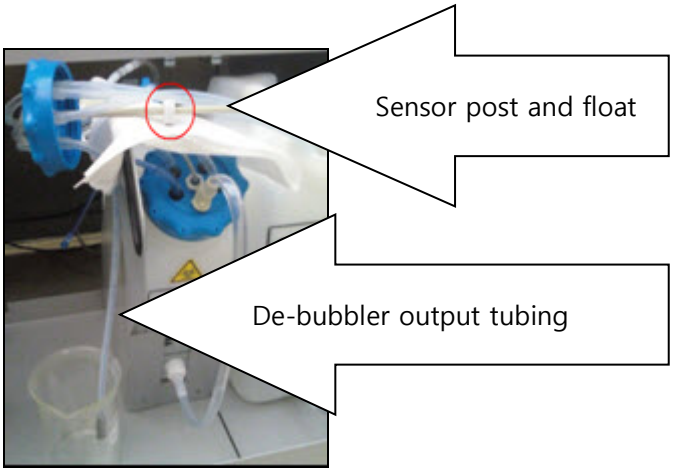
Step	Action
1	Press the **Maintenance** button on the Main Menu Bar. 
2	Select **Decontamination tubings** from the action list.
3	Press the **Start** button.
4	Disconnect the blue tubing connected to the 20 L system liquid container and place it into the empty 1 L collection container. This is the return tube from the de-bubbler mechanism. 
5	Put a plate into the plate loading tower, manually enter barcode identification data, and assign the assay **DB_CK** to it. Start the assay.
6	After the **DB_CK** assay has completed and the plate has been returned to the plate loading tower, verify that liquid has collected into the empty 1 L container from step 4. Record this verification on the monthly maintenance record.
7	Empty the liquid that has collected into the 1 L container from the blue tubing. **Note:** If there is no liquid in this 1 L container after the **DB_CK** assay has completed and it has been verified the blue tubing was correctly placed inside the container, then contact Technical Support. This may indicate a failure of the de-bubbler mechanism.
8	Connect the blue tubing back to the 20 L system liquid container lid.

Step	Action
9	Disconnect the system liquid containers at the two (2) in-line connectors (circled in the photograph below) and store the disconnected in-line filter in a secure place ready for reinstallation.  System liquid containers connected  System liquid containers disconnected  Disconnected in-line filter **Note:** If any part of the in-line filter or its associated tubing is discolored it should be discarded and a new filter and/or its associated tubing should be used when it is reinstalled.

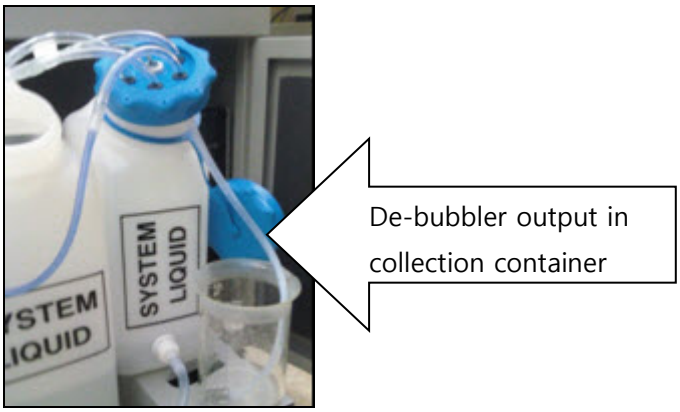
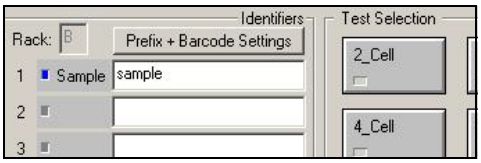
Step	Action
10	Remove the cap and tubing from the 20 L system liquid container and set aside on a clean paper towel. Remove the 10 L and 20 L system liquid containers from the system. Empty the PBS from both containers and fill the 20 L container with 2 L of the recommended cleaning solution.
11	Swish the cleaning solution vigorously in the 20 L container, ensuring all interior areas of the container are coated. Tilt the container forward to allow the solution to fill the inline filter connection port.  ntainer. Swish the cleaning solution vigorously s of the container are coated. Tilt the container solu to fill in the inline filter connection port.

Step	Action
12	Return the 10 L system liquid container to the NEO Iris. Place the system liquid cap and tubing into the 10 L container for decontamination. All tubing and the sensor post should be in the container. It is not necessary to screw the lid onto the container. **Note:** When placing the cap and tubing into the 10 L container the sensor may indicate insufficient volume; however there will be enough decontamination solution in the container to allow the assay to run and avoid additional alarms. Any system liquid empty alarms should be acknowledged.  20 L container lid and tubing placed in 10 L container
13	Put a plate into the plate loading tower, manually enter barcode identification data, and assign the assay **PrimeDec** to it. Start the assay.
14	The instrument will aspirate the recommended cleaning solution and allow it to soak within the system tubing for the 10 minute recommended soak time. The **PrimeDec** assay will complete once the recommended soak time has expired, and the plate will return to the plate loading tower

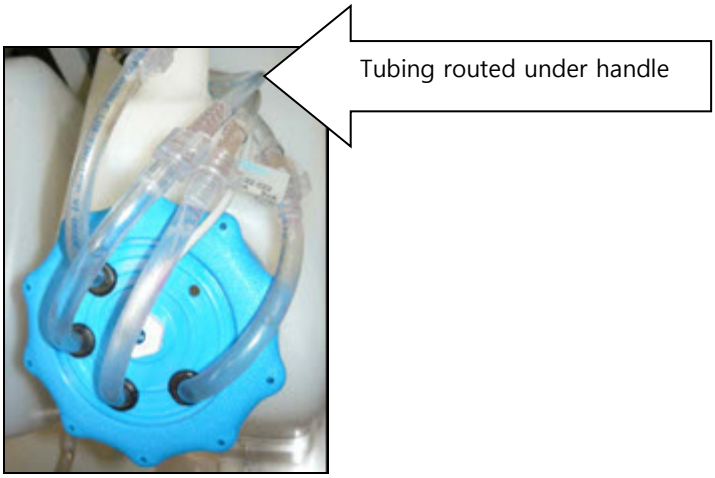
Step	Action
15	The 10 L and 20 L system liquid containers can each be rinsed when the plate returns to the plate loading tower at the completion of the PrimeDec assay. Remove the cap and tubing from the 10 L system liquid container and allow the solution to drain from the tubing back into the container. Set the cap and tubing aside on a clean WipeAll or paper towel. Rinse both containers with a minimum of 1000 mL of PBS a minimum of two (2) times. **Tap both 10 L and 20 L containers to ensure any residual cleaning solution is removed from the inline filter connection port each time the containers are rinsed and emptied completely.**
16	Return both of the empty containers to the instrument; however do not reconnect the system liquid containers at this time.  **Note:** So that you can optimize the use of the cleaning solution, during the decontamination period, you can empty the common waste container and then decontaminate it with the recommended cleaning solution that was used to clean the system liquid containers. The container must then be rinsed with deionized water prior to usage. Use some alcoholl wipes or the recommended cleaning solution to clean the inside of the common waste container lid, followed by deionized water. Return the clean common waste container to its proper place on the instrument. This waste container cleaning task must be performed on a weekly basis. Refer to **Cleaning the Common Waste Container** in this chapter for more details regarding the weekly cleaning of the common waste container.

Step	Action
17	With he cap and tubing still set aside, place only the de-bubbler tubing that extends from the bottom of the cap (de-bubbler output tubing) into the empty 1 L container. Fluid will collect in this container in step 18. **Note:** The sensor float must continue to be lifted to prevent system liquid empty warnings. 
18	Put a plate into the plate loading tower, manually enter barcode identification data, and assign the assay **ClrTube1** to it. Start the assay.
19	After the **ClrTube1** assay has completed, drain the remaining cleaner from the system liquid cap tubing into the collection container. Empty the 1L collection container.
20	Wipe the system liquid sensor (post and float) and the exterior of the tubing extending below the cap with a clean alcohol wipe, or recommended cleaning solution, followed by wiping with deionized water. Allow them to dry.

Step	Action
21	Fill the 10 L container with 9 L of PBS. Place the system liquid cap and tubing in the 10 L container. Place the de-bubbler tubing that extends from the bottom of the cap (de-bubbler output tubing) into the 1 L collection container. 
22	Put a plate into the plate loading tower, manually enter barcode identification data, and assign the assay **Prime1** to it. Start the assay.
23	After **Prime1** has completed, remove the cap and tubing from the 10L container. Allow any remaining liquid in the tubing to drain into the collection container. Set cap and tubing aside on a clean WipeAll or paper towel. Empty the 1 L collection container and place the de-bubbler tubing back into it. **Note:** The sensor float must continue to be lifted to prevent system liquid empty warnings.
24	Put a plate into the plate loading tower, manually enter barcode identification data, and assign the assay **ClrTube2** to it. Start the assay.
25	After the **ClrTube2** assay has completed, drain any remaining liquid from the system liquid cap tubing into the collection container. Empty the 1 L collection container.

Step	Action
26	Add 3L more of PBS to the 10 L container. Place the system liquid cap and tubing back into the 10 L container. Place the de-bubbler tubing that extends from the bottom of the cap (de-bubbler output tubing) into the 1 L collection container. 
27	Put a plate into the plate loading tower, manually enter barcode identification data, and assign the assay **Prime2** to it. Start the assay.
28	After **Prime2** has completed, empty the collection container. Place the debubbler tubing back into the empty collection container.
29	Load a clean untreated microplate into the tower, manually enter barcode identification data, and assign the assay **Prime3** to it.
30	Load a fresh centrifuged blood sample onto the NEO Iris with the barcode turned so that the NEO Iris cannot scan it. Use the **Recall** function to manually enter the barcode identification as **sample**. The typing of the word **sample** is case sensitive (all letters must be typed as lowercase). Start the assay (**Prime3**). 

Step	Action
31	When the **Prime3** assay completes, verify that there is no visible hemolysis in the wells of the plate. Record this verification on the monthly maintenance record. If there is visible hemolysis, the following troubleshooting techniques should be implemented: • The **Prime3** assay may be repeated. If hemolysis persists, the system liquid container may be checked for residual chlorine. • The PBS in the 10 L container may be checked for residual chlorine. If chlorine is present, discard PBS from 10 L, refill with fresh PBS, and repeat the **Prime3** assay. Verify no hemolysis is present before continuing.
32	Once it is verified that hemolysis is not present, empty the 1 L collection container and the remaining PBS from the 10 L container. Tap the 10 L container to ensure any residual liquid remaining in the inline filter connection port is removed and emptied.
33	Fill both the 20 L and 10 L system liquid containers with new PBS and return both containers to the system.  **Note:** You should only refill the containers with PBS if you are using this process as a monthly maintenance action and not as preparation for shipping the NEO Iris.
34	Connect both of the system liquid containers together using the two (2) in-line connectors (refer to step 9 for photographs). This connecting component, bridged by the single in-line filter, was previously stored in a secure place.

Step	Action
35	Return the system liquid cap and tubing to the 20 L system liquid container (including debubbler tubing). It is recommended that the reconnected tubing (and the liquid level sensing cable) be threaded though the handle of the 20 L container to prevent any potential rubbing of the tubing on the inside casing of the cabinet as the drawer is routinely pulled into and out of the cabinet. Make sure that the system liquid sensor float can move freely along the post, and is in the down position before securing the system liquid cap to the 20 L container. 
36	Verify that the caps are properly secured on the system liquid containers. The NEO Iris is now ready for use.

As Needed Maintenance Tasks

As Needed Tasks

The following tasks are to be completed on an as needed basis:

- Flushing the System Liquid
- Emptying the 20-liter System Liquid Container
- Performing the Pipettor Verification Test (PipTest)
- Performing the Positions Check (PosCheck)
- Performing the Syringe Change
- Checking the Residual Volume
- Removing and Reinserting the Manifold
- Using the Washer Teach Tool
- Checking the Manifold Probes
- Adjusting the Manifold Grub Screws
- Cleaning the Liquid Level Sensor
- Cleaning the Liquid Overflow Detection Mat
- Removing and Replacing a Syringe
- Removing and Replacing a Probe
- Cleaning the Reader Mirror and Light Diffuser
- Changing the Camera Lamp
- Replacing the Y-pusher

Flushing the System Liquid

Purpose

You should flush the system liquid lines with deionized water if you are shutting down the instrument for an extensive period of time.

This task can also be performed to flush deionized water out of the system liquid lines and replace with PBS.

Note: You can also perform the Flush System Liquid maintenance action as a total system prime to remove any air bubbles that may have entered the line. You can leave the wash buffer lines connected to the container and run PBS through the lines.

It is possible for a washer dispense error to occur while the *Flush Liquid System* action is being performed. The on-screen instructions describe this risk, but explain that this is a benign event and some additional error recovery instructions for that scenario are provided.

Procedure

To flush the system liquid:

Step	Action
1	Press the **Maintenance** button on the Main Menu Bar. 
2	Select **Flush Liquid System** from the action list.
3	Press the **Start** button.
4	Disconnect the clear washer and system liquid tubing, and set them aside.
5	Connect the blue tubing to the input connector on top of the waste container.
6	Place a plate in the tower, manually enter a plate ID, and assign the **PrimeAir** assay to it. Start the assay.

Step	Action
7	After the **PrimeAir** assay is completed, place the terminal portions of the clear washer and system liquid tubing into a container with at least 1.5 L of your chosen flushing liquid, e.g. de-ionized water.  **Note:** The blue tubing should still be connected to the waste container.
8	Place a plate in the tower, manually enter a plate ID, and assign the **PrimeDI** assay to it. Start the assay.  **Note:** After the assay completes, the system liquid throughout the NEO Iris will be y chosen flushing liquid, e.g. de-ionized water.
9	After the **PrimeDI** assay is completed, reconnect the clear washer and system liquid tubing to their original connections.
10	The blue tubing should remain connected to the waste container until the system liquid in the NEO Iris has been returned to PBS.

Emptying the 20-Liter System Liquid Container

Purpose

The purpose of emptying the 20-Liter System Liquid Container is to prepare the container prior to replacing liquid in it.

Before You Begin

Warning: Before you can physically empty the 20-liter system liquid container, you must remove it from the washer software. If you do not adjust the Wash Buffer dialog to reflect the buffer removal and a test is in process, the software still attempts to use the wash buffer, even when none is present. If this occurs, the associated NEO Iris tubing and pumps can run dry.

Procedure

To empty the 20-liter System Liquid Container:

Step	Action

1	Open the Wash Buffer dialog.
2	If the wash pump is in use, select the **Remove** button. The **red** **In use** circle turns **green**.
3	Remove the 20-liter system liquid container and empty it according to your standard laboratory procedure. The green **Fill Level** check mark (✔) for the wash buffer changes to a red exclamation symbol (❗).
4	Click **Done** to exit the Wash Buffers dialog. **Attention:** You must prime the pump after placing the 20-liter system liquid container back into the system prior to the pump's use.
5	Prime the NEO Iris Click the **Maintenance** button to access the Maintenance section of the software.  Select **Flush System Liquid**. Refer to **Flushing the System Liquid** for detailed instructions on how to start this maintenance action.

Performing the Pipettor Verification Test (PipTest)

Purpose

The purpose of performing the pipettor verification test is to verify the precision pipetting of each probe. This verification is required during NEO Iris installation and after a syringe exchange.

Note: If the PipTest fails, the operator must inspect the probe(s), tubing and syringe(s) for signs of incorrect installation and leaking connections, and correct any observed errors. The PipTest must then be repeated.

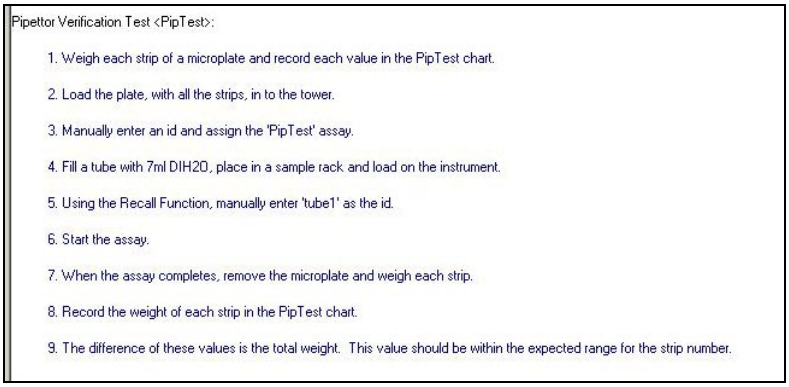
Required Tool(s)

The following tool(s) are required to complete this task:

- Scale
- Unused test tube

Procedure

To perform the pipettor verification test:

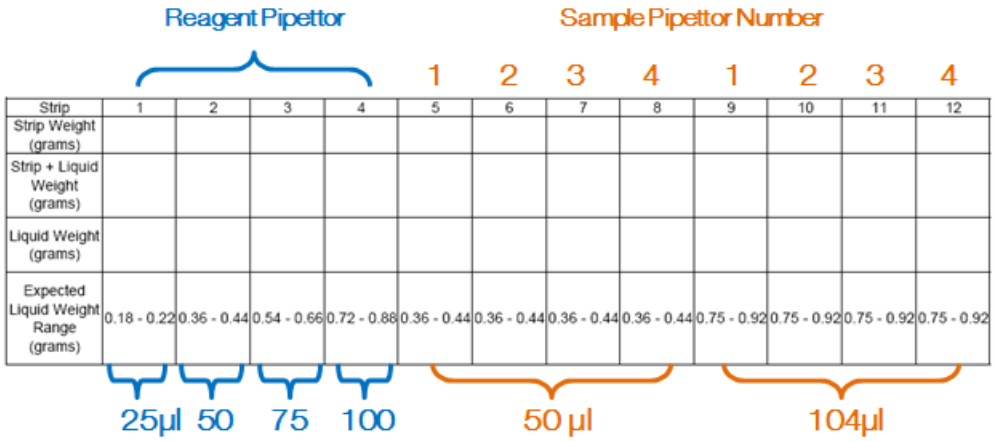
Step	Action
1	Press the **Maintenance** button on the Main Menu Bar. 
2	Select **Pipettor Verification Test** from the action list.
3	Press the **Start** button.
4	Follow the on-screen instructions: 

*	Extra instructions for PipTest Sample Loading (steps 4-5)

Step	Instructions
4	Load a tube with 7 ml of de-ionized water on the instrument with the barcode turned so that the system cannot scan it.
5	By using the Recall function, manually type **tube1** as the ID in the correct position of the rack. The typing of the word **tube1** is case sensitive (all letters must be typed as lowercase).

Recording PipTest Results According to Dispensing Pattern

The PipTest chart is designed to record results according to the instrument dispensing pattern, as illustrated below.



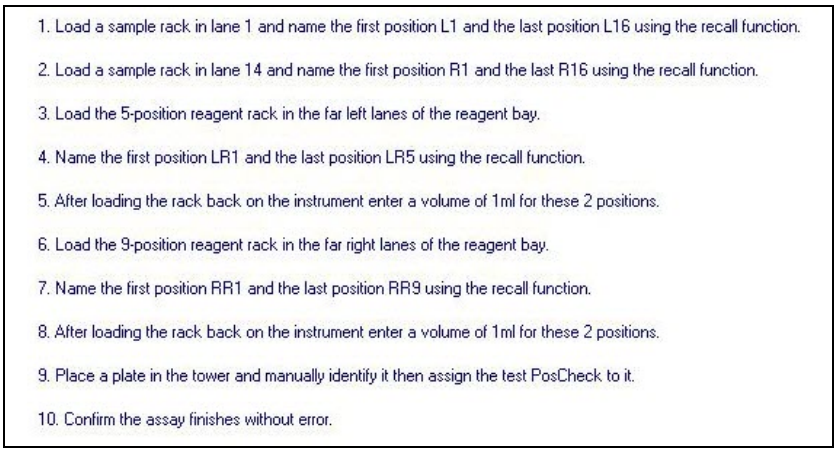
Performing the Positions Check (PosCheck)

Purpose

The purpose of performing the positions check is to verify the probes can access all the required areas within the 14-lane Bay, 5-lane Bay, plate pipetting positions, and wash stations. This verification is required during NEO Iris installation and after a probe exchange.

Procedure

To perform the pipettor positions check:

Step	Action
1	Press the **Maintenance** button on the Main Menu Bar. 
2	Select **Positions Check** from the action list.
3	Press the **Start** button.
4	Follow the on-screen instructions: 

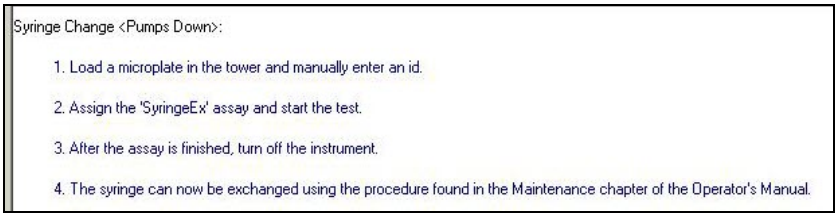
Performing the Syringe Change

Purpose

The purpose of performing the syringe change is to have the instrument move the syringe drive down on all diluter pumps so a syringe can be replaced if necessary.

Procedure

To perform the syringe change:

Step	Action
1	Press the **Maintenance** button on the Main Menu Bar. 
2	Select **Syringe Change** from the action list.
3	Press the **Start** button.
4	Follow the on-screen instructions: 
5	Follow the procedure for **Removing and Replacing a Syringe** that is included in this chapter.

Checking the Residual Volume

Purpose

Checking the residual volume is an as needed maintenance action used for troubleshooting purposes, such as when unexpected results are obtained. The purpose of checking the residual volume is to verify that the volume of liquid left in the wells is correct after the wash sequence.

Note: You must only perform this maintenance action at the request of Technical Support.

Required Tool(s)

The following tool(s) are required to complete this task:

- Scale
- Capture-R® Ready-Screen® or Capture-R® Select plate (see notes below)

Note: Either expired or in-date Capture-R® Ready-Screen® plates can be used. The same plate can be re-used up to ten (10) times if the plate dries between usages.

Using a wet plate for multiple runs during a single troubleshooting session: The same plate can be re-used up to twenty (20) times if the plate remains wet between usages (this could occur if there are failures that require adjustments and residual volume is run numerous times in a single day). The plate can either be tapped out between runs or re-run with the previous residual volume in the wells. After completion of a single troubleshooting session using a wet plate multiple times, the wet plate must be discarded.

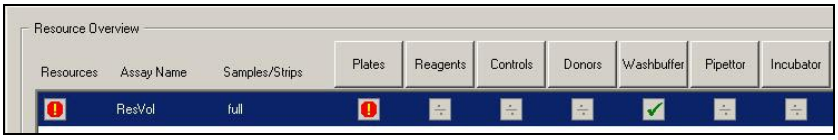
Note: In addition to Capture-R® Ready-Screen® plates, you are permitted to use Capture-R® Select plates to perform *Residual Volume*. However, unlike the Capture-R® Ready-Screen® plates, if a Capture-R® Select plate is used once, it must be discarded after that single use and a new plate must be used if the maintenance action needs to be repeated. Multiple use of the Capture-R® Select plates is not permitted.

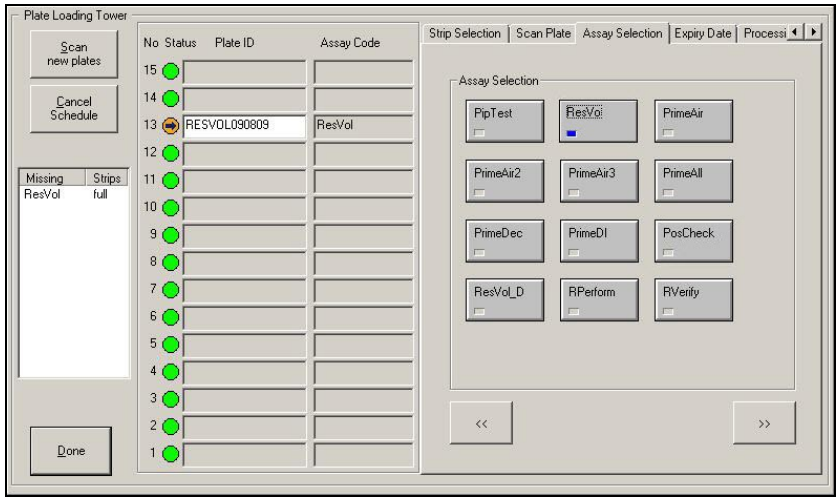
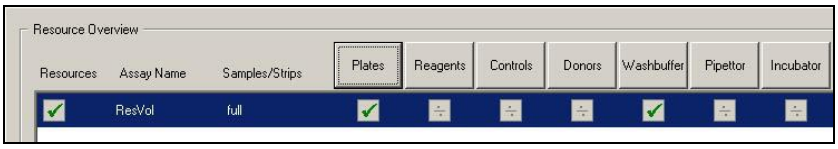
Plate types other than Capture-R® Ready-Screen® or Capture-R® Select are not acceptable for use

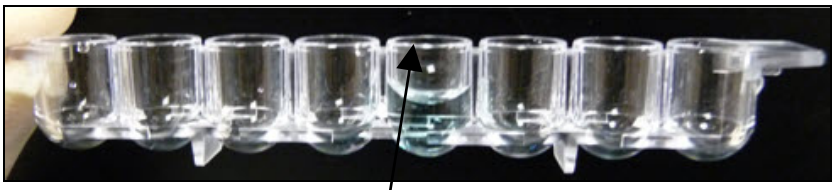
Procedure

To check the Residual Volume:

Step	Action

Step	Action
1	Press the **Maintenance** button on the Main Menu Bar. 
2	Select **Residual Volume** from the action list.
3	Press the **Start** button. The on-screen instructions will be displayed.
4	Press the **Continue** button. Select **ResVol** in the *Resource Overview* window. The system indicates that a plate is required to run this assay. 
5	Press the **Plates** button above the exclamation mark. The system displays the *Plate Loading Tower* dialog.
6	Weigh a Capture-R® Ready-Screen® plate with the scale and then correctly place the plate into a transport frame. Record the weight on the **NEO Iris Residual Volume Calculation Record**.  **Note:** If a wet plate is being re-used for multiple runs during a single troubleshooti session, you should use the original dry plate weight on the calculation record (line each of the wet run calculations during the session.
7	Load the plate in any position of the Plate Loading Tower.
8	Press the Assay Selection tab and then press the Plate ID field next to the orange LED.

Step	Action
9	Type a unique plate ID, such as current date, and choose the **ResVol** assay button from the assay selection area to the right. The system displays the selected assay next to the plate ID under the Assay Code column. 
10	Press the **Done** button. The system redisplays the *Resource Overview* window indicating that resources are sufficient to run the assay. 
11	Select **Start**. The transport system takes the plate to the washer module. The plate is returned to the tower when the task is finished.
12	Remove the plate from the tower and weigh it on the scale. Record the weight on the **NEO Iris Residual Volume Calculation Record**.
13	Subtract the weight from step **7** from the weight from step **13**. Record this calculated weight on the residual volume calculation record. Report this calculated weight to Technical Support.

Step	Action
14	Remove strips 1, 6, and 12 from the plate to verify that the remaining volume is even by holding the strips parallel to each other. If the volume is uneven, verify that the manifold is correctly mounted. If the problem persists, contact Technical Support to determine further action. **Note:** The residual volume is out of range if the residual volume between any two wells (within a strip and between strips) doubles (or greater).  **Note**: If the residual volume verification fails, Technical Support may recommend that the manifold must be removed so that the manifold probes can be checked for correct positioning using the manifold align tool. If this course of action is recommended by Technical Support, all of the prescribed maintenance tasks must be subsequently performed once the manifold is reinserted back into NEO Iris, which includes repeating the residual volume verification. **Warning**: The main maintenance screen indicates that this action is Due if the assay successfully completes. The system does not analyze the results on the instrument, so you must determine if the volume is acceptable. You are responsible for making the corrections necessary to satisfy these requirements.

Removing and Reinserting the Manifold

Purpose

The manifold can be removed and reinserted so that it can be flushed when a blocked manifold needle is suspected or when the Flow350 and/or the Flow200 maintenance tasks fail.

Phases

This procedure consists of two phases:

- Removing and Cleaning the Manifold
- Reinserting the Manifold

Required Materials

The following materials are required to complete this task.

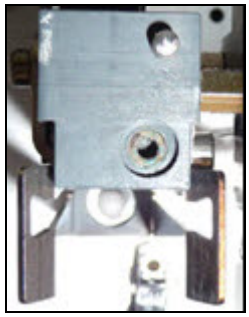
- Absorbent paper towel
- Stylus
- Plastic syringe
- Probe check and align tool

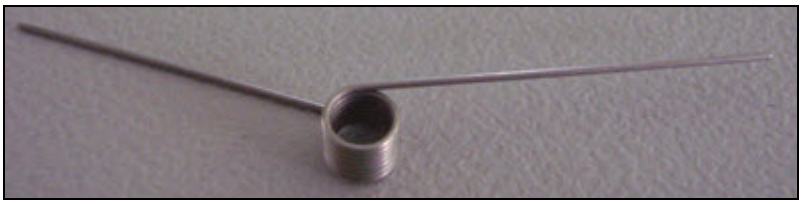
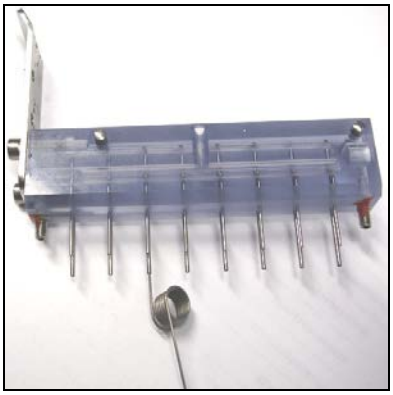
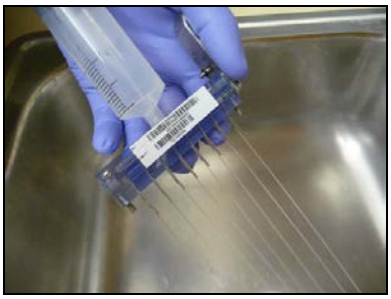
Removing and Cleaning the Manifold

To remove and clean the manifold:

Step	Action
1	Turn off the NEO Iris module.
2	Place an absorbent paper towel in the liquid overflow detection mat tray to absorb any drops of fluid that may fall when the manifold is moved to a position above the tray in the following step 3.

Step	Action
3	If the manifold probes are located down inside the trough, lift the manifold up above the trough to give the probes clearance and then gently slide the manifold to the right along the two (2) parallel x-rails so that is it removed from the direct area of the trough.  **Note:** Attempting to remove the manifold with the probes located down inside the trough without first lifting the probes clear and away from the trough can result in bent probes.

Step	Action
4	Manually loosen the thumb screw used to secure the manifold to its support arm by turning it counter-clockwise with your fingers and thumb until it detaches from the support arm. The location of the thumb screw is shown in the photograph below.  **Note:** The thumb screw will stay attached to the manifold front handle by the use of a containment device on the reverse side of the handle. **Note:** Do not adjust the two (2) securing screws located at the bottom of the manifold handle in any way. The location of the two (2) securing screws is shown in the photograph below. 
5	Grip the top handle tab and pull the manifold towards you. The manifold will detach from a small metal post. A small gray post will also be visible at the back of the support arm.  Metal post and small gray post visible on manifold supporting arm
6	Remove and discard the absorbent paper towel that was placed in the liquid overflow detection mat tray to absorb any drops of fluid in step 2.

Step	Action
7	To flush the manifold with PBS to unblock potentially blocked probes, you must use a plastic syringe filled with PBS to push PBS through the holes in the top of the manifold that supply the dispense probes and carry away the fluid from the aspiration probes. A stylus can be used to stylus out any resistant obstructions in the probes that cannot be removed by flushing with PBS. Two (2) sizes of stylus are provided, one for each probe type.  Stylus  Stylus the manifold  Flushing the manifold

Step	Action
8	Use the probe check and align tool to check the manifold probes. Straighten probe(s) if needed by gently pushing the necessary probe to a vertical position. 

Reinserting the Manifold

To reinsert the manifold:

Step	Action
1	Grip the top handle tab and push the manifold away from you into the manifold support arm so that the guiding tips on either side at the back of the manifold correctly engage the holding assembly. **Note:** Make sure that the manifold engages the small metal post and pushes back against the small gray post at the rear of the assembly.
2	Manually tighten the thumb screw to secure the manifold to its support arm by turning it clockwise with your fingers and thumb until it tightens into the support arm. The location of the thumb screw is shown in the photograph below. 
3	Power on the NEO Iris module.
4	Use the washer teach tool to teach the washer manifold its zero position.
5	Perform the weekly **Verifying the Washer** maintenance task.
6	Perform the **Checking the Residual Volume** maintenance task.

Using the Washer Teach Tool

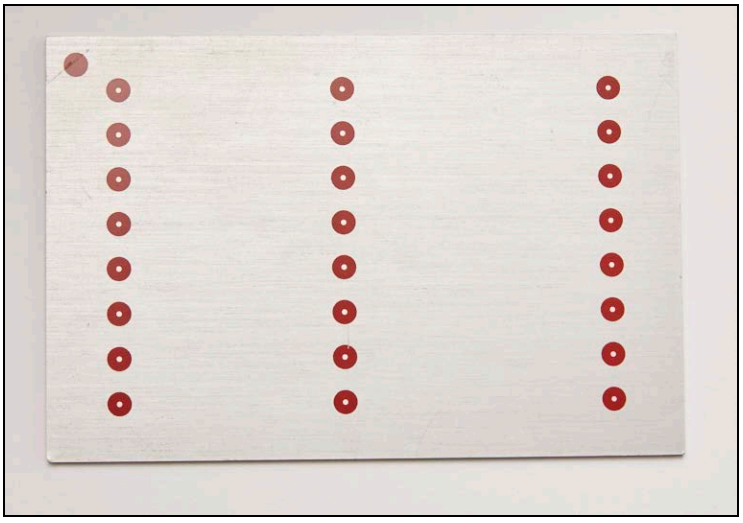
Purpose

The purpose of using the washer teach tool is to teach the washer manifold its zero position. This task must be performed on an as needed basis, when the manifold has been removed and replaced or when the **Checking the Residual Volume** maintenance task fails.

Required Tool(s)

The following tool(s) are required to complete this task:

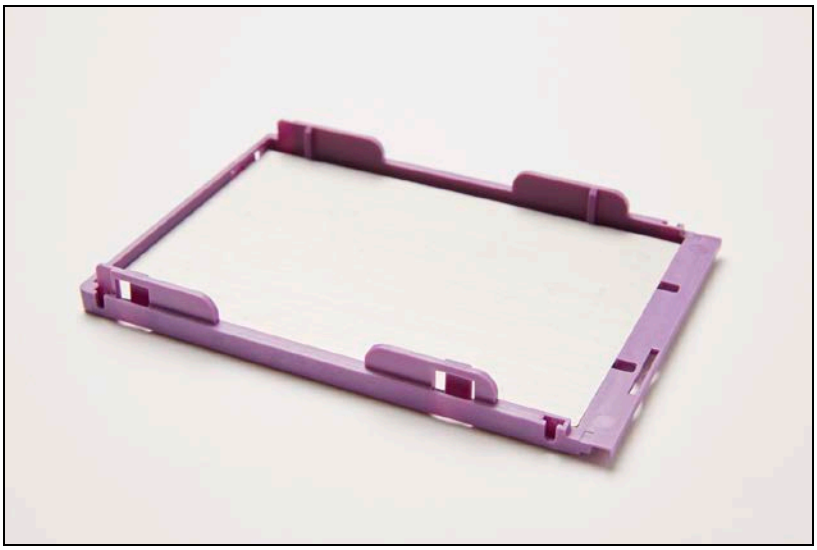
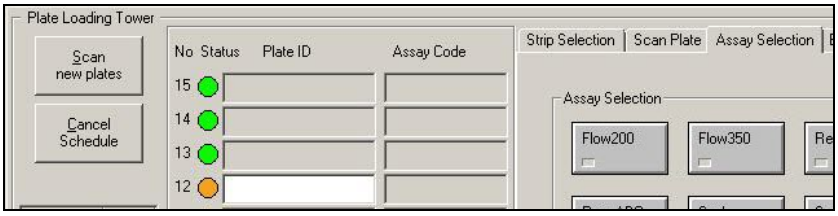
- 2 mm thick washer teach tool



Procedure

To use the washer teach tool:

Step	Action
1	Press the **Maintenance** button on the Main Menu Bar. 
2	Select **Teach Washer** from the action list.
3	Press the **Start** button. The onscreen instructions are displayed.
4	Press the **Continue** button. The **Resource Overview** window is displayed.

Step	Action
5	Select the **TeachWash** assay, which will highlight in **blue,** and press the **Plates** button above the **red** exclamation mark. The **Plate Loading Tower** dialog will be displayed.
6	Place the 2 mm thick washer teach tool fully down into a plate carrier, with the **red** dots facing DOWN. 
7	Place the loaded plate carrier into the plate loading tower into any available tower position.
8	Press the **Assay Selection** tab and select the **Plate ID** field next to the **orange** LED onscreen signal. 
9	Type a unique plate ID, such as the current date, and assign the **TeachWash** assay from the buttons to the right. The system displays the selected assay next to the **Plate ID** under **Assay Code**.
10	Press the **Done** button on the **Plate Loading Tower** dialog. The system returns to the **Resource Overview** window indicating that all resources are sufficient to run the assay.

Step	Action
11	Press the **Start** button on the **Resource Overview** window. The transport system takes the teach tool to the washer module. The manifold moves down to the teach tool at programmed positions. When the manifold detects the tool, that position is the value the instrument teaches as zero. This value is used when the manifold aspirates liquid form the wells. At the end of this process, the tool is returned back to the plate tower. **Note:** After the successful completion of the **TeachWash** assay, the main maintenance status screen indicates that **Teach Washer** is *Due*. The state remains unchanged.
12	Remove the tool from the plate tower and then the transport frame, and store it in a secure place for future use.

Checking the Manifold Probes

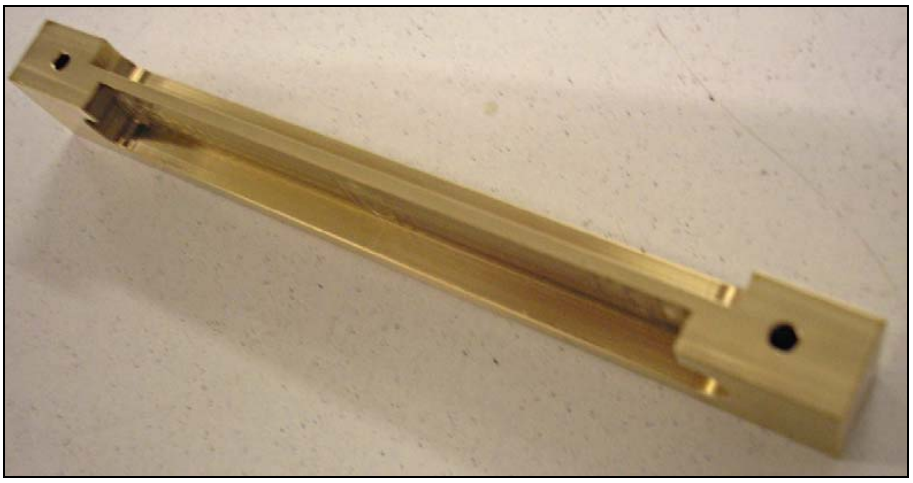
Purpose

The purpose of checking the manifold probes is to ensure that the probes are correctly positioned and not bent. This task must be performed on an as needed basis, when the manifold has been removed and replaced or when the **Checking the Residual Volume** maintenance task fails.

Required Tool(s)

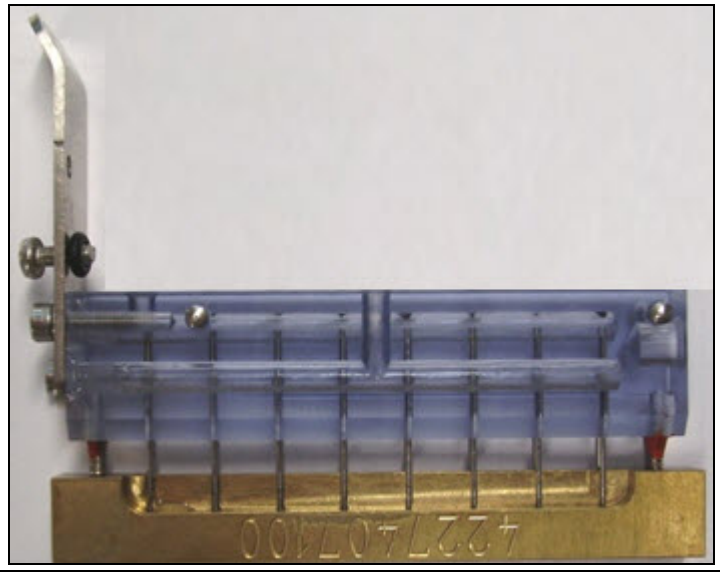
The following tool(s) are required to complete this task:

- Probe check and align tool



Procedure

To use the probe check and align tool:

Step	Action
1	Once the washer manifold is removed from the NEO Iris, slide it down onto the probe check and align tool. **Note:** The manifold will only securely slide down onto the tool in one orientation. The longer set of probes will slide down into the deeper tool groove and the shorter set of probes will slide down into the shallower tool groove on the opposite side of the tool. The two (2) grub screws (one on either end of the manifold) sit flush down onto the top of the tool. 

Step	Action
2	Check that the manifold probes are straight. Make sure that: a. All probe tips should be flush with the respective surfaces of the tool. b. The probes should be parallel to one another. The tool defines the spacing between aspirate and dispense probes. Slight corrections, by pushing the probes, are permitted to straighten any bent or misaligned probes. If probes are kinked, then the manifold must be replaced. 
3	Remove the manifold from the tool so that the manifold can be reinserted back into the NEO Iris washer module.

Adjusting the Manifold Grub Screws

Purpose

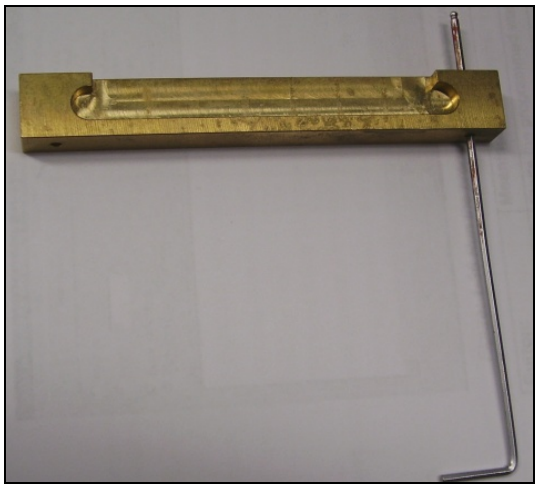
The purpose of adjusting the manifold grub screws is to ensure that the probes are correctly positioned in relation to the wash aspiration position when washing a plate. This task must be performed on an as needed basis when the manifold probes are checked and the probe tips are found not to be flush with the respective surfaces of the tool.

Note: This task should only be performed after express direction is received from Technical Support and under no circumstances should you undertake this task without that direction.

Required Tool(s)

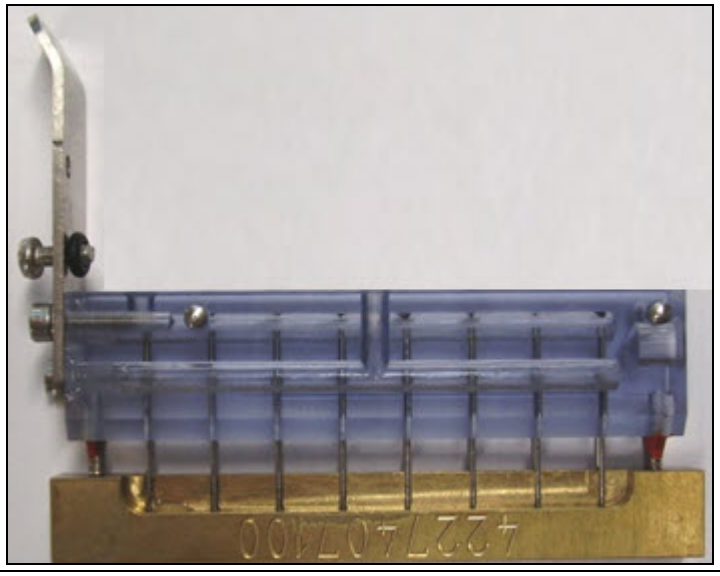
The following tool(s) are required to complete this task:

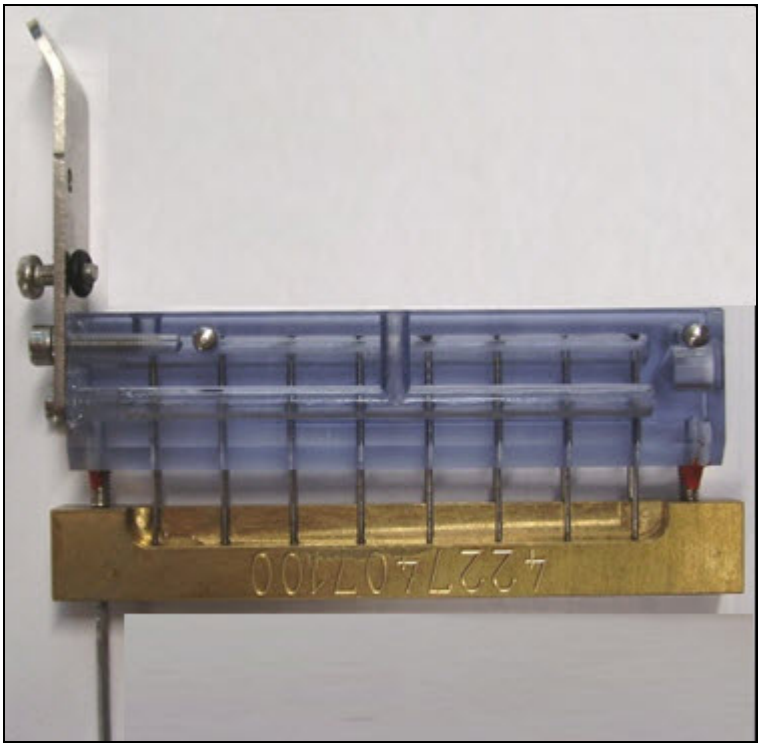
- Probe check and align tool
- 1.5 mm Allen wrench



Procedure

To adjust the manifold grub screws:

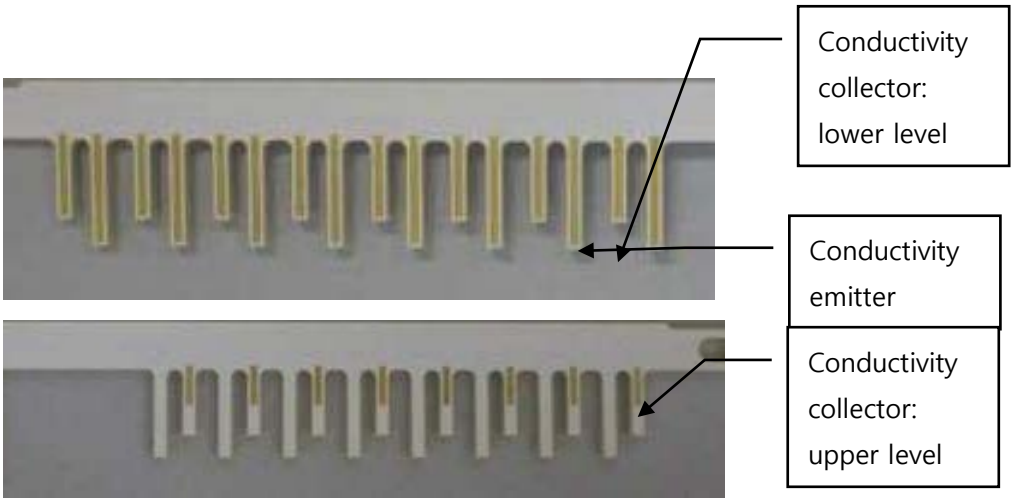
Step	Action
1	Once the washer manifold is removed from the NEO Iris, slide it down onto the probe check and align tool. **Note:** The manifold will only securely slide down onto the tool in one orientation. The longer set of probes will slide down into the deeper tool groove and the shorter set of probes will slide down into the shallower tool groove on the opposite side of the tool. The two (2) grub screws (one on either end of the manifold) sit flush down onto the top of the tool. 

Step	Action
2	If probe tips are not flush with the respective surfaces of the tool, use the 1.5 mm Allen wrench to adjust one or both of the grub screws as needed. The wrench slots in through the holes at each end of the tool and then engages with the grub screw directly adjacent to the hole. Once engaged, the wrench can be used to adjust the grub screw. A longer grub screw leads to more residual volume because the aspiration probes are raised relative to the plate surface. **Note:** Only make adjustments of less than a quarter (¼) turn at any one time. 
3	Remove the manifold from the tool so that the manifold can be reinserted back into the NEO Iris washer module.
4	Once the NEO Iris is ready for use, run the residual volume maintenance task. If the residual volume results are unacceptable, remove the washer manifold once again and repeat steps 1, 2 and 3 of this procedure until an acceptable residual volume result is obtained.

Cleaning the Liquid Level Sensor and Trough

Purpose

The Liquid Level Sensor (LLS) can be removed from the washer manifold trough, cleaned and reinserted if errors are generated that indicate that the washer manifold has aspiration or dispensing check failures, or that the LLS board is reporting an error. The LLS is used to measure conductivity in the washer manifold trough so that excess of liquid in the trough can be detected in the event of manifold aspiration or dispensing problems. There are eight (8) pairs of short and long fingers. Conductivity is measured between the pad at the end of the long finger (the emitter) and the two pads at the front and rear of the short finger (the two collectors). Both collector pads are at different relative levels (upper and lower) on the opposite sides of the short fingers. The LLS is one piece.



Note: This task must only be performed as needed.

Required Tool(s) and Materials

The following tools and materials are required to complete this task.

- Allen wrench or hex key for 2 mm hex screws.
- Source of room temperature de-ionized water.
- Disposable (soft bristle only) non-electric manual toothbrush.
- Disposable cotton swab

Note: Tap water must not be used; to reduce the risk of the use of chlorinated water which may also contain other unidentified contaminants.

Phases

This procedure consists of two phases:

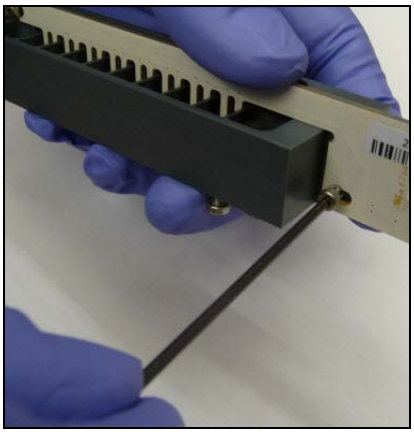
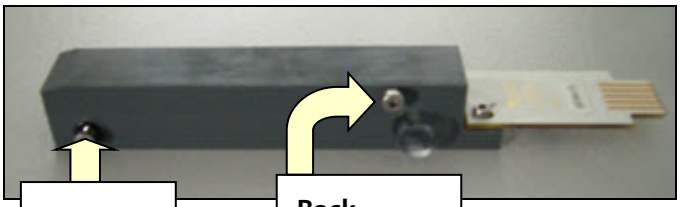
- Removing and cleaning the LLS
- Reinserting the LLS

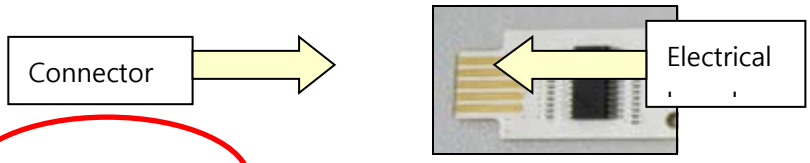
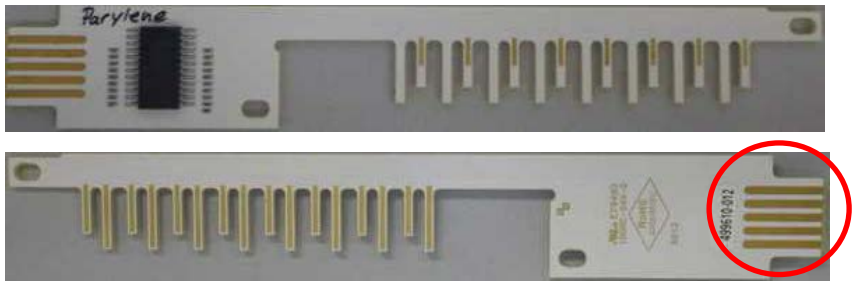
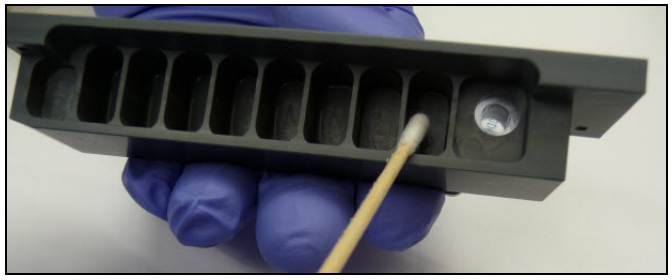
Removing and Cleaning the LLS

To remove and clean the LLS:

Step	Action
1	Turn off the NEO Iris.
2	If the manifold probes are located down inside the trough, lift the manifold up above the trough to give the probes clearance and then gently slide the manifold to the right along the two (2) parallel x-rails so that is it removed from the direct area of the trough.  **Note:** Attempting to slide the manifold to the right along the two (2) parallel x-rails with the manifold probes still located down inside the trough, without first lifting the manifold probes clear, can result in bent probes.

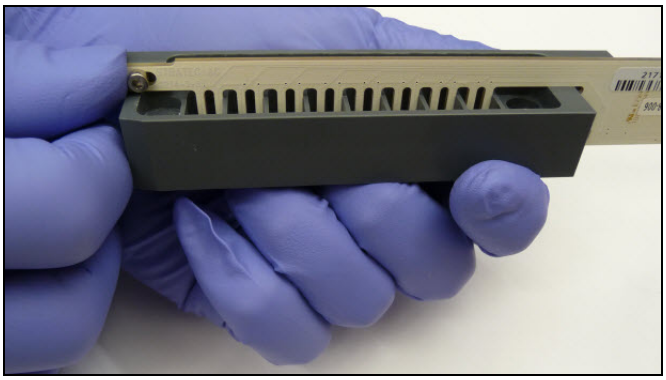
Step	Action
3	Pull the trough towards you by using your finger to horizontally pull the trough forward from the back so that the anchoring screws uncouple from the anchor slots. Raise the trough up and away from the anchoring base. 

Step	Action
4	On a flat surface away from the instrument, unscrew the two (2) screws of the LLS using the Allen wrench or hex key for 2 mm hex screws. Place the two (2) screws in a safe place ready for future use.  **Note:** When handling the manifold trough, do not adjust the two (2) anchoring pin screws on the base of the trough. These two (2) anchoring pin screws are positioned to optimally allow the removal and subsequent insertion of the trough and also to ensure maximum stability when the trough is in place in the washer module.  **Front** anchoring pin screw **Back** anchoring pin screw

Step	Action
5	Clean the LLS fingers with room temperature de-ionized water using the disposable toothbrush. **Note:** Do not brush, or bring the water into contact with, the connector (located on both sides of the LLS) or the electrical board at the end of the LLS. This can cause irreparable damage to the LLS which will then require replacement.  The connector (located on both sides of the LLS) and electrical board are circled on the photographs below. 
6	Inspect the golden sensor pads for corrosion or dirt. Repeat the LLS cleaning if necessary. Contact Technical Support if the LLS is corroded or cannot be cleaned, and therefore subsequently requires replacement.
7	Use the disposable cotton swab to clean the trough. 

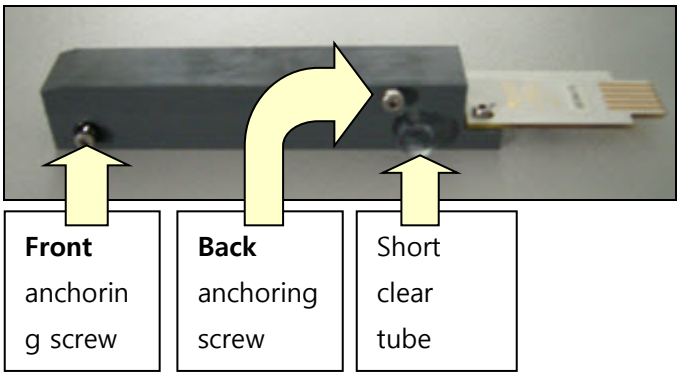
Reinserting the LLS

To reinsert the LLS:

Step	Action
1	Use the 2 mm Allen wrench or hex key to loosely attach the LLS back into the trough by only partially screwing down the two (2) LLS screws, so that the screws do not fall off the LLS/trough combination unit. **Note:** This is a preparatory step so that the long LLS sensor fingers can be correctly positioned before the two (2) LLS screws are tightened down securely using the 2 mm Allen wrench or hex key in step 2 below.
2	Push the LLS to the back of the trough (right side in picture) so that the long sensor fingers touch the well side walls. The purpose is to set the shorter fingers as far away from the left side walls as possible. Tighten the two (2) screws using the Allen wrench or hex key for 2 mm hex screws while pushing the board to the side. 

Step	Action
3	Rinse the priming trough wells and LLS attached to it (as shown below) with a solution of 70% isopropanol. Remove the residual isopropanol and rinse with DI water. Remove the residual liquid. **Note:** Only rinse parts of the sensors that are seated into the trough wells. 

Step	Action
4	Hold up the end of the trough nearest you at a slight upward vertical angle so that the **back** anchoring screw and the short clear tubing are lined up with the **back** anchoring slot and the tube hole respectively in the supporting base.



Preparing to line up the trough

Back of the trough lined up

Lower the trough down so that both of the anchoring screws are inserted into the two (2) anchoring screw slots of the supporting base. After the trough is lined up and level, push the trough away from you, to the back, until it is locked in position (refer to the photograph below).

Step	Action
5	Power on the instrument and allow Initialization to take place.  **Note:** Repeat the LLS cleaning procedure if the Initialization generates a washer manifold error. Contact Technical Support if the error persists after this second cleaning and Initialization.

Cleaning the Liquid Overflow Detection Mat

Purpose

The liquid overflow detection mat is orange in color and is located in the washer module. It is used to detect washer manifold fluid leaks over the plate washing area. If such leaks do occur, then a washer liquid overflow error message is displayed and the instrument is halted.

Required Materials

The following materials are required to complete this task.

- Absorbent paper towel

Procedure

To clean the liquid overflow detection mat:

Step	Action
1	After the washer liquid overflow error message is displayed, confirm that the screen indicates that the NEO Iris is stopped by the display of **Halted** in the status bar. 
2	Reach into the washer overflow mat (via the left side of the plate loading tower and above the centrifuge loading unit), with an absorbent paper towel to dry the mat completely so that there is no longer any liquid present.
3	Press the **OK** button of the error message to enter error recovery. Troubleshoot the fluid leak. Refer to **Chapter 11 – Troubleshooting the NEO Iris** for troubleshooting details.

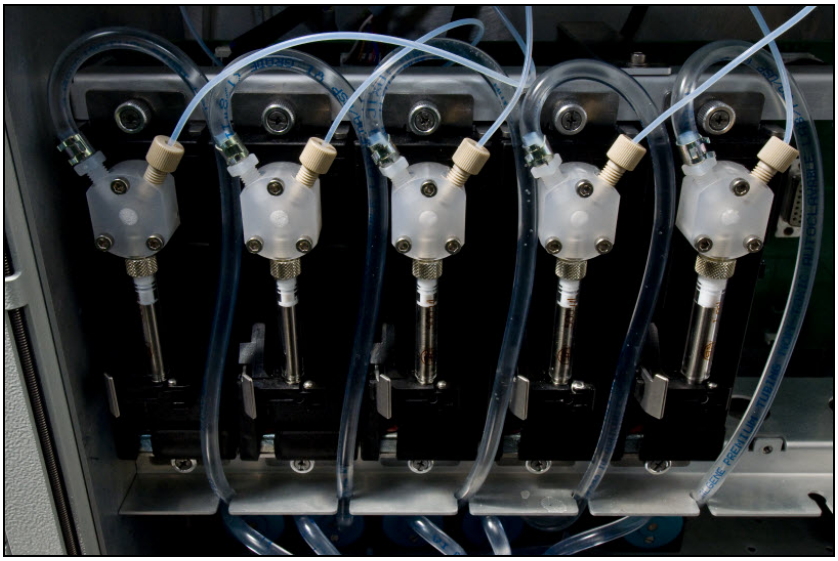
Removing and Replacing a Syringe

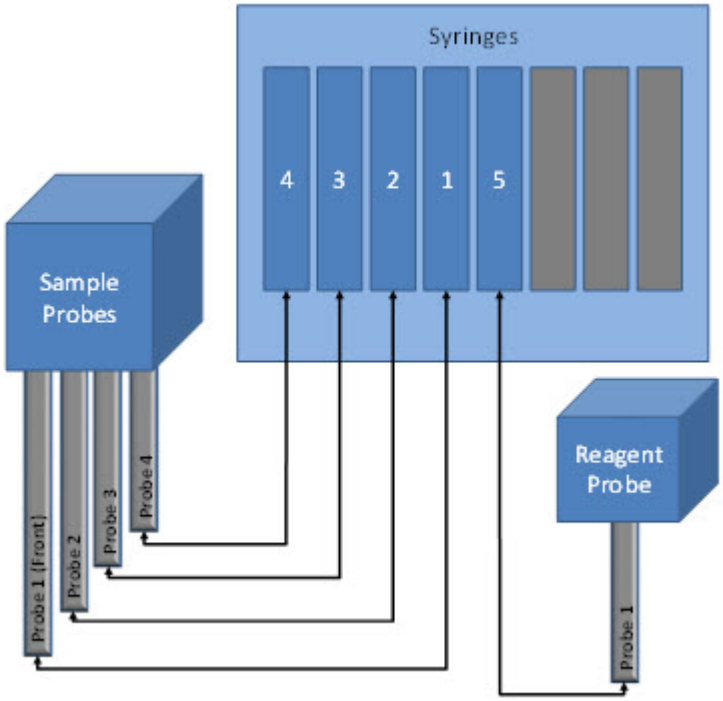
Purpose

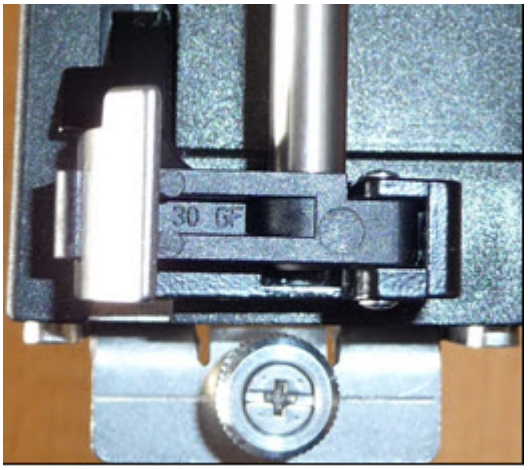
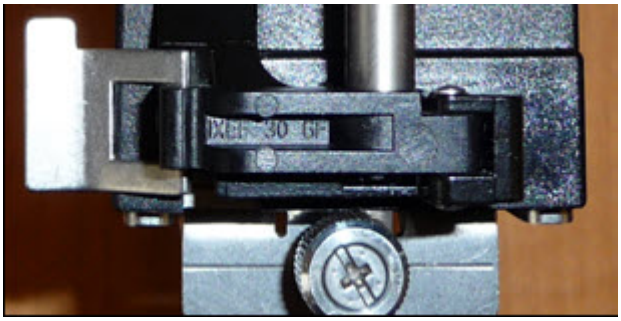
A syringe should be replaced when the pipettor verification test consistently fails.

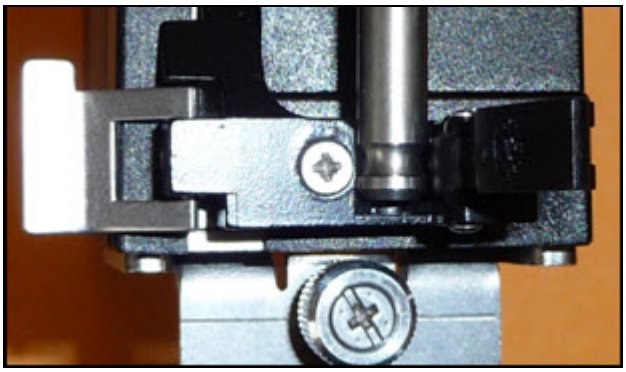
Procedure

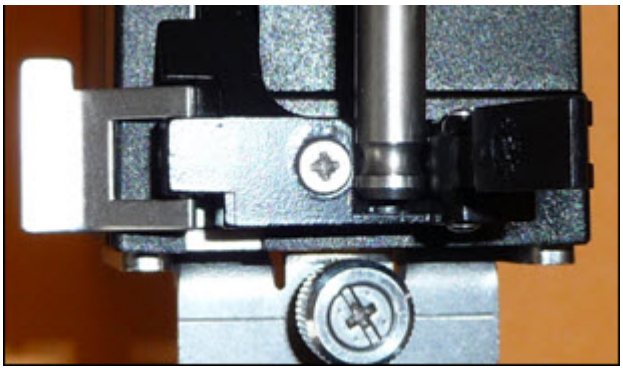
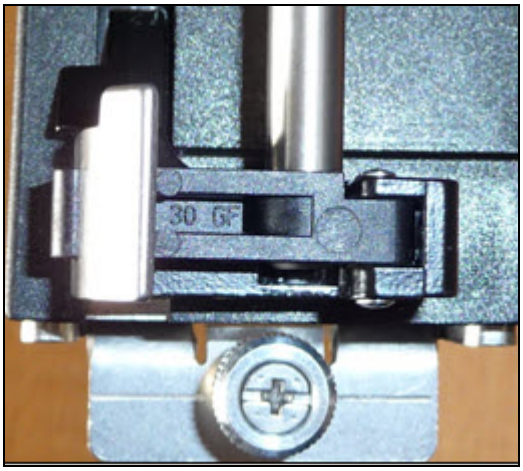
To remove and replace a syringe:

Step	Action
1	Run the **Syringe Change** maintenance action to prepare the position of the syringes so they are ready for removal.
2	After the assay is finished, turn off the NEO Iris power.
3	Disconnect the power cord from the NEO Iris next to the power switch on the side of the instrument.
4	Open the hood and move the right pipettor arm all the way to the left side of the loading bay taking care that the probes do not hit the sides of the bay. Open access will be available to the syringes. 

Step	Action
5	Place some absorbent material, such as a paper towel, under the syringe to be removed to catch a small amount of system fluid. The diagram below indicates which syringe is associated with which probe. 
6	If the probe of the syringe being replaced is not over a wash tower, place some absorbent material under it when the plunger is being pushed into the syringe, to collect any expressed fluid.

Step	Action
7	Pull the hinged square steel clip (on the clip assembly) of the syringe in question from the center to a left position so that the tension is released (refer to the sequence of photographs below). No tool is required for this clip release.  Example of syringe fully locked into dilutor pump with plunger extended  Close-up of syringe fully locked into dilutor pump using the clip assembly  Close-up of hinged square steel clip with tension released

Step	Action
8	Open the hinged black bar from the flat position to the perpendicular position, so that it points towards you. 
9	Grasp the knurled securing screw and unscrew the syringe barrel in a counter-clockwise direction to disconnect the barrel from the 3-way valve. 
10	Remove the syringe assembly and set it aside.
11	Place the new syringe in position at the 3-way valve, grasp the knurled screw, and twist the syringe clockwise to secure it to the valve. You must never use tools for this procedure. **Warning:** It is critical the syringe is held in perfect vertical orientation when twisting into the 3-way valve. Do not force the syringe. If there is resistance back it off and try again. **Warning:** Verify that you are replacing the syringe with another syringe of the same size. Replacing the syringe with a wrong-sized syringe causes pipettor inaccuracy and incorrect test results.

Step	Action
12	Grasp the plunger and pull it down low enough so that the groove on the terminal metal bulb rests over the matching ridge of the dilutor pump clip assembly. 
13	Close the hinged black bar back down to the flat position. The black bar should be flush with its counterpart on the diluter pump assembly (see step 12 above). **Note:** If the tip of the plunger is not seated correctly then the hinged black bar will not close to its flush position.
14	Close the hinged square steel clip to the right so that the hinged black bar over the syringe plunger is secured. The tip of the terminal metal bulb on the plunger must be visible below the bottom level of the hinged black bar.  **Note:** If the tip of the terminal metal bulb on the plunger is not visible below the level of the hinged black bar, this can indicate that the plunger is not seated correctly in the clip assembly.
15	Close the hood, plug the instrument power cord back in, and turn on the instrument. Allow the instrument to fully initialize.

Step	Action
16	Perform the Pipettor Verification Test (PipTest) to confirm proper syringe performance.

Removing and Replacing a Probe

Purpose

A probe should only be replaced when directed by Technical Support. Such scenarios can include:

- When a bent probe cannot be straightened by gentle manual bending.
- As part of an investigation of unexpected sample reactions.
- When probe adaptor problems present themselves, as diagnosed by Technical Support.

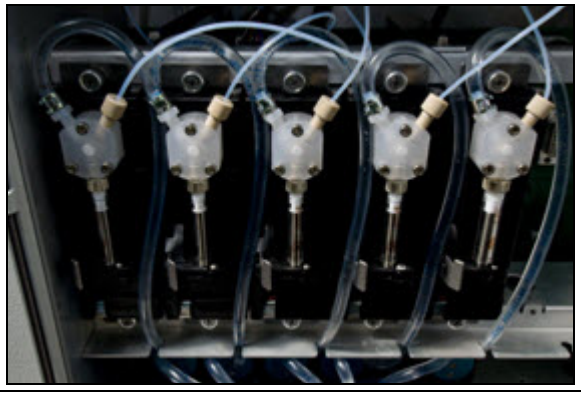
Required Tool(s)

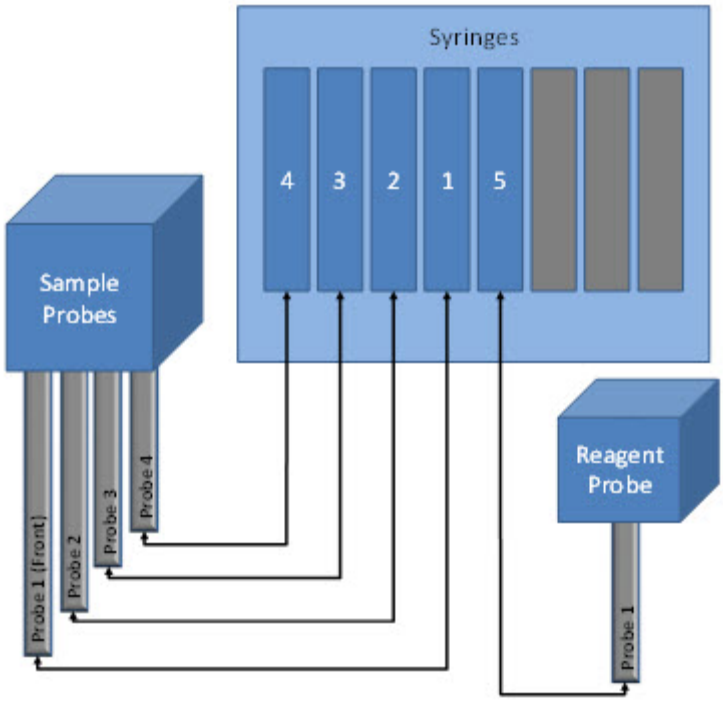
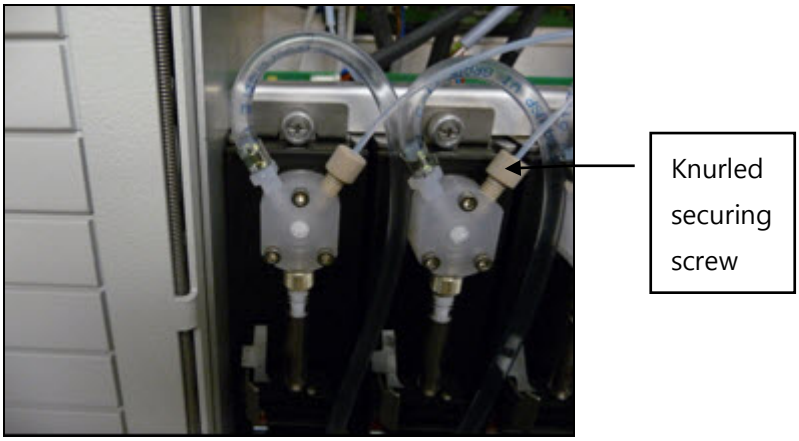
The following tools are required to complete this task:

- 2 mm Allen wrench
- Pair of laboratory scissors

Procedure

To remove and replace a probe:

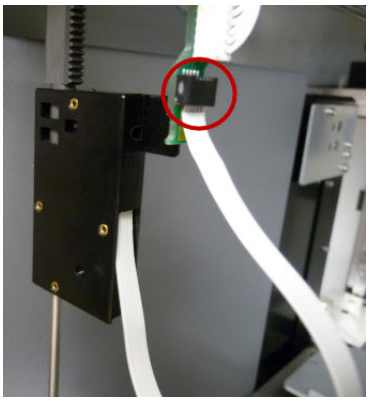
Step	Action
1	Switch off the NEO Iris module.
2	Lift up the instrument hood.
3	Move the right pipettor arm all the way to the right side of the NEO Iris module, taking care that the single probe does not hit the sides of the loading bay. Open access will be available to the syringes. 

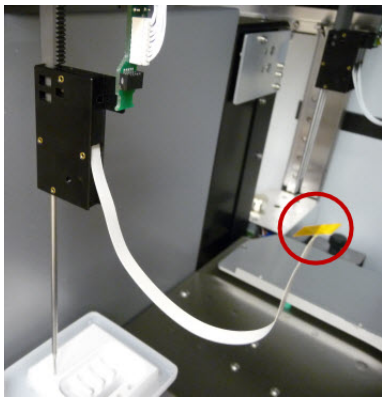
Step	Action
4	Determine which syringe is attached to the probe(s) in question using the diagram below. 
5	Reach into the body of the NEO Iris module and unscrew the knurled securing screw to detach the tubing to the top right of the selected syringe from the 3-way valve. 
6	Pull the attached tip at the end of the tubing off and also collect the plastic washer and knurled securing screw. **Note:** Place these three (3) items in a safe place for future use as potential spare parts. The new replacement probe will include all of the necessary unused fixtures.

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>7</td><td>Reach into the body of the NEO Iris module and use the pair of laboratory scissors to clean-cut the flared end of the tubing off the length of the tubing.

<u>Note:</u> The pair of laboratory scissors is required to cut the flared end of the tubing off because the next steps involve the pulling of this narrow tubing through extremely tight fitting sleeve tubing. If the flared end is not cut off using a pair of laboratory scissors, then the narrow tubing will not easily be pulled through the sleeve tubing as it should be able to be pulled.</td></tr>
<tr><td>8</td><td>Move the left arm to the right so that it is over the 14-lane bay, so that all the required probe adaptors can easily be accessed.

If the probe is to be changed on the right arm, move the right arm so that the single probe is located over the 14-lane bay.</td></tr>
<tr><td>9</td><td>Spread the probes on the left arm as necessary to easily access the required probe.</td></tr>
<tr><td>10</td><td>Gently detach the white ribbon cable from the slot on the required probe assembly by pulling downwards on the white cable. The other end of the cable will remain attached to the probe adaptor. The detached end of the cable has a small yellow tab affixed.

 
White ribbon cable attached to probe assembly slot

 
White ribbon cable detached from the probe assembly slot</td></tr>
<tr><td>11</td><td>Gently pull the probe downwards so that the probe adaptor screw is accessible with the 2 mm Allen wrench without the interference of the white ribbon cable connector area on the probe assembly.</td></tr>
</table>

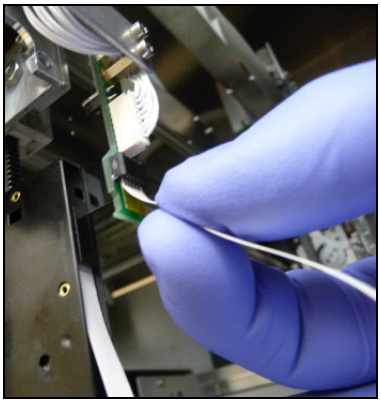
<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>12</td><td>Unscrew the probe adaptor from the z-rod using the 2 mm Allen wrench so that the adaptor is free from the z-rod.
<table>
<tr><td>  </td><td>  </td></tr>
<tr><td>2 mm Allen wrench engaged with the screw in the probe adaptor</td><td>Use the 2 mm Allen wrench to unscrew the probe adaptor</td></tr>
</table></td></tr>
<tr><td>13</td><td>Pull the combined probe/adaptor/tubing assembly down and away from the z-rod so that the detached tubing disappears from the syringe area and the tubing is gradually pulled through the protective sleeve tubing. Keep pulling until the probe/adaptor/tubing assembly is completely detached from the NEO Iris module. The tubing can be pulled from either directly under the z-rod or directly above the z-rod. Pulling the tubing above the z-rod may offer less resistance when compared to pulling under the z-rod.

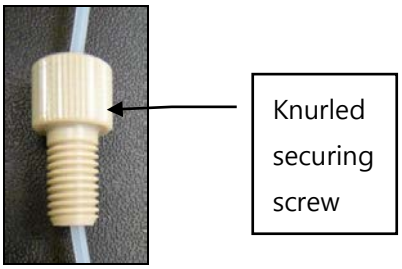
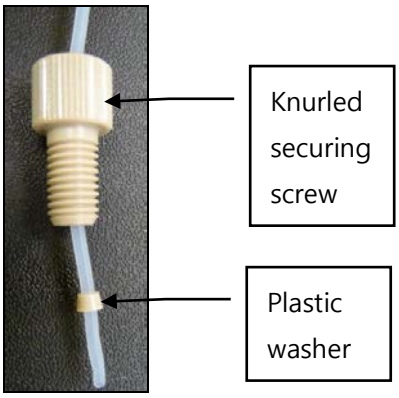
<u>Note:</u> Approximately three (3) to four (4) feet of tubing will be attached to the probe adaptor when it is completely removed from the NEO Iris module.</td></tr>
<tr><td>14</td><td><u>Inserting the new tubing</u>:

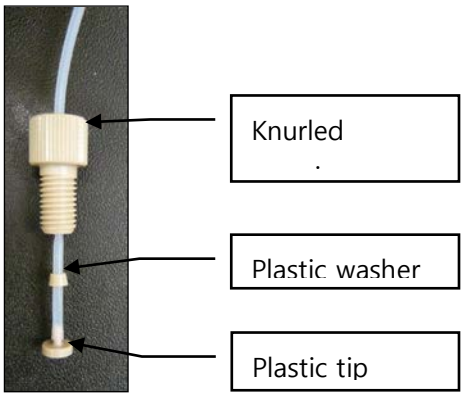
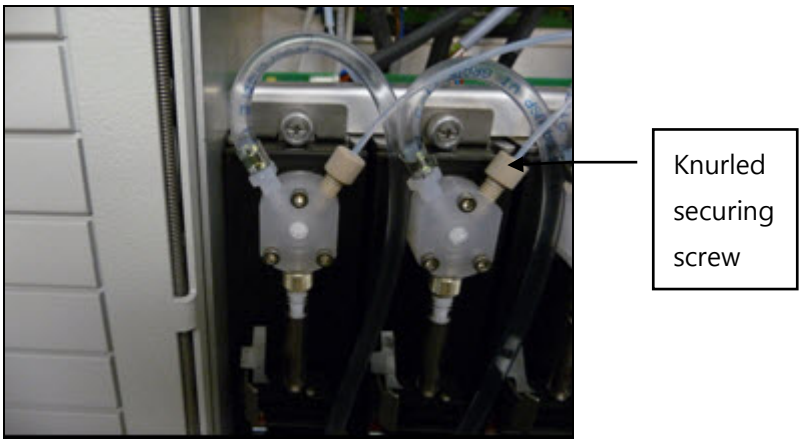
Take the new probe and thread the end of the tubing up through the empty z-rod.

After the tubing is through the z-rod, push the tubing into the sleeve tubing and continue to push all the way above the z-rod. Hold the sleeve tubing located above the z-rod so that the probe tubing glides up into sleeve tubing without pushing the sleeve tubing off the z-rod.</td></tr>
<tr><td>15</td><td>Keep pushing the tubing until the end of the tubing appears in the syringe area and the probe adaptor is flush up to the end of the z-rod.

<u>Note:</u> After the adaptor is in place on the z-rod, the guide tubing can be reseated into the z-rod if it has been dislodged from the top of the z-rod during the threading process in steps 14 and 15.</td></tr>
</table>

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>16</td><td>Screw the probe adaptor onto the z-rod using the 2 mm Allen wrench so that the adaptor is secured onto the z-rod.
<table>
<tr><td>  </td><td>  </td></tr>
<tr><td>2 mm Allen wrench engaged with screw in probe adaptor</td><td>Use the 2 mm Allen wrench to screw the probe adaptor onto the assembly</td></tr>
</table></td></tr>
<tr><td>17</td><td>Gently attach the white ribbon cable to the probe assembly by pushing the cable upwards into the corresponding slot on the probe assembly. Hold the cable just below the yellow tab when inserting.
 
<u>Note:</u> Inserting the cable with excessive force can cause kinking of the ribbon cable with possible breakage of some elements of the internal wiring.</td></tr>
<tr><td>18</td><td>Move the arm that received the new probe to its respective side of the NEO Iris module to provide unobstructed access to the syringes. Take care that the probes do not hit the sides of the loading bay.</td></tr>
</table>

Step	Action
19	Push the knurled securing screw up onto the end of the new tubing which hangs in the syringe area, with the screw thread facing downwards. 
20	Push the plastic washer up onto the end of the new tubing with the bevel facing up towards the knurled securing screw, but located below the knurled securing screw, which hangs in the syringe area. 

Step	Action
21	Push the plastic tip into the end of the new tubing, below the knurled securing screw and plastic washer, which hangs in the syringe area, so that the tip is fully secured into the tubing.  Plastic tip The knurled screw, plastic washer and tip will then be secured onto the end of the tubing. 
22	Screw the knurled securing screw to attach the tubing to the top right of the selected syringe on the 3-way valve. The plastic washer and tip should snug down into the threads of the valve on the 3-way valve when the knurled screw is secured. **Note:** Inserting the cable with excessive force can cause kinking of the ribbon cable with possible breakage of some elements of the internal wiring. 
23	Lower the NEO Iris module hood to the closed position.

Step	Action
24	Switch on the NEO Iris module. Allow the instrument to fully initialize. **Note:** The NEO Iris module must be switched on for at least thirty (30) minutes prior to using the camera module to read plates. The camera lamp must be provided sufficient time to warm up fully.
25	Perform the **Check Pipettor Reference**, **Positions Check** (PosCheck) **Pipettor Self Check** and **Pipettor Verification Test** (PipTest) maintenance tasks to confirm proper probe performance. **Note:** Look at the syringe(s) used in the probe replacement(s) to ensure that there is no leakage of fluid at the knurled screw interface on the 3-way valve. Leakage of fluid may indicate an inadequately positioned plastic washer and/or tip.

Cleaning the Reader Mirror and Light Diffuser

Purpose

The purpose of cleaning the reader mirror and light diffuser is to remove spills or dirt hampering the reader functionality.

You must perform this task as needed, such as when spills or dirt are identified as hampering the reader functionality.

Cleaning is also required if dirt or spills cause a test plate to be aborted at the clean read stage.

Required Tool(s)

The following tool(s) are required to complete this task:

- Isopropanol wipes
- Clean dry absorbent laboratory disposable wipes
- Flash light

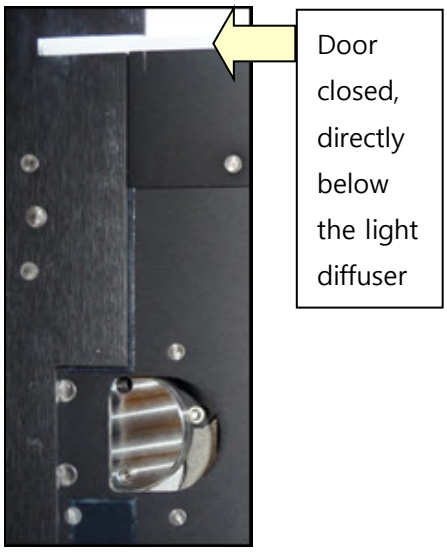
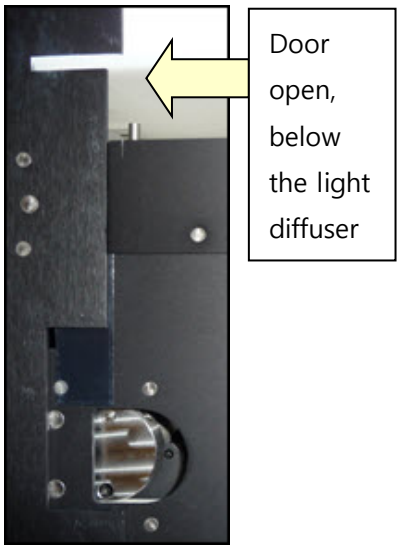
Procedure

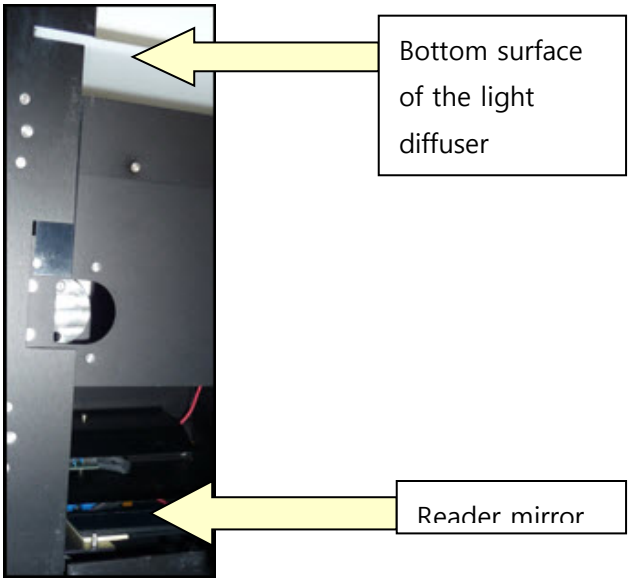
Note: Only follow this procedure when the NEO Iris is **switched off**.

To clean the reader mirror and light diffuser:

Step	Action
1	Power off the NEO Iris module.
2	Lift up the NEO Iris hood.
3	Move the 4-probe arm to the far right of the supporting X-rails.

Step	Action
4	Unscrew the two thumb screws holding the reader protective cover plate in place. Both screws are located on the top right and left corner of the cover plate respectively. These two screws are kept in place, by using internal springs to attach the screws to the cover plate when unscrewed from the body of the instrument.  Reader protective cover plate  Close-up of thumb screw in the top right corner of the cover plate
5	Lift the cover plate away from the body of the instrument and remove it from the instrument cavity. Store it in a safe location away from the instrument. The reader is visible when the cover is removed.

Step	Action
6	So that the light diffuser can be accessed for cleaning, the reader door must be opened to expose the bottom surface of the diffuser. A silver rotating wheel can be used to open or close the reader door. The hole in the silver wheel is in the top position when the door is closed (circled in yellow in the photo below). If the door is closed, open the door by using your finger to turn the silver wheel approximately 180° in a clockwise direction so that the hole in the wheel is in the bottom position (circled in green in the photo below). The wheel is located to the left of, and below, the reader door.  Closed position  Open position  Closed position  Open position

Step	Action
7	With the aid of the flash light for illumination, use an isopropanol wipe to gently clean the bottom surface of the light diffuser and also the reader mirror. The reader mirror is on the bottom of the reader cavity and the bottom surface of the light diffuser is in the top of the reader cavity.  The top surface of the light diffuser, in the bulb cavity, can also be cleaned if needed. **Note: Do not** remove the light diffuser to clean it. **Note:** You should clean the light diffuser first, followed by the reader mirror.
8	With the aid of the flash light for illumination, use a clean dry absorbent laboratory disposable wipe to dry the bottom surface of the light diffuser and also the reader mirror (there must be no streaks left on the mirror). The top surface of the light diffuser, in the bulb cavity, can also be dried if needed.
9	Lift the cover plate onto the body of the instrument through the instrument cavity. The internal cavity of the reader is now not visible when the protective cover is in place.
10	Screw the two thumb screws clockwise to secure the protective plate in place.
11	Close the NEO Iris hood.
12	Power on the NEO Iris module.

Step	Action
13	Complete the **Take Flatfield Images** maintenance task.  **Limitation:** The instrument must be switched on for at least thirty (30) minutes prior to beginning **Take Flatfield Images** maintenance task so that the reader lamp can warm up.

Changing the Camera Lamp

Purpose

The purpose of changing the camera lamp is to replace a malfunctioning lamp.

You must perform this task as needed, such as when the reader functionality is inadequate due to the lamp malfunctioning.

Procedure

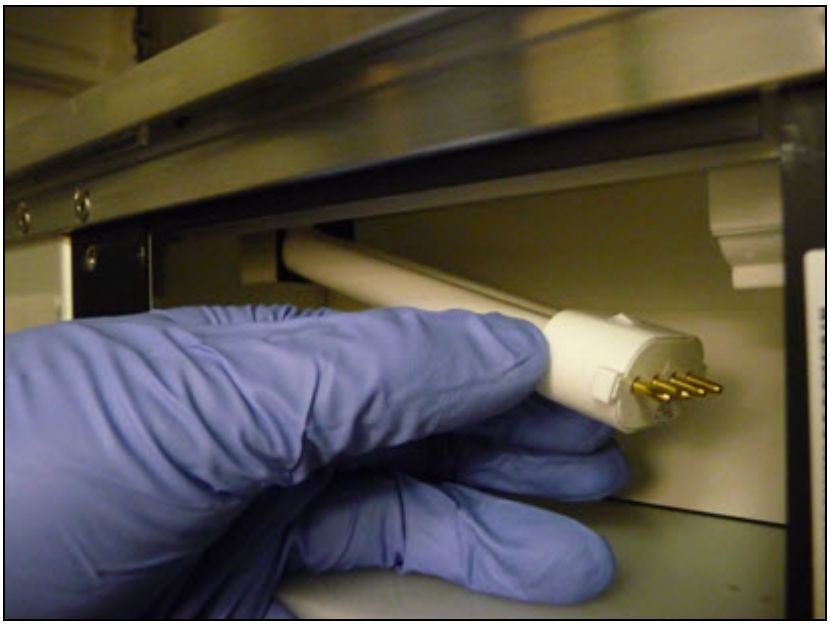
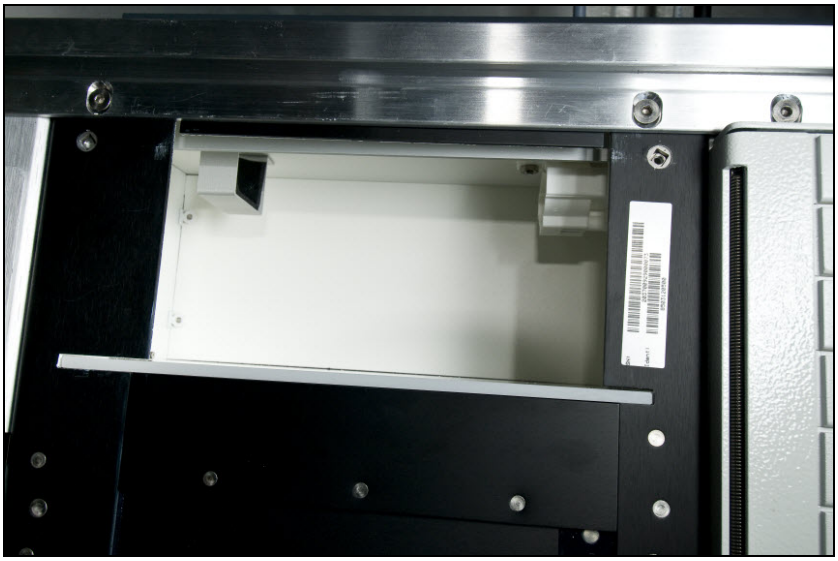
 **Note:** Only follow this procedure when the NEO Iris is **switched off**.

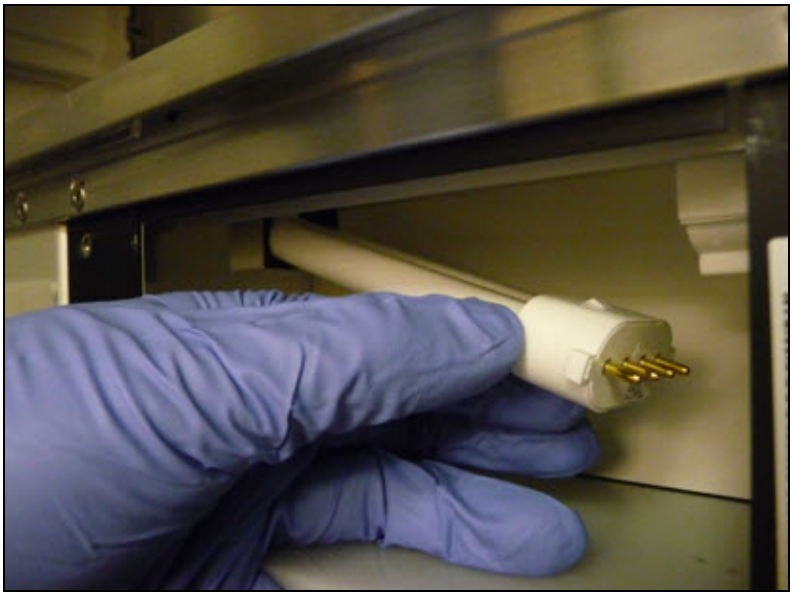
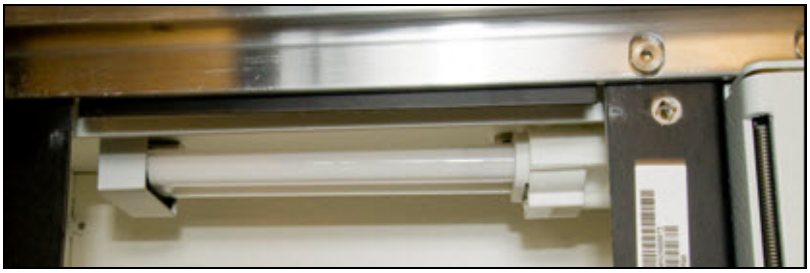
To change the camera lamp:

Step	Action
1	Power off the NEO Iris.
2	Lift up the NEO Iris hood.
3	Move the 4-probe arm to the far right of the supporting X-rails in the main body of the NEO Iris module.

Step	Action
4	Unscrew the two thumb screws holding the reader protective cover plate in place. Both screws are located on the top right and left corner of the cover plate respectively. These two screws are kept in place, by using internal springs to attach the screws to the cover plate when unscrewed from the body of the instrument.  Reader protective cover plate  Close-up of thumb screw in the top right corner of the cover plate
5	Lift the cover plate away from the body of the instrument and remove it from the instrument cavity. Store it in a safe location away from the instrument. The reader is visible when the cover is removed.
6	Open the door of the Plate Loading Tower and remove all of the plates from the tower. **Note:** Steps 6, 7, 8, 9, and 10 are the recommended best practice steps to remove and replace the lamp through the empty Plate Loading Tower. It is possible to remove and replace the lamp through the main body of the NEO Iris module. However the benefits of using your left hand through the Plate Loading Tower aperture are that: a. You will reduce the risk of damage to the 4-probe pipettor arm. b. You will also be able to stand looking through the main body of the NEO Iris module so that you can visually coordinate the use of your left hand, and not just rely on the use of tactile hand navigation.

Step	Action
7	Using your left hand, reach into the top of the exposed camera reader module through the open and empty Plate Loading Tower and grip the exposed base of the camera lamp, just visible above the camera lamp socket.  **Note:** The socket is to the right of the horizontal lamp installation assembly. Pull the lamp horizontally to the left, away from the lamp socket. **Note:** The glass tip of the lamp on the left hand side of the lamp installation rests in an open ended bracket that suspends the bulb from the top of the camera module.

Step	Action
8	Once the malfunctioning lamp is detached from its socket, angle the bulb down to gently remove it from the open ended bracket. Remove the lamp from the instrument through the Plate Loading Tower.  The brackets will now be empty (shown below). 

Step	Action
9	Using your left hand, insert the new lamp through the Plate Loading tower and hook the glass tip of the lamp into the open ended bracket on the left hand side of the lamp installation. Make enough clearance on the right hand side so that the lamp base can be pushed horizontally into the lamp socket. 
10	Push the lamp base firmly into the lamp socket. **Note:** the glass tip of the lamp should be held by the open ended bracket on the left hand side of the lamp installation. 
11	Lift the cover plate onto the body of the instrument through the instrument cavity. The internal cavity of the reader is now not visible when the protective cover is in place. **Note:** There is a sensor bracket at the base of the cover plate that must be slid into place at the base of the cover aperture.
12	Screw the two thumb screws clockwise to secure the protective plate in place.

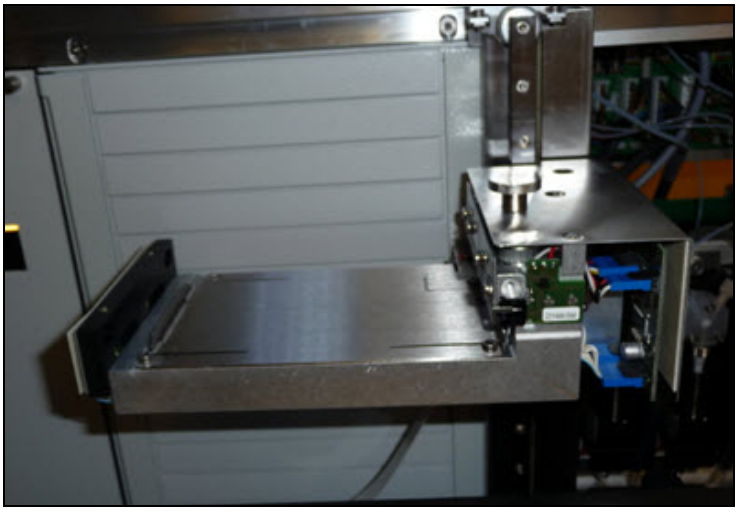
Step	Action
13	Close the NEO Iris hood.
14	Power the NEO Iris on.
15	Contact Technical Support to determine whether additional activities are required.

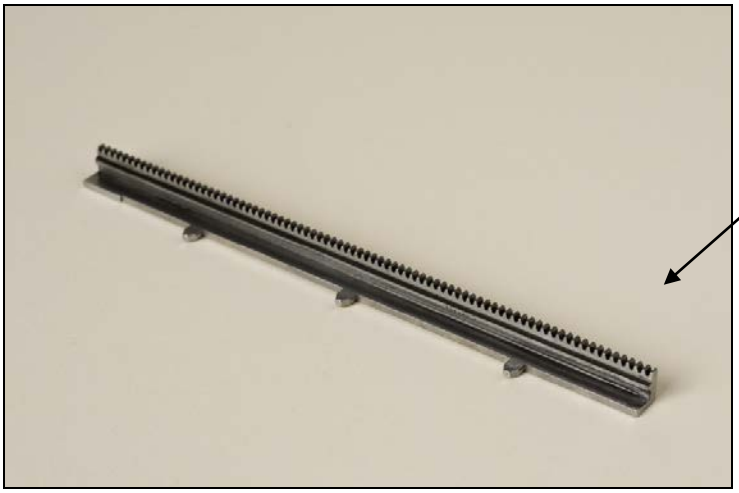
Replacing the Y-pusher

While performing error recovery after a plate jam, care should be taken when removing plates from the plate transport. If too much force is applied when removing the plates, it is possible that the Y- pusher may separate from the plate transport. Therefore it must be returned back to its correct location for correct NEO Iris operation to occur.

About the Y-pusher

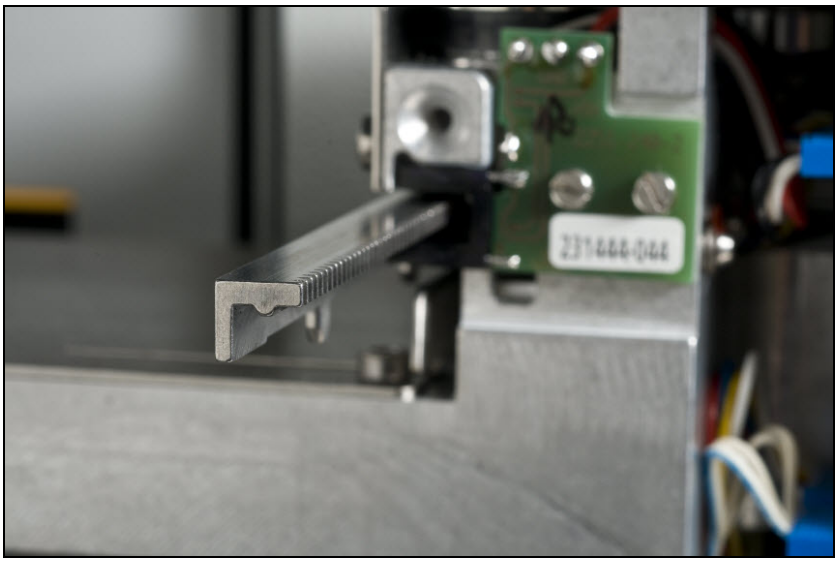
The Y-pusher is located on the plate transport. The Y-pusher is the arm that moves the plates onto and off the transport.

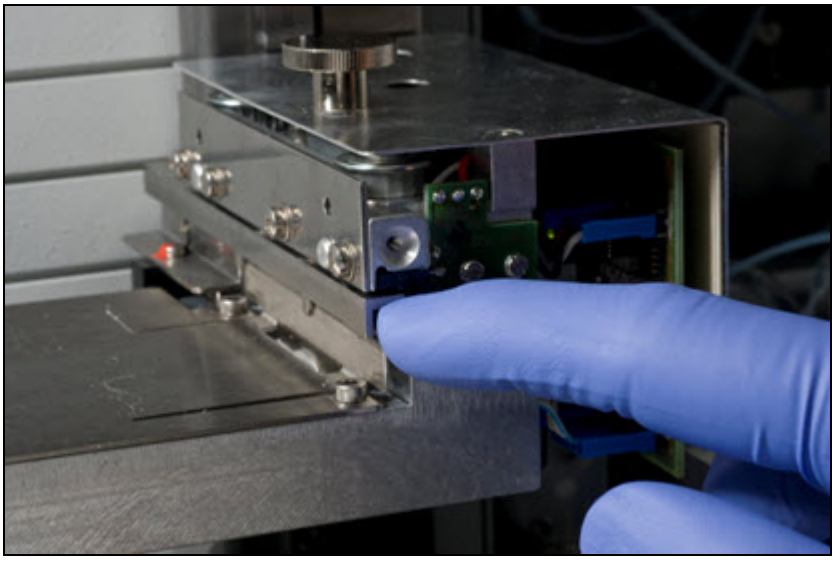




Procedure

To replace the Y-pusher:

Step	Action
1	Power off the NEO Iris module.
2	Open the NEO Iris hood.
3	Move the transport to an accessible position. **Note:** You must always use the silver knob on the top of the transport to move the transport around. Do not use any other part of the transport.
4	Position the Y-pusher with the teeth facing to the right and the 3 prongs facing downwards, so that the pusher looks like an upside down L. 

Step	Action
5	Gently slide the Y-pusher fully back into position by pushing it with your fingertip.  As you push, the Y-pusher should move freely, with some mechanical resistance, through the Y-axis plane of the NEO Iris module. 
6	Close the NEO Iris hood.
7	Power on the NEO Iris module. **Note:** After replacement of the Y-pusher, monitor the NEO Iris for transport related errors. Contact Technical Support if you need additional assistance.

Chapter 11: Troubleshooting the NEO Iris

In This Chapter

The NEO Iris is designed to automate error-free processing of blood samples. Nevertheless, errors can occur in practice. This chapter contains instructions on how to overcome such errors with minimum loss of assay results. Help screens are available in the software to aid you in error situations.

The Troubleshooting Process Steps

Troubleshooting consists of implementing a practical, systematic approach to problem solving. This approach focuses on:

- Observing, recognizing, and categorizing symptoms
- Identifying the probable cause(s)

The following troubleshooting model describes a four-step approach to defining symptoms, identifying problems, and implementing solutions. When troubleshooting the instrument you should also include considerations appropriate to your specific environment.

Identify the Problem

The first step in the troubleshooting approach is to identify the error. It is important to clearly state the error or problem with cause unknown.

Data Gathering

The second step in troubleshooting is data gathering. The observations, data and clues about the problem are collected in this step, without attributing any one clue or observation as the cause.

Four questions must be asked:

- *What*? For example, what operation was being performed at the time of the error?
- *When*? For example, when did the error occur?
- *Where*? For example, where did the error occur?
- *Who*? For example, who was operating the instrument when the error occurred?

It is important to make sure that data and observations be collected without attempting to determine the cause of the problem. All relevant data will be evaluated in the next step. It can be helpful to ask the following questions:

- ▶ What object is affected?
- ▶ What other objects could be affected but are not?
- ▶ Where do you see the problem?
- ▶ Where else could I expect to see this problem occur?
- ▶ Where on the object/instrument does the error occur?
- ▶ Where else on the object/instrument could this problem occur?
- ▶ When did the problem first occur?

- When else could the problem have occurred?
- When in the process flow does the problem occur?
- When else in the process flow has the error occurred?
- Is the problem repetitive?
- Is the problem random?
- In what pattern does the problem occur?
- How else could the pattern repeat itself?
- Does the problem occur for all operators?
- Does the problem occur for a specific operator?

Evaluate Cause

Once all relevant data, clues and observations have been gathered an evaluation can be performed. If you have experience with the problem it is acceptable to prioritize clues and observations to generate likely causes. Depending on the amount of data and the error being encountered it may be important to implement various evaluation methods.

Ask the following questions:

- Based on the data, what appears to be the likely cause?
- Based on my experience, what clues appear to be a likely cause?

Action Plan

Once the evaluation step is completed and a likely cause has been identified, the final step in troubleshooting an error is to implement an action plan. This step often consists of a standard operating procedure or some other step wise instruction that addresses or remedies the likely cause that was isolated in the previous step. Should the action plan fail to produce the expected change in the problem it would be necessary to return to the data gathering step and continue until the actual likely cause is identified and remedied

Using Error Codes to Troubleshoot

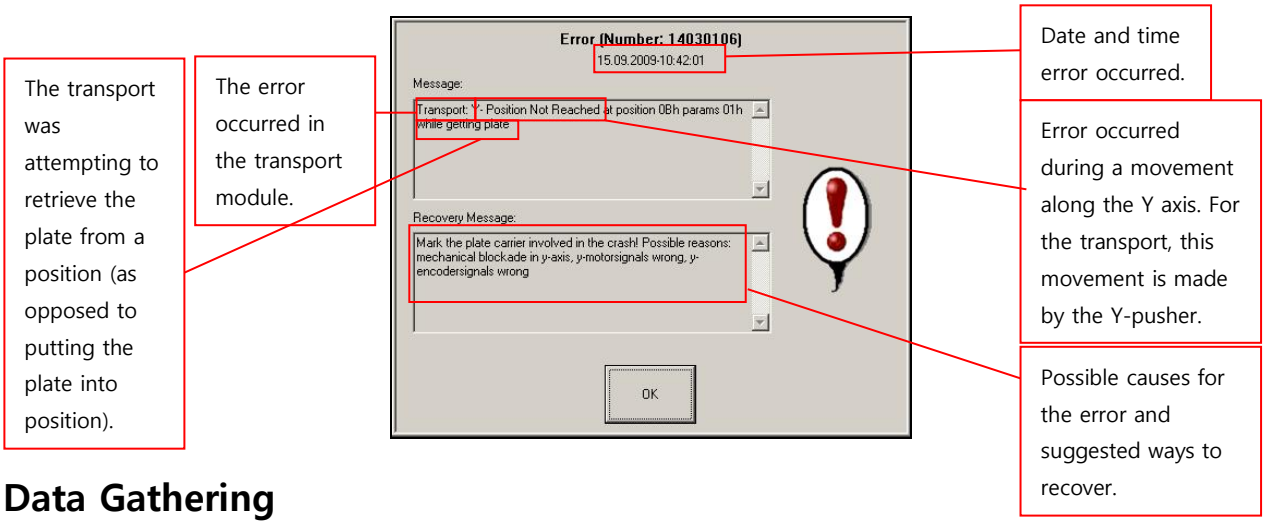
Error codes display when the instrument needs to provide you with some additional information or if something is causing the instrument to function improperly. You can apply the previously described troubleshooting steps.

Identify the Problem

The first step is to read the error message.

As a best practice, it is recommended that the operator press **F12** on the keyboard to silence the alarm and then press **Print Screen** on the keyboard to print the error message for future reference. The printed error message can be used as a tool by Technical Support to help make an accurate diagnosis.

It is essential that you determine what the error is before trying to recover from it. For example, in the error message below, you can determine the following:



Data Gathering

Observe the error code and instrument to gather information about the failure. Ask questions appropriate to the troubleshooting process to gather specific relevant data.

Evaluate Cause

Based on observations and the data gathered during the previous step it is important to isolate the likely cause of the hardware failure. The error code generated above indicates a hardware failure. The last two to three words of the error code normally identify the step at which the error occurred. The recovery message may also give clues to the likely cause of the error.

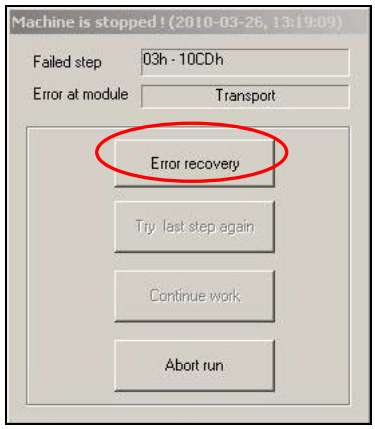
Note: The recovery messages for some errors instruct the operator to "Call Service". If you are able to recover from the error then it is not necessary to call Technical Support.

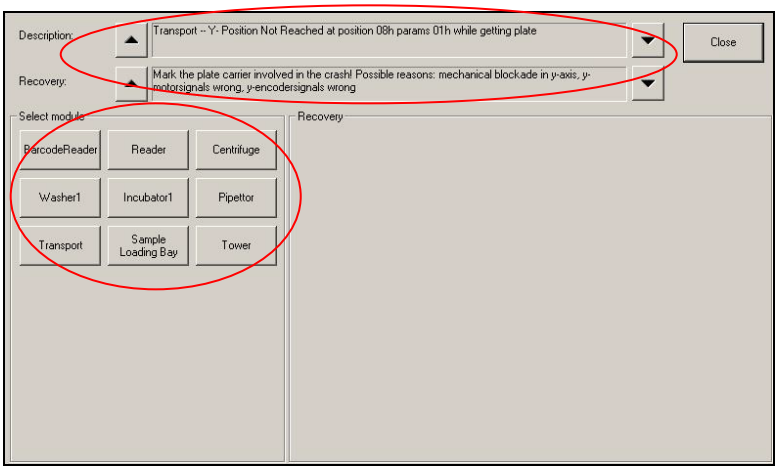
Action Plan

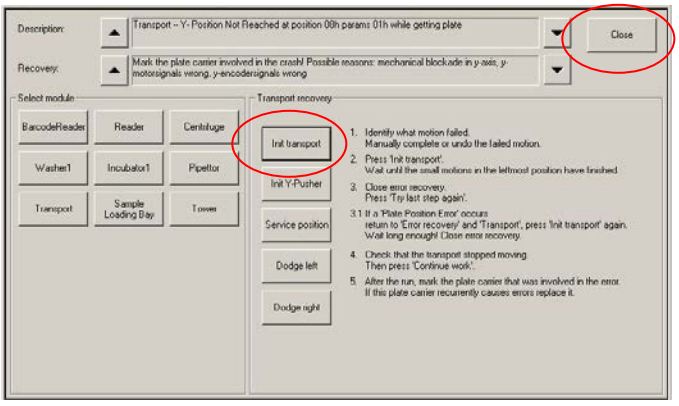
When acting to fix a hardware failure you must first clear any jam or blockade before initializing the module in question to prevent further errors and complete error recovery. You must manually clear the error and complete the step at which the error occurred or let the instrument make another attempt at completing the step at which the error occurred before continuing work.

Warning: During error recovery, the process control allows you to open the safety hood to access components manually. You must be cautious during manual instrument deck interventions, because while you resolve an error in one system module, other operations may remain active.

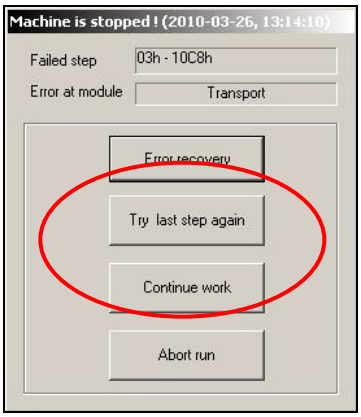
After completing your assessment of the likely cause, determining an action plan, and clearing any blockade, Error Recovery must be performed. The following steps will guide you through the Error Recovery process.

Step	Action
1	Press the **OK** button in the error message dialog. This silences the audible alarm, if it has not already been silenced by using the **F12** key. The *Machine is Stopped!* dialog is displayed on the screen, allowing access to the *Error recovery* dialog, via the **Error recovery** button. 

Step	Action
2	Always press the **Error recovery** button in the *Machine is stopped!* window to enter the *Error Recovery* window and, from there, perform manual or software supported error recovery actions.  The *Error Recovery* window provides initialization and recovery functions for each module. This window allows you to recover from the error or to abort the run immediately. **While you are in this window you will be able to open the safety hood without signaling the audible alarm and to manually manipulate the affected modules.** The *Description* and *Recovery* fields provide guidance as to the potential causes at the top of the window. The first word of the error message lists the module the error affected.

Step	Action
3	Press the appropriate module button from the *Select module* area. This will display recovery buttons and processes for the selected item.  Remember that, in most cases, the first word in the error message tells you which module you need to work with. Refer to the print screen you obtained of the original error if necessary. You should clear any visible blockade or plate jam before initializing the module, or you may cause further errors. Further errors could delay the error recovery process and ultimately exceed processing limits for some assay steps, leading to invalidated plate results. Once you select the module you will be working with, several buttons will become visible on the right side of the error recovery screen. The number of recovery buttons and processes vary between modules and are used to initiate movement of the components, or initialize the module. Some modules may only allow you to initialize the module, while others may also allow you to move a module to a specific position or to open and close a door. Initializing the module should be the first button selected in this window, after clearing any blockades. Once initialization is complete, other options may become available, if necessary, to complete error recovery. During the error recovery process, the instrument should be returned to the step at which the error occurred or the step immediately following the step at which the error occurred. This will depend on what was manually performed and what actions were performed when the module was initialized. The individual module error recoveries are described later in this chapter. **Note**: If the error occurred in the pipettor or washer module you should always select the **Abort plate** option after initializing the module in *Error recovery*.

Step	Action
4	When you are finished in the *Error recovery* dialog, press the **Close** button in the upper right corner of the window. 

Step	Action
5	You will again see the *Machine is stopped!* dialog, but note that the two middle buttons are now available to you:  **Try last step again** should be selected if you have not completed the step in which the error occurred either manually or via the software. This will signal the instrument to make another attempt to complete the step. For example, if the plate was being pulled onto the transport, and following initialization the plate is still not on the transport, **Try last step again** will signal the instrument to make another attempt to place the plate carrier onto the transport. Once the step is successfully completed, you will need to press **Continue work**. **Continue work** should be selected if: • You have manually completed the step in which the error occurred. For example, the transport experienced an error while getting the plate and, after resolving the error, you manually placed the plate onto the transport. • You have already selected **Try last step again** and that step was successfully completed by the instrument. • You have already selected **Try last step again** and no movement was made by the instrument. **Abort run** should be selected if you wish to abandon all plates in process or if you cannot recover from the current error. If this is selected, you should reinitialize the instrument before scheduling more tests. If **Continue work** is selected, all assays will resume processing and the affected plate will be flagged with the error. For any plate, the results will be invalid if the mechanical error occurred at the pipettor or washer modules or the plate remains in the incubator for more than 60 minutes.

Step	Action
	Hemagglutination assay plate results will be invalid if the plate is prevented from going from the centrifuge to the reader within a software encoded time, because of the risk that negative results, having suspended red blood cells, will have cells settling out and therefore cause reader interpretation problems. Solid Phase Red Cell Adherence plate results will be invalid if, following the pipetting of indicator red cells, the plate is prevented from going into the centrifuge within a software encoded time, because of the risk of indicator red cells being neutralized and therefore cause the subsequent risk of false negative results. Capture plate results will be invalid if, following the plate wash step, the plate is prevented from going to the Pipettor station within a software encoded time, because of the risk of monolayer drying, which could cause erroneous results.

Troubleshooting Software Failure

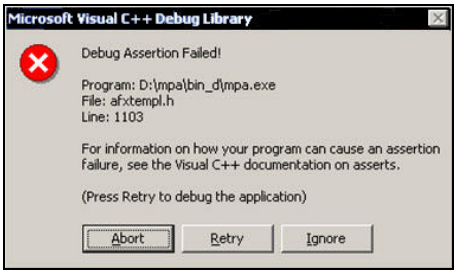
Although the instrument software is designed to minimize the occurrence of failures, you cannot entirely avoid software failures. The instrument design allows the hardware to continue working for some time, even when the main PC software is no longer running. This feature is dependent on the module activity at the time of the software failure.

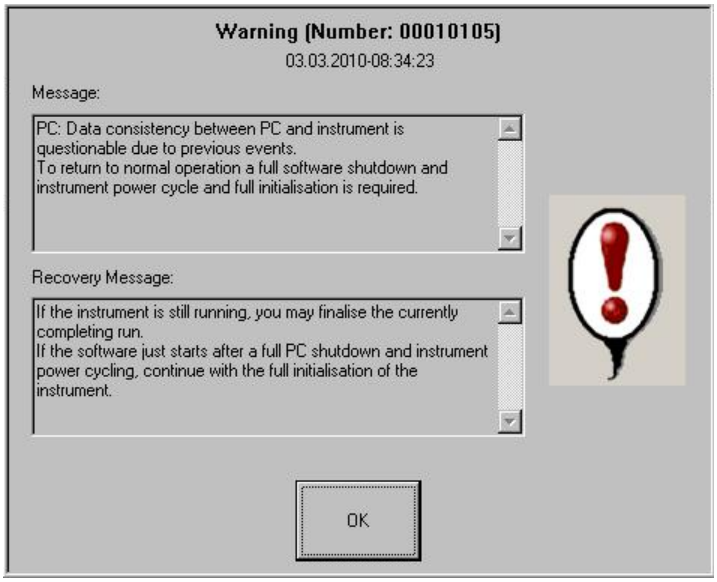
An example of a module activity that will continue in the event of software failure is the incubation phase of the incubator. This feature provides a chance to recover from a software failure without losing the assay run during which the failure occurred.

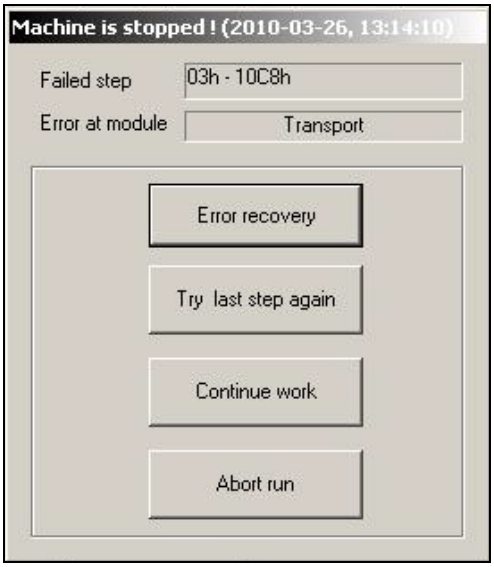
Note: You can try to complete the current run after software failure, but you must reboot the PC and power cycle the instrument before new runs can be started.

Resolving Software Failure Errors

To resolve software failure errors:

Step	Action
1	If the software fails, the system displays one of two error messages, the *Program Error* window or the *Microsoft Visual C++ Debug Library* window.  When the system displays the *Program Error* window, do not press **Cancel**. After the system creates an error log, the **Cancel** button changes to **OK**. You may then press **OK**. The system closes the message box and returns to the normal user interface.
2	 Press the **Retry** button in the *Microsoft Visual C++ Debug Library* window. The system creates an error log. The system closes the message box and returns to the normal user interface.
3	The system displays a *Create Diagnostic Archive* icon on the Windows desktop. Double-click this icon to automatically generate an archive of all information available about this software failure. In addition, you must make a note of the following information: • Date and time of software failure. • Description of operator actions before the error occurred. • Description of instrument actions before the error occurred. Call Technical Support with this information regarding the software failure.

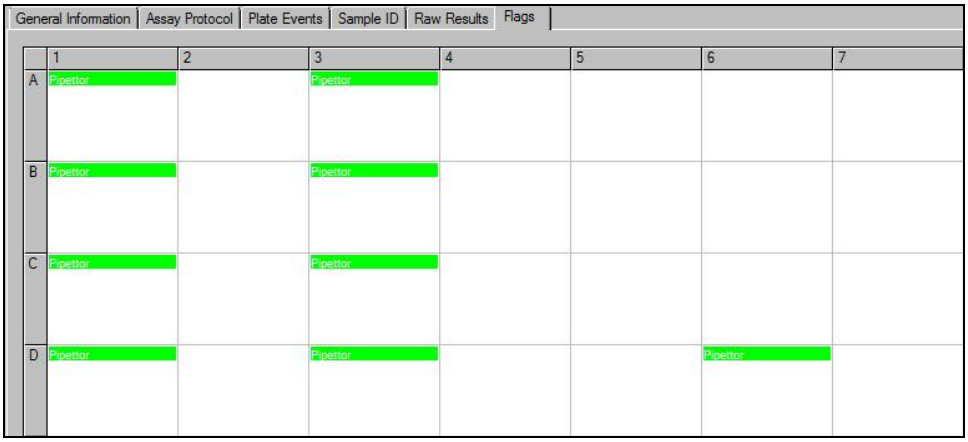
Step	Action
4	After collecting this information, restart the computer. This clears any partial software components still active in the memory and automatically restarts the main application. Because of the time these actions take, the instrument may have stopped moving and will automatically reactivate.
5	After logging into the software, the message regarding *Data consistency* will appear indicating that the software was improperly closed. All runs in progress will complete (if they were not performing a critical step) and the system will require a full shutdown and initialization prior to new runs being started. Press the **OK** button. 
6	However, because of the time delay, it is possible that the system will display a **Pipettor answer time-out** error message or there may be a visible stoppage in processing without an error message. To clear this message, you must press the **OK** button to enter the error message. If there is a visible stoppage, the instrument and software must be shutdown and initialized to continue.
7	You must then immediately press the **Close** button to exit the Error recovery window.

Step	Action
8	Press the **Continue work** button on the *Machine is stopped!* dialog.  In many cases, the instrument continues the current run and provides results for all plates that were active or scheduled when the failure occurred. However, errors in system processing can continue to occur, and you may be forced to abandon the run. If the instrument cannot recover following a software failure, it either does not start when you press the **Continue work** button, or stops again after a few actions. Any runs that do complete after the software had been unexpectedly closed will have a warning flag associated with them indicating this. The results are valid; however it is recommended the plates are viewed and verified for accuracy. **Warning:** After the current run is finished, you MUST shut down the software again, turn off the instrument, and then restart. If the attempt to complete the run fails, you must also shut down both the software and the instrument, and then restart. Normal operation resumes only after this complete shutdown of the instrument and the PC.

Pipettor Self Check Failures

Expected Results

When the Pipettor Self Check maintenance task is performed and the pass status is achieved, there are wells that are expected to be flagged and also wells that are expected to not contain flags. The expected sequence is illustrated in the screen image below.



Column	Expected Flags
1	Not Enough Liquid or No Liquid flags are acceptable
2, 4, 5, 7	No flags should be present
3 and 6	Not Enough Liquid Flags only are acceptable – No Liquid flags will cause the task to fail

During the task, each instrument probe pipetting activity can be mapped to a collection of wells. The pipetting map is described in the table below.

Note: The number 4 left probe is the probe furthest away from the front of the instrument and number 1 is nearest to the front.

Mapping	Left Probes	Right Probe
Row A (columns 1-4)	4	
Row B (columns 1-4)	3	

Row C (columns 1-4)	2	
Row D (columns 1-4)	1	
Row D (columns 5-7)		Right probe

Troubleshooting Failures

In the event of a failed status for the Pipettor Self Check task, you must view the plate flags to investigate the possible reasons for failure. There are many different reasons why the task can fail and from a troubleshooting perspective, the pattern or sequence of additional unexpectedly flagged or un-flagged wells can indicate the most likely causes of the failure. Some possible causes of failure are listed in the table below with some recommended recovery steps.

Note: The final step of any recommended recovery is to repeat the Pipettor Self Check task. You must contact Immucor Technical Support to report the problem if the recommended recovery is unsuccessful and the consequence is a persistently failing Pipettor Self Check task.

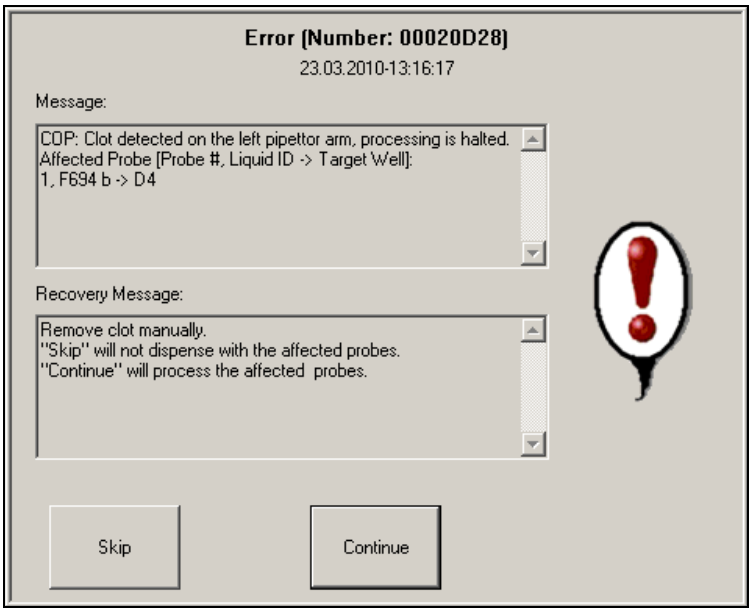
Column Number and Feature	Possible Reason for Failure	Recommended Recovery
No flag is generated for at least one of the wells in **column 1**	Aspiration failure – Possibly due to a blocked probe or failed syringe.	Inspect the syringes for leakage and replace as needed. Perform Initialization and any additional required maintenance as prescribed.
Flags are present in any of the wells of **column 2**	Air in the system liquid lines.	Initialize the instrument. Verify the connections of the pump rack location (below the syringes) if the air cannot be removed by priming. Reconnect any loose connections and repeat the system liquid priming.
	Syringe is damaged or is leaking and it may not be delivering enough liquid to the wells.	Inspect the syringes for leakage and replace as needed. Perform Initialization and any additional required maintenance as prescribed.
	Probes taught too high and unable to aspirate all of the	Verify Check Pipettor Reference positions are acceptable and verify the PCheck tool was

Column Number and Feature	Possible Reason for Failure	Recommended Recovery
	liquid in the tool.	properly loaded in transport frame
No flag is generated for at least one of the wells in **column 3**	Aspiration failure – Possibly due to a blocked probe or failed syringe.	Inspect the syringes for leakage and replace as needed. Perform Initialization and any additional required maintenance as prescribed.
No Liquid Flag generated in **column 3**	Probe(s) taught too high and unable to detect the remaining liquid	Verify Check Pipettor Reference positions are acceptable and verify the PCheck tool was properly loaded in transport frame
Flags are present in any of the wells of **column 4**	Air in the system liquid lines (which might be the result of a leak from the pump rack connections or the de-bubbler mechanism).	Initialize the instrument. Inspect the connections of the pump rack location (below the syringes) and also the de-bubbler mechanism if the air cannot be removed by priming. Reconnect any loose connections and repeat the system liquid priming.
	A rinse pump has failed and is not dispensing system liquid.	Contact Immucor Technical Support to report the problem.
	Too much foam is generated during the rinsing step.	Contact Immucor Technical Support to report the problem.
Flag is present in well **D** of **column 5**	Air in the system liquid lines.	Initialize the instrument. Verify the connections of the pump rack location (below the syringes) if the air cannot be removed by priming. Reconnect any loose connections and repeat the system liquid priming.
	Syringe is damaged or is leaking and it may not be delivering enough liquid to the wells.	Inspect the syringes for leakage and replace as needed. Perform Initialization and any additional required maintenance as prescribed.
No flag is generated for well **D** in **column 6**	Aspiration failure – Possibly due to a blocked probe or failed syringe.	Inspect the syringes for leakage and replace as needed. Perform Initialization and any additional required maintenance as

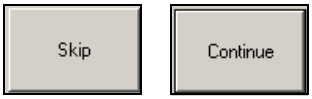
Column Number and Feature	Possible Reason for Failure	Recommended Recovery
		prescribed.
No Liquid Flag generated in **column 6**	Probe(s) taught too high and unable to detect the remaining liquid	Verify Check Pipettor Reference positions are acceptable and verify the PCheck tool was properly loaded in transport frame
Flag is present in well **D** of **column 7**	Air in the system liquid lines (which might be the result of a leak from the pump rack connections or the de-bubbler mechanism).	Initialize the instrument. Inspect the connections of the pump rack location (below the syringes) and also the de-bubbler mechanism if the air cannot be removed by priming. Reconnect any loose connections and repeat the system liquid priming.
	A rinse pump has failed and is not dispensing system liquid.	Contact Immucor Technical Support to report the problem.
	Too much foam is generated during the rinsing step.	Contact Immucor Technical Support to report the problem.

Clot Detection Recovery Process

If a probe detects a clot during sample aspiration, the system displays an error message alerting you to the event, and the probe remains stationary above the tube in question. This is your opportunity to inspect the tip of the probe for any hanging clots. If visible hanging clots need to be removed, lift up the NEO Iris hood while the error message is still being displayed and use an absorbent dry wipe to remove the hanging clot and clean the tip of the probe. If no hanging clots are visible, use either the **Skip** or **Continue** button to proceed.



You can press either the **Skip** or **Continue** button to clear the error message and cause the NEO Iris to proceed according to two (2) different protocols.



By pressing the **Skip** button, the probe is sent to the wash tower for cleaning before processing the remaining on-board samples. The sample that had contained the clot is bypassed and no results will be generated for that sample.

By pressing the **Continue** button, the probe will retry the sampling of the tube that was identifed as containing the clot. Repeating this aspiration step may cause another clot detection error. The clotted sample may be taken off the NEO Iris for further testing by an alternative methodology if required.

Troubleshooting Plate Transport Errors

Introduction

This section describes errors in the plate transport. They include

- Symptom 1: The plate transport does not get a plate out of a module.
- Symptom 2: The plate transport fails to put a plate into a module.

Note: If a plate transport error occurs, then it is recommended to mark the plate carrier involved with an identifying mark so that if additional plate transport errors occur in the future, the initial plate carrier can be tracked to determine if the causative factor is related to a specific defective plate carrier.

Common Causes of Plate Transport Errors

You may encounter various issues that can prevent the plate transport from working properly. The causes are separated into two types: those you may encounter during routine operation of the instrument, and those you may encounter during the error recovery process. You must be aware of these causes and the impact they can have on your NEO Iris.

Common causes during normal operation include, but are not limited to:

- Failure to snap the plate completely into the carrier (crashes at the reader)
- Strips that are not snapped completely into the frame (possible crash at reader or incubator)
- Object or material dropped into the path of the transport (impedes transport movement)
- Use of broken plate carriers (loose/missing pieces can impede movement of transport or Y-pusher)
- Failure to place the plate completely into the plate loading tower without closing the door (Y-pusher cannot reach plate to remove from tower)
- Loading a plate into the plate loading tower while the transport is accessing the tower (plate moves too far and impedes the transport as it moves in the X direction)

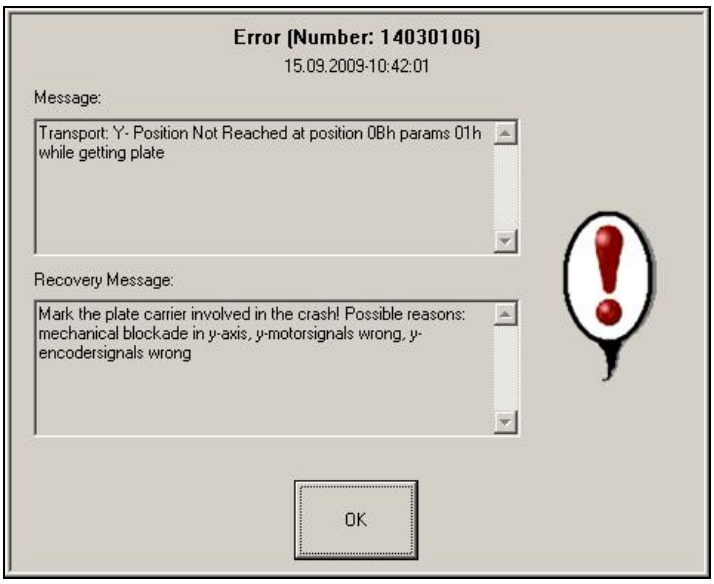
Common causes for additional errors during error recovery include, but are not limited to:

- Applying too much pressure to the Y-pusher when removing plates (causing misalignment of the Y-pusher)
- Not clearing a plate jam before initializing the transport (transport crashes when it begins to move)
- Not selecting **Init transport** when initializing the transport (transport may not be in the correct position to **Continue** or **Try last step again**)

Transport Fails to Remove a Plate from a Module

Error Message

Transport: Y-position not reached at position 08h params while getting plate



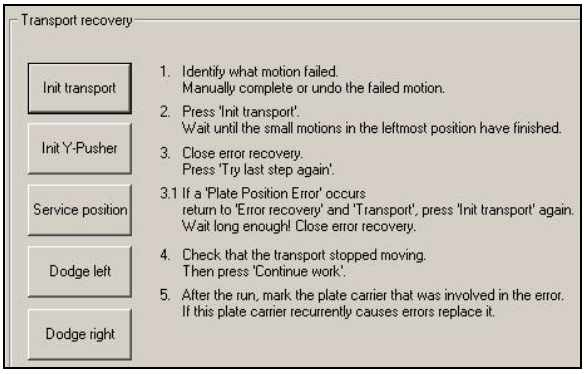
Potential Root Cause(s)

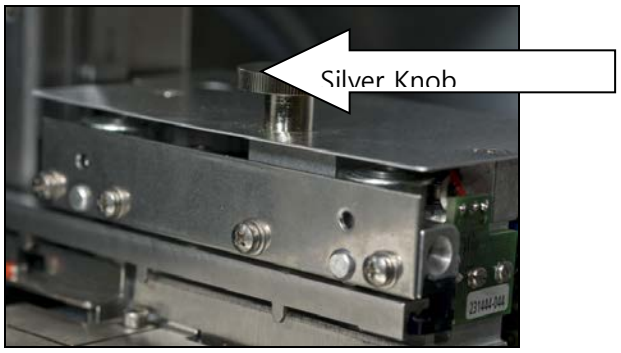
- Too much friction from the plate position in the module
- Transport frame broken or twisted
- Transport teach position at this module is sub-optimal
- Y-pusher may need to be cleaned

Procedure

To resolve this error:

Step	Action
1	Press the **F12** key to stop the alarm. Obtain a **Print Screen** of the message and then press the **OK** button on the message window.
2	The system displays the *Machine is stopped!* dialog**.** Press the **Error recovery** button.

Step	Action
3	The software is displaying the *Error Recovery* window. Press the **Transport** button. This will display recovery buttons and processes for the selected item.   **Note:** The **Init Y-Pusher** button can be used to initialize the Y-pusher. The **Dodge right** and **Dodge left** buttons can be used to slightly adjust the position of the transport. The **Service position** button can be used to move the position of the transport to the serviceable position **in front of the incubator module**.

Step	Action
4	Determine where the transport module is currently located on the instrument (Step 1 of on-screen instructions) **Scenario 1:** The plate carrier is still completely inside the position that it should have been taken from and the Y-pusher is partially or fully engaged in the plate carrier **OR** the plate carrier is partially pulled out of the position. The Y-pusher has encountered resistance during its motion. a. If the transport is at the reader, incubator, or either pipettor stations, open the hood to better access the transport b. Carefully grab the *Silver Transport Knob* (to the right of where the plate sits on the transport) and pull upwards slightly c. Push the plate fully onto the module or station that the transport is trying to pick it up d. Manually retract the Y-pusher back into the transport module e. Verify the transport can move freely f. Press the **Init transport** button (Step 2 of the onscreen instructions) and then follow the remaining on-screen *Transport recovery* instructions. Instructions are also available in step 3 of this procedure.  **Note:** If the plate transport must be moved, you must only hold the silver knob on top of the transport to move its position.

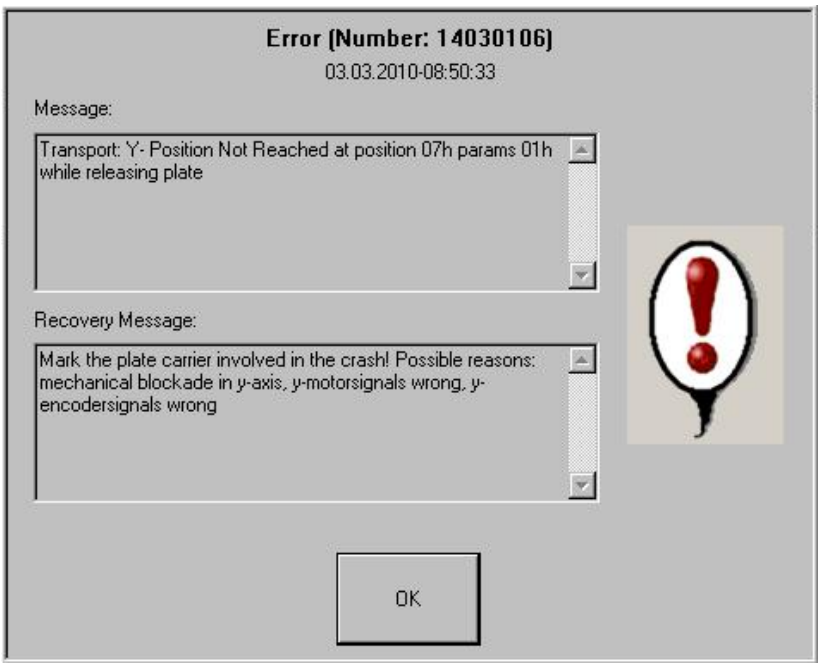
Step	Action
	Scenario 2: The plate carrier is still completely inside the position that it should have been taken from. The Y-pusher is not engaged in the plate carrier, because it encountered resistance while moving toward the plate carrier. The plate carrier is fully pulled out of its position and located almost on the plate transport. The carrier encountered resistance in the last few millimeters of the action. a. Press the **Init transport** button (Step 2 of the onscreen instructions) and then follow the remaining on-screen *Transport recovery* instructions. **Scenario 3:** The plate carrier is fully pulled out of its position and located almost on the plate transport. The carrier encountered resistance in the last few millimeters of the action. a. Press the **Init transport** button (Step 2 of the onscreen instructions). Do not press the **Try last step again** button because the failed step (i.e. unloading a. the plate onto the transport) has already been performed. Close *Error recovery* and then press the **Continue work** button.

Note: Refer to **Chapter 10 – Maintaining the NEO Iris** for information regarding the Y-pusher.

Transport Fails to Load a Plate into a Module

Error Message

Transport: Y-position not reached at position 08h params while getting plate

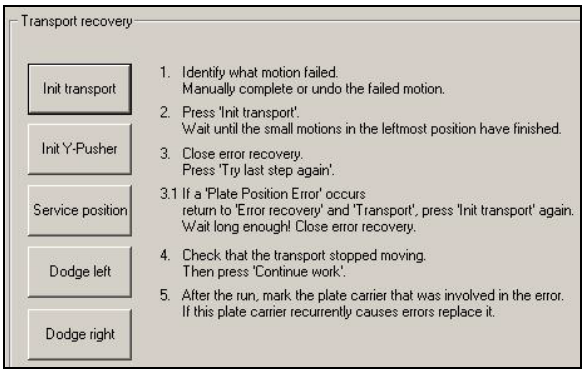


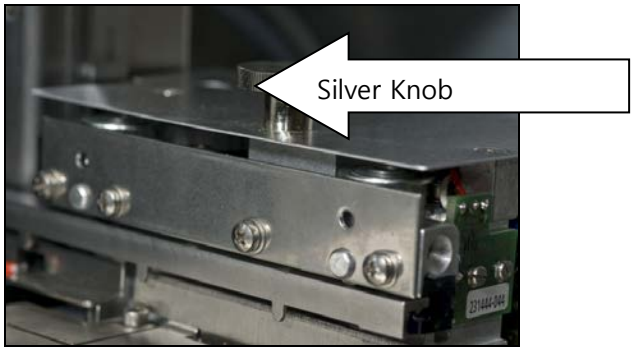
Potential Root Cause(s)

- Plate not seating fully in transport frame
- Transport frame broken or twisted
- Too much friction from the plate position in the module
- Transport teach position at this module is sub-optimal
- Y-pusher may need to be cleaned

Procedure

To resolve this error:

Step	Action
1	Press the **F12** key to stop the alarm. Obtain a **Print Screen** of the message and then Press the **OK** button on the message window.
2	The system displays the *Machine is stopped!* dialog**.** Press the **Error recovery** button.
3	The software is displaying the *Error recovery* window. Press the **Transport** button. This will display recovery buttons and processes for the selected item.   **Note:** The **Init Y-Pusher** button can be used to initialize the Y-pusher. The **Dodge right** and **Dodge left** buttons can be used to slightly adjust the position of the transport. The **Service position** button can be used to move the position of the transport to the serviceable position **in front of the incubator module**.

Step	Action
4	Determine where the transport module is currently located on the instrument (Step 1 of on-screen instructions) **Scenario 1:** The plate carrier is still almost completely on the transport system. It encountered resistance while moving toward the module position a. Press the **Init transport** button (Step 2 of the onscreen instructions) and then follow the remaining on-screen *Transport recovery* instructions. Instructions are also available in step 3 of this procedure. **Scenario 2:** The plate carrier is halfway inside the destination module position. The Y-pusher is partially or fully engaged in the plate carrier **OR** The plate carrier is almost completely in the module position. a. If the transport is at the reader, incubator, or either pipettor stations, open the hood to better access the transport. b. Carefully grab the *Silver Transport Knob* (to the right of where the plate sits on the transport) and pull upwards slightly. c. Push the plate fully onto the module or station that the transport is trying to pick it up. d. Manually retract the Y-pusher back into the transport module. e. Verify the transport can move freely. f. Press the **Init transport** button (Step 2 of the onscreen instructions). g. Do not press the **Try last step again** button because the failed step (i.e. loading the plate onto the destination module) has already been performed. h. Close *Error recovery* and then press the **Continue work** button.  **Note:** If the plate transport must be moved, you must only hold the silver knob on top of the transport to move its position.

Step	Action
	Scenario 3: The Y-pusher is no longer engaged with the plate carrier. It encountered resistance in the last few millimeters of the action a. Verify the plate is pushed fully onto the destination module Press the **Init transport** button (Step 2 of the onscreen instructions) and then follow the remaining on-screen *Transport recovery* instructions. Instructions are also available in step 3 of this procedure.

Note: Refer to **Chapter 10 – Maintaining the NEO Iris** for information regarding the Y-pusher.

Troubleshooting Pipettor Errors

Introduction

Various types of pipettor errors can occur, involving either the XYZ arm movements or the pumps. However, the recovery process to continue the current run is always the same. If the error is persistent, you are required to perform different actions to fix the various types of problems.

The complexity of the pipetting sequences renders it impossible for the system's error recovery routines to know exactly at which substep of a move the error occurred. Therefore, no **Try last step again** function is available for the pipettor, and no valid results can be expected from a plate that suffered a pipettor error.

The NEO Iris has two pipetting stations, left and right. Therefore two plates are frequently being pipetted simultaneously. For example, samples are transferred to a plate on the left side at the same time as reagents are dispensed onto a second plate on the right side. After a pipettor error, both arms need to be re-initialized, so the processing of both of these plates is disrupted.

After re-initializing the pipettor, it is recommended that you abort the processing of both affected plates. You can do this with the **Abort plate** button on the error recovery screen (if two plates are present, both are aborted). If you select this button, the remainder of the current pipetting sequence is finished, but then the system returns the plate(s) to the loading tower.

Warning: You should always select the **Abort plate** button (not the **Abort run** button). This will abort the plate with the error as well as the plate disrupted by re-initialization. Failure to select the **Abort plate** button allows processing to continue for a plate that may not be valid. If you select the **Continue work** button without aborting the plate, the system

will invalidate all results generated from the plate that suffered the pipettor error.

Pipettor Error Message

The *Message* field informs you

- That the pipettor is involved.
- Of the drive or component that failed.
- Of the error mode (open loop) during which the error occurred.

The *Recovery Message* field lists some possible reasons for failure and instructs you to call Technical Support for service.

The system can generate other error messages when the pipettor fails. The potential messages are:

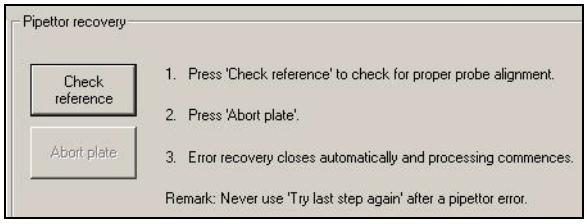
Error Message	Description
Left (or Right) X (or Y or Z) – Position not Reached.	The pipettor did not reach the position to which it was supposed to move. A mechanical blockage probably impeded the movement of the pipettor in the respective direction.
Left (or Right) Arm Move would cause Collision.	If the respective arm moves, the two arms would collide. Call Technical Support if this error occurs.
Move to undefined target.	The pipettor is sent to a target that is unknown to the pipettor. Call Technical Support if this error occurs.
Motor Error – Open Loop (Left or Right) X (or Y or Z) Overload.	The pipettor did not reach the position to which it was supposed to move. A mechanical blockage probably impeded the movement of the pipettor in the respective direction.
Diluter Error.	An error from the diluter pump. Call Technical Support if this error occurs.
Left (or Right) diluter answer timeout!	The dispense pumps did not communicate with the main processor on the instrument for an extended period of time. To rectify this error, open the **Error recovery** dialog and press the **Close** button (without initializing the pipettor), then press the **Continue work** button. The NEO Iris should proceed without causing an error.

Procedure

The initial recovery attempt to continue the current run is always the same, except for two error messages, *Diluter answer timeout* and *Left (or Right) Diluter answer timeout*. These can be recovered without causing a flag. All of the other causes require different solutions to resolve the underlying problem.

The table below describes how to troubleshoot a pipettor error:

Step	Action
1	Press the **F12** key to stop the alarm. Obtain a **Print Screen** of the message and then Press the **OK** button on the message window.

Step	Action
2	The system displays the *Machine is stopped!* dialog. Press the **Error recovery** button.
3	**The hood can be opened if needed.** The system displays the *Error Recovery* window. Press the **Pipettor** button. This will display recovery buttons and processes for the selected item. 
4	Check the NEO Iris to see where the pipettor probes are located. Lift the probes carefully upward out of any tubes or off of metallic surfaces. If the probes have visible red cells on them, gently clean each probe with an alcohol pad prior to continuing. Check to see if a probe was bent. If so, bend it back into a straight position at the very top of the probe while supporting the black probe adaptor with one hand.
5	Follow the on-screen *Pipettor recovery* instructions.
6	Press the **Check reference** button to verify the probe positions via the check pipettor reference maintenance task.  Perform any manual probe adjustments if necessary. **Note:** Refer to **Chapter 10 – Maintaining the NEO Iris** for more information regarding how to check the pipettor reference.
7	The **Abort plate** button becomes activated after the pipettor has been reinitialized. Press the **Abort plate** button to abandon processing of the plates that are on the pipetting stations.

Step	Action
8	A pop-up dialog indicating the plate(s) that aborted will appear and an audible alarm will be generated. The plate(s) will automatically be returned to the plate loading tower during the next scheduled transport step.  **Note:** There may be a delay before the plate is returned to the tower because the NEO Iris will wait until the time allotted for pipetting has expired.

Troubleshooting Centrifuge Errors

Introduction

Centrifuge recovery requires several manual steps, because centrifuge loading, centrifugation, and unloading consist of several substeps, each of which can fail. The **Try last step again** and **Continue work** buttons function on the substep level.

Centrifugation consists of the following system substeps and will be referenced below in the specific error recovery steps:

1. Place the plate on the load unit (a transport system step).
2. Open the centrifuge door.
3. Push the plate carrier into the centrifuge.
4. Close the centrifuge door.
5. Perform one or several centrifugation processes or shaking steps and brake afterwards.
6. Open the centrifuge door.
7. Pull the plate carrier from the centrifuge.
8. Close the centrifuge door.
9. Take the plate from the load unit (a transport system step).

For a successful recovery, the centrifuge, door, and load table subcomponents must ALL be in the appropriate states.

Centrifuge Fails to Initialize During Complete Initialization

Error Message

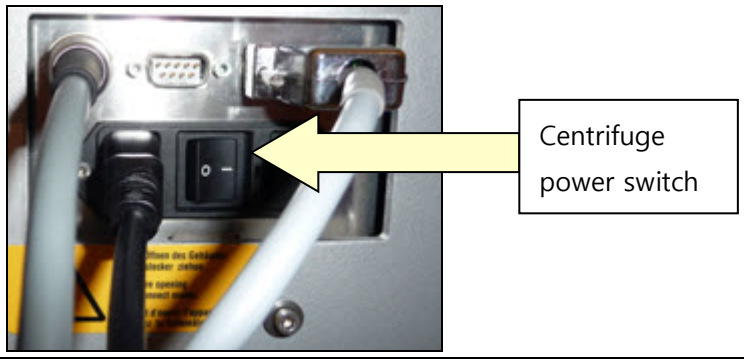
Centrifuge: Rotor Drive Error

Potential Root Cause(s)

- The main power for the centrifuge is OFF
- Something is obstructing the rotor movement
- Mechanical failure
- Failed recovery from previous mechanical error

Procedure

To resolve this error:

Step	Action
1	Press the **F12** key to stop the alarm. Obtain a **Print Screen** of the message and then press the **OK** button on the message window.
2	Press the **Abort run** button.
3	Cancel the initialization process by pressing the **Cancel** button in the current initialization window.
4	Verify that the mains power switch for the centrifuge is turned **ON** (the switch must be depressed in the **I** position). **Note:** The centrifuge power switch is located at the rear of the centrifuge near the power cord. 

Step	Action
5	Begin the NEO Iris initialization process by pressing the initialization main menu bar button and confirming the initialization process on the resulting confirmation dialog. 
6	Troubleshooting is complete if the initialization completes without error. If the error occurs again, continue to step number **7**.
7	Turn the centrifuge power **OFF** (the switch must be depressed in the **O** position).  **Note:** The centrifuge power switch is located at the rear of the centrifuge, next to the centrifuge power cord.
8	Remove the Centrifuge Loading Unit (CLU) cover (see item **A** in photo below), if it has not already been removed. Use a 2.5 mm Allen key to remove the Allen head screw (and its associated washer) that secures the CLU cover.  **A**: CLU cover. **B**: Centrifuge service hatch cover. a. Use a wrench to remove the four (4) nuts securing the service hatch cover (see item **B** in photo above). b. Remove the service hatch cover by lifting it away from the four permanent screw posts. You can now access the inside of the centrifuge through the hatch.

Step	Action
9	If there is a plate in the centrifuge, remove the white plate frame only from the rotor. The transport carrier cannot be removed at this time. If there is no plate in the centrifuge, skip to step number 10.
10	Push the transport frame as far into the centrifuge (away from you) as possible to ensure it is not the cause of the error.
11	Manually rotate the centrifuge rotor completely around to ensure there are no obstructions. Call Technical Support if the rotor will not rotate completely and the obstruction cannot be identified.
12	Install the service hatch. a. Hang the service hatch cover back onto the four permanent screws. b. Replace the four nuts securing the hatch cover by hand tightening them over the four associated screw posts and then use a wrench to securely tighten the nuts (see item **B** in photo above).
13	Install the CLU cover and use a 2.5 mm Allen key to replace the Allen head screw (and its associated washer) that secures the CLU cover.
14	Turn the centrifuge power back **ON** (the switch must be depressed in the **I** position). 
15	Initialize the NEO Iris by pressing the initialization main menu bar button and confirming the initialization process on the resulting confirmation dialog. 
16	Contact Technical Support if the error persists.

Plate Carrier Is Not Loaded Properly into Centrifuge

Error Messages

Centrifuge: Door Movement Error

Centrifuge: Plate present after loading

Potential Root Cause(s)

- Alignment issue
- Something is obstructing the plate loading
- Mechanical failure

If the plate fails to load, the plate position will dictate the error generated. If the plate fails early in the process, the Plate Present after loading message will be generated. If the plate fails towards the end of the process, the Door movement error will be generated because the plate is beyond the sensor and the door is trying to close. Usually a considerable amount of mechanical noise accompanies this error.

Procedure

To resolve this error:

Step	Action
1	Press the **F12** key to stop the alarm. Obtain a **Print Screen** of the message and then press the **OK** button on the message window.
2	The system displays the *Machine is stopped!* dialog. Press the **Error recovery** button.

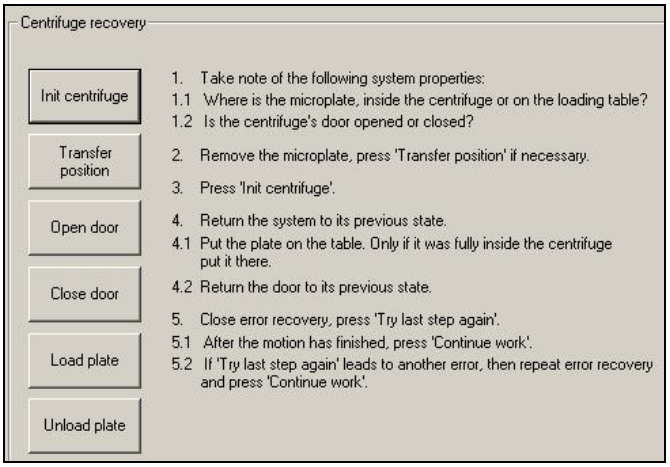
Step	Action
3	The system displays the *Error Recovery* dialog. Press the **Centrifuge** button. This will display recovery buttons and processes for the selected item.  Text is displayed in the *Centrifuge recovery* area describing symptoms to look for in the diagnosis of the problem. Follow the on-screen *Centrifuge recovery* instructions.
4	Remove the Centrifuge Loading Unit (CLU) cover. Use a 2.5 mm Allen key to remove the Allen head screw (and its associated washer) that secures the CLU cover. Remove the plate carrier, even if it is already partially or completely inside the centrifuge.
5	Press the **Init centrifuge** button. The CLU and centrifuge initialize, including attempting to unload a plate from the centrifuge. Wait until this is completely finished.
6	Return the plate carrier to the loading table.
7	Press the **Open door** button and then press the **Load plate** button, Contact Technical Support if this step fails.
8	Press **Close** to leave error recovery. The system displays the *Machine is stopped!* dialog. Press the **Continue work** button. Press the **OK** button on the verification dialog to indicate that affected modules have been initialized. The door closes. Centrifugation and test processing continues and the system closes the *Machine is stopped!* dialog after a few seconds.

Plate Carrier Is Not Unloaded Properly from Centrifuge

Error Message

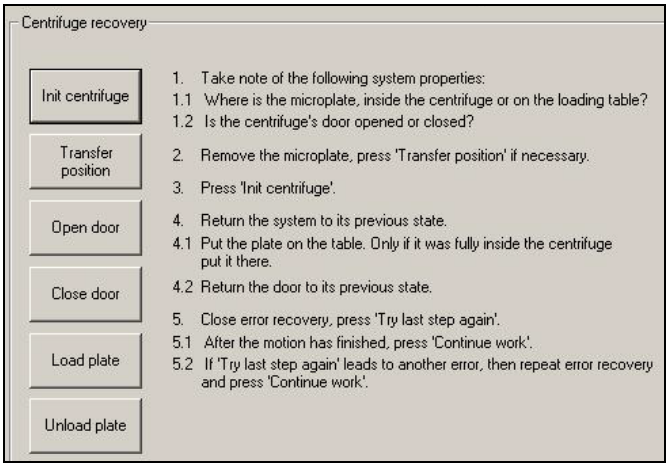
Centrifuge: No Plate present after loading

Potential Root Cause(s)

- Alignment issue causing gripper to lose plate in process
- Something is obstructing the plate unloading
- Mechanical failure

Procedure

To resolve this error:

Step	Action
1	Press the **F12** key to stop the alarm. Obtain a **Print Screen** of the message and then press the **OK** button on the message window.
2	The system displays the *Machine is stopped!* dialog. Press the **Error recovery** button.
3	The system displays the *Error Recovery* dialog. Press the **Centrifuge** button. This will display recovery buttons and processes for the selected item.  Text is displayed in the *Centrifuge recovery* area describing symptoms to look for in the diagnosis of the problem. Follow the on-screen *Centrifuge recovery* instructions.

Step	Action
4	Remove the Centrifuge Loading Unit (CLU) cover. Use a 2.5 mm Allen key to remove the Allen head screw (and its associated washer) that secures the CLU cover. Remove the plate carrier, even if it is partially or completely inside the centrifuge.  **Note:** If the plate has difficulty sliding out of the centrifuge, press the **Transfer position** button to attempt a re-alignment of the load position. Repeat this attempt to manually remove the plate.
5	Press the **Init centrifuge** button. The load unit and centrifuge initialize, including attempting to unload a plate from the centrifuge. Wait until this is completely finished.
6	Return the plate carrier to the loading table.
7	Press the **Open door** button.
8	Press the **Close** button to leave error recovery. The system displays the *Machine is stopped!* dialog. Press **Continue work**. Press the **OK** button on the verification dialog to indicate that affected modules have been initialized. The door closes. Centrifugation and test processing continues and the system closes the *Machine is stopped!* dialog after a few seconds.

Centrifuge Stalls

The system can generate other error messages when centrifugation stalls. The potential messages are:

Error Message	Description
Centrifuge: Error while moving vibration adjust motor.	Before actual centrifugation, movement of imbalance adjustment is impossible, there is friction, or there is a motor problem.
Centrifuge: Vibration adjust movement out of range or internal error.	Before or during centrifugation, movement of imbalance adjustment reached limits, plate weight is out of range, or centrifuge adjustment has changed.
Centrifuge: Vibration adjust movement lasts too long.	During centrifugation, the balance point cannot be found, the centrifuge is not mounted correctly, or mechanical play causes imbalance.

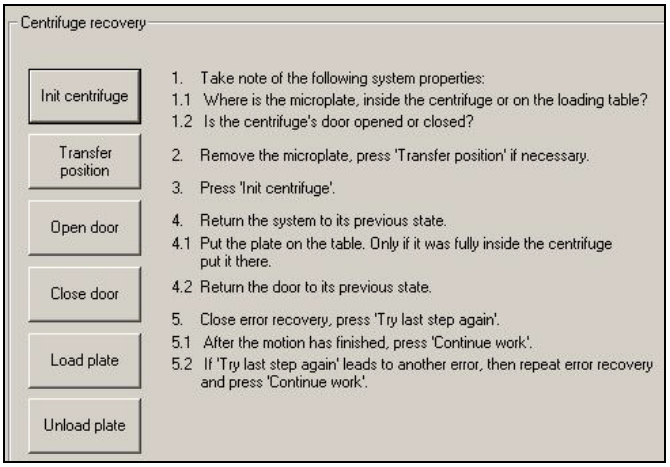
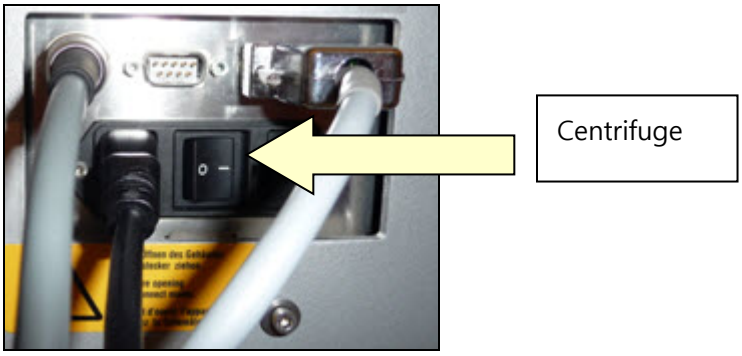
Error Message	Description
Centrifuge: Imbalance sensor value after imbalance compensation still too high.	During centrifugation, the balance point is found, but vibration level is too high, the centrifuge is not mounted correctly, or mechanical play causes imbalance.
Centrifuge: Vibration adjust sensor detected too much imbalance.	During centrifugation, the vibration level is above allowed limit, the centrifuge is not mounted correctly, or mechanical play causes imbalance.
Centrifuge: Rotor drive error: Open loop.	At the beginning of centrifugation: A possible motor or sensor failure. During centrifugation: A probable mechanical blockage or the plate carrier moved out of table.
Final centrifugation velocity not reached.	There is partial motor failure, power driver failure, or friction in bearings.

Although all of these different causes may require different solutions to resolve the underlying problem, the initial recovery to try and continue the current run is always the same.

Procedure

To resolve these errors:

Step	Action
1	Press the **F12** key to stop the alarm. Obtain a **Print Screen** of the message and then press the **OK** button on the message window.
2	The system displays the *Machine is stopped!* dialog. Press the **Error recovery** button.

Step	Action
3	The system displays the *Error Recovery* dialog. Press the **Centrifuge** button. This will display recovery buttons and processes for the selected item.  Text is displayed in the *Centrifuge recovery* area describing symptoms to look for in the diagnosis of the problem. Follow the on-screen *Centrifuge recovery* instructions.
4	Verify that the mains power switch for the centrifuge is turned **ON** (the switch must be depressed in the **I** position). **Note:** The centrifuge power switch is located at the rear of the centrifuge, next to the centrifuge power cord. 
5	Press the **Init centrifuge** button. If the centrifuge initializes without error, skip to step number **17**. If the error persists, continue to step number **6**.
6	Turn the centrifuge power **OFF** (the switch must be depressed in the **O** position).

Step	Action
7	The Centrifuge Loading Unit (CLU) cover (see item **A** in photo below) should already be removed. If it is not, remove it now. Use a 2.5 mm Allen key to remove the Allen head screw (and its associated washer) that secures the CLU cover.  **A**: CLU cover. **B**: Centrifuge service hatch cover. a. Use a wrench to remove the four (4) nuts securing the service hatch cover (see item **B** in photo above). b. Remove the service hatch cover by lifting it away from the four permanent screw posts. You can now access the inside of the centrifuge through the hatch.
8	Only remove the white plate frame from the rotor. The transport carrier cannot be removed at this time.
9	Push the transport frame as far into the centrifuge (away from you) as possible to ensure it is not the cause of the error.
10	Manually rotate the centrifuge rotor completely around to ensure there are no obstructions. Call Technical Support if the rotor will not rotate completely and the obstruction cannot be identified.

Step	Action
11	Replace the service hatch. a. Hang the service hatch cover back onto the four permanent screws. b. Replace the four nuts securing the hatch cover by hand tightening them over the four associated screw posts and then use a wrench to securely tighten the nuts (see item **B** in photo above).
12	Turn the centrifuge power back ON (the switch must be depressed in the I position). 
13	Press the **Init centrifuge** button. If the centrifuge initializes without error, continue to step number **14**. Contact Technical Support if the error continues.
14	Place the plate on the CLU if it was previously removed.
15	Install the CLU cover and use a 2.5 mm Allen key to replace the Allen head screw (and its associated washer) that secures the CLU cover.
16	Press the **Open door** button and then press the **Load plate** button. Press the **Close door** button.
17	Press the **Close** button to close the *Error recovery* dialog. The software displays the *Machine is stopped!* dialog. Press the **Try last step again** button. The centrifuge will attempt to perform the centrifuge step that generated the initial error.
18	Wait until the centrifugation or shake sequence is complete and then press the **Continue work** button. Press the **OK** button on the dialog to confirm that the affected module(s) have been initialized. The remaining assay sequences will be performed.

Troubleshooting Incubator Errors

Incubator Door Does Not Close

Error Message

Incubator: Flap jam while closing (open/close light barrier error)

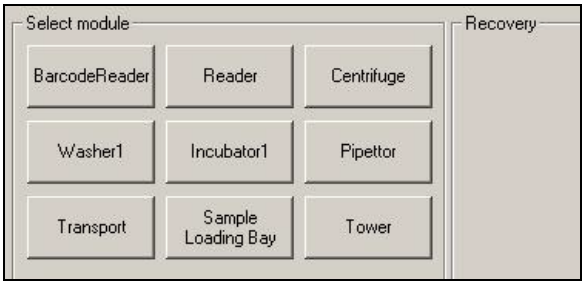
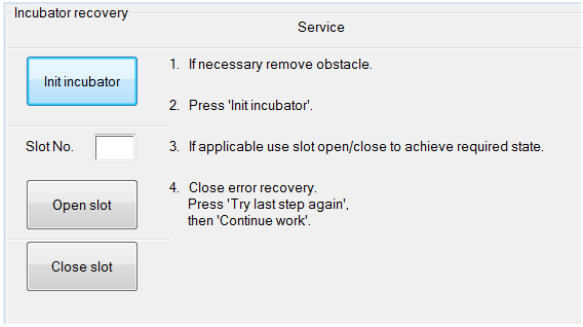
Potential Root Cause(s)

- There is something obstructing the incubator door from closing
- The sensor detecting a closed door state is defective

Procedure

To resolve this error:

Step	Action
1	Press the **F12** key to stop the alarm. Obtain a **Print Screen** of the message and then Press the **OK** button on the message window.
2	The system displays the *Machine is stopped!* dialog. Press the **Error recovery** button.

Step	Action
3	The system displays the *Error recovery* window. Press the **Incubator1** button.  This will display recovery buttons and processes for the selected item. 
4	Check to see whether anything is obviously jamming the door. The plate carrier might not be fully inserted into the incubator slot or friction in the slide mechanism of the door might be blocking its motion. Remove any visible obstruction. Push the plate fully into the incubator. **Note:** It may be necessary to disengage the transport Y-pusher from the plate frame if that is blocking the door movement.
5	Press the **Init incubator** button. All incubator bay doors should close during initialization. Contact Technical Support if this step fails.
6	Press the **Continue work** button. Press the **OK** button on the dialog to confirm that the affected module(s) have been initialized. Test processing continues and the system closes the *Machine is stopped!* dialog after a few seconds.

Incubator Door Does Not Open

Error Message

Incubator: Flap jam while open (open/close light barrier error)

Potential Root Cause(s)

- There is something obstructing the incubator door from opening
- The door is sticking and the friction was too great
- The sensor detecting a closed door state is defective

Procedure

To resolve this error:

Step	Action
1	Press the **F12** key to stop the alarm. Obtain a **Print Screen** of the message and then Press the **OK** button on the message window.
2	The system displays the *Machine is stopped!* dialog. Press **Error recovery**.
3	The system displays the *Error Recovery* window. Press the **Incubator1** button. This will display recovery buttons and processes for the selected item. 
4	Press the **Init incubator** button. All incubator bay doors should close during initialization. Contact Technical Support if this step fails.
5	Press the **Close** button to leave error recovery. The system displays the *Machine is stopped!* dialog. Press the **Try last step again** button. The incubator door that previously failed to open should open at this time.

Step	Action
6	Press the **Continue work** button. Press the **OK** button on the dialog to confirm that the affected module(s) have been initialized. Test processing continues and the system closes the *Machine is stopped!* window after a few seconds.

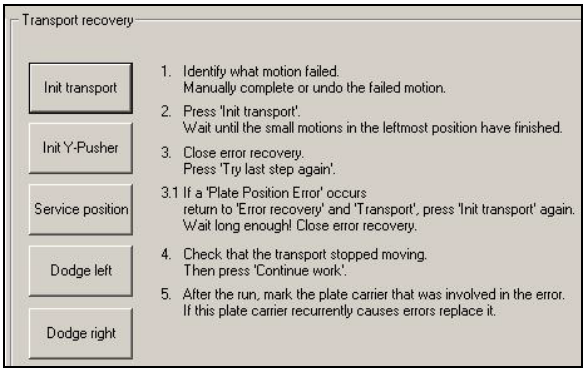
Wrong Incubator Door Opens

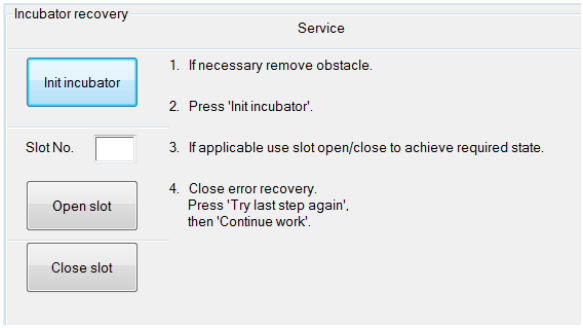
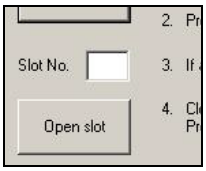
This results in a transport system error because the unexpectedly closed incubator door is a physical blockage to the transport.

- This can occur when two incubator doors are stuck together or if the door above the desired position falls down

Procedure

To resolve this error:

Step	Action
1	Press the **F12** key to stop the alarm. Obtain a **Print Screen** of the message and then Press the **OK** button on the message window.
2	The system displays the *Machine is stopped!* dialog. Press **Error recovery**.
3	The system displays the *Error recovery* window. Press the **Transport** button. This will display recovery buttons and processes for the selected item. 
4	Determine and take note of the slot that the transport was trying to access. It is most likely to be the one just under the open slot. It is possible that the flap directly above the opened slot has slipped down, closing the desired slot and opening the one above.
5	Press the **Init transport** button to initialize the transport. The transport slowly moves to the bottom left initialization position.

Step	Action
6	While the transport is initializing, press the **Incubator1** button. This will display recovery buttons and processes for the selected item. 
7	**Optional:** Manually slide the incorrectly opened door up to open the correct slot. If it does not stay in place, further action is necessary. Sticky liquid at the connection edge between the doors can cause this dropping of the door above the desired one. Clean the edges between the doors with absorbent material.
8	Enter the slot number (**Slot No.**) for the incubator bay that needs to be opened.  **Note:** Doors are numbered 1 (bottom-most) – 15 (top-most).  Press the **Open slot** button to open the selected door that the transport tried to access.
9	Press the **Close** button. The system displays the *Machine is stopped!* dialog. Press the **Try last step again** button.
10	Press the **Continue work** button. Press the **OK** button on the dialog to confirm that the affected module(s) have been initialized. The software closes the *Machine is stopped!* dialog after a few seconds.

Troubleshooting Washer Errors

The complexity of the washer sequences renders it impossible for the system's error recovery routines to know exactly at which strip position of a move the error occurred. Therefore, the **Try last step again** function should not be used for the washer, and no valid results can be expected from a plate that suffered a washer error.

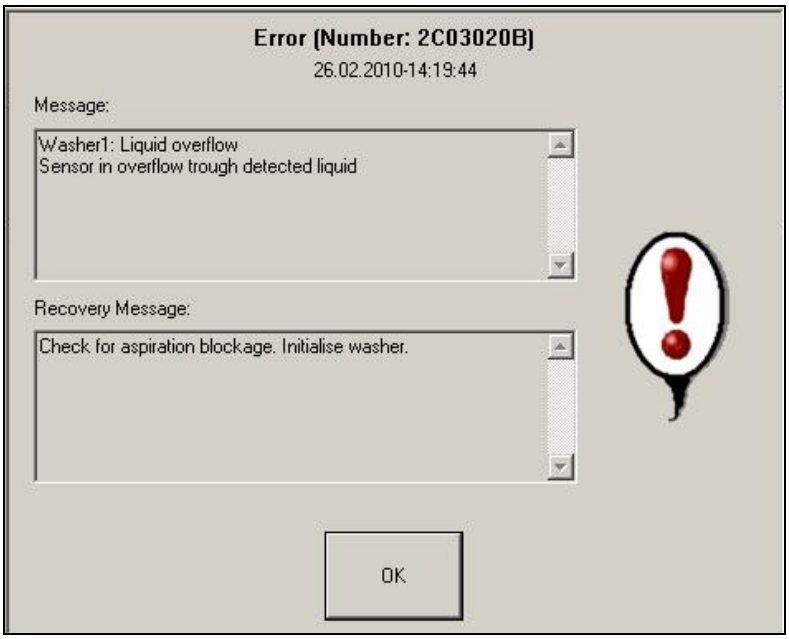
Liquid Handling Errors

The potential washer liquid handling messages and the corresponding troubleshooting steps are:

Liquid Overflow

Error Message

Washer1: Liquid overflow
Sensor in overflow trough detected liquid

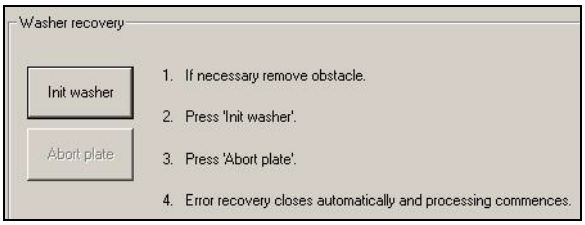


Potential Root Cause(s)

- Blocked aspiration channel
- Poor manifold positioning
- Strips not in expected positions for maintenance assays

Procedure

To resolve this error:

Step	Action
1	Press the **F12** key to stop the alarm. Obtain a **Print Screen** of the message and then press the **OK** button on the message window.
2	The system displays the *Machine is stopped!* dialog**.** Press the **Error recovery** button.
3	The system displays the *Error recovery* window. If the transport is in front of the washer, press the **Transport** button and then press the **Service position** button.  **Note:** This will move the transport to a position in front of the incubator and out of the way of the washer. Do not perform this step if the transport is not in front of the washer.
4	Press the **Washer1** button. This will display recovery buttons and processes for the selected item. 
5	Press the **Init washer** button (step 2 of the on screen recovery instructions). The manifold slowly moves to the left side of the washer.
6	Manually remove the plate from the washer module.
7	**Completely** dry the overflow trough using an absorbent towel. If an additional liquid overflow error occurs, initialize the washer again and continue drying the trough.
8	Return the plate to the washer module in the correct position
9	Press the **Abort plate** button. The software will automatically continue processing. The aborted plate will be returned to the tower by the transport module during the next scheduled transport step.
10	If it has been determined that the overflow error is a result of a blocked manifold channel, the manifold should be removed and cleaned according to the instructions in **Chapter 10 - Maintaining the NEO Iris**.

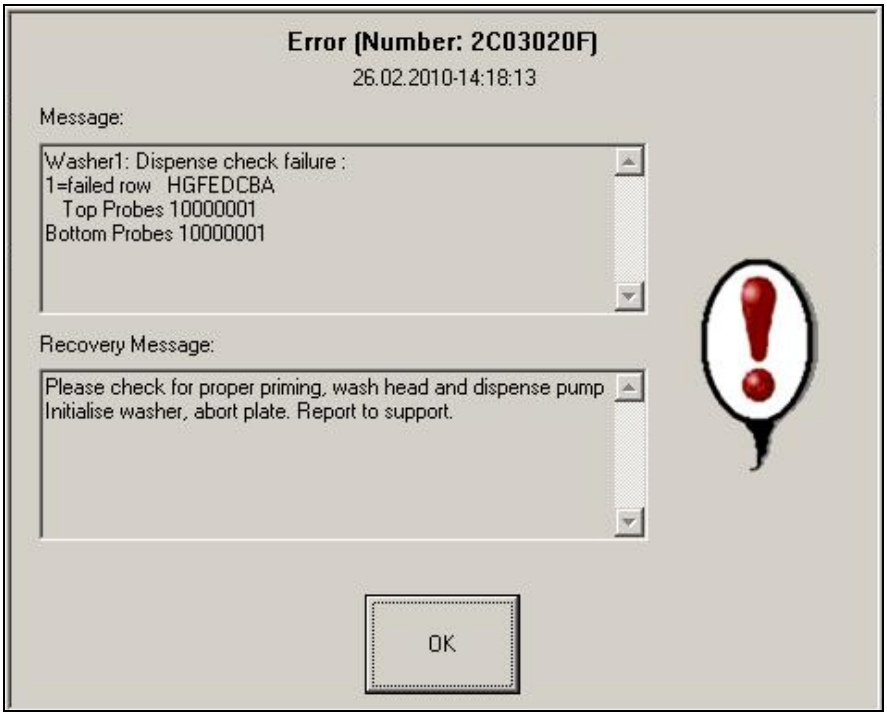
Dispense Check Failure

Error Message

Washer1: Dispense check failure:
1=failed row HGFEDCBA

Top Probes ????????

Bottom Probes ????????



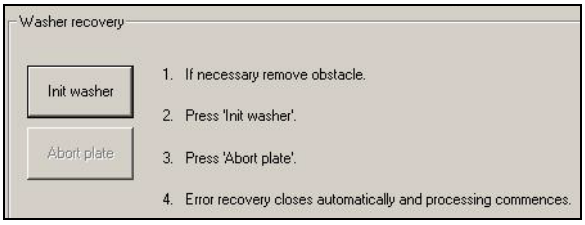
Potential Root Cause(s)

- Blocked dispense channel
- Poor seal between manifold and washer assembly
- Air bubbles in the tubing

Procedure

To resolve this error:

Step	Action
1	Press the **F12** key to stop the alarm. Obtain a **Print Screen** of the message and then press the **OK** button on the message window.

Step	Action
2	The system displays the *Machine is stopped!* dialog**.** Press the **Error recovery** button.
3	Use the Print Screen to analyze the error. a. The values displayed for the Top Probes and Bottom Probes should be analyzed. b. A value of '0' indicates the expected liquid has been detected in the well(s) and no error condition exists. c. A value of '1' indicates the expected liquid was not detected in the well(s) and an error condition does exist. These are the wells that must be investigated. d. In the example above, the expected volume was not detected in channels A and H.
4	Press the **Washer1** button. This will display recovery buttons and processes for the selected item. 
5	Press the **Init washer** button (step 2 of the on screen recovery instructions). The manifold slowly moves to the left side of the washer.
6	Press the **Abort plate** button. The software will automatically continue processing. The aborted plate will be returned to the tower by the transport module during the next scheduled transport step.
7	If it has been determined that the dispense error is a result of a blocked manifold channel, the manifold should be removed and cleaned according to the instructions in **Chapter 10 - Maintaining the NEO Iris**.

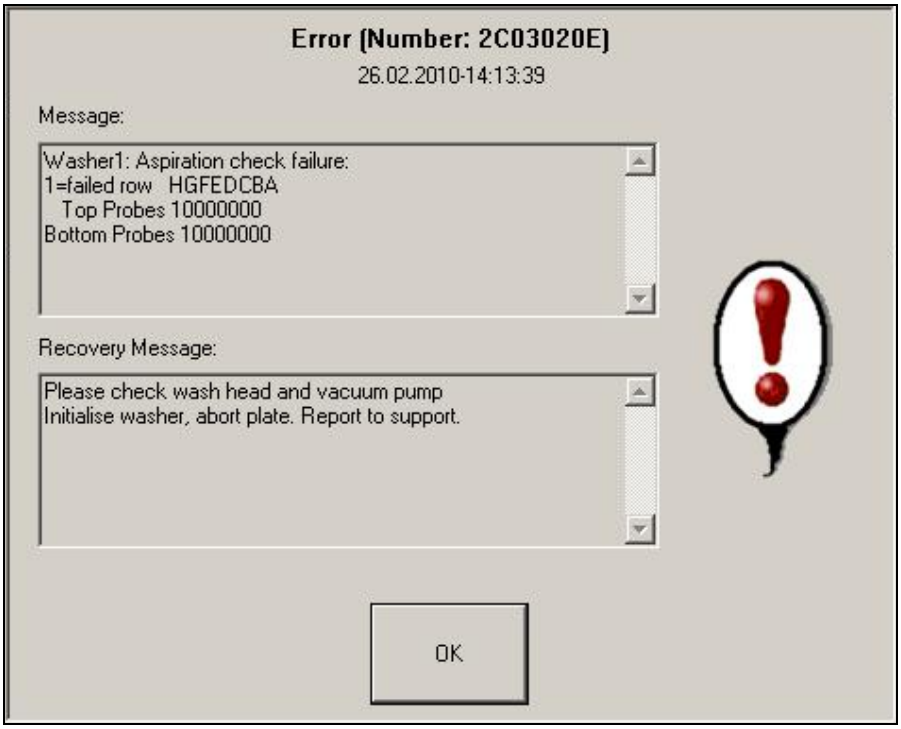
Aspiration Check Failure

Error Message

Washer1: Aspiration check failure:
1=failed row HGFEDCBA

Top Probes ????????

Bottom Probes ????????

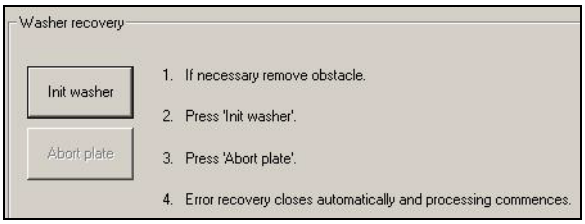


Potential Root Cause(s)

- Blocked aspiration channel
- Poor seal between manifold and washer assembly
- Vacuum pump failure
- Check valve failure

Procedure

To resolve this error:

Step	Action
1	Press the **F12** key to stop the alarm. Obtain a **Print Screen** of the message and then press the **OK** button on the message window.
2	The system displays the *Machine is stopped!* dialog**.** Press the **Error recovery** button.
3	Use the Print Screen to analyze the error. a. The values displayed for the Top Probes and Bottom Probes should be analyzed. b. A value of '0' indicates that all expected has been aspirated from the well(s) and no error condition exists. c. A value of '1' indicates that all expected has not been aspirated from the well(s) and an error condition does exist. These are the wells that must be investigated. d. In the example above, the too much liquid remained after aspiration and was detected in channel H.
4	Press the **Washer1** button. This will display recovery buttons and processes for the selected item. 
5	Press the **Init washer** button (step 2 of the on screen recovery instructions). The manifold slowly moves to the left side of the washer.
6	Press the **Abort plate** button. The software will automatically continue processing. The aborted plate will be returned to the tower by the transport module during the next scheduled transport step.
7	If it has been determined that the aspiration error is a result of a blocked manifold channel, the manifold should be removed and cleaned according to the instructions in **Chapter 10 - Maintaining the NEO Iris**.

Mechanical Problems

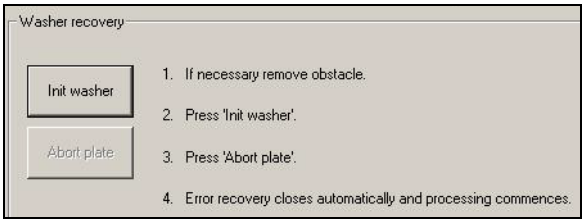
The system can generate other error messages when mechanical problems occur. The potential messages are:

Error Message	Description
Washer 1: Command () microplate missing.	There is no plate in the transport frame or the frame sensor is defective. Verify a microplate is loaded and call Technical Support if initialization does not resolve issue.
PC: Washer – horizontal (x-motor) positioning error.	The motor that moves the manifold over the plate could not reach the intended position. Verify whether anything, such as tubing, is hindering manifold movement.
Washer1: X movement error lost 17 steps. Mechanical blockage or drive damaged	If no physical blockage is obvious and the error is sporadic, contact Technical Support.
PC: Washer – vertical (z-motor) positioning error possibly incorrect height of bottom touch is detected:	The upward or downward movement is impeded by something like a mechanical blockage. Verify whether the manifold is in the correct position. If this error occurs at the priming trough, visually verify that the manifold aspiration/dispense needles are not hitting the side of the trough. This may be due to a displacement of the trough. Verify all of the test strips are seated in the plate frame and the plate frame is fully pressed into the transport frame.

Although the listed root causes can require different solutions to resolve the underlying problem, initial recovery is always the same to try to continue the current run.

Procedure

To resolve this error:

Step	Action
1	Press the **F12** key to stop the alarm. Obtain a **Print Screen** of the message and then press the **OK** button on the message window.
2	The system displays the *Machine is stopped!* dialog. Press the **Error recovery** button.
3	The system displays the *Error recovery* window. Press the **Washer1** button. This will display recovery buttons and processes for the selected item. 
4	Press the **Init washer** button (step 2 of the on screen recovery instructions). The manifold slowly moves to the left side of the washer.
5	Press the **Abort plate** button. The software will automatically continue processing. The aborted plate will be returned to the tower by the transport module during the next scheduled transport step.

Troubleshooting Camera Reader Errors

Introduction

Note: Camera reader recovery is a special case, because the transport processor controls the reader door. Therefore, the error module indicated is Transport. However the *Reader recovery* button must be utilized.

Errors in the image reading process itself, such as wrongly positioned plates or no light, generate an error message and no useful images. The affected plate will automatically be aborted. The machine does not enter the *Stopped* state. No recovery procedure is required. You need to investigate persistent image reading failures and eliminate their root cause.

If you must stop assay processing because the image reading persistently fails, it is recommended that the current schedule is **Canceled** to abort the processing. This leads to abandoning the assay processing completely while preserving unused reagent volume.

Reader Door Does Not Open or Close

Error Message

Transport: Reader Door Error (open or close)

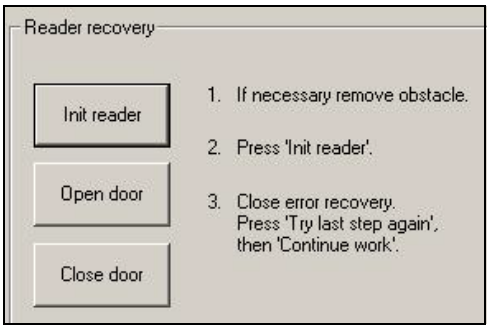
Potential Root Cause(s)

- Movement of door obstructed
- Reader door motor has failed
- Reader door sensors have failed

Procedure

To resolve this error:

Step	Action
1	Press the **F12** key to stop the alarm. Obtain a **Print Screen** of the message and then press the **OK** button on the message window.
2	The system displays the *Machine is stopped!* dialog. Press the **Error recovery** button.

Step	Action
3	Press the **Reader** button. This will display recovery buttons and processes for the selected item. 
4	Press the **Init reader** button.
5	Press the **Open door** and **Close door** buttons a few times to see whether the door is moving freely. If a jam is evident, try to remove the cause.
6	Press the **Open door** or **Close door** buttons, depending on the initial error.
7	Press the **Close** button to close the error recovery dialog. The system displays the *Machine is stopped!* dialog. Press the **Try last step again** button. Press the **Continue work** button. Press the **Yes** button on the dialog to confirm that the affected module(s) have been initialized. The reader loads or unloads the plate carrier and the door closes. The system closes the *Machine is stopped!* dialog after a few seconds.

Troubleshooting 14-lane and 5-lane Bay Errors

Introduction

There are some errors that can occur in the 14-lane and 5-lane bays. The software displays these errors in the *Event Log* (most loading bay errors do not result in pop-up dialogs). These errors are mainly related to the barcode scanning process.

Barcodes on Rack Could Not Be Interpreted

The rack appears with question marks and the Event Log error message informs you:

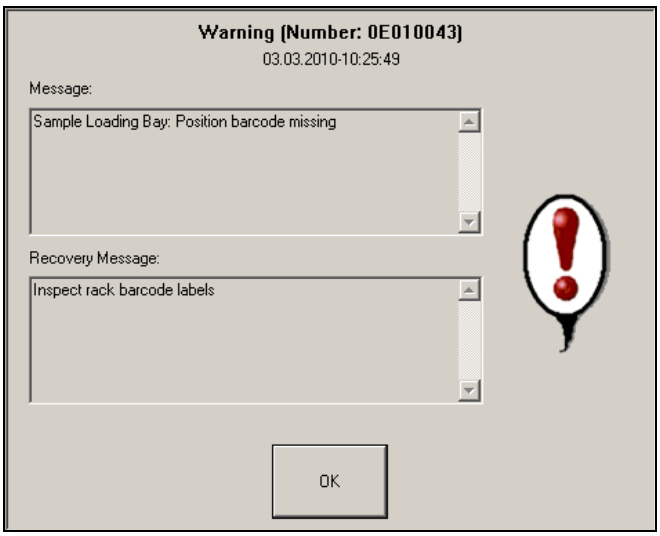
- That either the 14-lane or 5-lane bay and the PC are involved.
- That a barcode on the rack could not be interpreted.

Position Barcode Missing

If a rack is loaded and there is an issue reading one of the positional barcodes on the rack, the rack loading will be denied and a message will appear in a pop-up dialog and an entry will be made to the *Event Log*.

Note: The message will not appear in the log list scroll seen from the main screen.

- Remove the rack and inspect the positional barcodes
- If error repeats with the same rack, attempt to load a different rack



Procedure

To resolve this error:

Step	Action
1	Follow the steps for *Rescanning Unread Sample Barcodes* published in **Chapter 6 – Instrument Testing Operation**.  **Note:** When reinserting the rack, you must make sure that your fingers do not visually obstruct barcodes, including the rack ID barcode.
2	If the reader still cannot read the barcodes, remove the rack again and check to see if any of the barcodes on the rack are removed, dirty, incomplete, or otherwise unreadable. Replace the rack if necessary.
3	Close the loading bay dialog and allow the scanner to initialize. A message will appear in lower log list.
4	Open the loading bay dialog and attempt to scan the rack again. If the issue persists, initialize the instrument and retry the scan.
5	Contact Technical Support if the issue cannot be resolved.

Troubleshooting Plate Tower Errors

The plate tower errors relate to the opening and closing of the plate loading back shutter. The shutter is a mechanism which helps to consistently manually load plates into the tower so that the transport can use the same coordinates to remove plates. Prior to the transport loading or unloading from the tower, the shutter will be opened. Operators should not load plates during this time.

Plate Loading Shutter Will Not Close

Error Message

Tower: Plate Loading Shutter will not close

Potential Root Cause(s)

- Plate pushed into tower too far by operator while transport was accessing the module
- Transport did not push the plate far enough into the tower when loading
- Movement obstructed or mechanical failure

Procedure

To resolve this error:

Step	Action
1	Press the **F12** key to stop the alarm. Obtain a **Print Screen** of the message and then Press the **OK** button on the message window.
2	The system displays the *Machine is stopped!* dialog. Press the **Error recovery** button.
3	Open the tower door if it is currently closed.

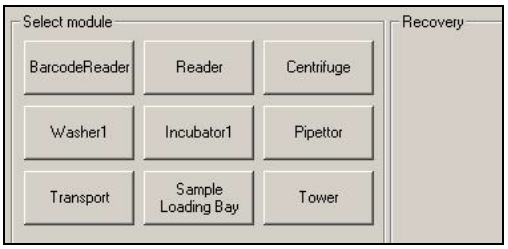
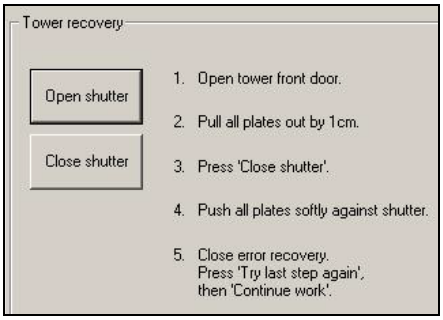
Step	Action
4	The system displays the *Error Recovery* dialog. Press the **Tower** button.  This will display recovery buttons and processes for the selected item. Follow the on screen instructions. 

Plate Loading Shutter Will Not Open

Error Message

Tower: Plate Loading Shutter will not open

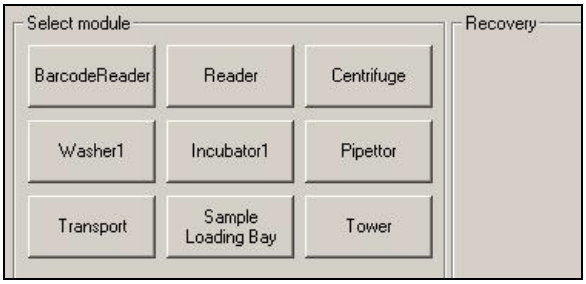
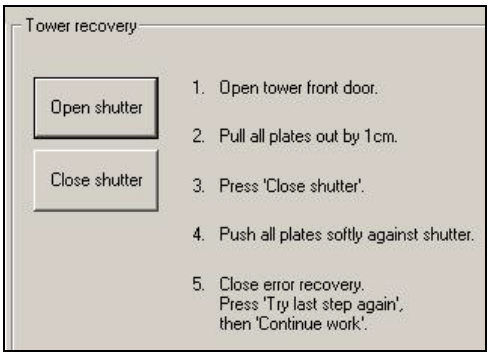
Potential Root Cause(s)

- Plate pushed into tower too far by operator while loading plates
- Movement obstructed or mechanical failure

Procedure

To resolve this error:

Step	Action
1	Press the **F12** key to stop the alarm. Obtain a **Print Screen** of the message and then press the **OK** button on the message window.
2	The system displays the *Machine is stopped!* dialog. Press the **Error recovery** button.

Step	Action
3	Open the tower door if it is currently closed.
4	The system displays the *Error Recovery* dialog. Press the **Tower** button.  This will display recovery buttons and processes for the selected item. Follow the on screen instructions. 

Chapter 12: Limitations of Use and Warnings

In This Chapter

This chapter is a collected list of all of the limitations of use and warnings that are located within the body of the text where they are most relevant to the information written. Each chapter and appendix is sequentially listed below with the limitations of use and warnings assigned to it.

Limitations of Use

Limitations by Chapter

The table below lists the Limitations of Use of the NEO Iris that are contained in the following chapters:

- Chapter 1 – Introduction to the NEO Iris
- Chapter 2 – Hardware Components
- Chapter 3 – System Software Navigation
- Chapter 4 – Security
- Chapter 5 – Instrument Start-Up
- Chapter 6 – Instrument Testing Operation
- Chapter 10 – Maintaining the NEO Iris
- Appendix A – Preparing the NEO Iris for First Use
- Attachment 1 for NEO Iris Operator Manual

Chapter 1 – Introduction to the NEO Iris

The following Limitations of Use are contained in this chapter:

Icon	Description
	**Limitation**: The Neo is for in vitro diagnostic use.
	**Limitation**: Barcodes can be no longer than 18 characters in length.

Icon	Description
	**Limitation**: Barcodes must have a module size larger than 0.2mm and a bar width ratio between 2.25:1 to 3:1. Decodability grade (grading system of A to F; A being best, F is failing) of C or better is required for consistent reading of barcodes on the instrument. This grade measures the bar width consistency throughout the barcode label. It is usually an indication of print quality of the barcode label. The minimum number of characters in the barcode is 3. The length of the barcode is variable but must be completely visible with a quiet zone (white space on each end of the label) of 3 mm when placed in the sample or donor rack. The minimum height of the barcode must be 10 mm. If barcodes have parameters outside of these specifications, barcode misreads can occur on the instrument. Pipe characters (|) are not permitted as part of a sample identification.
	**Limitation**: If samples have barcode identification information that is eighteen (18) characters in length and the first three (3) characters are identical to the first three (3) characters of the assay control material in assays which include plate or run controls, then the sample will be interpreted as a replicate of the control material. In this case, either the plate will fail unnecessarily (if the sample reacts differently than expected for the corresponding control), or the plate will pass but no results for that sample will be produced (if the sample reacts as expected for the corresponding control). Such a condition can also be exhibited when an assay such as crossmatch or antigen screening assay generates a set of circumstances such that the combination of donor and primary sample barcode identification information adds up to eighteen (18) characters and the primary sample identification begins with the same first three (3) characters as one of the control material barcode identifications.

	**Limitation**: A site visit by an Immucor representative is required to configure the Z position (downward) on the instrument for the C racks and the specific small-volume pediatric tubes in use at your site. C racks cannot be used on the instrument without this configuration. Sample probe crashes will occur without this configuration, when used in conjunction with the C racks. If differently sized small-volume pediatric tubes are subsequently used after the Z position configuration is performed using the originally designated small-volume pediatric tubes, re-configuration may be required to prevent possible sample probe crashes into the bottom of the new tubes.
	**Limitation**: Time stamps for instrument activity may not be accurate around Daylight Saving Time (DST) when a given activity spans a time period falling on both sides of the actual change of time for DST. The following recommendations are published to provide guidance on how to mitigate these time stamp inaccuracies. Allow assays to finish if they are already running during the DST change and remove the racks once processing is complete. Do not interact with the instrument (e.g. loading plates or starting assays) during the DST time change. Initialize the instrument after the DST time change is finished prior to beginning any further assays.

Chapter 2 – Hardware Components

The following Limitations of Use are contained in this chapter:

Icon	Description
	**Limitation**: Immucor requires the use of phosphate buffered (approximately 15mM) isotonic saline, pH 6.5-7.5 (PBS), on the NEO Iris system. Reactions between an antibody and its antigen may be weakened if acidic or unbuffered saline is used. Using saline and/or deionized water in PBS preparation from sources with systems in place to control proliferation of microbes helps to reduce the chance for microbial bioburden on the system. Excessive microbial bioburden can cause degradation of system or assay performance.
	**Limitation**: At least 250 µl of packed red blood cells need to be present in a sample tube to ensure that the probe picks up red blood cells and not plasma (only for those assays that require red blood cells). At least 500 µl of plasma or serum needs to be present in a sample tube to ensure that the probe picks up plasma or serum.
	**Limitation**: Laboratory ambient temperature and humidity affects the room temperature incubation bays, and an elevated ambient room temperature may disrupt assays that need to be incubated at specified temperature ranges, as published in the relevant package insert.
	**Limitation**: The NEO Iris must be switched on at least 30 minutes prior to the first plate read to allow the reader lamp to warm up. Reading of plates prior to completion of this warming period can cause incorrect negative reading of weakly positive reactions.

Chapter 3 – System Software Navigation

The following Limitations of Use are contained in this chapter:

Icon	Description
	**Limitation**: The timestamps for assay plate events that occur simultaneously with the end of Daylight Saving Time (DST) may not accurately reflect the actual time of those events, and it is not possible to predict what these timestamps will display due to their erratic nature. However, in this instance, the assay is successfully completed and the results are unaffected. These erratic timestamps are limited to the end of DST. By running the instrument initialization after the end of DST, the time stamping process is corrected. The timestamps for assay plate events that occur simultaneously with the beginning of DST are accurate and do not exhibit the same erratic features as the timestamps at the end of DST.
	**Limitation**: Validate Method is otherwise known as reflex testing. Reflex testing can only be ordered once per assay in response to results for a given sample number. The instrument WILL NOT order reflex testing again if that sample (with the same barcode) is repeated with the same assay on the instrument at a later phlebotomy date. This may cause incomplete test results to be indicated as final and made available for export. For example, when a sample is run and assigned the result of A Pending, the reflex testing procedure orders the reflex assay of Weak_D. If the sample tests positive for Weak D, then the final result of A Weak D will be released. A few days later, another sample with the same barcode is tested on the instrument and the result of A Pending is assigned again. However, on this occasion, the instrument WILL NOT order the reflex assay of Weak_D, and this second result of A Pending will be the final result. The historic and latest final results are not identical. This limitation also applies to the reflexive ordering of antibody ID testing for antibody screen positive samples. The consequence is that the second antibody identification test in the history of a given sample number will not be ordered for the second antibody screen positive sample, and so on for subsequent samples. After the instrument database is archived and the data is removed from the database, the reflex testing procedure will again order a reflex assay on a given sample ID that requires it, because the current sample ID is again new to the instrument software.
	**Limitation**: After the reflex testing procedure begins on a sample ID, the value of the result element not being resolved is not updated. For example, if a sample ID is run using the

Icon	Description
	ReflexABO assay and is assigned the result of B NTD, the reflex testing procedure will order a repeat of the ReflexABO assay to resolve result element 2 (the Rh result). If the result from this repeated ReflexABO assay is O Rh Positive, the reflex testing procedure will continue and the current result would be B Rh Positive. The ABO result of O that was determined during the repeat testing is not considered for incorporation into the final result.
	**Limitation**: In the event of an instrument computer hard drive crash, all data will be lost from the computer. Any data that was not previously archived will be lost.
	**Limitation**: Other than the Test per Assay Report, the outputs from the *Statistics* tab within the Utilities dialog must be verified on site by the end user. Immucor makes no claims as to the accuracy of those outputs.
	**Limitation**: The camera reader will verify the presence of clean and correctly positioned strips on a plate before starting an assay. If the reader detects the presence of strips that should have been deselected, such as wrong position of used strips, then the plate is aborted.
	**Limitation**: If an incorrect, but valid, plate expiration date is entered and an assay using this plate lot is run, then the incorrect expiration date is stored for that lot in the software. If the incorrect date is then corrected in the software following this assay run, and this correct date is further into the future than the original incorrect date, the data management system cannot update the incorrect stored date. Consequently, if an assay is run using this plate lot again, at a date of testing between the original incorrect date and the corrected date, then these results will be displayed in the Plate View window with an associated warning message of **Plate failed criteria, please check Interpretation Failures**. The validity of these results is not compromised by this chain of events that generated this warning message, and these results can still be exported or printed.
	**Limitation**: Stopping the system with the **Emergency Stop** button interrupts instrument sampling.

Chapter 4 – Security

The following Limitations of Use are contained in this chapter:

Icon	Description
	**Limitation**: It is not possible to: • Assign to a new user higher user rights than the current operator. • Edit the user rights or change the password of a user with higher user rights than the current user. • Add a user who is already present on the user list.

Chapter 5 – Instrument Start-Up

The following Limitations of Use are contained in this chapter:

Icon	Description
	**Limitation**: The instrument must be switched on at least thirty (30) minutes prior to the first plate read to allow the reader lamp to warm up. Reading of plates prior to completion of this warming period can cause incorrect negative reading of weakly positive reactions.
	**Limitation**: The **Use DMS Archive** check box control option allows you to view archived results that are saved on a disk using the DMS. You can only view archived results through the DMS by inserting the disk into the drive of the computer.
	**Limitation**: The COP: Serial Buffer Deleted error message may appear during initialization. In this case click the **OK** button. However, if this error occurs in other situations it is recommended to complete the current run(s) but do not start any new plates. Initialize the instrument using the Initialize button before starting new plates.
	**Limitation**: Once the Auto Logoff has occurred, only users with equal or higher access rights than the user that was logged in when the Auto Logoff was triggered are able to access the system.

Chapter 6 – Instrument Testing Operation

The following Limitations of Use are contained in this chapter:

Icon	Description
	**Limitation**: When a sample is actively being tested by an assay and the same assay is requested again for that same sample from the LIS, a second request is added. This will cause the sample to appear in the Resource Overview window for a duplicate test. To avoid this, open and close the Loading Bay dialog (via Load Samples of the Start Run Assistant) AFTER the LIS worklist orders have been received but BEFORE the Resource Overview window is opened.
	**Limitation**: Excluding QC assays, some assays will not be processed under the following conditions: A corQC EXTEND Standard vial loaded in the 5-lane bay will be recognized; however this reagent will be listed as missing in the *Resource Overview* window due to the risk of a probe arm crash. When running a DAT assay, a DAT Positive Control Cell vial loaded in the 5-lane bay will be recognized; however this reagent will be listed as missing in the Resource Overview window due to the risk of a probe arm crash. Under both of these scenarios, the assays will not be able to be scheduled until the necessary reagent is loaded into the 14-lane bay.
	**Limitation**: When you insert a rack into the activated lane, the system scans the barcodes. The system displays the barcode data and interpretation (reagent name, lot number, expiration date) on the right-hand side of the on-screen dialog. The system also displays the volume remaining in each container. In the case of Immucor lot numbered reagent vials, the volume is based on the full volume of the container (for new vials) or the remaining volume (if the vial was previously used on the instrument). If the actual volume is less than that displayed (for example, if the reagent vial has also been used for manual testing), you may enter a reduced volume. It is not possible to enter an increased volume for the bottle.

Icon	Description
	**Limitation**: If a reagent expires during a testing process, the results will not be flagged. For example, a reagent that will expire after midnight is loaded onto the instrument and scheduled to an assay before midnight of the expiration date. However, the test will not be completed until after midnight when that vial has expired. The instrument prevents any test runs with this vial in the future.
	**Limitation**: When running the Crossmatch assay, if there are not sufficient wells remaining on a plate to accommodate the scheduled number of crossmatch tests for a given sample such as a sample to be crossmatched with three donor units and only one well remains on a plate, then the three tests will be batched on the next plate, leaving the remaining well on the first plate unused. If subsequent samples are scheduled for crossmatch assay, then the instrument cannot backtrack to the unused well(s) on the previous plate such as the one unused well in this example. Under these circumstances, such wells will remain unused.
	**Limitation**: If the common waste container is full and the waste icon turns red during sample processing, you will lose the interrupted testing run only if critical processing points exceed acceptable time limits because of excessive time removing the waste. Examples of exceeding critical acceptable limits are: • Too much time has elapsed between ABORh plate shaking and reading. • A Capture-R Ready-Screen plate is incubated beyond the programmed time limit.

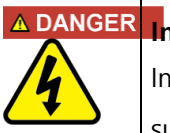
Chapter 10 – Maintaining the NEO Iris

The following Limitations of Use are contained in this chapter:

Icon	Description
	**Limitation**: Maintenance actions for the NEO Iris verify that specific modules of the instrument are functioning at the required specifications. The actions described are critical to the NEO Iris assay performance. If a maintenance item is not successfully performed for a module within the required time interval, then any assays that use that module will not run. For example, all assays use the reader. If you do not perform the daily **Pipettor Self Check** task then all assays are locked down and no assays can run.
	**Limitation:** Before using any cleaning or decontamination methods except those recommended by the manufacturer, users should check with the manufacturer that the proposed method will not damage the equipment.
	**Limitation**: Immucor requires the use of phosphate buffered (approximately 15mM) isotonic saline, pH 6.5-7.5 (PBS), on the NEO Iris system. Reactions between an antibody and its antigen may be weakened if acidic or unbuffered saline is used. Using saline and/or deionized water in PBS preparation from sources with systems in place to control proliferation of microbes helps to reduce the chance for microbial bioburden on the system. Excessive microbial bioburden can cause degradation of system or assay performance.
	**Limitation**: The instrument must be switched on for at least thirty (30) minutes prior to take flatfield images so that the reader lamp can warm up.
	**Limitation**: The instrument must be switched on for at least thirty (30) minutes prior to beginning **Take Flatfield Images** maintenance task so that the reader lamp can warm up.

Appendix A – Preparing the NEO Iris for First Use

The following Limitations of Use are contained in this appendix:

Icon	Description
	**Limitation**: Adequate space must be provided for ventilation and also accessing the instrument, both during operation and in the event of servicing. The cabinet has two (2) spacing pins which are 4.8 inches (12.1 cm) in length. The instrument must be positioned such that an overall clearance distance of 30 inches (76.2 cm) must be maintained between the back of the instrument and the wall. This 30 inches (76.2 cm) includes the length of the spacing pins.
	**Improper connection of mains supply** Improper connection of the instrument and the peripheral devices to the mains supply can cause serious personal injury with potentially deadly consequences and material damage (e.g. fire). • Only use grounded connection and extension cables with sufficient capacity (voltage and current) to connect the instrument and any peripheral devices to the mains power supply. • Never remove ground connections. • Grounding of the instrument and its peripheral devices to the same protective earth potential shall be ensured. • The use of a multi-outlet power strip is not allowed! • Only use power cables that fulfill the minimum requirements for this instrument.
	**Limitation**: **Service**: The instrument should be serviced by Immucor authorized service personnel. Only qualified technical personnel should perform troubleshooting and service procedures on internal components.
	**Limitation**: **Environmental conditions**: Do not expose the instrument to temperature extremes. For proper operation, ambient temperature range should remain between 18°C and 30°C. Performance may be adversely affected if temperatures fluctuate above or below this range. • Shipping and storage temperature range: 0°C to 40°C. • Relative humidity range: 20% to 80% (non-condensing). • For use at altitudes up to 2,000 meters above mean sea level.

Icon	Description
	**Limitation:** Before using any chemicals (e.g. decontamintion solutions) except those recommended by the manufacturer, users should check with the manufacturer that chemicals will not damage the equipment or create potential hazards.
	**Limitation**: **Warranty**: Failure to follow preventive maintenance protocols may void the warranty. Refer to **Chapter 10 – Maintaining the NEO Iris**.
	**Limitation**: Changes or modifications to this unit not expressly approved by the manufacturer could void the user's authority to operate the equipment.
	**Limitation**: Do not install additional software on the PC. This will void your warranty and service contract. Third-party software can interfere with the controlling software and result in a loss of sample data.
	**Limitation**: **Warranty**: You must save all of the original packaging materials. If you need to ship the instrument to Immucor for repair or replacement, the original packing must be used. Other forms of commercially available packing are not recommended and can void your warranty.
	**Limitation**: You must decontaminate the instrument before it is repackaged. Follow the procedures in **Chapter 10 – Maintaining the NEO Iris** to decontaminate the instrument. The responsible laboratory authorities must state on the shipping documents that the instrument has been decontaminated and provide a signature for verification. Immucor reserves the right to refuse to accept an instrument that does not have such a decontamination statement.

Attachment 1 for NEO Iris Operator Manual

The following Limitations of Use are contained in this attachment:

Icon	Description
	**Limitation**: At least 250 µl of packed red blood cells need to be present in a sample tube to ensure that the probe picks up red blood cells and not plasma (only for those assays that require red blood cells). At least 500 µl of plasma or serum needs to be present in a sample tube to ensure that the probe picks up plasma or serum.
	**Limitation**: Red blood cell samples only collected with EDTA anticoagulants can be tested on the instrument. The use of other anticoagulants for testing on the instrument must be verified in the corresponding reagent Instructions for Use. Serum samples can also be tested on the instrument for tests that do not require red cells. Samples obtained from tubes containing neutral gel separators may produce falsely positive results and should therefore not be tested on the instrument.
	**Limitation**: The dead volume, or the depth to which probes cannot reach, is 200 µl of sample.
	**Limitation**: When loading a test tube, containing red blood cell donor unit segment contents, into a Donor rack for compatibility testing with the IgG_XM assay, the contents of the test tube must not exceed a liquid height of 1.3 inches, otherwise the clot detection mechanism can be falsely alarmed.

Icon	Description
⚠	**Limitation**: Samples that exhibit excessive hemolysis should not be tested on the instrument. Samples that exhibit a hemolysis grade of 3+ or greater must not be tested on the instrument, because they may generate erroneous results. Refer to the photograph below for a hemolysis grade of 3+ (color guide). For assays using Capture-R® Select, do not use hemolyzed samples for creating a monolayer. Fragmented red blood cell membranes will interfere with monolayer formation. 
⚠	**Limitation:** Samples that exhibit excessive lipemia should not be tested on the instrument. Samples that exhibit a dosage above 600 mg/dL of lipids must not be tested on the instrument because they may generate erroneous results.
⚠	**Limitation** :Samples that exhibit excessive icterus should not be tested on the instrument. Samples that exhibit a dosage above 30 mg/dL of bilirubin must not be tested on the instrument because they may generate erroneous results.
⚠	**Limitation**: Instrument studies have demonstrated that the probe washes are sufficient to prevent carry-over of samples that have an antibody titer of up to 1024 (typical of those samples encountered in a blood bank setting). It is important to note that these studies apply only to routine patient or donor samples. Sample material that is provided in surveys has been shown to occasionally cause carry-over at lower titers (a result of the manufacturing process for these materials).
⚠	**Limitation**: For assays using Capture-R® Ready-Screen® and Capture-R® Ready-ID® microplates, avoid testing previously frozen specimens that have undergone multiple freeze-thaw cycles, as these may give erroneous or inconsistent test results.

Incidents related to the device:

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Warnings

Warnings by Chapter

The table below lists the warnings for the Neo that are contained in the following chapters:

- Chapter 1 – Introduction to the NEO Iris
- Chapter 2 – Hardware Components
- Chapter 3 – System Software Navigation
- Chapter 6 – Instrument Testing Operation
- Chapter 7 – Test Results
- Chapter 10 – Maintaining the NEO Iris
- Chapter 11 – Troubleshooting the NEO Iris
- Appendix A – Preparing the NEO Iris for First Use

Chapter 1 – Introduction to the NEO Iris

The following warnings are contained in this chapter:

Icon	Description
	**Warning**: Blood samples, liquid waste, used microplates, and consumed liquid reagent containers contain potentially biohazardous material.
	**Warning**: Always wear protective gloves and clothing when handling blood samples, liquid waste, used microplates, or consumed liquid reagent containers. All blood samples, liquid waste, used microplates, and consumed liquid reagent containers must be discarded following the standard practice of the laboratory.
	**Warning**: All blood products must be treated as potentially infectious. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.
	**Warning**: Follow basic electrical hazard awareness to reduce the risk of injury due to prohibited electricity exposure.

	**Warning**: Follow all of the necessary precautions to prevent exposure to and potential injury from instrument mechanical movement. Keep all instrument protective covers in place when operating the instrument to reduce the risk of operator injury due to instrument mechanical movement.
	**Warning**: Follow all of the necessary precautions to prevent exposure to and potential injury from barcode laser scanners. Do not look directly into the laser beam of scanners or any reflections of the beam from a mirror-like surface. Exposure to the laser beam light can cause eye damage and permanent injury.

Chapter 2 – Hardware Components

The following warnings are contained in this chapter:

Icon	Description
	**Warning**: Inadvertent operator collision with the cabinet doors or the pull out cabinet shelf can cause operator injury.
	**Warning**: Do not try to access the loading tower when the transport system is accessing the loading tower . You may cause a plate transport error or crash situation if you ignore the plate loading tower alerts.
	**Warning**: Never attempt to reach the washer area while the NEO Iris is operating. You may disrupt the instrument or injure yourself. The instrument switches off power to the motors if resistance to movement is encountered.
	**Warning**: Do not remove a rack when the indicator LED is flashing red, as this can damage the pipetting system and invalidates all test results on samples in the rack. Also, do not load a rack when the LED is solid red. The barcodes are not read and the reagents or samples will not be used.
	**Warning**: Open field access is required to provide continuous access for sample/reagent loading during full system operation. Never try to access tubes or vials while their rack is still in the loading bay. Always pull their rack completely out before accessing individual positions. Unauthorized access to the loading bay is strictly prohibited and could injure you.
	**Warning**: It is important to keep your hands away from the pipetting area to avoid potential injury due to the moving instrument.
	**Warning**: You must not bump, knock, rest up against or otherwise come into physical contact with the centrifuge module because you may cause balancing errors or centrifuge loading and unloading issues. By causing these errors or issues, you could therefore interfere with assay processing. No items should be stored on top of the centrifuge cover including, but not limited to, sample or reagent racks, books, documents or other laboratory consumables and supplies.
	**Warning**: The liquid waste is potentially biohazardous material. Always wear protective gloves and clothing when handling the liquid waste. If any liquid waste is spilled, clean it up

Icon	Description
	immediately following the standard practice of the laboratory.
	**Warning**: Used plates and consumed liquid reagent vials contain potentially biohazardous material. Always wear protective gloves and clothing when handling used plates. If any liquid from a plate is spilled, clean it up immediately following the standard practice of the laboratory.

Chapter 3 – System Software Navigation

The following warnings are contained in this chapter:

Icon	Description
	**Warning**: You must be careful to make sure that the samples in one given rack are of a single prefix type. It is your responsibility to check this data. If you have mixed samples of different prefixes, all samples will have the same prefix added to that which you entered. Thereby, identification errors could occur if the operator fails in this tube data check.
	**Warning**: If an incorrect plate expiration date is entered, which is beyond the actual expiration date of the plate, and an assay using this plate lot is run at a date after the actual expiration date, but before the erroneously entered software expiration date, then the validity of the results is compromised, even though the results will appear legitimate. It is the operator's responsibility to enter the correct plate expiration date into the software.

Chapter 6 – Instrument Testing Operation

The following warnings are contained in this chapter:

Icon	Description
	**Warning**: Inspect all reagents and controls for the presence of foam before placing on the instrument. Do not vigorously agitate blood grouping anti-sera or controls. Shaking will produce foam in the vial that can cause the Liquid Level Detection (LLD) feature of the pipetting system to aspirate foam and/or air rather than reagent. This will produce incorrect results or an error.
	**Warning**: Before placing reagents on the instrument, you must remove the bottle caps. You are advised to remove and discard the dropper by pulling the dropper from the bulb. When you remove the reagents from the instrument for storage, you must place the caps back on the bottles. To avoid cross contamination of reagents, it is important that you place the caps on the correct bottles. Mixing caps can result in erroneous test results. Immucor-approved disposable vial caps can alternatively be used instead of replacing the saved original vial caps. Contact Technical Support for information regarding these caps.
	**Warning**: If you do not add the stirballs to the cell suspensions, the results may be invalid or incorrect. Do not touch the stirballs. You should add them directly to the cellular reagent vials using the dispenser provided. Contamination and neutralization of cellular reagents can occur if the stirballs are touched. You must only add one stirball per vial of cellular reagent. Do not add more than one stirball per vial.
	**Warning**: If you are using two or more instruments, then the specific reagent vials for each instrument must be dedicated for use on that single instrument to ensure correct reagent volume tracking. If the actual reagent volume (less than the software numeric volume) is not sufficient for the number of tests scheduled, the instrument will produce invalid results and samples will need to be rescheduled for testing.
	**Warning**: Incorrectly placing a plate in a transport frame may cause damage to the pipetting system and other modules on the instrument in addition to wasted resources.
	**Warning**: Loading a plate with an incorrect strip orientation results in invalid results and can create a biohazardous spill on the instrument. Incorrect orientation includes strips inserted upside-down in a white plate frame.

Icon	Description
	**Warning**: Loading incorrect strips in a white plate frame can produce incorrect sample results without warning. For example, loading Capture-R Ready-Screen strips in a barcoded Capture-R Select white frame is incorrect.
	**Warning**: When using Capture-R Ready-Screen or Ready-ID strips, load only the number of strips that are required for testing, as indicated in the *Resource Overview* window. Do not use Capture-R Ready-Screen or Ready-ID strips for testing that have previously traveled though the NEO Iris system on a plate frame, but were not used for testing.
	**Warning**: You must not place new plates into the tower while the transport system is accessing that module. Wait a few seconds after the transport has left the module, and then insert the new plates.
	**Warning**: You can load and store Capture strips (excluding Capture-R Ready-Screen and Ready-ID) on the instrument, outside of the storage pouch, according to the time limitations printed in the relevant package inserts. However, it is the operator's responsibility to keep track of the on-board Capture strip storage time. The instrument will provide no alerts if the on-board storage time is exceeded and will not flag results generated from such strips.
	**Warning**: Removing racks while the probes are accessing the tubes or vials from those rack results in damage to the probes and invalidated results. Wait until the LED for the rack is blinking green before removing.
	**Warning**: The operator must first open the loading bay dialog in order to remove sample and reagent racks. A continuous orange LED indicates that the samples are not required for the current processing. However, continuous orange can also indicate that outstanding tests remain for at least one sample in the rack that is not scheduled as part of the current processing.
	**Warning**: Prematurely removing a sample or reagent rack will invalidate results.
	**Warning**: Used plates contain potentially biohazardous material. Wear protective gloves and clothing at all times when handling used plates. If any liquid is spilled, clean it up immediately following standard laboratory practice.

Chapter 7 – Test Results

The following warnings are contained in this chapter:

Icon	Description
	**Warning**: Refer to **Attachment 1 for Neo Operator Manual** for a list of assays with equivocal reactions that cannot be edited.

Chapter 10 – Maintaining the NEO Iris

The following warnings are contained in this chapter:

Icon	Description
	**Warning**: If a maintenance action requires the manual entry of a plate ID, do not input an ID with 2 digits of alpha characters followed by numeric characters. Because the software may recognize this ID scheme as that of a sample testing plate, entry of a plate expiration date will be required. Entry of a plate expiration date is not part of the instructions for maintenance actions.
	**Warning**: Results can be adversely affected if the system liquid container is filled with anything other than PBS (e.g. de-ionized water).
	**Warning**: Filling the container with the incorrect fluid adversely affects Solid Phase Red Cell Adherence reactions.
	**Warning**: Blood samples, liquid waste, used micro-well strips, and consumed liquid reagent vials contain potentially bio-hazardous material. Always wear protective gloves and clothing when handling blood samples, liquid waste, used micro-well strips, or consumed liquid reagent vials. All blood samples, liquid waste, used micro-well strips, and consumed liquid reagent vials must be discarded following the standard practice of the laboratory. All blood products must be treated as potentially infectious. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.
	**Warning**: This maintenance task can only be performed when the NEO Iris is not active. You should only use this function for minor corrections. If a probe is badly bent, you should straighten it or replace it. Resetting a badly bent probe can result in crashes as the hardware tries to move to positions outside of the mechanical boundaries of its reach.
	**Warning**: You can open the instrument hood during this maintenance action to access the probes. When accessing the instrument deck, you must not move the pipetting turntable. Moving the turntable results in an instrument crash.

Icon	Description
	**Warning**: The main maintenance screen indicates that this action is Due if the assay successfully completes. The system does not analyze the results on the instrument, so you must determine if the volume is acceptable. You are responsible for making the corrections necessary to satisfy these requirements.
	**Warning**: Immucor requires that the quality control (QC) assay for agglutination tests is performed on the system every day, or prior to the use of agglutination reagents. The primary objective of QC is to ensure that the loaded reagents are satisfactory.
	**Warning**: Repeated QC failures in absence of a reagent related cause can be an indication of conditions that have impacted instrument system performance (i.e. pipetting, centrifugation, incubation, etc), or that an incorrect system liquid (deionized H2O rather than PBS) may have been loaded.
	**Warning:** For the QC3_Cell assay, the correct position for the Capture-R® Ready-Screen® (3) strip in a Capture-R® Ready-Screen® (3) white plate frame is at strip position one (1). The instrument will not check for the correct placement of the Capture-R® Ready-Screen® (3) strip in the white plate frame. You must make sure of the correct placement of this strip yourself. Incorrect placement of this single strip can result in test material being pipetted onto the pipetting station surface, an overflow error in the washer, and a failed quality control. Unused Capture-R® Ready-Screen® (3) strips should not be present in any of the other positions of the plate. It is not required that strip positions two (2) to twelve (12) of the white plate frame be occupied by any strips at all. Those positions can be left empty, but all strip positions should be activated in the software. The Strip Selection tab in the Plate Loading Tower dialog must indicate that all twelve (12) strips are available even though only the strip at position (1) is present.
	**Warning**: You should not initiate this maintenance function if an assay is scheduled to use the reader. Leaving a microplate in the reader during this action affects the analysis of results.
	**Warning**: Failure to archive results according to the configured time schedule interval, at a minimum, can result in the accumulation of excessive result data on the instrument computer which can lead to the slowing down of the speed of the computer processing and activity.

Icon	Description
	**Warning**: You must not enter the Archive tab of the Utilities window while the NEO Iris is processing, otherwise there is a risk that conversion of results could be interrupted and that results could need to be re-sent.
	**Warning**: Before you can physically empty the 20 liter system liquid container, you must remove it from the washer software. If you do not adjust the Wash Buffer dialog to reflect the buffer removal and a test is in process, the software still attempts to use the wash buffer, even when none is present. If this occurs, the associated NEO Iris tubing and pumps can run dry.
	**Warning**: The main maintenance screen indicates that this action is Due if the assay successfully completes. The system does not analyze the results on the instrument, so you must determine if the volume is acceptable. You are responsible for making the corrections necessary to satisfy these requirements.
	**Warning**: It is critical the syringe is held in perfect vertical orientation when twisting into the 3-way valve. Do not force the syringe. If there is resistance back it off and try again.
	**Warning**: Verify that you are replacing the syringe with another syringe of the same size. Replacing the syringe with a wrong-sized syringe causes pipettor inaccuracy and incorrect test results.

Chapter 11 – Troubleshooting the NEO Iris

The following warnings are contained in this chapter:

Icon	Description
	**Warning**: During error recovery, the process control allows you to open the safety hood to access components manually. You must be cautious during manual instrument deck interventions, because while you resolve an error in one system module, other operations may remain active.
	**Warning**: After the current run is finished, you MUST shut down the software again, turn off the instrument, and then restart. If the attempt to complete the run fails, you must also shut down both the software and the instrument, and then restart. Normal operation resumes only after this complete shutdown of the instrument and the PC.

Icon	Description
	**Warning**: You should always select the **Abort plate** button (not the **Abort run** button). This will abort the plate with the error as well as the plate disrupted by re-initialization. Failure to select the **Abort plate** button allows processing to continue for a plate that may not be valid. If you select the **Continue work** button without aborting the plate, the system will invalidate all results generated from the plate that suffered the pipettor error.

Appendix A – Preparing the NEO Iris for First Use

The following warnings are contained in this appendix:

Icon	Description
	**Warning**: The power input module is being used as a separator and therefore the instrument has to be setup in a way that the appliance inlet has to be accessible from the outside in an emergency (e.g. fire) to be able to pull the power cord or plug.
	**Warning**: **Internal voltage**: Always turn off the power switch and unplug the power supply before cleaning the outer surface of the instrument.
	**Warning**: **Potential biohazards**: Adequate safety precautions should be taken, as outlined in the assay's package insert. Always wear safety glasses and appropriate protective equipment, such as chemically resistant rubber gloves and apron. Dispose of waste in an approved manner. Decontaminate the instrument per the guidelines given in Chapter 10 – Maintaining the NEO Iris.
	**Warning**: **Unspecified use**: Failure to operate this equipment according to the guidelines and safeguards specified in this manual could result in a hazardous condition.
	**Warning**: **Qualified personnel**: Some maintenance procedures must be performed with the instrument's front cover hood elevated. Only qualified personnel—trained in the hazards involved when operating the instrument while open—are allowed to conduct these procedures, as moving parts may pose pinch or crush hazards.
	**Warning**: **Excessive humidity**: Operate the instrument on a flat surface away from excessive humidity.
	**Warning**: **Excessive ambient light**: Avoid instrument exposure to direct sunlight as it can reduce the performance range of the instrument.
	**Warning**: **on/off switch accessibility.** Do not block the right side of the instrument, as the on/off switch must be easily accessible at all times.

Icon	Description
NOTICE	**Cleaning, disinfection or decontamination** Observe the following aspects during cleaning, disinfection or decontamination because otherwise breakdowns or damage can be the result. • Disinfect or decontaminate components with recommended cleaning solution. • Only use liquid cleaning, disinfection or decontamination solutions with a moistened cleaning tissue. • Use only approved cleaning, disinfection or decontamination solutions and methods (Refer to **Chapter 10: Maintaining the NEO Iris**). • Avoid cleaning, disinfection or decontamination solutions to come into contact with bearings and guides, as otherwise the greasy film may dissolve! • Do not use cleaning, disinfection or decontamination solutions in the proximity of circuit boards, light barriers and acrylic glass surfaces! • Do not pour or spray liquid cleaning, disinfection or decontamination solutions into the instrument. • Do not autoclave containers and components for liquids or waste.
NOTICE	**Handling of decontamination products** Pay attention to managing the decontamination products, because they are harmful as indicated. • Strictly follow the local and national provisions, legislation and laboratory regulations. • Do not use bleach! • Do not use improper decontamination products. Use the recommended cleaning solution to decontaminate the instrument (Refer to **Chapter 10: Maintaining the NEO Iris**). • Only use decontamination solutions in accordance with the respective instructions for use and MSDS!
	**Warning**: **Disposal**: This instrument must be fully decontaminated prior to disposal. This instrument contains printed circuit boards and wiring with lead solder. Dispose of the instrument according to Directive 2012/19/EU, "on waste electrical and electronic equipment (WEEE)" or local ordinances.

Appendix A: Preparing the NEO Iris for First Use

In This Appendix

An Immucor representative must unpack and install the instrument because it contains sensitive electrical equipment and requires correct handling, adjustment, and testing before use. This appendix only provides the unpacking, installation, and setup information that is of interest to the operator. Contact Immucor for more information about the instrument installation.

Verifying all Parts Are Present

The following is a list of all the major parts that are delivered. The Immucor representative verifies that all parts are present during the installation process.

Item	Quantity
NEO Iris, including modules and main hood.	1
Personal Computer (PC)**:** Application software installed by manufacturer, including all applicable licenses.  **Note:** Each PC belongs to a specific instrument because instrument-specific parameters are installed on each hard disk.	1
Touch screen monitor**:** • 17″ size (minimum) • TFT active matrix panel	1
Trackball	1
Keyboard	1
Barcode hand scanner	1
Cabinet	1
System liquid containers	2
Common waste container	1
Waste shuttle container	1
Reagent (**R**) racks (12 position) 10ml vial Reagent (**S**) racks (9 position) 10ml vial Reagent (**T**) racks (5 position) 57ml (43mm diameter) vial	Number determined by specific on-site requirements.
Reagent (**Z**) racks (6 position) 50ml trough	1

Item	Quantity

Sample racks (16 position)**:**
• Tube**: A** Sample Rack 16–17 x 100mm
• Tube**: B** Sample Rack 12–13 x 75–100mm
• Tube**: C** Sample Rack
  ○ Adaptor**:** 12–16mm outer diameter
  ○ Tube**:** Minimum 9mm inner diameter
  ○ Tube Height**:** 75mm–100mm
Note: Contact Technical Support for information regarding the use of approved pediatric tubes.
• Donor**: D** Donor Rack 12mm diameter tube
	Number determined by specific on-site requirements.

Plate carriers	15
Power cords and fuses	5 fuses 2 EU power cords
Accessory kit	1

Environmental Conditions and General Safety Features

The instrument must be located in an appropriate environment. This section describes the necessary environment for the instrument and also the general safety features.

- For indoor use only.
- Installation dimensions**:** 86.6 inches (220 cm) width **X** 35.4 inches (90 cm) depth **X** 73.2 inches (186 cm) height. There should be an additional 22.4 inches (57 cm) of empty space in front of the cabinet to allow the cabinet doors to fully swing open. There should be an additional 6 inches (15.2 cm) of empty space above the instrument to allow raising of the hinged hood.
- Weight of the instrument**:** 924 lbs (420 kg). The supporting floor must be capable of bearing the load of the instrument.
- Ventilation (non-drafting environment)**:** Installation Category per IEC 61010-1
- Pollution Degree 2**:** For use in areas where there is normally nonconductive pollution; however, temporary conductivity caused by condensation can occur.
- Installation category II**:** The instrument should be run only connected to a standard low voltage system being able to cope with potential excess voltage peaks.

- You must place the instrument on the cabinet provided. The cabinet provides ample space for storing the system liquids containers, liquid waste, PC and UPS. The cabinet also has wheels allowing for easy access to the instrument in the event that instrument service is required and it must be temporarily moved for that service work.

Limitation: Adequate space must be provided for ventilation and also accessing the instrument, both during operation and in the event of servicing. The cabinet has two (2) spacing pins which are 4.8 inches (12.1 cm) in length. The instrument must be positioned such that an overall clearance distance of 30 inches (76.2 cm) must be maintained between the back of the instrument and the wall. This 30 inches (76.2 cm) includes the length of the spacing pins.

Warning: The power input module is being used as a separator and therefore the instrument has to be setup in a way that the appliance inlet has to be accessible from the outside in an emergency (e.g. fire) to be able to pull the power cord or plug.

Improper connection of mains supply

Improper connection of the instrument and the peripheral devices to the mains supply can cause serious personal injury with potentially deadly consequences and material damage (e.g. fire).

- Only use grounded connection and extension cables with sufficient capacity (voltage and current) to connect the instrument and any peripheral devices to the mains power supply.
- Never remove ground connections.
- Grounding of the instrument and its peripheral devices to the same protective earth potential shall be ensured.
- The use of a multi-outlet power strip is not allowed!
- Only use power cables that fulfill the minimum requirements for this instrument.

Warning: Internal voltage: Always turn off the power switch and unplug the power supply before cleaning the outer surface of the instrument.

Warning: Potential biohazards: Adequate safety precautions should be taken, as outlined in the assay's package insert. Always wear safety glasses and appropriate protective equipment, such as chemically resistant rubber gloves and apron. Dispose of waste in an approved manner. Decontaminate the instrument per the guidelines given in **Chapter 10 – Maintaining the NEO Iris**.

Warning: Unspecified use: Failure to operate this equipment according to the guidelines and safeguards specified in this manual could result in a hazardous condition.

Warning: Qualified personnel: Some maintenance procedures must be performed with the instrument's front cover hood elevated. Only qualified personnel—trained in the hazards involved when operating the instrument while open—are allowed to conduct these procedures, as moving parts may pose pinch or crush hazards.

Limitation: Service: The instrument should be serviced by Immucor authorized service personnel. Only qualified technical personnel should perform troubleshooting and service procedures on internal components.

Warning: Excessive humidity: Operate the instrument on a flat surface away from excessive humidity.

Warning: Excessive ambient light: Avoid instrument exposure to direct sunlight as it can reduce the performance range of the instrument.

Limitation: Environmental conditions: Do not expose the instrument to temperature extremes. For proper operation, ambient temperature range should remain between 18°C and 30°C. Performance may be adversely affected if temperatures fluctuate above or below this range.

- Shipping and storage temperature range**:** 0°C to 40°C.
- Relative humidity range**:** 20% to 80% (non-condensing).
- For use at altitudes up to 2,000 meters above mean sea level.

Warning: on/off switch accessibility. Do not block the right side of the instrument, as the on/off switch must be easily accessible at all times.

NOTICE

Cleaning, disinfection or decontamination

Observe the following aspects during cleaning, disinfection or decontamination because otherwise breakdowns or damage can be the result.

- Disinfect or decontaminate components with recommended cleaning solution.
- Only use liquid cleaning, disinfection or decontamination solutions with a moistened cleaning tissue.
- Use only approved cleaning, disinfection or decontamination solutions and methods (Refer to **Chapter 10: Maintaining the NEO Iris**).
- Avoid cleaning, disinfection or decontamination solutions to come into contact with bearings and guides, as otherwise the greasy film may dissolve!
- Do not use cleaning, disinfection or decontamination solutions in the proximity of circuit boards, light barriers and acrylic glass surfaces!
- Do not pour or spray liquid cleaning, disinfection or decontamination solutions

into the instrument.

- Do not autoclave containers and components for liquids or waste.

NOTICE **Handling of decontamination products**

Pay attention to managing the decontamination products, because they are harmful as indicated.

- Strictly follow the local and national provisions, legislation and laboratory regulations.
- Do not use bleach!
- Do not use improper decontamination products. Use the recommended cleaning solution to decontaminate the instrument (Refer to **Chapter 10: Maintaining the NEO Iris**).
- Only use decontamination solutions in accordance with the respective instructions for use and MSDS!

Limitation: Before using any chemicals (e.g. decontamintion solutions) except those recommended by the manufacturer, users should check with the manufacturer that chemicals will not damage the equipment or create potential hazards.

Limitation: Warranty: Failure to follow preventive maintenance protocols may **void** the warranty. Refer to **Chapter 10 – Maintaining the NEO Iris**.

Limitation: Changes or modifications to this unit not expressly approved by the manufacturer could **void** the user's authority to operate the equipment.

User Safety

This device has been type tested by an independent laboratory, and it was found to meet the requirements of the following:

North America

Underwriters Laboratories UL 61010-1:2012

"Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements"

Canadian Standards Association CAN/CSA C22.2 Nr. 61010-1-12 (R2022)

"Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use, Part 1: General Requirements"

Also see other standards listed under CE Mark

International

IEC 61010-1:2010/AMD1:2016/COR1:2019

"Safety requirement for electrical equipment for measurement, control, and laboratory use. Part 1, General requirements"

Also see other standards listed under CE Mark

CE **Based on the testing described below and information contained herein, this instrument bears the CE mark.**

Regulation (EU) 2017/746 In Vitro Diagnostics

Compliance with the requirements of the Directive, including Risk Assessment, Quality System Certification, and Product registration with competent authorities.

EN 61010-1:2010+A1:2019

"Safety requirement for electrical equipment for measurement, control and laboratory use. Part 1, General requirements"

EN 61010-2-020:2017

"Particular requirements for laboratory centrifuges"

EN 61010-2-081:2015

"Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes"

EN 61010-2-101:2017

"Particular requirements for in vitro diagnostic (IVD) medical equipment"

EMC EC Directive 2014/30/CE Electromagnetic Compatibility

EN 61326-1 (2013)

Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements

EN 61326-2-6 (2013)

Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2 – 6: Particular requirements – In vitro diagnostic (IVD) medical equipment

(IEC 61326-2-6:2020)

Emissions – CLASS A

The system has been type tested by an independent, accredited testing laboratory and found to meet the requirements of EN 61326-2-6**:**2013 for Radiated Emissions and Line Conducted Emissions.

Immunity

The system has been type tested by an independent, accredited testing laboratory and found to meet the requirements of EN 61326-2-6**:**2013 for Immunity.

Directive 2012/19/EU Waste Electrical and Electronic Equipment

Disposal Notice:

This instrument contains printed circuit boards and wiring with lead solder. Dispose of the instrument according to Directive 2012/19/EU, "on waste electrical and electronic equipment (WEEE)."

Making the Connections

This section outlines the connections required for the operation of the instrument, including**:**

- Instrument connections
- PC connections

Instrument Connections

This section describes the instrument connections.

Descriptions

The NEO Iris connects to the main power supply through the power cord connected to the power socket on the right side of the instrument. A second power cord is connected to the back of the centrifuge module.

A Universal Serial Bus (USB) connection transfers data between the PC and the instrument. For more information about connecting the USB connection, refer to PC Connections in this appendix.

Universal Serial Bus (USB) connections connect the PC directly to the CMOS cameras in the instrument plate reader module.

The connections for the system liquid link the system liquid container in the cabinet to the washer module of the instrument. The system liquid connections are comprised of tubing for system liquid and tubing for liquid waste. A cable electronically connects the washer sub-modules, the instrument and system liquid containers.

The connections for the pipettor liquid system link the system liquid container and common waste container in the cabinet to the pipetting system of the instrument.

For correct alignment and safe placement, the rear feet of the instrument must fit into the welded metal rings on top of the cabinet.

PC Connections

This section describes the PC connections.

Descriptions

A standard PC power cord connects the PC to the voltage supply. A USB connection transfers data between the PC and the instrument.

Connection to an LIS can be achieved by a serial connection or the network (LAN) adaptor.

The monitor, trackball and keyboard (via the barcode hand scanner) are connected in the same manner as a standard PC. The touch screen electronics of the monitor are connected to the USB connection.

A standard PC power cord connects the monitor to the voltage supply.

The power cords of the monitor, PC and instrument are connected to the UPS.

Using an Uninterruptible Power Supply (UPS)

The NEO Iris is a computer-controlled instrument that electronically stores both test requests and test results. You can lose the current run data (but not the data that has previously been generated) if the power supply to the system is interrupted. Using an Uninterruptible Power Supply (UPS) with an incorporated power conditioner is required to operate the instrument. Approximately 15 minutes of battery power is available from the UPS to run the instrument in the absence of wall outlet power.

Software Installation

The software for the instrument is preinstalled on the PC.

Limitation: Do not install additional software on the PC. This will void your warranty and service contract. Third-party software can interfere with the controlling software and result in a loss of sample data.

Setting Up the Instrument

The instrument is dedicated for use with Immucor reagents. Nevertheless, you can configure several functions according to the specific needs of the laboratory. You can configure the following parameters**:**

- Operator name and access rights
- Operator password
- Frequency of archiving results

For more information about configuration, refer to **Chapter 4 – Security**.

Completing the Post-Installation Check

After the Immucor representative has finished the installation, you must check all of the components of the instrument for proper functioning. To check the components, you must follow the procedures described in **Chapter 10 – Maintaining the NEO Iris**.

Verifying the Installation

An installation and operational qualification process is completed by Immucor after the instrument has been installed.

The installation and operational qualification process confirms that**:**

- The operating environmental conditions are met.
- The Immucor documentation is supplied.
- The mechanical safety features are active.
- All calibration results are acceptable.
- The necessary instrument modules function correctly.
- The assays that have been configured for laboratory requirements are correctly prepared and interpreted.

Removal of the Instrument

This section describes the steps to be taken prior to**:**

- Shipment of the instrument back to the manufacturer.
- Waste disposal of the instrument.

Shipment to Manufacturer

If it is necessary to remove the instrument from the laboratory and ship it back to the manufacturer, an Immucor representative must repackage it into the original packaging.

Limitation: Warranty: You must save all of the original packaging materials. If you need to ship the instrument to Immucor for repair or replacement, the original packing must be used. Other forms of commercially available packing are not recommended and can void your warranty.

Limitation: You must decontaminate the instrument before it is repackaged. Follow the procedures in **Chapter 10 – Maintaining the NEO Iris** to decontaminate the instrument. The responsible laboratory authorities must state on the shipping documents that the instrument has been decontaminated and provide a signature for verification. Immucor reserves the right to refuse to accept an instrument that does not have such a decontamination statement.

Disposal to Waste Facilities

If it is necessary to dispose of the instrument to waste facilities, you must decontaminate the instrument before it is discarded. Follow the procedures in **Chapter 10 – Maintaining the NEO Iris** to decontaminate the instrument.

Warning: Disposal: This instrument must be fully decontaminated prior to disposal.

This instrument contains printed circuit boards and wiring with lead solder. Dispose of the instrument according to Directive 2012/19/EU, "on waste electrical and electronic equipment (WEEE)" or local ordinances.

Appendix B: Maintenance Records

In This Appendix

This appendix provides master forms of the NEO Iris maintenance records.

Use copies of these master forms to record results of the maintenance procedures as described in **Chapter 10 – Maintaining the NEO Iris**.

Maintenance Forms

The following forms are in this section:

- NEO Iris Daily Maintenance Record
- NEO Iris Weekly Maintenance Record
- NEO Iris Monthly Maintenance Record
- NEO Iris PipTest Chart: Precision and Accuracy
- NEO Iris Residual Volume Calculation Record

NEO Iris Daily Maintenance Record

Instructions for use: Operator(s) must perform the maintenance requirement at the specified time. Ink initials of the operator in the designated box(es) signify successful completion of the task(s). Refer to **Chapter 10 – Maintaining the NEO Iris** for written information about daily maintenance requirements.

FACILITY			MONTH/YEAR			INSTRUMENT #	

MAINTENANCE REQUIREMENT																															
DATE	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**
Hardware and Fluids:																															
Perform a complete NEO Iris module and PC shutdown followed immediately by powering both items on.																															
Check and refill system liquid container if necessary.																															
Empty waste container.																															
Clean and initialize: check that liquid is coming outside the probes and that no overflow occurs.																															
Check the pipettor reference.																															
Pipettor Self Check																															
Operator																															

NEO Iris Weekly Maintenance Record

Instructions for use: Operator(s) must perform the maintenance requirement at the specified time. The date of each weekly activity must be entered in the table. Ink initials of the operator in the designated box(es) signify successful completion of the task(s). Refer to **Chapter 10 – Maintaining the NEO Iris** for written information about weekly maintenance requirements.

FACILITY		**INSTRUMENT #**	
MONTH/YEAR:			
MAINTENANCE REQUIREMENT			
		Operator Notation:	**Operator**	**Date**
Perform the actions below in the numbered sequence:			
1. Power off the NEO Iris module (**only** the module and not the PC).			
2. Fill probe rinse cup and waste cup of both pipettor wash towers with recommended cleaning solution; and expose for prescribed contact time.			
3. Common waste Container: **(a)** Empty and rinse with the recommended cleaning solution. **(b)** Clean inside of lid with alcohol wipes or recommended cleaning solution. **(c)** Empty and rinse with deionized water. **(d)** Empty and reconnect the container.			
4. Inspect syringes for leakage and check tightness of barrels.			
5. Power on the NEO Iris module and allow initialization to occur.  **Note**: the instrument must be powered back on for a minimum of thirty (30) minutes to allow the reader lamp to warm up before using the reader module to read plates.			
6. Reader: Clean the mirror and Take new Flat-field images			
7. Perform results Archive.			

NEO Monthly Maintenance Record

Instructions for use: Operator(s) must perform the maintenance requirement at the specified time. The date of each monthly activity must be entered in the table. Ink initials of the operator in the designated box(es) signify successful completion of the task(s). Refer to **Chapter 10 – Maintaining the NEO Iris** for detailed written information about monthly maintenance requirements.

FACILITY		YEAR		MONTH		INSTRUMENT #	

MAINTENANCE REQUIREMENT		
Operator Notation:	**Operator**	**Date**
Software: Clear Test Data.		
Run the **DECONTAMINATION** procedure (**Decontaminate tubings** maintenance action). Make notation of the following specific steps:		
After he **DB_CK** assay is finished, verify that liquid has collected into the collection container from the blue tubing.		
After the **Prime3** assay is finished, verify that there is no visible hemolysis in the wells of the plate.		

NEO Iris PipTest Chart: Precision and Accuracy

Refer to **Chapter 10 - Maintaining the NEO Iris** for written information about the Pipettor Verification Test (PipTest)

Strip	1	2	3	4	5	6	7	8	9	10	11	12
Beginning Weight												
Ending Weight												
Actual Volume												
Expected Volume	0.18-0.22	0.36-0.44	0.54-0.66	0.72-0.88	0.36-0.44	0.36-0.44	0.36-0.44	0.36-0.44	0.75-0.92	0.75-0.92	0.75-0.92	0.75-0.92

Outcomes acceptable ? Check one (1) box only (**Yes** or **No**).

Yes ☐

No ☐

Instrument Number: _____

Name of Site: _____

Operator: _____

Date: _____ ☐

NEO Iris Residual Volume Calculation Record

Instructions for use: Operator(s) must perform this maintenance action on an as needed basis only at the request of Technical Support.

Ink initials of the operator in the designated box signify completion of the task. Refer to **Chapter 10 – Maintaining the NEO Iris** for written information about the residual volume action.

FACILITY		**INSTRUMENT serial number**	

NEO Iris Residual Volume	**Item descriptor**			
Operator notation:	**Operator**	**Date**	**Weight**	**Scale Serial Number**
A. Record operator initials and date of performance:				
B. Record weight of plate before test process:			**g**	
C. Record weight of plate after test process:			**g**	
D. Subtract weight before test from weight after test:			**g**	
E. Record serial number of electronic scale:				

Appendix C: Hardware Technical Data

In This Appendix

This appendix contains a summary of both general technical data about the instrument and module specific data.

Hardware Technical Data

General Data

This section describes the general technical data for the instrument.

Area	Requirement
Power Requirements	
Voltage	100 – 240 V
Frequency	50 – 60 Hz
Current consumption	4 – 1.7 A
Mean power consumption	250 W
Fuse	250 VAC, T4 AH
Dimensions	
Instrument with cabinet	• Width (without monitor track): 63 inches (160 cm) • Width (with monitor track): 86.6 inches (220 cm) • Depth: 35.4 inches (90 cm) • Height: 73.2 inches (186 cm)
Weight	
Instrument	926 lbs (420 kg)
Connections	
LIS to PC	Serial RS232 or LAN (network)
PC to instrument	USB
Internal instrument	CAN bus

Personal Computer (PC)

This section describes the hardware technical data for the instrument PC and its software.

Area	Requirement
Hardware	
Processor	Intel Core 2 Duo
Memory	Greater than or equal to 1 GB
Drives	1 DVD drive
Ports	USB (2 front and 6 rear) 2 serial 1 parallel
Touch-screen monitor	TFT active matrix panel
Keyboard	QWERTY, AZERTY, or QWERZ (depending upon local requirements)
Handheld barcode scanner	Keyboard wedge type
Trackball	PS/2 Microsoft compatible
Software	
Operating System	Windows 7
Software version	Greater than or equal to 1.6.11
Data storage capacity	Greater than or equal to 80 GB, capable of storing approximately 225,000 results.

Cabinet

This section describes the hardware technical data for the instrument cabinet.

Area	Description
Doors	Three Doors
System liquid	
Common waste container	1
Number of system liquid containers	2

Plate Loading Tower

This section describes the hardware technical data for the instrument plate loading tower.

Area	Description
Dimensions	• Width: 7.2 inches (18.4 cm) • Depth: 4.4 inches (11.2 cm) • Height: 15 inches (38.2 cm)
Positions	15

Transport System

This section describes the hardware technical data for the instrument transport system, including the plate barcode scanner.

Area	Description
Dimensions	• Width: 45.3 inches (115 cm) • Depth: 5.3 inches (13.5 cm) • Height: 16.9 inches (43 cm)
Transportation Time	Maximum 1 minute

Plate Barcode Scanner	
Dimensions	• Width: 3.1inches (8 cm) • Depth: 2 inches (5 cm) • Height: 0.9 inches (2.25 cm)
Connection	RS232
Barcode type	Code 128
Optimum reading distance	2 inches (5 cm)

14-lane and 5-lane Bays

This section describes the hardware technical data for the instrument 14-lane and 5-lane bays.

Area	Description
14-lane bay	
Dimensions	• Width: 14.8 inches (37.6 cm) • Depth: 15.9 inches (40.3 cm) • Height: 4.8 inches (12.2 cm)
Lanes	14
5-lane bay	
Dimensions	• Width: 6.4 inches (16.2 cm) • Depth: 12.8 inches (32.4 cm) • Height: 4.8 inches (12.2 cm)
Lanes	5
Sample/reagent vial barcode scanner	
Barcode types	• Codabar • Code 128 • Code 39 • Interleaved 2 of 5 • ISBT 128 (concatenated barcodes are not supported)
Barcode quality	Module width must be above 0.167 mm for the narrowest barcode feature. Ratio: greater than or equal to 1:2. Print quality must be Class A or B ANSI X3.182 or DIN EN 1635.
Maximum fraction of reading failures	$1 : 10^4$
Maximum fraction of reading error	$1 : 10^7$

Pipetting System

This section describes the hardware technical data for the instrument pipetting system.

Area	Description
Pipettors	
Wash station dimensions	Width: 1.3 inches (3.4 cm) Depth: 2.4 inches (6 cm) Height: 5.9 inches (14.9 cm)
Modes of function	Aspirating Dispensing Multi dispensing Priming Washing (steel probes)
Channels	1x4 probes, 1x1 probes
Volume range	Stainless steel probes: 1–1000 µl Definable in increments of 1µl
Dispensing accuracy	<2% for 100 to 500 µl <5% for 25 µl
Aspirating accuracy	<5% for 10 µl
Liquid viscosity	Maximum 10 mPa
System liquid container capacity	20L system liquid container connected to 10 liter refill container
Pump Rack	
Dimensions	Width: 14.9 inches (37.9 cm) Depth: 8.7 inches (22 cm) Height: 13.8 inches (35 cm)

Area	Description
Probe washing pumps	Membrane type pumps
Syringe pumps	Sample: 500 µl Reagent: 1000 µl

Incubator

This section describes the hardware technical data for the instrument incubator.

Area	Description
Dimensions	Width: 8.6 inches (21.9 cm) Depth: 7.3 inches (18.5 cm) Height: 14.9 inches (37.8 cm)
Temperature range	38°C – 40°C zone Ambient zone
Setting resolution	1°C
Evaporation	< 2 µl per well (Uncovered plates at 37°C for 1 hour with 100 µl distilled water per well).
Incubation Time	
Range	5-1440 minutes
Resolution	1 min

Washer

This section describes the hardware technical data for the instrument washer.

Area	Description
Dimensions	Width: 8.7 inches (22 cm) Depth: 7.5 inches (19 cm) Height: 14.8 inches (37.5 cm)
Modes of operation	Plate mode and strip mode
Aspiration time	Programmable
Dispense volume range	50 to 2500 µl per well with direct overfill aspiration.
Viscosity of initial well contents	Up to 10 mPa
Maximum number of wash steps	8

Centrifuge

This section describes the hardware technical data for the instrument centrifuge.

Power Requirements	
Voltage	100 – 240 V
Frequency	50 – 60 Hz
Current consumption	4 – 1.7 A
Power consumption	200 W
Fuse	250 VAC, T4 AH
Area	**Description**

Dimensions	Width: 21.38. inches (54.3 cm) Depth: 15.28 inches (38.8 cm) Height: 22.76 inches (57.8 cm)
Weight	95 lbs (43 kg)
Modes of operation	Spinning Shaking
g-force	2–1200 RCF

Connections	
Description of connector	**Connected to**
Centrifuge Loading Unit	Loading Unit at the left side of the NEO Iris instrument
RS232	PC (For service use only)
CAN Connector	NEO Iris instrument
Power Supply	Separate power connector

Instrument setup (connections) must be performed by trained service personnel only (refer to **Limitation: Service** and **Warning: Qualified personnel** in **Chapter 12: Limitations of Use and Warnings** and in **Appendix A**)

Camera Reader

This section describes the hardware technical data for the instrument camera reader.

Area	Description
Dimensions	Width: 8.7 inches (22 cm) Depth: 7.5 inches (19 cm) Height: 14.8 inches (37.5 cm)
Modes of operation	Image reading

Resolution	1280 x 1024 Plate image 140 x 140 Well image

Glossary of Terms

In This Glossary

This glossary contains the definitions of the terms used in the NEO Iris Operator Manual regarding the NEO Iris hardware and software.

Glossary

The table below lists the terms found in the NEO Iris Operator Manual in alphabetical order with their corresponding definitions.

Term	Definition
14-lane and 5-lane bays	The 14-lane and 5-lane bays are areas of the NEO Iris deck equipped to contain the blood sample tubes and reagent vials required for pipetting. The 14-lane bay is designed to accommodate both sample tubes and reagent vials. The 5-lane bay is designed to only accommodate reagent vials, and not sample tubes.
Assay Profile	Assay Profile buttons are site-customized buttons that can be built to combine two or more assays. Profiles are a group of assays that can be selected together and therefore make assay selection more efficient.
Barcode	A barcode is a series of varying width vertical lines (called bars) and spaces. There are different combinations of the bars and spaces, which represent different characters. Unique barcode character sequences are used to uniquely identify an item that the barcode is affixed to.
Cabinet	The NEO Iris cabinet is used as a surface on which to place the NEO Iris, as well as a compartment in which to store external system components, such as the computer.
Centrifuge	The on-board centrifuge is located at the left-hand side of the NEO Iris and is used to spin or shake microplate strips.
Common Waste Container	The common waste container is located in the cabinet and is used as a system collection vessel for liquid biohazardous waste.
Emergency Stop Button	The Emergency Stop button is located in the middle of the on-screen Status Bar and if pressed, will stop all NEO Iris actions.
Event Log	The Event Log is located to the left of the Emergency Stop button on the Status Bar and displays a list of event messages that have been generated since the last database clean-up.
Export Protocol	The Export Protocol describes the computer file structure used in the transfer of electronic data from the computer to a Laboratory Information System (LIS).

Term	Definition
Fuse	A fuse is an electrical safety device which will blow or melt if the current flowing through it exceeds a specified value.
Incubator	The incubator provides the necessary temperature environment for the incubation steps of the assays performed on the NEO Iris platform.
Initialization	Initialization is a NEO Iris process whereby the whole of the NEO Iris system is reset. This process includes returning all modules to their home positions.
Instrument Settings	The instrument settings piece of the NEO Iris software is the software portal where the operator user name, password, and user rights are defined.
Light Emitting Diode (LED)	LEDs are diodes that contain a semi-conductor chip that emits light within a very narrow frequency range when connected in a circuit. LEDs that emit different colors are made of different semi-conductor materials and require different energies to light them.
Login	The Login button displayed on the Main Menu Bar of the NEO Iris software screen is the portal button to access the Login screen that allows an operator to log into the NEO Iris software.
Machine Monitor	The Machine Monitor is a graphical user interface displayed on the NEO Iris software screen that reflects both the deck structure of the NEO Iris and the pattern of the workflow.
Main Menu Bar	The Main Menu Bar is displayed on the top of the NEO Iris software screen and is composed of several portal buttons that, if pressed, allow operator access to various NEO Iris software functional areas.
Maintenance	Maintenance actions for the NEO Iris are performed on a scheduled basis to verify that specific modules of the NEO Iris are functioning at the required specifications.
Manifold	The manifold is the detachable wash head, which when correctly secured in the NEO Iris microplate washing module, is used to physically dispense clean wash fluid into test wells requiring a wash step and also remove contaminated post-wash fluid out of the test wells.

Term	Definition
NEO Iris	The NEO Iris is an immunohematology device designed as a platform for in vitro diagnostic blood sample testing.
Passwords and User Access Rights	The NEO Iris employs user names, passwords, and access rights to restrict access to various levels of the NEO Iris software to authorized operators only. Unauthorized operators are refused access.
Pipetting System	The pipetting system aspirates liquids from a defined source and deposits them in a defined destination.
Plate Carrier	All microplates are transported on plate carriers. The plate carrier is a plastic frame containing springs and opposed mechanical stops on the inside of the frame to hold the microplate firmly and correctly in place.
Plate List	The Plate List displays data regarding all microplates that have been processed. The operator can also use the plate list to search for, view, and delete microplate data.
Plate Loading Tower	Plates are loaded into and removed from the NEO Iris via the plate loading tower, which is located on the left hand side of the NEO Iris deck.
Pump	A pump is a machine or device for raising, compressing, or transferring fluids.
Racks	Racks are used on the NEO Iris for the loading and unloading of sample tubes and reagent vials into and out of the 14-lane and 5-lane bays on the NEO Iris deck.
Regions of Interest (ROI)	ROIs are predetermined coordinates on a camera image of a microplate well that are analyzed through an algorithm to determine the result of that well.
Report	A NEO Iris report is printed blood sample data organized in a logical sequence, such as by numeric sequence or by calendar sequence.
Schedule	A schedule is a plan for performing work or achieving an objective, specifying the order and allotted time for each part. The NEO Iris schedule is the sequence of events that the NEO Iris must perform to complete the requested assays.
Shutdown	Shutdown is a cessation of operations or activity. The NEO Iris shutdown procedure guides the operator through the necessary steps to close down the NEO Iris.

Term	Definition
Start Run Assistant	The Start Run Assistant button, located on the Main Menu Bar, is used to access the Start Run Assistant. The Start Run Assistant is an intuitive guide for the operator to start assay runs.
Trackball	A trackball is a computer screen pointing device that does not require movement on a pad, but uses manual rotation of a ball around a fixed coordinate to move the visible pointer across the computer screen.
Transport System	The transport system moves microplates (each plate being held in a plate carrier) between the different NEO Iris modules located across the NEO Iris deck.
Touch-Screen Monitor	The NEO Iris monitor screen is pressure sensitive such that, by pressing the screen at a designated coordinate, the operator can initiate a designated NEO Iris action.
Upload Worklist	The Upload Worklist function is the process used to upload a worklist from an LIS or external computer to the NEO Iris computer.
UPS (or UPM)	The NEO Iris computer is connected to an Uninterruptible Power Supply (UPS) or Uninterruptible Power Manager (UPM) with an integral power conditioner. The UPS (or UPM) provides a consistent source of electricity (without excessive electrical noise output voltage) and also provides short periods of backup power in the event of power loss in the vicinity of the NEO Iris.
Utilities	The NEO Iris Utilities function allows the operator to view event logs and statistics as well as archive data.
Wash Stations (four probes and single probe)	Wash stations for both the four probes and single probe arms are used to clean the probes after a pipetting procedure. This cleaning prevents cross-contamination due to carry-over of blood samples and/or reagents. The wash stations are also used to prime the liquid system prior to its first use.
Washer (Microplate)	The NEO Iris microplate washer is used to physically dispense clean wash fluid into test wells requiring a wash step and also remove contaminated post-wash fluid out of the test wells. The washer uses a predetermined volume of wash fluid per well.

Term	Definition
Worklist Editor	The NEO Iris Worklist Editor function allows the operator to view, edit, and request assays for blood samples already stored in the NEO Iris software.
XYZ Movement	The transport system allows movement of the microplate and its plate carrier in the X, Y, and Z direction. The X-direction is defined as being horizontal left to right NEO Iris. The Y-direction is defined as being horizontal front to back. The Z-direction is defined as being vertical top to bottom.

Attachment I: NEO Iris Operator Manual

In This Attachment

This attachment describes the reagents and cutoff values used for the NEO Iris assays. It also includes basic assay procedural steps.

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The sample screen displays and sample printouts in this Attachment 1 for NEO Iris Operator Manual are for information and illustration purposes only. Immucor makes no representations or warranties about the accuracy or reliability of the information presented on the screen displays, and this information is not to be used for clinical or maintenance evaluation.

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Document Revision History

Date	Version	Page	Description
MAY 2016	NEO Iris_EU-001-100 (A-I)	N/A	First Version of Attachment 1 for NEO Iris Operating Manual
JUL2016	NEO Iris_EU-001-101 (A-I)	I-4	Update of the limitations on interfering substances for Lipemia and Icterus (Levels defined)
JUN2017	NEO Iris_EU-001-102 (A-I)	Attachment 1: NEO Iris Operator Manual	Manufacturer new address and Document Revision History List of assays updated Change the Anti-A positive cutoff range for samples from 70 to 100 to 58 to 100 for ABO assays
NOV2018	NEO Iris_EU-001-103 (A-I)	I-12, I33, I34, I53, I57	Capture-CMV included
SEP2021	NEO Iris_EU-002-103 (A-I)	I-29	Revised Cut-Offs for the Crossmatch assays (XMatch_E and XMatch_S).
JAN2022	NEO Iris_EU-003-103 (A-I)	I-9	Anti-D NOVACLONE is used in the vertical ABDCHECK assay
OCT2022	NEO Iris_EU-004-103 (A-I)	I-7,I-8, I-18,I-19	immuClone Rh-Hr Control is used in the horizontal ABDLONG and BABY_BG assays

Sample Requirements

Limitation: At least 250 µl of packed red blood cells need to be present in a sample tube to ensure that the probe picks up red blood cells and not plasma (only for those assays that require red blood cells).

At least 500 µl of plasma or serum needs to be present in a sample tube to ensure that the probe picks up plasma or serum.

Limitation: Red blood cell samples only collected with EDTA anticoagulants can be tested on the instrument. The use of other anticoagulants for testing on the instrument must be verified in the corresponding reagent Instructions for Use. Serum samples can also be tested on the instrument for tests that do not require red cells. Samples obtained from tubes containing neutral gel separators may produce falsely positive results and should therefore not be tested on the instrument.

Limitation: The dead volume, or the depth to which probes cannot reach, is 200 µl of sample.

Note: Red blood cell donor unit segments can be tested on the instrument using the forward ABO and Rh blood grouping assays and Crossmatch. You must remove segments from blood bags and cut them so that the contents can be dispensed into a test tube with a diameter of 12 mm. It is recommended that you label the test tube with a unit ID barcoded label taken from the correct blood bag. You must then insert the test tube into the Donor rack for testing on the instrument.

Limitation: When loading a test tube, containing red blood cell donor unit segment contents, into a Donor rack for compatibility testing with the Crossmatch assay, the contents of the test tube must not exceed a liquid height of 3.3cm (1.3 inches), otherwise the clot detection mechanism can be falsely alarmed.

Limitation: Samples that exhibit excessive hemolysis should not be tested on the instrument.Samples that exhibit a hemolysis grade of 3+ or greater must not be tested on the instrument, because they may generate erroneous results. Refer to the photograph below for a hemolysis grade of 3+ (color guide). For assays using Capture-R® Select, do not use hemolyzed samples for creating a monolayer. Fragmented red blood cell membranes will interfere with monolayer formation.

Limitation: Samples that exhibit excessive lipemia should not be tested on the instrument. Samples that exhibit a dosage above 600 mg/dL of lipids must not be tested on the instrument because they may generate erroneous results.

Limitation :Samples that exhibit excessive icterus should not be tested on the instrument. Samples that exhibit a dosage above 30 mg/dL of bilirubin must not be tested on the instrument because they may generate erroneous results.

Limitation: Instrument studies have demonstrated that the probe washes are sufficient to prevent carry-over of samples that have an antibody titer of up to 1024 (typical of those samples encountered in a blood bank setting). It is important to note that these studies apply only to routine patient or donor samples. Sample material that is provided in surveys has been shown to occasionally cause carry-over at lower titers (a result of the manufacturing process for these materials).

Limitation: For assays using Capture-R® Ready-Screen® and Capture-R® Ready-ID® microplates, avoid testing previously frozen specimens that have undergone multiple freeze-thaw cycles, as these may give erroneous or inconsistent test results.

Assay Descriptions

List of Assays

Assay Description	Assay Short Name	Used Reagents	Microplates used
	Blood Grouping	**Horizontal/12 wells per strip**	
Forward ABO Blood Grouping	ABDCHECK	1. NOVACLONE Anti-A 2. NOVACLONE Anti-B 3. NOVACLONE Anti-D 4. NOVACLONE Diluent Control	Untreated microplates
Forward ABO Blood Grouping	ABDCHECK2	1. immuClone Anti-A 2. immuClone Anti-B 3. immuClone Anti-D rapid 4. immuClone Rh-Hr Control	Untreated microplates
Forward and reverse ABO Blood Grouping	ABORH	1. NOVACLONE Anti-A 2. NOVACLONE Anti-B 3. Referencells A1 4. Referencells B 5. NOVACLONE Anti-D 6. NOVACLONE Diluent Control	Untreated microplates
Forward and reverse ABO Blood Grouping	ABORH2	1. immuClone Anti-A 2. immuClone Anti-B 3. Referencells A1 4. Referencells B 5. immuClone Anti-D rapid 6. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay Short Name	Used Reagents	Microplates used
	Blood Grouping	**Horizontal/12 wells per strip**	
Forward and reverse ABO Blood Grouping	ABDLONG	1. NOVACLONE Anti-A 2. NOVACLONE Anti-B 3. NOVACLONE Anti-AB 4. Referencells A1 5. Referencells A2 6. Referencells B 7. Referencells O 8. Autocontrol 9. NOVACLONE Anti-D 10. immuClone Anti-D rapid 11. immuClone Rh-Hr Control	Untreated microplates
Forward and reverse ABO Blood Grouping	ABDLONG2	1. immuClone Anti-A 2. immuClone Anti-B 3. immuClone Anti-AB 4. Referencells A1 5. Referencells A2 6. Referencells B 7. Referencells O 8. Autocontrol 9. NOVACLONE Anti-D 10. immuClone Anti-D rapid 11. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay Short Name	Used Reagents	Microplates used

	Blood Grouping	**Horizontal/12 wells per strip**	
Forward ABO Blood Grouping	BABY_BG	1. immuClone Anti-A 2. NOVACLONE Anti-A 3. immuClone Anti-B 4. NOVACLONE Anti-B 5. immuClone Anti-AB 6. NOVACLONE Anti-AB 7. NOVACLONE Anti-D 8. immuClone Anti-D rapid 9. immuClone Rh-Hr Control	Untreated microplates
Subgroup "A" testing	A_subg	1. Anti-A1 (Lectin) 2. immuClone Anti-H 3. immuClone Rh-Hr Control	Untreated microplates
Forward ABO Blood Grouping	AB_CTR	1. NOVACLONE Anti-A 2. NOVACLONE Anti-B 3. NOVACLONE Diluent Control	Untreated microplates
Forward ABO Blood Grouping	AB_CTR2	1. immuClone Anti-A 2. immuClone Anti-B 3. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay Short Name	Used Reagents	Microplates used
	Blood Grouping	**Horizontal/12 wells per strip**	
Rh Blood Group	RHFORMEL	1. immuClone Anti-C(1) 2. immuClone Anti-C(2) 3. immuClone Anti-c(1) 4. immuClone Anti-c(2) 5. immuClone Anti-E(1) 6. immuClone Anti-E(2) 7. immuClone Anti-e(1) 8. immuClone Anti-e(2) 9. immuClone Anti-K(1) 10. Automated Anti-Kell 11. immuClone Rh-Hr Control	Untreated microplates
Rh Blood Group	PHENO16	1. immuClone Anti-C(1) 2. immuClone Anti-c(1) 3. immuClone Anti-E(1) 4. immuClone Anti-e(1) 5. immuClone Anti-K(1) 6. immuClone Rh-Hr Control	Untreated microplates
Rh Blood Group (Specific Kell testing)	AG_K	1. immuClone Anti-K(1) 2. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay Short Name	Used Reagents	Microplates used
	Blood Grouping	**Horizontal/12 wells per strip**	
Rh Blood Group (Specific Kell testing)	Kell	1. immuClone Anti-K(1) 2. Automated Anti-Kell 3. immuClone Rh-Hr Control	Untreated microplates
Rare phenotype testing	AG_M	1. immuClone Anti-M 2. immuClone Rh-Hr Control	Untreated microplates
Rare phenotype testing	Cw_IgM	1. immuClone Anti-Cw 2. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay Short Name	Used Reagents	Microplates used
	Blood Grouping	**Vertical/8 wells per strip**	
Forward ABO Blood Grouping	ABDCHECK	1. NOVACLONE Diluent Control 2. NOVACLONE Anti-A 3. NOVACLONE Anti-B 4. NOVACLONE Anti-D	Untreated microplates

Assay Description	Assay Short Name	Used Reagents	Microplates used
	Blood Grouping	**Vertical/8 wells per strip**	
Forward ABO Blood Grouping	ABDCHECK2	1. immuClone Rh-Hr Control 2. immuClone Anti-A 3. immuClone Anti-B 4. immuClone Anti-D rapid	Untreated microplates
Forward and reverse ABO Blood Grouping	ABDFULL	1. NOVACLONE Diluent Control 2. NOVACLONE Anti-A 3. NOVACLONE Anti-B 4. NOVACLONE Anti-AB 5. immuClone Anti-D rapid 6. NOVACLONE Anti-D 7. Referencells A1 8. Referencells B	Untreated microplates
Forward and reverse ABO Blood Grouping	ABDFULL2	1. immuClone Rh-Hr Control 2. immuClone Anti-A 3. immuClone Anti-B 4. immuClone Anti-AB 5. immuClone Anti-D rapid 6. NOVACLONE Anti-D 7. Referencells A1 8. Referencells B	Untreated microplates

Assay Description	Assay Short Name	Used Reagents	Microplates used
	Blood Grouping	**Vertical/8 wells per strip**	
Forward and reverse ABO Blood Grouping	ABOD12_I	1. immuClone Rh-Hr Control 2. immuClone Anti-A 3. immuClone Anti-B 4. immuClone Anti-AB 5. immuClone Anti-D rapid 6. Referencells A1 7. Referencells B	Untreated microplates
Forward and reverse ABO Blood Grouping	ABOD12NC	1. NOVACLONE Diluent Control 2. NOVACLONE Anti-A 3. NOVACLONE Anti-B 4. NOVACLONE Anti-AB 5. NOVACLONE Anti-D 6. Referencells A1 7. Referencells B	Untreated microplates
Forward ABO Blood Grouping	Baby_BG	1. NOVACLONE Diluent Control 2. NOVACLONE Anti-A 3. NOVACLONE Anti-B 4. NOVACLONE Anti-AB 5. immuClone Anti-D rapid 6. NOVACLONE Anti-D	Untreated microplates

Assay Description	Assay Short Name	Used Reagents	Microplates used
	Blood Grouping	**Vertical/8 wells per strip**	
Forward ABO Blood Grouping	Baby_BG2	1. immuClone Rh-Hr Control 2. immuClone Anti-A 3. immuClone Anti-B 4. immuClone Anti-AB 5. immuClone Anti-D rapid 6. NOVACLONE Anti-D	Untreated microplates

Assay Description	Assay Short Name	Used Reagents	Microplates used
	Blood Grouping	**Vertical/8 wells per strip**	
Forward ABO Blood Grouping	ABODBB_I	1. immuClone Rh-Hr Control 2. immuClone Anti-A 3. immuClone Anti-B 4. immuClone Anti-AB 5. immuClone Anti-D rapid	Untreated microplates
Subgroup "A" testing	A_subg	1. Anti-A1 (Lectin) 2. immuClone Anti-H 3. immuClone Rh-Hr Control	Untreated microplates
Substance "H" testing	AG_H	1. immuClone Anti-H 2. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay Short Name	Used Reagents	Microplates used
	Blood Grouping	**Vertical/8 wells per strip**	
Rh Blood Group	PHENO12	1. immuClone Anti-C(1) 2. immuClone Anti-c(1) 3. immuClone Anti-E(1) 4. immuClone Anti-e(1) 5. immuClone Anti-K(1) 6. immuClone Rh-Hr Control	Untreated microplates
Rh Blood Group	PHENO	1. immuClone Anti-C(1) 2. immuClone Anti-c(1) 3. immuClone Anti-E(1) 4. immuClone Anti-e(1) 5. Automated Anti-Kell 6. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay Short Name	Used Reagents	Microplates used
	Blood Grouping	**Vertical/8 wells per strip**	
Rh Blood Group (Specific Kell testing)	AG_K	1. Automated Anti-Kell 2. immuClone Rh-Hr Control	Untreated microplates
Rare phenotype testing	AG_M	1. immuClone Anti-M 2. immuClone Rh-Hr Control	Untreated microplates

Rare phenotype testing	Cw_IgM	1. immuClone Anti-Cw 2. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay Short Name	Used Reagents	Microplates used
	QC		
QC	**QC**	According to customer specific requirements	Untreated microplates

Assay Description	Assay Short Name	Generic name	Microplates used
	Capture-R Ready Screen		
RBC antibody screen (pooled cells)	Pool_Cell	Capture-R RS Pooled Cells	Capture-R RS Pooled
RBC antibody screen (2-cell)	2_Cell	Capture-R RS 2 Cells	Capture-R RS I and II
RBC antibody screen (3-cell)	3_Cell	Capture-R RS 3 Cells	Capture-R RS 3
RBC antibody screen (4-cell)	4_Cell	Capture-R RS 4 Cells	Capture-R RS 4
RBC antibody panel	Ab_ID	Capture-R RS Identification	Capture-R RS ID
RBC antibody panel	ExtendDP	Capture-R RS Identification Extend1	Capture-R RS ID Extend1

Assay Description	Assay Short Name	Generic name	Microplates used
	Capture-R Ready Screen		
RBC antibody panel	ExtendDN	Capture-R RS Identification Extend2	Capture-R RS ID Extend2
	Capture-CMV		
CMV detection	CMV	Capture-CMV	Capture-CMV

Limitations, Warnings and Notes

Icon	Description
	**Limitation:** The purpose of the Monoclonal Control for the Weak_D assays is to serve as a sample control. It is expected to indicate those sample related conditions that could lead to false positive well results and, therefore, a false positive interpretation for the test. When the Monoclonal Control well yields a positive result for a sample, then the instrument will give an interpretation of invalid.
	**Limitation:** The purpose of the Monoclonal Control for the Kell and Rh phenotyping assays is to serve as a sample control for Immucor low protein blood grouping reagents. It is expected to indicate those sample related conditions that could lead to spontaneous agglutination with low protein reagents and, therefore, a false positive interpretation for the test. When the Monoclonal Control well yields a positive result, then the instrument will give an interpretation of invalid.

Icon	Description
	**Limitation:** Certain blood sample factors have a high likelihood of causing no-type-determined (NTD) ABO or Rh (D) interpretations. These include serological factors due to the inheritance of weakly expressed gene products by certain diseases (such as leukemia), through the transfusion or transplantation of ABO and Rh (D) allogeneic red blood cell products, or due to the patient's age. Instrument NTD results can also occur due to the interference caused by certain sample conditions, such as higher-than-normal levels of lipid, bilirubin, free plasma hemoglobin, clots, or aggregates. It is possible that when two or more of these factors occur simultaneously, believable but erroneous test results (i.e., mistype) might occur. Forward only ABO-Rh testing has a higher risk of mistype due to the absence of the reverse type results. Hazardous mistypes may occur, such as an A sample being interpreted as group AB, or an Rh (D) negative sample being interpreted as Rh (D) positive. For this reason, ABO-Rh results should always be compared to the patient or donor's history. Additionally, sample preparation and exclusion instructions contained in the relevant reagent direction circulars should be followed precisely. Before decisions about medical treatment are made or red blood cell products are released for transfusion, ABO and Rh (D) test results should be verified. This verification can consist of an immediate spin crossmatch or a result comparison to a second current or historical ABO and Rh (D) test by the same or an alternative method. This limitation applies to all ABO-Rh assays, both with and without a reverse test.
	**Limitation:** The Reverse ABO Blood Group assay is intended to screen for ABO antibodies in plasma. This provides a presumptive indication of the red blood cell ABO group for the individual from which the plasma was collected. The absence of the corresponding forward group test subjects the results of this assay to several potential sources of error. These include serological factors due to the donor's age, immunological state, the presence of an IgM allo or autoantibody, transfusion or transplantation status or disease states. Sample related conditions such as higher-than-expected levels of lipids, bilirubin, free plasma hemoglobin, clots or aggregates may also be a factor. **This assay cannot be used (alone) to determine the ABO group as part of pre-transfusion testing in a patient population, or to determine ABO group for blood components intended for transfusion**.
	**Limitation:** The red blood cell crossmatch assay (XMatch_E/XMatch_S) is intended only for the detection of incompatibilities due to IgG antibodies. The red blood cell crossmatch assay (XMatch_E/XMatch_S*)* is **not** intended for the detection of incompatibilities due to IgM antibodies, such as ABO incompatibilities.

Icon	Description
	**Limitation:** The NEO Iris software manages the results obtained based on Capture-R Ready-ID strip placement. To assure proper sample and well identification, it is necessary to load the Capture-R Ready-ID strips into the plate carrier, so that the left strip (L) (containing donors 1–8) is occupying an odd-numbered column position of the strip carrier. The strip must not be placed in the holder such that the left strip is occupying an even-numbered column position.

Correct Strip Positions

Column Position

Row Position	1	2	3	4	5	6	7	8	9	10	11	12
A	L	R	L	R	L	R	L	R	L	R	L	R
B	L	R	L	R	L	R	L	R	L	R	L	R
C	L	R	L	R	L	R	L	R	L	R	L	R
D	L	R	L	R	L	R	L	R	L	R	L	R
E	L	R	L	R	L	R	L	R	L	R	L	R
F	L	R	L	R	L	R	L	R	L	R	L	R
G	L	R	L	R	L	R	L	R	L	R	L	R
H	L	R	L	R	L	R	L	R	L	R	L	R

Incorrect Strip Positions

Column Positions

Row Position	1	2	3	4	5	6	7	8	9	10	11	12
A		L	R	L	R	L	R	L	R	L	R	
B		L	R	L	R	L	R	L	R	L	R	
C		L	R	L	R	L	R	L	R	L	R	
D		L	R	L	R	L	R	L	R	L	R	
E		L	R	L	R	L	R	L	R	L	R	
F		L	R	L	R	L	R	L	R	L	R	
G		L	R	L	R	L	R	L	R	L	R	
H		L	R	L	R	L	R	L	R	L	R	

If this convention is not followed, the software will not recognize that the strips are misplaced and errors will occur. This scenario also applies to the Extend assays.

Icon	Description
	**Limitation:** Capture-R® Ready Indicator Red Cells should be used no more than 24 hours after a stir ball has been added to the vial. Vials of reagents, other than Indicator Red Cells, that have remained continuously on the NEO Iris for 72 hours (3 days) should be removed and replaced with fresh vials. Vials of reagents, other than Indicator Red Cells, that are removed from the NEO Iris when not in use and refrigerated can be used up to their expiration dates.
	**Limitation:** In order to maintain the integrity of the DAT Positive Control Cell reagent after a stir ball has been added to the vial, Immucor recommends the following restrictions on reagent vial usage: (a) a maximum of 72 hours of continuous use on the NEO, or (b) a maximum of 7 days of intermittent use on the NEO Iris when the reagent vial is on-board daily for a maximum of 16 hours followed by intervening periods of refrigerated storage.
	**Limitation:** The NEO Iris cannot reliably detect hemagglutination reactions that are graded as 1+ or less in test tube methodology.
	**Warning:** When running the reagent quality control (QC) assays, only one lot of each reagent must be loaded onto the NEO.
	**Warning:** The grading of reactions on the NEO Iris must only be regarded as an approximation when compared to off-line visual grading by laboratory technical staff.
	**Warning:** For the QC3_Cell assay, the correct position for the Capture-R® Ready-Screen® (3) strip in a Capture-R® Ready-Screen® (3) white plate frame is at strip position one (1). The instrument will not check for the correct placement of the Capture-R® Ready-Screen® (3) strip in the white plate frame. You must make sure of the correct placement of this strip yourself. Incorrect placement of this single strip can result in test material being pipetted onto the pipetting station surface, an overflow error in the washer, and a failed quality control. Unused Capture-R® Ready-Screen® (3) strips should not be present in any of the other positions of the plate. It is not required that strip positions two (2) to twelve (12) of the white plate frame be occupied by any strips at all. Those positions can be left empty, but all strip positions should be activated in the software. The *Strip Selection* tab in the *Plate Loading Tower* dialog must indicate that all twelve (12) strips are available even though only the strip at position (1) is present.
	**Note:** The Ag_K assay has a negative control well associated with each sample tested on the microplate. This control well contains the sample red blood cell suspension, Specimen Diluent and the Monoclonal Control reagent.

Icon	Description
	**Note:** A negative control well containing Monoclonal Control is included with each sample tested using various assays to detect spontaneously agglutinated red blood cells and potential issues with the centrifugation and shake steps.
	**Note:** The full and forward-only blood grouping assays have been configured to require a strong positive (3-4+) reaction of the Anti-A, Anti-B, Anti-A,B and Anti-D reagents in order to return a positive well result. Weak positive reactivity with one of these reagents will return an equivocal "?" well result. This is so that clinical conditions resulting in 2+ reactivity or less can be made readily evident and may be investigated as needed according to your local on-site procedures and regulations. Such clinical conditions may include, but are not be limited to, ABO subgroups, D variants, and mixed-field reactions due to post bone marrow transplantation relapse or post blood transfusion.

Assay Cutoffs

List of Horizontal Assay Cutoffs

Horizontal Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
ABDCHECK	NOVACLONE Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	NOVACLONE Anti-B NOVACLONE Anti-D NOVACLONE Diluent Control	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+(not reported)	N/A	N/A
		4+	76	100
ABDCHECK2	immuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	immuClone Anti-B immuClone Anti-D rapid immuClone Rh-Hr Control	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A

Horizontal Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
		3+(not reported)	N/A	N/A
		4+	76	100
ABORH	NOVACLONE Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	NOVACLONE Anti-B NOVACLONE Anti-D NOVACLONE Diluent Control	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+(not reported)	N/A	N/A
		4+	76	100
	Referencells A1 Referencells B	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
ABORH2	immuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100

Horizontal Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
	immuClone Anti-B immuClone Anti-D rapid immuClone Rh-Hr Control	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+(not reported)	N/A	N/A
		4+	76	100
	Referencells A1 Referencells B	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
ABDLONG	NOVACLONE Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	NOVACLONE Anti-B NOVACLONE Anti-A,B NOVACLONE Anti-D immuClone Anti-D rapid immuClone Rh-Hr Control	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+(not reported)	N/A	N/A
		4+	76	100
	Referencells A1 Referencells A2	0	0	23
		?	23	28

Horizontal Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
	Referencells B Referencells O Autocontrol	1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
ABDLONG2	immuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	immuClone Anti-B immuClone Anti-A,B NOVACLONE Anti-D immuClone Anti-D rapid immuClone Rh-Hr Control	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+(not reported)	N/A	N/A
		4+	76	100
	Referencells A1 Referencells A2 Referencells B Referencells O Autocontrol	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
BABY_BG	immuClone Anti-A NOVACLONE Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A

Horizontal Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
		3+ (not reported)	N/A	N/A
		4+	58	100
	immuClone Anti-B NOVACLONE Anti-B immuClone Anti-A,B NOVACLONE Anti-A,B NOVACLONE Anti-D immuClone Anti-D rapid immuClone Rh-Hr Control	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+(not reported)	N/A	N/A
		4+	76	100
A_subg	Anti-A1 (Lectin) immuClone Anti-H immuClone Rh-Hr Control	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	80
		4+	80	100
AB_CTR	NOVACLONE Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	NOVACLONE Anti-B NOVACLONE Diluent Control	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A

Horizontal Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
		4+	76	100
AB_CTR2	immuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	immuClone Anti-B immuClone Rh-Hr Control	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
RHFORMEL	immuClone (1) Anti-C immuClone (2) Anti-C immuClone (1) Anti-c immuClone (2) Anti-c immuClone (1) Anti-E immuClone (2) Anti-E immuClone (1) Anti-e immuClone (2) Anti-e immuClone Rh-Hr Control	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	100
	immuClone (1) Anti-K	0	0	23
		?	23	35
		1+ (not reported)	N/A	N/A

Horizontal Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
		2+	35	50
		3+	50	80
		4+	80	100
	Automated immuClone Anti-K	0	0	23
		?	23	50
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	50	80
		4+	80	100
PHENO16	immuClone (1) Anti-C immuClone (1) Anti-c immuClone (1) Anti-E immuClone (1) Anti-e immuClone Rh-Hr Control	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	100
	immuClone (1) Anti-K	0	0	23
		?	23	35
		1+ (not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	100
AG_K	immuClone (1) Anti-K	0	0	23
		?	23	35
		1+ (not reported)	N/A	N/A
		2+	35	50
		3+	50	80

Horizontal Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
		4+	80	100
	immuClone Rh-Hr Control	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	100
Kell	immuClone (1) Anti-K	0	0	23
		?	23	35
		1+ (not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	100
	Automated immuClone Anti-K	0	0	23
		?	23	50
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	50	80
		4+	80	100
	immuClone Rh-Hr Control	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	100
AG_M	immuClone Anti-M	0	0	23

Horizontal Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	75	100
	immuClone Rh-Hr Control	0	0	23
		?	23	80
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	80	100
Cw_IgM	immuClone Anti-Cw	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	100
	immuClone Rh-Hr Control	0	0	23
		?	23	80
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	80	100

List of Vertical Assay Cutoffs

Vertical Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
ABDCHECK	NOVACLONE Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	NOVACLONE Anti-B NOVACLONE Anti-D NOVACLONE Diluent Control	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+(not reported)	N/A	N/A
		4+	76	100
ABDCHECK2	immuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	immuClone Anti-B immuClone Anti-D rapid immuClone Rh-Hr Control	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+(not reported)	N/A	N/A
		4+	76	100

Vertical Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
ABDFULL	NOVACLONE Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	NOVACLONE Anti-B NOVACLONE Anti-A,B NOVACLONE Anti-D immuClone Anti-D rapid NOVACLONE Diluent Control	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+(not reported)	N/A	N/A
		4+	76	100
	Referencells A1 Referencells B	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
ABDFULL2	immuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	immuClone Anti-B immuClone Anti-A,B	0	0	30
		?	30	76

Vertical Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
	immuClone Anti-D rapid immuClone Rh-Hr Control	1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+(not reported)	N/A	N/A
		4+	76	100
	Referencells A1 Referencells B	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
ABOD12_I	immuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	immuClone Anti-B immuClone Anti-A,B immuClone Anti-D rapid immuClone Rh-Hr Control	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+(not reported)	N/A	N/A
		4+	76	100
	Empty Row (Vide)	0	0	30
		? (not reported)	N/A	N/A
		Positive	30	100
	Referencells A1	0	0	23

Vertical Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
	(GRA1) Referencells B (GRB)	?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
ABOD12NC	NOVACLONE Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	NOVACLONE Anti-B NOVACLONE Anti-A,B NOVACLONE Anti-D NOVACLONE Diluent Control	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+(not reported)	N/A	N/A
		4+	76	100
	Empty Row (Vide)	0	0	30
		? (not reported)	N/A	N/A
		Positive	30	100
	Referencells A1 (GRA1) Referencells B (GRB)	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100

Vertical Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
Baby_BG	NOVACLONE Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	NOVACLONE Anti-B NOVACLONE Anti-A,B NOVACLONE Anti-D immuClone Anti-D rapid NOVACLONE Diluent Control	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+(not reported)	N/A	N/A
		4+	76	100
Baby_BG2	immuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	immuClone Anti-B immuClone Anti-A,B NOVACLONE Anti-D immuClone Anti-D rapid immuClone Rh-Hr	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+(not reported)	N/A	N/A
		4+	76	100
ABODBB_I	immuClone Anti-A	0	0	30
		?	30	58

Vertical Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	immuClone Anti-B immuClone Anti-A,B immuClone Anti-D rapid immuClone Rh-Hr Control	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+(not reported)	N/A	N/A
		4+	76	100
A_subg	Anti-A1 (Lectin) immuClone Anti-H immuClone Rh-Hr Control	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	80
		4+	80	100
AG_H	immuClone Anti-H immuClone Rh-Hr Control	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	80
		4+	80	100
Pheno12	immuClone (1) Anti-C immuClone (1) Anti-c immuClone (1) Anti-E immuClone (1) Anti-e	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A

Vertical Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
	immuClone Rh-Hr Control	3+	75	80
		4+	80	100
	immuClone (1) Anti-K	0	0	23
		?	23	35
		1+ (not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	100
Pheno	immuClone (1) Anti-C immuClone (1) Anti-c immuClone (1) Anti-E immuClone (1) Anti-e immuClone Rh-Hr Control	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	100
	Automated immuClone Anti-K	0	0	23
		?	23	50
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	50	80
		4+	80	100
AG_K	Automated immuClone Anti-K	0	0	23
		?	23	50
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	50	80

Vertical Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
		4+	80	100
	immuClone Rh-Hr Control	0	0	23
		?	23	50
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	50	80
		4+	80	100
AG_M	immuClone Anti-M	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	75	100
	immuClone Rh-Hr Control	0	0	23
		?	23	80
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	80	100
Cw_IgM	immuClone Anti-Cw	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	100
	immuClone Rh-Hr	0	0	23

Vertical Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
	Control	?	23	80
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	80	100
Pool_Cell 2_Cell 4_Cell	All	0	0	20
		?	20	30
		1+	30	45
		2+	45	65
		3+	65	90
		4+	90	100
3_Cell	Screening wells	0	0	20
		?	20	30
		1+	30	45
		2+	45	65
		3+	65	90
		4+	90	100
	IgG coated positive control well	0	0	30
		?	-	-
		1+	30	45
		2+	45	65
		3+	65	90
		4+	90	100
Ab_ID ExtendDP ExtendDN	Sample	0	0	20
		?	20	30
		1+	30	45

Vertical Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
		2+	45	65
		3+	65	90
		4+	90	100
	Positive Control	0	0	30
		?	-	-
		1+	30	45
		2+	45	65
		3+	65	90
		4+	90	100
	Negative Control	0	0	30
		?	-	-
		1+	30	45
		2+	45	65
		3+	65	90
		4+	90	100
DAT	All	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100
XMATCH_E XMATCH_S	All	0	0	5
		?	5	15
		1+	15	30
		2+	30	60
		3+	60	90

Vertical Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
		4+	90	100
Weak_D1, Weak_D2	Anti-D	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100
	immuClone Rh-Hr Control	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100
AG_Cw	Anti-Cw micro	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100
	Negative Control micro	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100
AG_Fya	Anti-Fy(a) micro	0	0	20

Vertical Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100
	Negative Control micro	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100
AG_Fyb	Anti-Fy(b) micro	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100
	Negative Control micro	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100
AG_Jka	Anti-Jk(a) micro	0	0	20
		?	20	40
		1+	40	50

Vertical Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
		2+	50	72
		3+	72	90
		4+	90	100
	Negative Control micro	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100
AG_Jkb	Anti-Jk(b) micro	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100
	Negative Control micro	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100
AG_k_li	Anti-k (Cellano) micro	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100

Vertical Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
	Negative Control micro	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100
AG_S	Anti-S micro	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100
	Negative Control micro	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100
AG_s_li	Anti-s micro	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100
	Negative Control micro	0	0	20
		?	20	40
		1+	40	50

Vertical Assays				
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
		2+	50	72
		3+	72	90
		4+	90	100
ANTIGENS	Anti-Fy(a) micro Anti-Fy(b) micro Anti-Jk(a) micro Anti-Jk(b) micro Anti-S micro Anti-s micro	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100
	Negative Control micro	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100

N/A = Not Applicable

Assay Abbreviation	Reaction	Neg <=	Pos >
CMV	Not Applicable	45.5	45.5

Assay Reagent Component Grid

Reagents & Microplates	Pool_Cell	2_Cell	3_Cell	4_Cell	Ab_ID	ExtendDP	ExtendDN	CMV
Capture LISS	X	X	X	X	X	X	X	X
Capture-R Ready Indicator Red Cells	X	X	X	X	X	X	X	
Capture-R Positive Control Serum (Weak)	X	X		X	X	X	X	
Capture-R Negative Control Serum	X	X		X	X	X	X	
Capture-R Ready-Screen (Pooled Cells)	X							
Capture-R Ready-Screen(I and II)		X						
Capture-R Ready-Screen (3)			X					
Capture-R Ready-Screen (4)				X				
Capture-R Ready-ID					X			
Capture-R Ready-ID Extend I						X		
Capture-R Ready-ID Extend II							X	
Capture-CMV Indicator Red Cells								X
Capture-CMV Positive Control Serum (Weak)								X
Capture-CMV Negative Control Serum								X
Capture-CMV								X

Assay Description	Assay Short Name	Used Reagents	Microplates used
	Capture-R Select		
Direct Antiglobulin Test (DAT)	DAT	N/A (only controls)	Capture-R Select Plates
Weak D testing	Weak_D1	1. NOVACLONE Anti-D	Capture-R Select Plates
Weak D testing	Weak_D2	1. NOVACLONE Anti-D 2. immuClone Rh-Hr Control	Capture-R Select Plates
RBC crossmatch for donor-samples in EDTA tubes	XMatch_E	N/A (only controls)	Capture-R Select Plates
RBC crossmatch for segment donor-samples	XMatch_S	N/A (only controls)	Capture-R Select Plates

Assay Description	Assay Short Name	Used Reagents	Microplates used
	Capture Select - Rare Antigens		
Capture-R Cw Antigen	AG_Cw	1. Anti-Cw micro 2. Negative Control micro	Capture-R Select Plates
Capture-R Fya Antigen	AG_Fya	1. Anti-Fya micro 2. Negative Control micro	Capture-R Select Plates
Capture-R Fyb Antigen	AG_Fyb	1. Anti-Fyb micro 2. Negative Control micro	Capture-R Select Plates
Capture-R Jka Antigen	AG_Jka	1. Anti-Jka 2. Negative Control micro	Capture-R Select Plates
Capture-R Jkb Antigen	AG_Jkb	1. Anti-Jkb micro 2. Negative Control micro	Capture-R Select Plates

Assay Description	Assay Short Name	Used Reagents	Microplates used
	Capture Select - Rare Antigens		
Capture-R k Antigen	AG_k_li	1. Anti-Cellano micro 2. Negative Control micro	Capture-R Select Plates
Capture-R S Antigen	AG_S	1. Anti-S micro 2. Negative Control micro	Capture-R Select Plates
Capture-R s Antigen	AG_s_li	1. Anti-s micro 2. Negative Control micro	Capture-R Select Plates
Capture-R Antigens	ANTIGENS	1. Anti-Fya micro 2. Anti-Fyb micro 3. Anti-Jka micro 4. Anti-Jkb micro 5. Anti-S micro 6. Anti-s micro 7. Empty 8. Negative Control micro	Capture-R Select Plates

Assay Procedural Steps

Before You Begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert. Package inserts are also the source of information for limitations of the reagents in use.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
ABORH ABORH_2	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells. Remove the caps from the blood sample tubes. 3. Select the necessary number of untreated microplates for use. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Referencells® A1 and B to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the ABORH or the ABORH_2 assay to the blood samples, either manually or following the upload worklist procedure. 8. Start the ABORH or the ABORH_2 assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the ABORH or the ABORH_2 assay, and records and interprets blood sample results. 9. At the completion of the NEO Iris ABORH or the ABORH_2 assay, click the Results button on the main menu bar to access the blood sample results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
ABDLONG ABDLONG2	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells. Remove the caps from the blood sample tubes. 3. Select the necessary number of untreated microplates for use. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Referencells® A1, A2, B and O to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the ABDLONG or the ABDLONG2 assay to the blood samples, either manually or following the upload worklist procedure. 8. Start the ABDLONG or the ABDLONG2 assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the ABDLONG or the ABDLONG2 assay, and records and interprets blood sample results. 9. At the completion of the NEO Iris ABDLONG or the ABDLONG2 assay, click the Results button on the main menu bar to access the blood sample results

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
ABDCHECK ABDCHECK2	1. Bring all reagents, donor segment blood samples and blood samples (if applicable) to 18–30°C before testing. 2. Centrifuge the blood sample collection tubes to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge these samples. 3. Select the necessary number of untreated microplates for use. 4. Remove reagent vial caps. 5. Load reagents, microplates, and blood samples (and/or donor samples) onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 6. Assign the ABDCHECK or the ABDCHECK2 assay to the blood samples (and/or donor samples), either manually or following the upload worklist procedure. 7. Start the ABDCHECK or the ABDCHECK2 assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the ABDCHECK or the ABDCHECK2 assay, and records and interprets the blood sample (and/or donor samples) results. 8. At the completion of the NEO Iris ABDCHECK or the ABDCHECK2 assay, click the Results button on the main menu bar to access the blood sample (and/or donor samples) results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
BABY_BG	1. Bring all reagents, donor segment blood samples and blood samples (if applicable) to 18–30°C before testing. 2. Centrifuge the blood sample collection tubes to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge these samples. 3. Select the necessary number of untreated microplates for use. 4. Remove reagent vial caps. 5. Load reagents, microplates, and blood samples (and/or donor samples) onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 6. Assign the BABY_BG assay to the blood samples (and/or donor samples), either manually or following the upload worklist procedure. 7. Start the BABY_BG assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the BABY_BG assay, and records and interprets the blood sample (and/or donor samples) results. 8. At the completion of the NEO Iris BABY_BG assay, click the Results button on the main menu bar to access the blood sample (and/or donor samples) results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
AB_CTR AB_CTR2	1. Bring all reagents, donor segment blood samples and blood samples (if applicable) to 18–30°C before testing. 2. Centrifuge the blood sample collection tubes to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge these samples. 3. Select the necessary number of untreated microplates for use. 4. Remove reagent vial caps. 5. Load reagents, microplates, and blood samples (and/or donor samples) onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 6. Assign the AB_CTR or the AB_CTR2 assay to the blood samples (and/or donor samples), either manually or following the upload worklist procedure. 7. Start the AB_CTR or the AB_CTR2 assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the AB_CTR or the AB_CTR2 assay, and records and interprets the blood sample (and/or donor samples) results. 8. At the completion of the NEO Iris AB_CTR or the AB_CTR2 assay, click the Results button on the main menu bar to access the blood sample (and/or donor samples) results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
A_subg	1. Bring all reagents, donor segment blood samples and blood samples (if applicable) to 18–30°C before testing. 2. Centrifuge the blood sample collection tubes to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge these samples. 3. Select the necessary number of untreated microplates for use. 4. Remove reagent vial caps. 5. Load reagents, microplates, and blood samples (and/or donor samples) onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 6. Assign the A_subg assay to the blood samples (and/or donor samples), either manually or following the upload worklist procedure. 7. Start the A_subg assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the A_subg assay, and records and interprets the blood sample (and/or donor samples) results. 8. At the completion of the NEO Iris A_subg assay, click the Results button on the main menu bar to access the blood sample (and/or donor samples) results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
RHFORMEL PHENO16	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples (and/or donor samples), onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 5. Assign the RHFORMEL or the PHENO16 assay to the blood samples (and/or donor samples), either manually or following the upload worklist procedure. 6. Start the RHFORMEL or the PHENO16 assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the RHFORMEL or the PHENO16 assay, and records and interprets blood samples results. 7. At the completion of the NEO Iris RHFORMEL or the PHENO16 assay, click the Results button on the main menu bar to access the blood samples results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
AG_K Kell	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples (and/or donor samples), onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 5. Assign the AG_K or the Kell assay to the blood samples (and/or donor samples), either manually or following the upload worklist procedure. 6. Start the AG_K or the Kell assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the AG_K or the Kell assay, and records and interprets plasma/serum sample results. 7. At the completion of the NEO Iris AG_K or the Kell assay, click the Results button on the main menu bar to access the blood samples results.
AG_M	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples (and/or donor samples), onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 5. Assign the AG_M assay to the blood samples (and/or donor samples), either manually or following the upload worklist procedure. 6. Start the AG_M assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the AG_M assay, and records and interprets blood samples results. 7. At the completion of the NEO Iris AG_M assay, click the Results button on the main menu bar to access the blood samples results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
Cw_IgM	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples (and/or donor samples), onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 5. Assign the Cw assay to the blood samples (and/or donor samples), either manually or following the upload worklist procedure. 6. Start the Cw assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the Cw assay, and records and interprets blood samples results. 7. At the completion of the NEO Iris Cw assay, click the Results button on the main menu bar to access the blood samples results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
ABDCHECK ABDCHECK2	1. Bring all reagents, donor segment blood samples and blood samples (if applicable) to 18–30°C before testing. 2. Centrifuge the blood sample collection tubes to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge these samples. 3. Select the necessary number of untreated microplates for use. 4. Remove reagent vial caps. 5. Load reagents, microplates, and blood samples (and/or donor samples) onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 6. Assign the ABDCHECK or the ABDCHECK2 assay to the blood samples (and/or donor samples), either manually or following the upload worklist procedure. 7. Start the ABDCHECK or the ABDCHECK2 assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the ABDCHECK or the ABDCHECK2 assay, and records and interprets the blood sample (and/or donor samples) results. 8. At the completion of the NEO Iris ABDCHECK or the ABDCHECK2 assay, click the Results button on the main menu bar to access the blood sample (and/or donor samples) results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
ABDFULL ABDFULL2 ABOD12_I ABOD12_NC	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells. Remove the caps from the blood sample tubes. 3. Select the blood samples to separate the plasma from the red blood cells. Remove the caps from the blood sample tubes. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Referencells® A1 and B to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the ABFULL, ABDFULL2, ABOD12_I or the ABOD12_NC assay to the blood samples, either manually or following the upload worklist procedure. 8. Start the ABFULL, ABDFULL2, ABOD12_I or the ABOD12_NC assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the ABFULL, ABDFULL2, ABOD12_I or the ABOD12_NC assay, and records and interprets blood sample results. 9. At the completion of the NEO Iris ABFULL, ABDFULL2, ABOD12_I or the ABOD12_NC assay, click the Results button on the main menu bar to access the blood sample results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
Baby_BG Baby_BG2 ABODBB_I	1. Bring all reagents, donor segment blood samples and blood samples (if applicable) to 18–30°C before testing. 2. Centrifuge the blood sample collection tubes to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge these samples. 3. Select the necessary number of untreated microplates for use. 4. Remove reagent vial caps. 5. Load reagents, microplates, and blood samples (and/or donor samples) onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 6. Assign the Baby_BG, Baby_BG2 or the ABODBB_I assay to the blood samples (and/or donor samples), either manually or following the upload worklist procedure. 7. Start the Baby_BG, Baby_BG2 or the ABODBB_I assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the Baby_BG, Baby_BG2 or the ABODBB_I assay, and records and interprets the blood sample (and/or donor samples) results. 8. At the completion of the NEO Iris Baby_BG, Baby_BG2 or the ABODBB_I assay, click the Results button on the main menu bar to access the blood sample (and/or donor samples) results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
PHENO12 PHENO	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples (and/or donor samples), onto the NEO Iris. 5. Follow the procedures in Chapter 6 – Instrument Testing Operation. 6. Assign the PHENO12 or the PHENO assay to the blood samples (and/or donor samples), either manually or following the upload worklist procedure. 7. Start the PHENO12 or the PHENO assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the PHENO12 or the PHENO assay, and records and interprets blood samples results. 8. At the completion of the NEO Iris PHENO12 or the PHENO assay, click the Results button on the main menu bar to access the blood samples results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
AG_K	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples (and/or donor samples), onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 5. Assign the AG_K assay to the blood samples (and/or donor samples), either manually or following the upload worklist procedure. 6. Start the AG_K assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the AG_K assay, and records and interprets blood samples results. 7. At the completion of the NEO Iris AG_K assay, click the Results button on the main menu bar to access the blood samples results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
A_subg	1. Bring all reagents, donor segment blood samples and blood samples (if applicable) to 18–30°C before testing. 2. Centrifuge the blood sample collection tubes to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge these samples. 3. Select the necessary number of untreated microplates for use. 4. Remove reagent vial caps. 5. Load reagents, microplates, and blood samples (and/or donor samples) onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 6. Assign the A_subg assay to the blood samples (and/or donor samples), either manually or following the upload worklist procedure. 7. Start the A_subg assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the A_subg assay, and records and interprets the blood sample (and/or donor samples) results. 8. At the completion of the NEO Iris A_subg assay, click the Results button on the main menu bar to access the blood sample (and/or donor samples) results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
AG_H	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples (and/or donor samples), onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 5. Assign the AG_H assay to the blood samples (and/or donor samples), either manually or following the upload worklist procedure. 6. Start the AG_H assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the AG_H assay, and records and interprets blood samples results. 7. At the completion of the NEO Iris AG_H assay, click the Results button on the main menu bar to access the blood samples results.
AG_M	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples (and/or donor samples), onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 5. Assign the AG_M assay to the blood samples (and/or donor samples), either manually or following the upload worklist procedure. 6. Start the AG_M assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the AG_M assay, and records and interprets blood samples results. 7. At the completion of the NEO Iris AG_M assay, click the Results button on the main menu bar to access the blood samples results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
Cw_IgM	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples (and/or donor samples), onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 5. Assign the Cw assay to the blood samples (and/or donor samples), either manually or following the upload worklist procedure. 6. Start the Cw assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the Cw assay, and records and interprets blood samples results. 7. At the completion of the NEO Iris Cw assay, click the Results button on the main menu bar to access the blood samples results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
Pool_Cell	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the blood samples from the red blood cells/clot. Remove the caps from the blood sample tubes. 3. Remove the Capture-R® Ready-Screen® (Pooled Cells) microplate frame and the desired number of Capture-R® Ready-Screen® (Pooled Cells) strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the Pool_Cell assay to the blood samples, either manually or following the upload worklist procedure. 8. Start the Pool_Cell assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the Pool_Cell assay, and records and interprets the blood sample results. 9. At the completion of the NEO Iris Pool_Cell assay, click the Results button on the main menu bar to access the blood sample results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
2_Cell	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the blood samples from the red blood cells/clot. Remove the caps from the blood sample tubes. 3. Remove the Capture-R® Ready-Screen® (I and II) microplate frame and the desired number of Capture-R® Ready-Screen® (I and II) strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the 2_Cell assay to the blood samples, either manually or following the upload worklist procedure. 8. Start the 2_Cell assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the 2_Cell assay, and records and interprets the blood sample results. 9. At the completion of the NEO Iris 2_Cell assay, click the Results button on the main menu bar to access the blood sample results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
3_Cell	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the blood samples from the red blood cells/clot. Remove the caps from the blood sample tubes. 3. Remove the Capture-R® Ready-Screen® (3) microplate frame and the desired number of Capture-R® Ready-Screen® (3) strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the 3_Cell assay to the blood samples, either manually or following the upload worklist procedure. 8. Start the 3_Cell assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the 3_Cell assay, and records and interprets the blood sample results. 9. At the completion of the NEO Iris 3_Cell assay, click the Results button on the main menu bar to access the blood sample results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
QC3_Cell	1. Bring all reagents to 18–30°C before testing. 2. Remove the Capture-R® Ready-Screen® (3) plate frame and one (1) Capture-R® Ready-Screen® (3) strip from the pouch. Place the strip in position one (1). 3. Remove reagent vial caps. 4. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells to be used. Gently agitate each vial to resuspend the red blood cells. 5. Load reagents and plates onto the NEO Iris following the procedures in **Chapter 6 – Instrument Testing Operation**. 6. Start the **QC3_Cell** assay following the procedures in **Chapter 10 – Maintaining the NEO**. The NEO Iris automatically performs the **QC3_Cell** assay, and records and interprets the **QC3_Cell** results. 7. At the completion of the NEO Iris **QC3_Cell** assay, press the **Results** button on the main menu bar to access the results. A **QC3_Cell** report will print automatically.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
4_Cell	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the blood samples from the red blood cells/clot. Remove the caps from the blood sample tubes. 3. Remove the Capture-R® Ready-Screen® (4) microplate frame and the desired number of Capture-R® Ready-Screen® (4) strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the 4_Cell assay to the blood samples, either manually or following the upload worklist procedure. 8. Start the 4_Cell assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the 4_Cell assay, and records and interprets the blood sample results. 9. At the completion of the NEO Iris 4_Cell assay, click the Results button on the main menu bar to access the blood sample results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
Ab_ID	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the blood samples from the red blood cells/clot. Remove the caps from the blood sample tubes. 3. Remove the Capture-R® Ready-ID® microplate frame and the desired number of Capture-R® Ready-ID® strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the Ab_ID assay to the blood samples, either manually or following the upload worklist procedure. 8. Start the Ab_ID assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the Ab_ID assay, and records the blood sample results. 9. At the completion of the NEO Iris Ab_ID assay, click the Results button on the main menu bar to access the blood sample results. If any wells are reported positive, you must cross-reference this data with the lot-specific Capture-R® Ready-ID® Master List to determine the antibody identification (if any exists).

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
ExtendDP	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the blood samples from the red blood cells/clot. Remove the caps from the blood sample tubes. 3. Remove the Capture-R® Ready-ID® Extend I microplate frame and the desired number of Capture-R® Ready-ID® Extend I strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the ExtendDP assay to the blood samples, either manually or following the upload worklist procedure. 8. Start the ExtendDP assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the ExtendDP assay, and records the blood sample results. 9. At the completion of the NEO Iris ExtendDP assay, click the Results button on the main menu bar to access the blood sample results. If any wells are reported positive, you must cross-reference this data with the lot-specific Capture-R® Ready-ID® Extend I Master List to determine the antibody identification (if any exists).

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
ExtendDN	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the blood samples from the red blood cells/clot. Remove the caps from the blood sample tubes. 3. Remove the Capture-R® Ready-ID® Extend II microplate frame and the desired number of Capture-R® Ready-ID® Extend II strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the ExtendDN assay to the blood samples, either manually or following the upload worklist procedure. 8. Start the ExtendDN assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the ExtendDN assay, and records the blood sample results. 9. At the completion of the NEO Iris ExtendDN assay, click the Results button on the main menu bar to access the blood sample results. If any wells are reported positive, you must cross-reference this data with the lot-specific Capture-R® Ready-ID® Extend II Master List to determine the antibody identification (if any exists).

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
DAT	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood sample collection tubes to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge these samples. 3. Remove the Capture-R® Select microplate frame and the desired number of Capture-R® Select strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells, corQC™ EXTEND Standard and DAT Positive Control Cell to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples (and/or donor samples) onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the DAT assay to the blood samples (and/or donor samples), either manually or following the upload worklist procedure. 8. Start the DAT assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the DAT assay, and records and interprets the blood sample (and/or donor samples) results. 9. At the completion of the NEO Iris DAT assay, click the Results button on the main menu bar to access the blood sample (and/or donor samples) results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
Weak_D1 Weak_D2	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells. Remove the caps from the blood sample tubes. 3. Remove the Capture-R® Select microplate frame and the desired number of Capture-R® Select strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells and corQC™ EXTEND Standard to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the Weak_D1 or the Weak_D2 assay to the blood samples, either manually or following the upload worklist procedure. The NEO Iris software can automatically assign the Weak_D1 or the Weak_D2 assay to the necessary blood samples if the software is configured to do so. This configuration is optional. 8. Start the Weak_D1 or the Weak_D2 assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the Weak_D1 or the Weak_D2 assay, and records and interprets the blood sample results. 9. At the completion of the NEO Iris Weak_D1 or the Weak_D2 assay, click the Results button on the main menu bar to access the blood sample results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
XMatch_E XMatch_S	1. Bring all reagents, donor segment blood samples and blood samples to 18–30°C before testing. 2. Centrifuge the blood sample collection tubes to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge these samples. 3. Remove the Capture-R® Select microplate frame and the desired number of Capture-R® Select strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells and corQC™ EXTEND Standard to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, blood samples and donor segment blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the XMatch assay to the blood samples, either manually or following the upload worklist procedure. 8. Start the XMatch assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the XMatch assay, and records and interprets the compatibility results. 9. At the completion of the NEO Iris XMatch assay, click the Results button on the main menu bar to access the compatibility results.
AG_Cw AG_Fya AG_Fyb AG_Jka AG_Jkb AG_k_li AG_S AG_S_li	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells. Remove the caps from the blood sample tubes. 3. 3. Remove the Capture-R® Select microplate frame and the desired number of Capture-R® Select strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells and corQC™ EXTEND Standard to be used. Gently agitate each vial to resuspend the red blood cells.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
	6. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the corresponding assay (AG_#) to the blood samples, either manually or following the upload worklist procedure. The NEO Iris software can automatically assign the corresponding assay (AG_#) to the necessary blood samples if the software is configured to do so. This configuration is optional. 8. Start the corresponding assay (AG_#) following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the corresponding assay (AG_#) and records and interprets the blood sample results. 9. At the completion of the NEO Iris corresponding assay (AG_#), click the Results button on the main menu bar to access the blood sample results.
ANTIGENS	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells. Remove the caps from the blood sample tubes. 3. 3. Remove the Capture-R® Select microplate frame and the desired number of Capture-R® Select strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells and corQC™ EXTEND Standard to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the ANTIGENS assay to the blood samples, either manually or following the upload worklist procedure. The NEO Iris software can automatically assign the ANTIGENS to the necessary blood samples if the software is configured to do so. This configuration is optional. 8. Start the ANTIGENS following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the ANTIGENS, and records and interprets the blood sample results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
	9. At the completion of the NEO Iris ANTIGENS assay, click the Results button on the main menu bar to access the blood sample results.
QC	1. Bring all reagents to 18–30°C before testing. 2. Select one clean untreated microplate for use. 3. Remove reagent vial caps. 4. Add one stirball to each new vial of Referencells® A1, A2, B and 0, and corQC™ EXTEND Complete to be used. Gently agitate each vial to resuspend the red blood cells. 5. Load reagents and microplates onto the NEO Iris using the procedures in the Reagent QC (see Chapter 6 – Instrument Testing Operation) 6. The NEO Iris automatically performs the QC assay, and records and interprets the QC results. 7. At the completion of the NEO Iris QC assay, click the Results button on the main menu bar to access the QC results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
CMV	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma/serum from the red blood cells/clot. Remove the caps from the blood sample tubes. 3. Remove the Capture-CMV® microplate frame and the desired number of Capture-CMV® strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-CMV Indicator Red Cells to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the CMV assay to the blood samples, either manually or following the upload worklist procedure. 8. Start the CMV assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO automatically performs the CMV assay, and records and interprets the blood sample results. 9. At the completion of the NEO CMV assay, press the Results button on the main menu bar to access the blood sample results.

Test Results and Interpretation

Introduction

The NEO Iris generates a result for each well read by the instrument and an interpretation of the results. Each NEO Iris assay has predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported as Negative, Positive, Equivocal, or Invalid. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for all assays include:

Indicator	Name	Description
+	Positive	The reaction value is greater that the positive cutoff value.
-	Negative	The reaction value is less than or equal to the negative cutoff value.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater that the negative cutoff value or equal to or less than the positive cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

Editing Test Results

For selected assays, the operator can edit well results that the NEO Iris identifies as Equivocal (identified as "?"). Only equivocal results can be edited. No positive or negative results reported by the NEO Iris can be edited. Refer to the table of Result Interpretations for a list of those assays with equivocal ranges that cannot be edited.

When results are edited, the NEO Iris creates an audit trail and flags results as edited on the NEO Iris Reports. The operator is only able to edit test well results. The operator cannot edit sample result interpretations.

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO Iris process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	Possible Well Results	Possible Test Interpretations
ABDCHECK ABDCHECK2 ABORH ABORH2 ABDLONG ABDLONG2 ABDFULL ABDFULL2 Baby_BG Baby_BG2	+, - , ?, X	ABO Interpretations: A, B, AB, O, NTD/Mixed field ?, *INV* Rh Interpretations: Positive, Negative, NTD/Mixed field ?, *INV*.
ABOD12NC ABOD12_I ABODBB_I	+, - , ?, X	ABO Interpretations: A, B, AB, O, IND / DP, *INV* Rh Interpretations: Positive, Negative, IND / DP, *INV*.
AB_CTR AB_CTR2	+, - , ?, X	ABO Interpretations: A, B, AB, O, NTD/Mixed field ?, *INV*,
RHFORMEL PHENO16 PHENO12	+, - , ?, X	CcEe Interpretations: CcEe, CcEE, Ccee, CCEe, CCEE, CCee, ccEe, ccEE, ccee, NTD/Mixed field ?, *INV* Kell Interpretations: K+, K- NTD/Mixed field ?, *INV*
PHENO	+, - , ?, X	CcEe Interpretations: CcEe, CcEE, Ccee, CCEe, CCEE, CCee, ccEe, ccEE, ccee, IND / DP, *INV* Kell Interpretations: K+, K- IND / DP, *INV*

Assay	Possible Well Results	Possible Test Interpretations
A_subg	+, - , ?, X	A1, A2, A_int, *INV*, NTD
AG_K Kell	+, - , ?, X	K+, K-, NTD/Mixed field ?, *INV*
AG_M	+, - , ?, X	M+, M-, NTD/Mixed field ?, *INV*
Cw_IgM	+, - , ?, X	Cw+, Cw-, NTD/Mixed field ?, *INV*
AG_H	+, - , ?, X	Positive, negative, NTD, *INV*
Pool_Cell, 2_Cell	+, -, ?*, X	Positive, Negative, No_Int, *INV*
3_Cell Ab_ID ExtendDP, ExtendDN	+, -, ?*, X	Positive, Negative, No_Int, *INV*, Ctrl Fail  **Note: Ctrl Fail** indicates that the per sample positive control well (4th well in 3_Cell and 15th well in Ab_ID, ExtendDN, and ExtendDP) has failed. This control well must react at least 3+ in order for the sample test result to be valid. If the control well is less than 3+, then the interpretation given will be **Ctrl Fail**.
QC3_Cell	+,-,?,X	Qualified, Failed  **Note:** The positive control well (4th well for each set of 4 wells per test) must react at 1+ for both the weak positive control and the negative control so that the control results can be categorized as valid. If either of these 4th wells is less than 1+, then the interpretation for the QC result will be **Failed**. The

Assay	Possible Well Results	Possible Test Interpretations
		test wells for the weak positive control (1st, 2nd and 3rd wells of 4) must react at 1+ so that the control result can be categorized as valid. If one or more of the 1st, 2nd or 3rd wells, for the weak positive control, is less than 1+, then the interpretation for the QC result will be **Failed**.
Weak_D1 Weak_D2	+, -, ?, X	Positive, Negative, *INV*, NTD
XMatch_E XMatch_S	+, - , ?*,X	Sample Interpretations: IgG Comp (Check ABO Comp), Incompatible, No_Int, *INV* Control Interpretations: Positive, Negative, No_Int, *INV*
DAT	+, - , ?*,X	Positive, Negative, No_Int, *INV*
AG_Cw		Cw+, Cw-, NTD, *INV*
AG_Fya		Fya+, Fya-, NTD, *INV*
AG_Fyb		Fyb+, Fyb-, NTD, *INV*
AG_Jka		Jka+, Jka, NTD, *INV*
AG_Jkb	+,-,?*,X	Jkb+, Jkb-, NTD, *INV*
AG_k_l	+,-,?*,X	k+, k-, NTD, *INV*
AG_S	+,-,?*,X	S+, S-, NTD, *INV*
AG_s_li	+,-,?*,X	s+, s-, NTD, *INV*
ANTIGENS	+,-,?*,X	Fy(a) interpretation: Fya+, Fya-, NTD, *INV* Fy(b) interpretation: Fyb+, Fyb-, NTD, *INV* Jk(a) interpretation: Jka+, Jka, NTD, *INV* Jk(b) interpretation: Jkb+, Jkb-, NTD, *INV* S interpretation : S+, S-, NTD, *INV* s interpretation: s+, s-, NTD, *INV*
CMV	+, - , X	Sample Interpretations: Positive, Negative, *INV* Control Interpretations: Positive, Negative, *INV*, No_Int

Note: Assays that include the use of two different Anti-D reagents and yield a positive result with one Anti-D reagent, but a negative result with the other Anti-D reagent for a given sample, will generate an NTD result related to the Rh (D) testing. This can be due to, but is not limited to, reduced D antigen epitope representation on the red blood cell membrane, or the presence of a D variant. Resolution of this discrepancy can include, but is not limited to, Weak D testing and off-line testing with a battery of assorted Anti-D reagents to investigate the presence of D antigen variations, as dictated by your local on-site policies and procedures.

Key for Table of Well Results and Test Interpretations by Assay

The two (2) tables below describe the possible well test results per the Result Interpretations section of this attachment.

Well Result	**Description**
*	Equivocal results that may be edited. Run controls for these assays cannot be edited.
+	Positive
-	Negative
?	Equivocal
X	Invalid

Test Interpretation	**Description**
Ctrl Fail	Control Failed
No_Int	No Interpretation
INV	Invalid
NTD	No Type Determined
NTD/Mixed field ?	No Type Determined or possible Mixed Field
IND / DP	No Type Determined or possible Mixed Field

Attachment II: NEO Iris Operator Manual

In This Attachment

This attachment describes the interface specifications and message structure to be used in the transfer of data from the NEO Iris to an LIS.

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Scope

This document describes the structure to be used in the transfer of data between the Immucor NEO Iris instrument to a Laboratory Information System (LIS).

To ensure industry standardization the popular ASTM protocol is used in formatting the data structure as well as data communication transfer. This is based on the American Society for Testing and Materials designations: **E1381-02 and E1394 – 97**. These standards are more recently recognized as LIS1-A and LIS2-A, respectively.

Essential Information for Communication

Connectivity for data transfer is accomplished with the industry standard LIS1-A (*Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems* ~ Formerly ASTM E1381). Connectivity can be configured to use either Serial or Socket communication.

Serial Communication

For serial communication, connectivity will make use of an available 9-pin male serial port on the NEO Iris computer. The default connection properties for serial communication are:

Baud Rate	9600
Data Bits	8
Stop Bits	1
Parity	None

The contact pin assignments for serial communication are as follows:

			Direction	
Contact No.	**EIA Circuit**	**Description**	**Instrument**	**LIS**
1	…	Shield	…	No Connection
2	BA	Receive Data	Input	Output
3	BB	Transmit Data	Output	Input
5	AB	Signal Ground	…	…

Socket Communication

For Socket communication, the traffic will traverse over a TCP/IP network, where the NEO Iris instrument will behave as the client in the connection relationship. It is expected that the LIS behave as the Server. The LIS Host/Server IP address and port number must be known prior to the NEO Iris configuration and the host must be ready (in listening mode) to establish a viable socket connection.

Important Note Regarding Network Connectivity

When connecting to a TCP/IP network, as with a socket connection, it is important that the NEO Iris instrument be protected from malicious network threats. Risk of vulnerability is greatly minimized with the use of a firewall device. A firewall device is a hardware component, supplied by Immucor as part of the NEO Iris instrument system, that will restrict access between the NEO Iris instrument and the facility network to block unwanted use or abuse. The NEO Iris instrument will connect to the firewall device, which in turn will connect to the facility network. Serial interface connectivity does not carry through the firewall device as serial communication is not TCP/IP traffic. Please note that antivirus or additional third party software cannot be loaded on the NEO Iris computer. Doing so may impact the safety and support of the NEO Iris.

General Communication Flow

In the setup for the NEO Iris to receive order messages from the LIS, an ASTM formatted host query is generated upon loading samples on the instrument and clicking on the "Download Requests" button from the Start Run Assistant. The LIS is expected to create a response (order) to the host query message should it find matching order(s) on the LIS system. The NEO Iris is not expecting a negative or blank response if no match is found. Order messages to the NEO Iris instrument will be processed upon receipt and the assay request(s) added to the instrument Worklist.

Once results are available on the NEO Iris, the user can approve and export the results. If desired, the auto-export feature can be implemented on the NEO Iris to automatically generate the export without user intervention. This process bypasses the approval step and immediately exports results when testing is complete. Auto-export is configured per assay by Immucor Technical Support.

Serial and Socket Data Transfer

There are three distinct phases in transferring information between the NEO Iris instrument and the LIS. In each phase, one system directs the operation and is responsible for continuity of the communication. The three phases assure that the actions of the sender and the receiver are coordinated. The three phases are establishment, transfer, and termination. Although they are briefly described here as an overview, the LIS1-A specification should be reviewed for complete details.

Establishment Phase (Link Connection)

The establishment phase determines the direction of information flow and prepares the receiver to accept information. The NEO Iris will notify the LIS receiver that information is available under the following circumstances: host query and result export.

When either a host query or result message is available, the NEO Iris will initiate the establishment phase to notify the LIS that information is available. After the NEO Iris determines that the link is in a neutral state, it will transmit the <ENQ> transmission control character to the LIS. The NEO Iris will ignore all responses other than <ACK>, <NAK>, and <ENQ>. If the LIS responds with the <ACK> transmission control character, the establishment phase ends and the transfer phase begins.

When the LIS as a sender is ready to transmit order information to the NEO Iris in response to a host query, it is expected that the LIS will transmit the <ENQ> transmission control character. The NEO Iris will respond with the <ACK> transmission control character to move communication to the transfer phase.

Transfer Phase

During the transfer phase, the NEO Iris may transmit messages to or receive messages from the LIS. The transfer phase will continue until all messages are transmitted. Messages are comprised of Records which are expected to be transferred in frames, with each frame containing a maximum of 247 characters. Records longer than 240 characters are divided between two or more frames. Every record must begin a new frame. A frame is one of two types—an intermediate frame or an end frame. The frame structure is illustrated below; however, further explanation on the structure of the frame, including how the frame number and checksum are calculated, can be found in the LIS1-A specification.

Intermediate Frame	End Frame
<STX>FNText<ETB>C1C2<CR><LF>	<STX>FNText<ETX>C1C2<CR><LF>
Where	
<STX>	Start of Text transmission control character
FN	Single digit Frame Number 0 to 7
Text	Data Content of Message
<ETB>	End of Transmission Block transmission control character
<ETX>	End of Text transmission control character
C1	Most significant character of check sum 0 to 9 and A to F
C2	Least significant character of checksum 0 to 9 and A to F
<CR>	Carriage Return ASCII character
<LF>	Line Feed ASCII character

The NEO Iris follows the rules outlined for acknowledgements to each frame. An <ACK> signifies that the last frame was received successfully and indicates readiness to receive another frame. A <NAK> signifies that the last frame was not successfully received and indicates readiness to receive the frame again. An <EOT> signifies the last frame was received successfully, but an interrupt is requested.

Termination Phase (Link Release)

The termination phase returns the data link to the clear or neutral state. The NEO Iris will notify the LIS that all messages have been sent by sending the <EOT> transmission control character. At this point, the NEO Iris will regard the data link to be in a neutral state. Upon receiving <EOT>, the LIS should also regard the data link to be in the neutral state.

Data Characters

All data will be represented as eight-bit, single-byte, coded graphic character values as defined in ISO 8859-1:1987. The eight-bit values, within the range from 0 to 127 of ISO 8859-1987 correspond to the ASCII standard character set. Values from 0 to 31 are disallowed with the exception of 7 (BEL), 9 (Horizontal Tab), 11 (Vertical Tab), and 13 (CR), where 13 is reserved as a record terminator. Values from 32 to 126 and from 128 to 254 are allowed. Values 127 and 255 are also not allowed.

Allowed characters: 7, 9, 11, 12, 13, 32-126, 128–254

Disallowed characters: 0–6, 8, 10, 14-31, 127, 255

All records are to be terminated with character 13 (CR).

The message structure and the record structure are detailed in the sections that follow.

Result Message Structure

The following outlines the structure of result messages as they would be transmitted from the NEO Iris instrument. Result messages will contain the Header (H), Patient (P), Order (O), Result (R), and Terminator (L) records. Result messages for the IgG_XM assay will contain the Comment (C) record to supply the identification of the donor sample used in testing.

Header Record

Bolded items are fixed data, sub-components are numbered under 'Use' column.

Field	Field Name	Use	Description of use
1	Record type ID	**H**	Identifies record as a header record
2	Delimiter Definition	**₩^&**	Definition of delimiters
3	Message Control ID	unused	
4	Access Password	unused	
5	Sender Name or ID	**NEO**	Fixed instrument ID
6	Sender Street Address	unused	
7	Reserved Field	unused	
8	Sender Telephone	unused	
9	Characteristic of Sender	unused	
10	Receiver ID	**LIS**	Fixed Receiver ID
11	Special Instructions	either Manual Edit or (null)	Test edited flag Manual Edit = test data has been edited Can be null
12	Processing ID	unused	
13	Version No.	nn	Reflects version level of the specification

14	Date and time of message	YYYYMMDDHHMMSS	Current date and time of message

Example:

```
H|\^&|||NEO|||||LIS|||LIS2-A2|20100219083911
```

Patient Record

The Patient (P) Record is sent as a placeholder. The P Record will be blank.

Field	Field Name	Use	Description of use
1	Record Type ID	**P**	Identifies Record as a Patient Information record
2	Sequence Number	**1**	Fixed sequence number

Example:

P|1

Order Record

Bolded items are fixed data, sub-components are numbered under 'Use' column.

Field	Field Name	Use		Description of use
1	Record type ID	**O**		Identifies record as an order record
2	Sequence Number	**1**		Fixed sequence number
3	Specimen ID	variable		Sample Number
4	Instrument Specimen ID	unused		
5	Universal Test ID	1	Universal Test ID	^^^Assay Code
		2	Universal Test ID Name	
		3	Universal Test ID Type	
		4	Instrument Code	
6-31	Fields 6-31 are unused			

Example:

```
O|1|002650||^^^ABORH
```

Result Record

Bolded items are fixed data, sub-components are numbered under 'Use' column.

Note: Please refer to Table 1 for a listing of possible values for Field 3.4 – Assay Codes.

Note: Please refer to Table 2 for a listing of possible values for Field 4 (Measurement Value) of the Result Record.

Note: Refer to Table 3 for well identification of the result pattern.

Field	Field Name	Use		Description of use
1	Record type ID	**R**		Identifies record as a result record
2	Sequence Number	**1**		Fixed sequence number
3	Universal Test ID	1	Universal Test ID	Reserved by standard
		2	Universal Test ID Name	Reserved by standard
		3	Universal Test ID Type	Reserved by standard
		4	variable	Instrument Assay Code
4	Measurement Value	1	variable	Graded Well Reaction Pattern
		2	variable	Interpretation
5	Units	unused		
6	Reference Range	unused		
7	Result Abnormal Flags	unused		
8	Nature of Abnormality	unused		
9	Result Status	**F**		Fixed – denotes final result
10	Date of Change in Instrument	unused		
11	Operator Identification	1	variable	Performed by User Name
		2	variable	Exported by User Name

Field	Field Name	Use		Description of use
12	Date/Time test started	unused		
13	Date/Time test completed	YYYYMMDDHHMMSS		Date and time created
14	Instrument Identification	1	variable	Instrument Serial Number
		2	variable	Plate Name

Example:

```
R|1|^^^ABORH|--44-33^O Positive|||||F||Melissa^Brent||20100219083911|
5030090002^UA5288913
```

Table 1 - Instrument Assay Codes

Field	Description	Instrument Codes			
		Blood Grouping	Antibody Screen/Panels	Antigen Phenotyping	Other
O Record 5.4 R Record 3.4	Assay Name	ABORH ABORH_2 ReflexABO FWD_ABORH ReflexFWD Weak_D Weak_D_F Rev_ABO ABORH_AB ABO_AB_2 RfxABO_AB FWDABO_AB RfxFWD_AB Wk_D_AB Wk_D_F_AB QCTEST QCTEST_AB	Pool_Cell 2_Cell 3_Cell Ab_ID ExtendDN ExtendDP QC3_Cell	Ag_CcEe Ag_CcE Ag_C RH2 Ag_c RH4 Ag_E RH3 Ag_e RH5 Ag_Kell QC_CcEe QC_CcE QC_C RH2 QC_c RH4 QC_E RH3 QC_e RH5 QC_Kell	DAT CMV IgG_XM

Table 2 - Result Record Field 4 Measurement Values

SUB-COMPONENT 1	
Assay	**Possible Values for Reaction Pattern**
All Assays	-, 1, 2, 3, 4, ?, X

SUB-COMPONENT 2		
Assay	**Interpretation Values**	
	ABO Portion	**Rh Portion**
ABORH ABORH_2 ABORH_AB ABO_AB_2 FWD_ABORH FWDABO_AB	A, B, AB, O, NTD, *INV*	Positive, Negative, NTD, *INV*
ReflexABO ReflexFWD RfxABO_AB RfxFWD_AB	A, B, AB, O, NTD, *INV*, Offline, ReflexABO Pending or ReflexFWD Pending or RfxABO_AB Pending or RfxFWD_AB Pending	Positive, Negative, Pending, NTD, *INV*, Offline, RPT Weak_D Pending or Weak_D_F Pending or Wk_D_AB Pending or Wk_D_F_AB Pending, ReflexABO Pending or ReflexFWD Pending or RfxABO_AB Pending or RfxFWD_AB Pending
Rev_ABO	A, B, AB, O, NTD, *INV*	

SUB-COMPONENT 2	
Assay	**Interpretation Values**
Weak_D Weak_D_F Wk_D_AB	Positive, Negative, NTD, *INV*

SUB-COMPONENT 2	
Assay	**Interpretation Values**
Wk_D_F_AB	
Pool_Cell 2_Cell DAT	Positive, Negative, No_Int, *INV*
3_Cell Ab_ID ExtendDN ExtendDP	Positive, Negative, No_Int, Ctrl Fail, *INV*
QCTEST QCTEST_AB QC3_Cell QC_CcEe QC_CcE QC_C RH2 QC_c RH4 QC_E RH3 QC_e RH5 QC_Kell	Qualified, Failed
IgG_XM	IgG Comp (Check ABO Comp), Incompatible, No_Int, *INV*
CMV	Positive, Negative, *INV*
Ag_C RH2	C+, C-, NTD, *INV*
Ag_c RH4	c+, c-, NTD, *INV*
Ag_E RH3	E+, E-, NTD, *INV*

SUB-COMPONENT 2		
Assay	**Interpretation Values**	
Ag_e RH5	e+, e-, NTD, *INV*	
Ag_Kell	K+, K-, NTD, *INV*	
	C c Interpretations	**E e Interpretations**
Ag_CcEe	C+ c+, C+ c-, C- c+, C+ NTD, C- NTD, NTD c+, NTD c-, NTD NTD, *INV*	E+ e+, E+ e-, E- e+, E+ NTD, E- NTD, NTD e+, NTD e-, NTD NTD, *INV*
Assay	**C c Interpretations**	**E Interpretations**
Ag_CcE	C+ c+, C+ c-, C- c+, C+ NTD, C- NTD, NTD c+, NTD c-, NTD NTD, *INV*	E+, E-, NTD, *INV*

Table 3 - LIS Well Result Identification for Result Record Field 4 Measurement Values

Assay	Test phase	
ABORH ABORH_2 ReflexABO	1	Anti-A
	2	Anti-B
	3	Anti-D series 4
	4	Anti-D series 5
	5	Monoclonal Control
	6	A1-Cell
	7	B-Cell
ABORH_AB ABO_AB_2 RfxABO_AB	1	Anti-A
	2	Anti-B
	3	Anti-A,B
	4	Anti-D Series 4
	5	Anti-D Series 5
	6	A1-Cell
	7	B Cell
	8	Monoclonal Control
FWD_ABORH ReflexFWD	1	Anti-A
	2	Anti-B
	3	Anti-D series 4
	4	Monoclonal Control
FWDABO_AB RfxFWD_AB	1	Anti-A
	2	Anti-B

Assay	Test phase	
Ab_ID ExtendDN ExtendDP	1	Cell 1
	2	Cell 2
	3	Cell 3
	4	Cell 4
	5	Cell 5
	6	Cell 6
	7	Cell 7
	8	Cell 8
	9	Cell 9
	10	Cell 10
	11	Cell 11
	12	Cell 12
	13	Cell 13
	14	Cell 14
	15	Positive Control
	16	Negative Control
Ag_CcEe	1	Anti-C
	2	Anti-c
	3	Anti-E
	4	Anti-e
	5	Monoclonal Control

Assay	Test phase	
	3	Anti-A,B
	4	Anti-D Series 4
	5	Monoclonal Control
Rev_ABO	1	A1-Cell
	2	B-Cell
Weak_D Weak_D_F Wk_D_AB Wk_D_F_AB	1	Monoclonal Control
	2	Anti-D Series 4
Pool_Cell	1	Cell 1
2_Cell	1	Cell 1
	2	Cell 2
3_Cell	1	Cell 1
	2	Cell 2
	3	Cell 3
	4	Positive Control
IgG_XM	1	IgG Compatibility
DAT	1	DAT result
CMV	1	CMV result
QCTEST	1	Anti-A & A1-Cell
	2	Anti-A & B-Cell
	3	Anti-B & B-Cell
	4	Anti-B & A1-Cell
	5	Anti-D series 4 & QC Cell

Assay	Test phase	
Ag_C RH2	1	Monoclonal Control
	2	Anti-C
Ag_c RH4	1	Monoclonal Control
	2	Anti-c
Ag_E RH3	1	Monoclonal Control
	2	Anti-E
Ag_e RH5	1	Monoclonal Control
	2	Anti-e
Ag_Kell	1	Monoclonal Control
	2	Anti-Kell
QC_CcEe	1	Anti-C / C positive cells
	2	Anti-c / c positive cells
	3	Anti-E / E positive cells
	4	Anti-e / e positive cells
	5	Anti-C / C negative cells
	6	Anti-c / c negative cells
	7	Anti-E / E negative cells
	8	Anti-e / e negative cells
QC_Kell	1	Anti-Kell / K positive cells
	2	Anti-Kell / K negative cells
QCTEST_AB	1	Anti-A & A1 Cell
	2	Anti-A & B Cell
	3	Anti-B & B Cell
	4	Anti-B & A1 Cell

Assay	Test phase	
	6	Anti-D series 4 & A1-Cell
	7	Anti-D series 5 & QC Cell
	8	Anti-D series 5 & B-Cell

Assay	Test phase	
	5	Anti-D series 4 & QC Cell
	6	Anti-D series 4 & A1 Cell
	7	Anti-D series 5 & QC Cell
	8	Anti-D series 5 & B Cell
	9	Anti-A,B & A1 Cell
	10	Anti-A,B & B Cell
	11	Anti-A,B & QC Cell

Assay	Test phase	
Ag_CcE	1	Anti-C
	2	Anti-c
	3	Anti-E
	4	Monoclonal Control
QC_CcE	1	Anti-C / C positive cells
	2	Anti-C / C negative cells
	3	Anti-c / c positive cells
	4	Anti-c / c negative cells
	5	Anti-E / E positive cells
	6	Anti-E / E negative cells
QC_C RH2	1	Anti-C / C positive cells
	2	Anti-C / C negative cells
QC_c RH4	1	Anti-c / c positive cells
	2	Anti-c / c negative cells
QC_E RH3	1	Anti-E / E positive cells
	2	Anti-E / E negative cells
QC_e RH5	1	Anti-e / e positive cells
	2	Anti-e / e negative cells

Comment Record

The Comment (C) Record is sent with the IgG_XM assay. The purpose of the C Record is to contain the ID of the donor unit used in the IgG_XM assay.

Bolded items are fixed data, sub-components are numbered under 'Use' column.

Field	Field Name	Use		Description of use
1	Record type ID	**C**		Identifies record as a comment record
2	Sequence Number	**1**		Fixed sequence number
3	Comment source	**I**		Fixed text
4	Comment Text	1	**Donor**	Fixed text
		2	variable	Donor ID used in IgG_XM assay
5	Comment Type	unused		

Example:

```
C|1|I|Donor^W037908150261
```

Terminator Record

Bolded items are fixed data.

Field	Field Name	Use	Description of use
1	Record type ID	**L**	Identifies record as a terminator
2	Sequence Number	**1**	Fixed at 1
3	Termination Code	**N**	Fixed at N – normal termination

Example:

```
L|1|N
```

Host Query Message Structure

The following outlines the structure of host query from the NEO Iris instrument. Host Query messages will contain Header (H), Request (Q), and Terminator (L) Records.

Header Record

Bolded items are fixed data.

Field	Field Name	Use	Description of use
1	Record type ID	**H**	Identifies record as a header record
2	Delimiter Definition	**₩^&**	Definition of delimiters
3	Message Control ID	unused	
4	Access Password	unused	
5	Sender Name or ID	**BBX**	Fixed text
6	Sender Street Address	unused	
7	Reserved Field	unused	
8	Sender Tel.	unused	
9	Characteristic of Sender	unused	
10	Receiver ID	**AURORA**	Fixed text
11	Special Instructions	unused	
12	Processing ID	unused	
13	Version No.	nn	Reflects version level of the specification
14	Date and time of message	YYYYMMDDHHMMSS	Date and time order generated

Example:

```
H|\^&|||BBX||||AURORA|||LIS2-A2|20100219083911
```

Request Record

Bolded items are fixed data.

Field	Field Name	Use	Description of use
1	Record type ID	**Q**	Identifies record as a request record
2	Sequence Number	**1**	Query Sequence number 1 – n
3	Starting Range ID No.	aaannn	Multiple sample barcodes separated with repeat delimiter.
4	Ending Range ID No.	unused	
5	Universal test ID	ALL	Will always be requesting all tests requested for a sample.
6	Nature of request time limit	unused	
7	Beginning request date/time	unused	
8	Ending request date/time	unused	
9	Requesting Physician name	unused	
10	Requesting Physician telephone	unused	
11	User Field 1	unused	
12	User Field 2	unused	
13	Request information status code	**O**	Test order request

Example:

- **Single**
  `Q|1|W126987||ALL|||||||O`
- **Multiple**
  `Q|1|0790048\\0790032\0790016\0790003||ALL|||||||O`

Terminator Record

Bolded items are fixed data.

Field	Field Name	Use	Description of use
1	Record type ID	**L**	Identifies record as a terminator
2	Sequence Number	**1**	Fixed at 1
3	Termination Code	**N**	Fixed at N = Normal termination

Example:

```
L|1|N
```

Order Message Structure

The following outlines the structure of order messages to the NEO Iris instrument. Order messages shall contain Header (H), Patient (P), Order (O), and Terminator (L) Records.

Header Record

Bolded items are fixed data.

Field	Field Name	Use	Description of use
1	Record type ID	**H**	Identifies record as a header record
2	Delimiter Definition	**₩^&**	Definition of delimiters
3	Message Control ID	unused	
4	Access Password	unused	
5	Sender Name or ID	**LIS**	Fixed text
6	Sender Street Address	unused	
7	Reserved Field	unused	
8	Sender Tel.	unused	
9	Characteristic of Sender	unused	
10	Receiver ID	**BBX**	Fixed text
11	Special Instructions	unused	
12	Processing ID	unused	
13	ASTM Version No.	nn	Aurora file version number
14	Date and time of message	YYYYMMDDHHMMSS	Date and time order generated

Patient Record

At minimum, an empty Patient (P) Record should be sent to maintain the hierarchal message structure. The LIS can optionally send data in the P Record, however, data sent in the P Record is currently ignored by NEO.

Field	Field Name	Use	Description of use
1	Record Type ID	**P**	Identifies Record as a Patient Information record
2	Sequence Number	**1**	Sequence number (1-n)

Order Record

Bolded items are fixed data, sub-components are numbered under 'Use' column.

Note: Please refer to Table 1 for a listing of possible values for Assay Codes.

Field	Field Name	Use		Description of use
1	Record type ID	**O**		Identifies record as an order record
2	Sequence Number	1		Sequence number (1-n)
3	Specimen ID	1	aaannnn	Alphanumeric Sample ID
		2	aaannnn	Alphanumeric Donation ID when ordering crossmatch assay. NULL if not crossmatch assay
4	Instrument Specimen ID	unused		
5	Universal Test ID	1	Universal Test ID	Reserved by standard
		2	Universal Test ID Name	Reserved by standard
		3	Universal Test ID Type	Reserved by standard
		4	Instrument Code	Assay Code for the order
6	Priority	**R**		Fixed at R = Routine
7	Request Order Date	unused		
8	Specimen Collection Date	unused		
9	Collection End Time	unused		
10	Collection Volume	unused		
11	Collector ID	unused		
12	Action Code	unused		
13	Danger Code	unused		
14	Relevant Clinical Info	unused		
15	Date Specimen Received	unused		
16	Specimen Descriptor	a		S = Sample

Field	Field Name	Use	Description of use
			C = Crossmatch Request
17	Ordering Physician	unused	
18	Physician Tel No.	unused	
19	User Field 1	unused	
20	User Field 2	unused	
21	Laboratory Field 1	unused	
22	Laboratory Field 2	unused	
23	Report Date/Time	unused	
24	Instrument Charge	unused	
25	Instrument Section ID	unused	
26	Report Type	**F**	Fixed at F = Final
	Remaining Fields are unused.		

Terminator Record

Field	Field Name	Use	Description of use
1	Record type ID	**L**	Identifies record as a terminator
2	Sequence Number	**1**	Sequence number
3	Termination Code	**N**	Fixed at N = Normal termination

Message Examples

The following illustrates examples of each of the three message types, Result, Host Query, and Order messages.

Result Messages:

ABORH

```
H|\^&|||NEO|||||LIS|||LIS2-A2|20100224194036
P|1
O|1|R142960||^^^ABORH
```

```
R|1|^^^ABORH|--44-33^O
Positive|||||F||Donna^Brent||20100216151816|5030090012^UA5645409
L|1|N
```

IgG_XM

```
H|\^&|||NEO|||||LIS|||LIS2-A2|20100224194400
P|1
O|1|R38536||^^^IgG_XM
R|1|^^^IgG_XM|-^IgG Comp (Check ABO Comp)|||||F||Jimmy^Brent||20100202092230|5030090012^SC07901917
C|1|L|Donor^LS061504
L|1|N
```

2_Cell

```
H|\^&|||NEO|||||LIS|||LIS2-A2|20100224194255
P|1
O|1|24531R552567842999||^^^2_Cell
R|1|^^^2_Cell|41^Positive|||||F||Stacy^Melissa||20100209103925|5030090012^X25702
688
L|1|N
```

FWD_ABORH

```
H|\^&|||NEO|||||LIS|||LIS2-A2|20100224194504
P|1
O|1|R112196||^^^FWD_ABORH
R|1|^^^FWD_ABORH|-44-^B
Positive|||||F||Yolanda^Donna||20100202092221|5030090001^UA4431019
L|1|N
```

Host Query Message:

```
H|\^&|||BBX|||||AURORA|||LIS2-A2|20100219083911
Q|1|Sample01\Sample02\Barcode0815\12345||ALL||||||||O
L|1|N
```

Order Messages:

Non-Crossmatch

```
H|\^&|||LIS|||||BBX|||LIS2-A2|20100219083911
P|1
O|1|3467852^||^^^ABORH|R||||||||||S|||||||||F
L|1|N
H|\^&|||LIS|||||BBX|||LIS2-A2|20100219083911
P|1
O|1|123456^||^^^2_Cell|R||||||||||S|||||||||F
L|1|N
```

Multiple Orders

```
H|\^&|||LIS|||||BBX|||LIS2-A2|20100219083911
P|1
O|1|123456^||^^^ABORH|R|||||||||S|||||||||F
O|2|123456^||^^^2_Cell|R|||||||||S|||||||||F
P|2
O|1|123654^||^^^ABORH|R|||||||||S|||||||||F
O|2|123654^||^^^2_Cell|R|||||||||S|||||||||F
L|1|N
```

Crossmatch

```
H|\^&|||LIS|||||BBX|||LIS2-A2|20100219083911
P|1
O|1|107216^GC18201||^^^IgG_XM|R|||||||||C|||||||||F
L|1|N
```

Attachment III: NEO Iris Operator Manual

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results and interpretations, and interface data used for the ABO Titration assays.

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How this Attachment is Organized

In This Section

This section describes the organization of this attachment, including:

- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons

Notational Conventions

This attachment uses a page numbering system that includes a prefix of the attachment number (III) hyphenated with the page number. Sequential lists that describe step-by-step procedures are included as numbered lists.

The footer of each page contains the current attachment version identified using a nine character hyphenated format combined with a five character attachment alpha-numeric identifier (AIII) in parentheses. The first three characters (NEO Iris) identify the instrument. The second set of three characters identifies this document as an attachment to the operator manual (001). The final set of three characters identifies the version of the attachment associated with the operator manual. 100 designates version 1; 200 designates a full version 2 update; and so on.

Limitations of Use and Warnings

Limitations of use and warnings are located in this attachment, specifically in the body of the text where they are most relevant to the information. An icon draws your attention to limitations of use and warnings.

Use of Icons

The following icons appear in this attachment to alert you of warnings or limitations of use.

Icon	Type of Warning	Related to...
	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Consult instructions for use	

ABO Titration Assay Description

Introduction

Intended Use

The assays are for the determination of titer of IgM or IgG Anti-A and Anti-B antibodies from serum or plasma on the NEO Iris™ automated analyzer.

The clinical interpretation and clinical cut offs will be established by the user.

The titer screen assays are for the detection of high titer anti-A and Anti-B antibodies from serum or plasma on the NEO Iris™ automated analyzer.

Description of assays

The following table lists the ABO titration assays on the NEO Iris. The titration assays for the determination of titer of IgM antibodies exist in a horizontal and in a vertical configuration.

Antibody determination	Assay Description	Assay Button Abbreviation	Assay titer range	Samples on 96-well plate	Microplates Used	Assay configuration
IgG	**low titer range assays** 8-well titration	LT_IgG_A1 LT_IgG_A2 LT_IgG_B	1 – 128 (doubling dilutions)	12	Capture-R® Select	Vertical
	high titer range assays 8-well titration	HT_IgG_A1 HT_IgG_A2 HT_IgG_B	16 and 64 - 4096 (doubling dilutions from 64)	12		
	titer screen assays 4-well titration	Ts_IgG_A1 Ts_IgG_A2 Ts_IgG_B	16 - 128 (doubling dilutions)	24		

Antibody determination	Assay Description	Assay Button Abbreviation	Assay titer range	Samples on 96-well plate	Microplates Used	Assay configuration
IgM	**low titer range assays** 8-well titration	LT_IgM_A1 LT_IgM_A2 LT_IgM_B	1 - 128 (doubling dilutions)	12	Galileo Microplate	
	titer screen assays 4-well titration	Ts_IgM_A1 Ts_IgM_A2 Ts_IgM_B	16 - 128 (doubling dilutions)	24		
	low titer range assays 8-well titration	LT_IgM_A1 LT_IgM_A2 LT_IgM_B	1 - 128 (doubling dilutions)	8		Horizontal
	titer screen assays 4-well titration	Ts_IgM_A1 Ts_IgM_A2 Ts_IgM_B	16 - 128 (doubling dilutions)	24		

Limitations, Warnings and Notes

Icon	Description
	Limitation**:** Capture-R® Select plates: Strips removed from pouches should be used within 16 hours. Capture-R® Ready Indicator Red Cells should be used no more than 24 hours after a stir ball has been added to the vial. Vials of reagents other than Indicator red cells, that have remained continuously on the NEO Iris for 72 hours (3 days) should be removed and replaced with fresh vials. Vials of reagents, other than Indicator red cells, that are removed from the NEO Iris when not in use and refrigerated can be used up to their expiry dates.

Icon	Description
	Warning: Inspect all reagents for the presence of foam before placing on the instrument when performing any assay. Do not vigorously agitate reagents. Shaking will produce foam in the vial that can cause the Liquid Level Detection (LLD) function of the pipetting system to erroneously aspirate foam and/or air rather than reagent. This will produce incorrect results or an error.
	Warning: If you are using two or more instruments, then the specific reagent vials for each instrument must be dedicated for use on that single instrument to ensure correct reagent volume tracking. If the actual reagent volume (less than the software numeric volume) is not sufficient for the number of tests scheduled, the instrument will produce invalid results and samples will need to be rescheduled for testing.
	Warning: If you do not add the stirballs to the Capture-R® Indicator Red Cells suspensions or to the Referencells®, the results may be invalid or incorrect. Do not touch the stirballs. You should add them directly to the cellular reagent vials using the dispenser provided. Contamination of cellular reagents can occur if the stirballs are touched. You must only add one stirball per vial of cellular reagent. Do not add more than one stirball per vial.
	Warning: In rare occasions a possible result for a sample tested on a titration assays is "check for inconsistent grading". The instrument will not provide a titer result. Inconsistent grading implies that one or more well grading result within the dilution series of a sample are higher than the previous well grading result despite higher dilution (refer to table "List of Cutoffs). A sample that shows the grading failure needs to be repeated.

Icon	Description
	Warning: Serum and CPDA specimens For low titer IgG assays, the undiluted well of the titration series occasionally gives an invalid result due to the red cell monolayer being destroyed if plasma drawn in CPDA or serum is used. The NEO Iris will report the titration as invalid due to a monolayer check II failure. EDTA specimens have not shown any failures caused by destruction of the red cell monolayer. EDTA specimens are the preferred tube type to use in the low titer IgG ABO titration assays. For serum and CPDA specimens that give invalid results, it is recommended to repeat the test. For serum and CPDA specimens that persistently give invalid results, the specimen needs to be drawn in EDTA and the test needs to be repeated.

<table>
<tr><th>Icon</th><th>Description</th></tr>
<tr><td>  </td><td>Warning: A negative result for the undiluted specimen may indicate that the specimen was not added or that there is no antibody detected.

If a negative result or a titer below the assay's range is obtained in low titer range IgM assays (LT_IgM_A1, LT_IgM_A2, LT_IgM_B), titer screen assays (Ts_IgM_A1, Ts_IgM_A2, Ts_IgM_B, Ts_IgG_A1, Ts_IgG_A2, Ts_IgG_B) or high titer range IgG assays (HT_IgG_A1, HT_IgG_A2, HT_IgG_B) the instructions on how to proceed are described in the following table:

<table>
<tr><th>Assay</th><th>Low Titer Range</th><th>High Titer Range</th><th>Titer Screen</th></tr>
<tr><td>IgG</td><td>The assay includes a color check as a process control for specimen addition</td><td>If result is below the range of the assay or negative, confirm with corresponding low titer range assay</td><td>If result is below the range of the assay or negative, confirm with corresponding low titer range assay</td></tr>
<tr><td>IgM</td><td>If result is negative, confirm with appropriate reverse typing method (i.g. tube test)</td><td>n/a</td><td>If result is below the range of the assay or negative, confirm with corresponding low titer range assay</td></tr>
</table>
</td></tr>
<tr><td>  </td><td>Warning: To prevent contamination of specimens that are to be tested multiple times over an extended period of time it is recommended to aliquot and freeze samples instead of loading one aliquot serveral times on and off the instrument.</td></tr>
</table>

Icon	Description
	Limitation: Samples that exhibit excessive hemolysis or lipemia, or are icteric, should not be tested on the instrument. Samples that exhibit a hemolysis concentration of more than 116 mg/dl in Low titer IgM assays, 300 mg/dl in Low titer IgG assays and 583 mg/dl in high titer IgG assays must not be tested on the instrument, because they may generate erroneous results. Color check in low titer IgG range assays can detect excessive hemolysis and invalids the result. Samples that exhibit a triglyceride concentration of more than 266 mg/dl in Low titer IgM assays, 270 mg/dl in Low titer IgG assays and 4025 mg/dl in high titer IgG assays must not be tested on the instrument, because they may generate erroneous results. Icteric samples (conjugated bilirubin) are tested until a concentration of of 23.7 mg/dl in Low titer IgM assays , 22.5 mg/dl in Low titer IgG assays and 22.4 mg/dl in high titer IgG assays without showing erroneous results. Icteric samples (unconjugated bilirubin) are tested until a concentration of 18.2 mg/dl in Low titer IgM assays , 18.6 mg/dl in Low titer IgG assays and 18.2 mg/dl in high titer IgG assays without showing erroneous results.
	Limitation: At least 500µl of plasma or serum needs to be present in a sample tube to ensure that the probe picks up plasma or serum.
	Warning: Although specimens stored on the clot have been shown to be stable over 14 days, it is advised to store specimens off the clot as this removes the potiential for hemolysis.
	Limitation: For the horizontal IgM range assay, the user needs to load a full plate and select all strips to start the assay regardless of the samples to be tested on the plate. The plate is not to be reloaded to the instrument. The event log alerts the user that empty or too dense wells are detected. The message refers to empty wells on the plate that are detected by the system and does not have impact on test results.

ABO Titration Cutoffs and Reagent Components

List of Cutoffs

Assay Abbreviation	Grade	Lower Limit >	Upper Limit <=
LT_IgG_A1	0	0,0	35,0
LT_IgG_A2	?	35,0	35,0
LT_IgG_B	1+	35,0	50,0
HT_IgG_A1	2+	50,0	72,0
HT_IgG_A2	3+	72,0	90,0
HT_IgG_B	4+	90,0	99,9
Ts_IgG_A1			
Ts_IgG_A2			
Ts_IgG_B			

Assay Abbreviation	Grade	Lower Limit >	Upper Limit <=
LT_IgM_A1	0	0,0	25,0
LT_IgM_A2	?	25,0	25,0
LT_IgM_B	1+	25,0	35,0
Ts_IgM_A1	2+	35,0	50,0
Ts_IgM_A2	3+	50,0	80,0
Ts_IgM_B	4+	80,0	99,9

Assay Reagent Component Grid

Reagents and Microplates	LT_IgG_A1	LT_IgG_A2	LT_IgG_B	HT_IgG_A1	HT_IgG_A2	HT_IgG_B	Ts_IgG_A1	Ts_IgG_A2	Ts_IgG_B	LT_IgM_A1	LT_IgM_A2	LT_IgM_B	Ts_IgM_A1	Ts_IgM_A2	Ts_IgM_B
Capture-R® Select	X	X	X	X	X	X	X	X	X						
UntreatedMicroplates (barcoded)										X	X	X	X	X	X
Reagent Red Blood cells (Referencells – Group A1)	X			X			X			X			X		
Reagent Red Blood cells (Referencells – Group A2)		X			X			X			X			X	
Reagent Red Blood cells (Referencells – Group B)			X			X			X			X			X
Capture-R® Ready Indicator Red Cells	X	X	X	X	X	X	X	X	X						
Capture® LISS	X	X	X	X	X	X	X	X	X						

ABO Titration Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is

intended as summarized steps only and is not intended as a substitute for the detailed package insert.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
LT_IgM_A1 LT_IgM_A2 LT_IgM_B Ts_IgM_A1 Ts_IgM_A2 Ts_IgM_B	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells. Remove the caps from the blood sample tubes. (100µl per sample is used for LT_IgM_A1, LT_IgM_A2, LT_IgM_B assay; 15µl per sample is used for Ts_IgM_A1, Ts_IgM_A2 or Ts_IgM_B assay) 3. Remove reagent vial caps. 4. Add one stirball to each new vial of Referencells® A1, A2 and B to be used. Gently agitate each vial to resuspend the red blood cells. 5. Load reagents, microplates, and blood samples onto the NEO Iris™ following the procedures in Chapter 6 – Instrument Testing Operation. 6. Assign the assay LT_IgM_A1, LT_IgM_A2, LT_IgM_B, Ts_IgM_A1, Ts_IgM_A2 or Ts_IgM_B to the blood samples, either manually or following the upload worklist procedure. 7. Start the LT_IgM_A1, LT_IgM_A2, LT_IgM_B, Ts_IgM_A1, Ts_IgM_A2 or Ts_IgM_B assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris™ automatically performs the LT_IgM_A1, LT_IgM_A2, LT_IgM_B, Ts_IgM_A1, Ts_IgM_A2 or Ts_IgM_B assay, and records and interprets blood sample results. 8. At the completion of the NEO Iris™ LT_IgM_A1, LT_IgM_A2, LT_IgM_B, Ts_IgM_A1, Ts_IgM_A2 or Ts_IgM_B assay, click the Results button on the main menu bar to access the blood sample results. 9. Assay endpoint: This is determined automatically as the last result above the cut off, which is set at 25 for IgM titration assays.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
LT_IgG_A1 LT_IgG_A2 LT_IgG_B HT_IgG_A1 HT_IgG_A2 HT_IgG_B Ts_IgG_A1 Ts_IgG_A2 Ts_IgG_B	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells. Remove the caps from the blood sample tubes. (100µl per sample is used for LT_IgG_A1, LT_IgG_A2, LT_IgG_B assay; 15µl per sample is used for HT_IgG_A1, HT_IgG_A2, HT_IgG_B, Ts_IgG_A1, Ts_IgG_A2 or Ts_IgG_B assay) 3. Remove the Capture-R® Select microplate frame and the desired number of Capture-R® Select strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells and Referencells® A1, A2 and B to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris™ following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the LT_IgG_A1, LT_IgG_A2, LT_IgG_B, HT_IgG_A1, HT_IgG_A2, HT_IgG_B, Ts_IgG_A1, Ts_IgG_A2 or Ts_IgG_B assay to the blood samples, either manually or following the upload worklist procedure. The NEO Iris™ software can automatically assign the LT_IgG_A1, LT_IgG_A2, LT_IgG_B, HT_IgG_A1, HT_IgG_A2, HT_IgG_B, Ts_IgG_A1, Ts_IgG_A2 or Ts_IgG_B assay to the necessary blood samples if the software is configured to do so. This configuration is optional. 8. Start the LT_IgG_A1, LT_IgG_A2, LT_IgG_B, HT_IgG_A1, HT_IgG_A2, HT_IgG_B, Ts_IgG_A1, Ts_IgG_A2 or Ts_IgG_B assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris™ automatically performs the LT_IgG_A1, LT_IgG_A2, LT_IgG_B, HT_IgG_A1, HT_IgG_A2, HT_IgG_B, Ts_IgG_A1, Ts_IgG_A2 or Ts_IgG_B assay, and records and interprets the blood sample results. 9. At the completion of the NEO Iris™ LT_IgG_A1, LT_IgG_A2, LT_IgG_B, HT_IgG_A1, HT_IgG_A2, HT_IgG_B, Ts_IgG_A1, Ts_IgG_A2 or Ts_IgG_B assay, click the Results button on the main menu bar to access the blood sample results. 10. Assay endpoint: This is determined automatically as the last result above the cut off, which is set at 35 for IgG titration assays.

ABO Titration Results and Interpretations

Introduction

The NEO Iris™generates a result for each well read by the instrument and an interpretation of the results. The ABO Titration assay has predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported Positive, Negative or Invalid. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for ABO Titration assay includes:

Indicator	Name	Description
+	Positive	The reaction value is greater than the cutoff value.
-	Negative	The reaction value is less than or equal to the cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

The ABO Titration assays are designed to be read automatically by the instrument, and even though you cannot edit reactions or results, you can still view the images of the assay reactions by using the instrument software. Reaction features are described in the associated reagent package inserts.

Editing Test Results

For the ABO Titration assays, no instrument generated result can be edited.

Result Interpretations

The result interpretation is based on the reaction pattern of test well results. Final titer interpretation is listed in the three tables below for each titration assay.

LT_IgG_A1 LT_IgG_A2 LT_IgG_B LT_IgM_A1 LT_IgM_A2 LT_IgM_B		**Dilution (per well)**							
		1	**2**	**4**	**8**	**16**	**32**	**64**	**128**
Titer	**Negative**	-	-	-	-	-	-	-	-
	1	+	-	-	-	-	-	-	-
	2	+	+	-	-	-	-	-	-
	4	+	+	+	-	-	-	-	-
	8	+	+	+	+	-	-	-	-
	16	+	+	+	+	+	-	-	-
	32	+	+	+	+	+	+	-	-
	64	+	+	+	+	+	+	+	-
	≥128	+	+	+	+	+	+	+	+
	Check for inconsistent grading								

HT_IgG_A1 HT_IgG_A2 HT_IgG_B		Dilution (per well)							
		16	**64**	**128**	**256**	**512**	**1024**	**2048**	**4096**
Titer	**≥16**	+	-	-	-	-	-	-	-
	64	+	+	-	-	-	-	-	-
	128	+	+	+	-	-	-	-	-
	256	+	+	+	+	-	-	-	-
	512	+	+	+	+	+	-	-	-
	1024	+	+	+	+	+	+	-	-
	2048	+	+	+	+	+	+	+	-
	4096	+	+	+	+	+	+	+	+
	<16 or negative	-	-	-	-	-	-	-	-
	Check for inconsistent grading								

Ts_IgG_A1 Ts_IgG_A2 Ts_IgG_B Ts_IgM_A1 Ts_IgM_A2 Ts_IgM_B		**Dilution (per well)**			
		16	**32**	**64**	**128**
Titer	**16**	+	-	-	-
	32	+	+	-	-
	64	+	+	+	-
	≥128	+	+	+	+
	<16 or negative	-	-	-	-
	Check for inconsistent grading				

Interface Specification Information

ABO Titration assays information for the interface specification, detailed below, is supplemental information to **Attachment II for NEO Iris Operator Manual**. Refer to **Attachment II for NEO Iris Operator Manual** for a full description of the interface specification.

Result Record and Field 4 Measurement Values

<table>
<tr><th>Field</th><th>Description</th><th colspan="2">Possible Values</th></tr>
<tr><td>R 3.4</td><td>Assay Name</td><td colspan="2">LT_IgG_A1, LT_IgG_A2, LT_IgG_B, HT_IgG_A1, HT_IgG_A2, HT_IgG_B, Ts_IgG_A1, Ts_IgG_A2, Ts_IgG_B, LT_IgM_A1, LT_IgM_A 2, LT_IgM_B,Ts_IgM_A1, Ts_IgM_A2, Ts_IgM_B,</td></tr>
<tr><td>R 4.1</td><td>Original graded result</td><td colspan="2">-, 1, 2, 3, 4, X</td></tr>
<tr><td rowspan="4">R4.2</td><td rowspan="4">Interpreted Result 1</td><td>Corresponding Assay</td><td>Possible Values</td></tr>
<tr><td>LT_IgG_A1
LT_IgG_A2
LT_IgG_B
LT_IgM_A1
LT_IgM_A2
LT_IgM_B</td><td>1, 2, 4, 8, 16, 32, 64, ≥128, Check for inconsistent grading, *INV*</td></tr>
<tr><td>HT_IgG_A1
HT_IgG_A2
HT_IgG_B</td><td>≥16, 64, 128, 256, 512, 1024, 2048, 4096, <16 or negative, Check for inconsistent grading, *INV*</td></tr>
<tr><td>Ts_IgG_A1
Ts_IgG_A2
Ts_IgG_B
Ts_IgM_A1
Ts_IgM_A2
Ts_IgM_B</td><td>16, 32, 64, ≥128, <16 or negative, Check for inconsistent grading, *INV*</td></tr>
</table>

LIS Well Result Identification for Field 4 Measurement Values (R 4.1)

Assay	Test phase	
LT_IgG_A1 LT_IgG_A2 LT_IgG_B LT_IgM_A1 LT_IgM_A2 LT_IgM_B	1	Dilution 1:1
	2	Dilution 1:2
	3	Dilution 1:4
	4	Dilution 1:8
	5	Dilution 1:16
	6	Dilution 1:32
	7	Dilution 1:64
	8	Dilution 1:128

Assay	Test phase	
HT_IgG_A1 HT_IgG_A2 HT_IgG_B	1	Dilution 1:16
	2	Dilution 1:64
	3	Dilution 1:128
	4	Dilution 1:256
	5	Dilution 1:512
	6	Dilution 1:1024
	7	Dilution 1:2048
	8	Dilution 1:4096

Assay	Test phase	
Ts_IgG_A1 Ts_IgG_A2 Ts_IgG_B Ts_IgM_A1 Ts_IgM_A2 Ts_IgM_B	1	Dilution 1:16
	2	Dilution 1:32
	3	Dilution 1:64
	4	Dilution 1:128

Attachment IV: NEO Iris Operator Manual

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results, interpretations and interface data used for the Monoclonal Jka/Jkb assay.

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- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons

Notational Conventions

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Use of Icons

The following icons appear in this attachment to alert you of warnings or limitations of use.

Icon	Type of Warning	Related to...
	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Consult instructions for use	

Monoclonal Jka/Jkb Assay Description

Introduction

Intended Use

Anti-Jk^{a} (Monoclonal) Gamma-clone® and Anti-Jk^{b} (Monoclonal) Gamma-clone® blood grouping reagents are intended for the detection of Jka (JK1) and Jkb (JK2) antigens, respectively, on red blood cells by direct hemagglutination on the NEO Iris® automated analyzer.

List of assays

The following table lists the monoclonal Jka/Jkb assay on the NEO Iris. The assay exists in a horizontal and in a vertical configuration.
Due to a transition period two (2) assay versions will be available for the NEO Iris for a certain time.

Version 1.00:

Assay Description	Assay short name	Used reagents	Microplates Used
	Blood grouping	**Horizontal/12 wells per strip**	
Monoclonal Jka/Jkb	AG_Jkab_m	1. Monoclonal Control 2. Anti-Jk^{a} (Monoclonal) Gamma-clone® 3. Anti-Jk^{b} (Monoclonal) Gamma-clone®	Untreated microplates
	Blood grouping	**Vertical/8 wells per strip**	
Monoclonal Jka/Jkb	AG_Jkab_m	1. Monoclonal Control 2. Anti-Jk^{a} (Monoclonal) Gamma-clone® 3. Anti-Jk^{b} (Monoclonal) Gamma-clone®	Untreated microplates

Version 2.00i:

Assay Description	Assay short name	Used reagents	Microplates Used
	Blood grouping	**Horizontal/12 wells per strip**	
Monoclonal Jka/Jkb	AG_Jkab_m	1. Monoclonal Control 2. Anti-Jk^{a} (Monoclonal) Gamma-clone® 3. Anti-Jk^{b} (Monoclonal) Gamma-clone® 4. GammaZyme-B™ 5. Specimen Diluent	Untreated microplates
	Blood grouping	**Vertical/8 wells per strip**	
Monoclonal Jka/Jkb	AG_Jkab_m	1. Monoclonal Control 2. Anti-Jk^{a} (Monoclonal) Gamma-clone® 3. Anti-Jk^{b} (Monoclonal) Gamma-clone® 4. GammaZyme-B™ 5. Specimen Diluent	Untreated microplates

Limitations, Warnings and Notes

Icon	Description
	Limitation: The purpose of the Monoclonal Control for AG_Jkab_m assay is to serve as a sample control for Immucor low protein blood grouping reagents. It is expected to indicate those sample related conditions that could lead to spontaneous agglutination with low protein reagents and, therefore, a false positive interpretation for the test. When the Monoclonal Control well yields a positive result, then the instrument would not report the blood type.
	Limitation: Vials of reagents, that have remained continuously on the NEO Iris for 72 hours (3 days) should be removed and replaced with fresh vials. Vials of reagents that are removed from the NEO Iris when not in use and refrigerated can be used up to their expiration dates.
	Limitation: The NEO Iris cannot reliably detect hemagglutination reactions that are graded as 1+ or less in test tube methodology. The NEO Iris does not generate an interpretation of mixed-field. Such a mixed-field reaction will be interpreted as positive, negative, or equivocal.
	Limitation: The grading of reactions on the NEO Iris must only be regarded as an approximation when compared to off-line visual grading by laboratory technical staff.

Monoclonal Jka/Jkb Assay Cutoffs and Reagent Components

List of Cutoffs

Version 1.00:

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
AG_Jkab_m	Monoclonal control	0	0	20
		?	20	23
		1+	23	35
		2+	35	50
		3+	50	75
		4+	75	99
	Anti-Jk[a] (Monoclonal) Gamma-clone®	0	0	20
		?	20	23
		1+	23	35
		2+	35	50
		3+	50	75
		4+	75	99
	Anti-Jk[b] (Monoclonal) Gamma-clone®	0	0	20
		?	20	23
		1+	23	35
		2+	35	50
		3+	50	75
		4+	75	99

Version 2.00i:

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
AG_Jkab_m	Monoclonal control	0	0	25
		?	25	28
		1+	28	35
		2+	35	50
		3+	50	80
		4+	80	99
	Anti-Jk[a] (Monoclonal) Gamma-clone®	0	0	25
		?	25	28
		1+	28	35
		2+	35	50
		3+	50	80
		4+	80	99
	Anti-Jk[b] (Monoclonal) Gamma-clone®	0	0	25
		?	25	28
		1+	28	35
		2+	35	50
		3+	50	80
		4+	80	99

Monoclonal Jka/Jkb Assay Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert. Package inserts are also the source of information for limitations of the reagents in use.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
AG_Jkab_m	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples, onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 5. Assign the AG_Jkab_m assay to the blood samples either manually or following the upload worklist procedure. 6. Start the AG_Jkab_m assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the AG_Jkab_m assay, and records and interprets blood sample results. 7. At the completion of the NEO Iris AG_Jkab_m assay, click the Results button on the main menu bar to access the blood samples results.

Monoclonal Jka/Jkb Assay Results and Interpretations

Introduction

The NEO Iris®generates a result for each well read by the instrument and an interpretation of the results. The Monoclonal Jka/Jkb Assay has predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported Positive, Negative, Invalid or Equivocal. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for Monoclonal Jka/Jkb Assay includes:

Indicator	Name	Description
+	Positive	The reaction value can be considered as positive.
-	Negative	The reaction value can be considered as negative.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater than the negative cutoff value or equal to or less than the positive cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO Iris process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	Possible Well Results	Possible Test Interpretations
AG_Jkab_m	+(1, 2, 3, 4), -, ?[1], X	Kidd interpretations: Jka+, Jka-, Jkb+, Jkb-, NTD, Ctrl failure[2], *INV*

[1] Equivocal results that may be edited.

[2] Test Interpretation only applicable for Assay Version 2.00i

Key for Table of Well Results and Test Interpretations by Assay

The two (2) tables below describe the possible well test results per the Result Interpretations section of this attachment.

Well Result	Description
+	Positive
-	Negative
?	Equivocal
X	Invalid

Test Interpretation	Description
INV	Invalid
NTD	No Type Determined
Ctrl failure*	Control failure

* Test Interpretation only applicable for Assay Version 2.00i

Interface Specification Information

The Monoclonal Jka/Jkb assay information for the interface specification, detailed below, is supplemental information to **Attachment II for the NEO Iris Operator Manual (EU).** Refer to **Attachment II for the NEO Iris Operator Manual (EU)** for a full description of the interface specification.

Result Record Field 4 Measurement Values

SUB-COMPONENT 1		
Assay	**Possible Values for Reaction Pattern**	
All Assays	-, 1, 2, 3, 4, ?, X	
SUB-COMPONENT 2		
Assay	**Interpretation Values**	
AG_Jkab_m	**Jka Interpretation**	**Jkb Interpretation**
	Jka+, Jka-, NTD, Ctrl failure[1], *INV*	Jkb+, Jkb-, NTD, *INV*
AG_Jkab_m[2]	Jka+ Jkb+, Jka- Jkb+, Jka+ Jkb-, Jka- Jkb-, NTD, Ctrl failure[1], *INV*	

[1] Interpretation value only applicable for Assay Version 2.00i

[2] Applicable for alternative Aurora file with one Element

LIS Well Result Identification for Result Field 4 Measurement Values

Assay	**Test phase**	
AG_Jkab_m	1	Anti-Jk^{a} (Monoclonal) Gamma-clone®
	2	Anti-Jk^{b} (Monoclonal) Gamma-clone®
	3	Monoclonal Control

Attachment V: NEO Iris Operator Manual

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results and interpretations, and interface data used for the modified Antigens Assays ANTIGENS4 and ANTIGENS5.

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How this Attachment is Organized

In This Section

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- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons

Notational Conventions

This attachment uses a page numbering system that includes a prefix of the attachment number (V) hyphenated with the page number. Sequential lists that describe step-by-step procedures are included as numbered lists.

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Limitations of Use and Warnings

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Use of Icons

The following icons appear in this attachment to alert you of warnings or limitations of use.

Icon	Type of Warning	Related to…
	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Consult instructions for use	

Modified Antigens Assays Description

Introduction

Intended Use

Within the original Antigens assay (ANTIGENS) Immucors blood grouping reagents Anti-Fy(a) micro, Anti-Fy(b) micro, Anti-Jk(a) micro and Anti-Jk(b) micro, Anti-S micro, Anti-s micro are intended for the detection of the Fya (FY1), Fyb (FY2), Jka (JK1) and Jkb (JK2) antigens, S (MNS 3), s (MNS 4) antigens on red blood cells by the Capture R method.
The two modified Antigens assays (ANTIGENS4 and ANTIGENS5) are intended for the detection of following rare antigens on human erythrocytes:

ANTIGENS4: Fya (FY1), Fyb (FY2), S (MNS 3), s (MNS 4) antigens on red blood cells by the Capture R method.
ANTIGENS5: Fya (FY1), Fyb (FY2), Jka (JK1), S (MNS 3), s (MNS 4) antigens on red blood cells by the Capture R method.

List of assays

The following table lists the modified Antigens assays on the NEO Iris.

Assay Description	Assay short name	Used reagents	Microplates Used
	Capture Select - Rare Antigens		
Capture-R Antigens	ANTIGENS4	Anti-Fy(a) micro Anti-Fy(b) micro Empty Empty Anti-S micro Anti-s micro Empty Negative Control micro	Capture-R Select Plates

Assay Description	Assay short name	Used reagents	Microplates Used
Capture-R Antigens	ANTIGENS5	Anti-Fy(a) micro Anti-Fy(b) micro Anti-Jk(a) micro Empty Anti-S micro Anti-s micro Empty Negative Control micro	Capture-R Select Plates

Limitations, Warnings and Notes

Icon	Description
	Limitation: Capture-R® Ready Indicator Red Cells should be used no more than 24 hours after astir ball has been added to the vial. Vials of reagents, other than Indicator Red Cells, that have remained continuously on the NEO Iris for 72 hours (3 days) should be removed and replaced with fresh vials. Vials of reagents, other than Indicator Red Cells, that are removed from the NEO Iris when not in use and refrigerated can be used up to their expiration dates.
	Limitation: Capture-R® Select plates: Strips removed from pouches should be used within 16 hours.
	Limitation: The grading of reactions on the NEO Iris must only be regarded as an approximation when compared to off-line visual grading by laboratory technical staff.

Modified Antigens Assays Cutoffs and Reagent Components

List of Cutoffs

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ANTIGENS4	Anti-Fy(a) micro Anti-Fy(b) micro Anti-S micro Anti-s micro Negative Control micro	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ANTIGENS5	Anti-Fy(a) micro Anti-Fy(b) micro Anti-Jk(a) micro Anti-S micro Anti-s micro Negative Control micro	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	100

Modified Antigens Assays Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert. Package inserts are also the source of information for limitations of the reagents in use.

Assay Button Abbreviation	**Brief Synopsis of Assay Procedural Steps**
ANTIGENS4 ANTIGENS5	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells. Remove the caps from the blood sample tubes. 3. Remove the Capture-R® Select microplate frame and the desired number of Capture-R® Select strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the assay ANTIGENS4 / ANTIGENS5 to the blood samples, either manually or following the upload worklist procedure. The NEO Iris software can automatically assign the assay ANTIGENS4 / ANTIGENS5 to the necessary blood samples if the software is configured to do so. This configuration is optional. 8. Start the assay ANTIGENS4 / ANTIGENS5 following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the assay ANTIGENS4 / ANTIGENS5, and records and interprets the blood smaple results. 9. At the completion of the NEO Iris assay ANTIGENS4 / ANTIGENS5, click the Results button on the main menu bar to access the blood sample results.

Modified Antigens Assays Results and Interpretations

Introduction

The NEO Iris generates a result for each well read by the instrument and an interpretation of the results. Each NEO Iris assay has predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported as Negative, Positive, Equivocal, or Invalid. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for the modified Antigens assays ANTIGENS4 and ANTIGENS5 include:

Indicator	Name	Description
+	Positive	The reaction value is greater than the positive cutoff value.
-	Negative	The reaction value is less than or equal to the negative cutoff value.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater than the negative cutoff value or equal to or less than the positive cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

Editing Test Results

For selected assays, the operator can edit well results that the NEO Iris identifies as Equivocal (identified as "?"). Only equivocal results can be edited. No positive or negative results reported by the NEO Iris can be edited. Refer to the table of Result Interpretations for a list of those assays with equivocal ranges that cannot be edited.

When results are edited, the NEO Iris creates an audit trail and flags results as edited on the NEO Iris Reports. The operator is only able to edit test well results. The operator cannot edit sample result interpretations.

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO Iris process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	**Possible Well Results**	**Possible Test Interpretations**
ANTIGENS4	+,-,?*,X	Fy(a) interpretation: Fya+, Fya-, NTD, *INV* Fy(b) interpretation: Fyb+, Fyb-, NTD, *INV* S interpretation : S+, S-, NTD, *INV* s interpretation: s+, s-, NTD, *INV*
ANTIGENS5	+,-,?*,X	Fy(a) interpretation: Fya+, Fya-, NTD, *INV* Fy(b) interpretation: Fyb+, Fyb-, NTD, *INV* Jk(a) interpretation: Jka+, Jka-, NTD, *INV* S interpretation : S+, S-, NTD, *INV* s interpretation: s+, s-, NTD, *INV*

*Equivocal results that may be edited.

Key for Table of Well Results and Test Interpretations by Assay

The two (2) tables below describe the possible well test results per the Result Interpretations section of this attachment.

Well Result	Description
+	Positive
-	Negative
?	Equivocal
X	Invalid

Test Interpretation	Description
INV	Invalid
NTD	No Type Determined

Attachment VI: NEO Iris Operator Manual

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results and interpretations, and interface data used for assays to provide basic blood type, Rh status and/or Kell and/or CDE.

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In This Section

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- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons

Notational Conventions

This attachment uses a page numbering system that includes a prefix of the attachment number (VI) hyphenated with the page number. Sequential lists that describe step-by-step procedures are included as numbered lists.

The footer of each page contains the current attachment version identified using a nine character hyphenated format combined with a five character attachment alpha-numeric identifier (AVI) in parentheses. The first three characters (NEO Iris) identify the instrument. The second set of three characters identifies this document as an attachment to the operator manual (001). The final set of three characters identifies the version of the attachment associated with the operator manual. 100 designates version 1; 200 designates a full version 2 update; and so on.

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Use of Icons

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Icon	Type of Warning	Related to...

	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Consult instructions for use	

Assay Description

Introduction

Intended Use

The described assays are designed to provide basic blood type, Rh status and/or Kell and/or CDE which can include both forward testing (of red blood cell) and reverse testing (of plasma/serum). Assays are based on direct agglutination technology for the NEO Iris™ automated analyzer.

List of assays

The following table lists the described assays on the NEO Iris. The assays exist in a horizontal and/or vertical configuration.

Assay Description	Assay short name	Used reagents	Microplates Used
	Blood grouping	**Horizontal/12 wells per strip**	
Forward and Reverse ABO Blood Grouping	ABDLONG	1. NOVACLONE Anti-A 2. NOVACLONE Anti-B 3. NOVACLONE Anti-AB 4. A1-Cell 5. A2-Cell 6. B-Cell 7. O-Cell 8. Autocontrol 9. NOVACLONE Anti-D 10. immuClone Anti-D rapid 11. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay short name	Used reagents	Microplates Used
Forward and Reverse ABO Blood Grouping	ABDLONG2	1. immuClone Anti-A 2. immuClone Anti-B 3. immuClone Anti-AB 4. A1-Cell 5. A2-Cell 6. B-Cell 7. O-Cell 8. Autocontrol 9. NOVACLONE Anti-D 10. immuClone Anti-D rapid 11. immuClone Rh-Hr Control	Untreated microplates
Forward and Reverse ABO Blood Grouping incl. CDE	ABDLONG3	1. NOVACLONE Anti-A 2. NOVACLONE Anti-B 3. NOVACLONE Anti-AB 4. A1-Cell 5. A2-Cell 6. B-Cell 7. O-Cell 8. Autocontrol 9. NOVACLONE Anti-D 10. immuClone Anti-D rapid 11. immuClone Anti-CDE 12. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay short name	Used reagents	Microplates Used
Forward and Reverse ABO Blood Grouping incl. CDE	ABDLONG4	1. immuClone Anti-A 2. immuClone Anti-B 3. immuClone Anti-AB 4. A1-Cell 5. A2-Cell 6. B-Cell 7. O-Cell 8. Autocontrol 9. NOVACLONE Anti-D 10. immuClone Anti-D rapid 11. immuClone Anti-CDE 12. immuClone Rh-Hr Control	Untreated microplates
Forward and Reverse ABO Blood Grouping incl. Kell	ABDLONGK	1. NOVACLONE Anti-A 2. NOVACLONE Anti-B 3. NOVACLONE Anti-AB 4. A1-Cell 5. A2-Cell 6. B-Cell 7. O-Cell 8. Autocontrol 9. NOVACLONE Anti-D 10. immuClone Anti-D rapid 11. Automated immuClone Anti-Kell 12. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay short name	Used reagents	Microplates Used
Forward and Reverse ABO Blood Grouping incl. Kell	ABDLONG2K	1. immuClone Anti-A 2. immuClone Anti-B 3. immuClone Anti-AB 4. A1-Cell 5. A2-Cell 6. B-Cell 7. O-Cell 8. Autocontrol 9. NOVACLONE Anti-D 10. immuClone Anti-D rapid 11. Automated immuClone Anti-Kell 12. immuClone Rh-Hr Control	Untreated microplates
	Blood grouping	**Horizontal/6 wells per strip**	
Forward ABO Blood Grouping	ABD6_I	1. ImmuClone Rh-Hr Control 2. immuClone Anti-A 3. immuClone Anti-B 4. immuClone Anti-AB 5. immuClone Anti-D rapid 6. NOVACLONE Anti-D	Untreated microplates
Forward ABO Blood Grouping	ABD6_N	1. NOVACLONE Diluent Control 2. NOVACLONE Anti-A 3. NOVACLONE Anti-B 4. NOVACLONE Anti-AB 5. immuClone Anti-D rapid 6. NOVACLONE Anti-D	Untreated microplates

Assay Description	Assay short name	Used reagents	Microplates Used
Forward ABO Blood Grouping incl. CDE	ABD6CDE_I	1. ImmuClone Rh-Hr Control 2. immuClone Anti-A 3. immuClone Anti-B 4. immuClone Anti-AB 5. immuClone Anti-D rapid 6. immuClone Anti-CDE	Untreated microplates
Forward ABO Blood Grouping incl. CDE	ABD6CDE_N	1. NOVACLONE Diluent Control 2. NOVACLONE Anti-A 3. NOVACLONE Anti-B 4. NOVACLONE Anti-AB 5. immuClone Anti-D rapid 6. immuClone Anti-CDE	Untreated microplates
Forward ABO Blood Grouping incl. Kell	ABD6K_I	1. ImmuClone Rh-Hr Control 2. immuClone Anti-A 3. immuClone Anti-B 4. immuClone Anti-AB 5. immuClone Anti-D rapid 6. Automated immuClone Anti-Kell	Untreated microplates
Forward ABO Blood Grouping incl. Kell	ABD6K_N	1. NOVACLONE Diluent Control 2. NOVACLONE Anti-A 3. NOVACLONE Anti-B 4. NOVACLONE Anti-AB 5. immuClone Anti-D rapid 6. Automated immuClone Anti-Kell	Untreated microplates
	Blood grouping	**Horizontal/4 wells per strip**	
Reverse ABO Blood Grouping	ABO_REV	1. A1 cell 2. A2 cell 3. B cell 4. O cell	Untreated microplates
	Blood grouping	**Vertical/4 wells per strip**	

Assay Description	Assay short name	Used reagents	Microplates Used
Reverse ABO Blood Grouping	ABO_REV	1. A1 cell 2. A2 cell 3. B cell 4. O cell	Untreated microplates
	Blood grouping	**Vertical/8 wells per strip**	
Forward and Reverse ABO Blood Grouping	ABODFULL	1. NOVACLONE Diluent Control 2. NOVACLONE Anti-A 3. NOVACLONE Anti-B 4. immuClone Anti-D rapid 5. NOVACLONE Anti-D 6. A1-Cell 7. B-Cell 8. O-Cell	Untreated microplates
Forward and Reverse ABO Blood Grouping	ABODFULL2	1. immuClone Rh-Hr Control 2. immuClone Anti-A 3. immuClone Anti-B 4. immuClone Anti-D rapid 5. NOVACLONE Anti-D 6. A1-Cell 7. B-Cell 8. O-Cell	Untreated microplates

Limitations, Warnings and Notes

All further limitations, warnings and notes that relate to the described assays are defined in the Operator Manual Chapter 12: Limitations of Use and Warnings and in Attachment I of the NEO Iris instrument.

Icon	Description

Icon	Description
	Limitation: The Reverse ABO Blood Group assay (i.e. ABO_REV) is intended to screen for ABO antibodies in plasma. This provides a presumptive indication of the red blood cell ABO group for the individual from which the plasma was collected. The absence of the corresponding forward group test subjects the results of this assay to several potential sources of error. These include serological factors due to the donor's age, immunological state, the presence of an IgM allo- or autoantibody, transfusion or transplantation status or disease states. Sample related conditions such as higher-than-expected levels of lipids, bilirubin, free plasma hemoglobin, clots or aggregates may also be a factor. This assay cannot be used (alone) to determine the ABO group as part of pre-transfusion testing in a patient population, or to determine ABO group for blood components intended for transfusion.

Cutoffs and Reagent Components

List of Cutoffs

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABDLONG	NOVACLONE Anti-A	0	0	30
		?	30	58
		1+ (not reported)	58N/A	58N/A
		2+ (not reported)	N/A58	N/A58
		3+ (not reported)	N/A58	N/A58
		4+	58	100
	NOVACLONE Anti-B	0	0	30
		?	30	76

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	NOVACLONE Anti-AB	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	A1-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	A2-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+	50	76
		4+	76	100
	B-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	O-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	Autocontrol	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	NOVACLONE Anti-D	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-D rapid	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Rh-Hr Control	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABDLONG2	ImmuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	ImmuClone Anti-B	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-AB	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	A1-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	A2-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	B-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	O-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Autocontrol	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	NOVACLONE Anti-D	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-D rapid	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Rh-Hr Control	0	0	30
		?	30	76

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABDLONG3	NOVACLONE Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	NOVACLONE Anti-B	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+ (not reported)	N/A	N/A
		4+	76	100
	NOVACLONE Anti-AB	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	A1-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	A2-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	B-Cell	0	0	23
		?	23	28

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	O-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	Autocontrol	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	NOVACLONE Anti-D	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	ImmuClone Anti-D rapid	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-CDE	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Rh-Hr Control	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABDLONG4	ImmuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	ImmuClone Anti-B	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-AB	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+ (not reported)	N/A	N/A
		4+	76	100
	A1-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	A2-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	B-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	O-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+	50	76
		4+	76	100
	Autocontrol	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	NOVACLONE Anti-D	0	0	30
		?	30	76
		1+	76	76
		2+	76	76
		3+	76	76
		4+	76	100
	ImmuClone Anti-D rapid	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-CDE	0	0	30
		?	30	76

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Rh-Hr Control	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABDLONGK	NOVACLONE Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		4+	58	100
	NOVACLONE Anti-B	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	NOVACLONE Anti-AB	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	A1-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	A2-Cell	0	0	23

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	B-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	O-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	Autocontrol	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	NOVACLONE	0	0	30

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Anti-D	?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-D rapid	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	Automated immuClone Anti-Kell	0	0	23
		?	23	50
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	50	80
		4+	80	100
	ImmuClone	0	0	30

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Rh-Hr Control	?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABDLONG2K	ImmuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	ImmuClone Anti-B	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-AB	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	A1-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	A2-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	B-Cell	0	0	23

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	O-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	Autocontrol	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	NOVACLONE Anti-D	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		4+	76	100
	ImmuClone Anti-D rapid	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	Automated immuClone Anti-Kell	0	0	23
		?	23	50
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	50	80
		4+	80	100.
	ImmuClone Rh-Hr Control	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		4+	76	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABD6_I	ImmuClone Rh-Hr Control	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	ImmuClone Anti-B	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-AB	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-D rapid	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	NOVACLONE Anti-D	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABD6_N	NOVACLONE Diluent Control	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	NOVACLONE Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	NOVACLONE	0	0	30

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Anti-B	?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	NOVACLONE Anti-AB	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-D rapid	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	NOVACLONE	0	0	30

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Anti-D	?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABD6CDE_I	ImmuClone Rh-Hr Control	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+ (not reported)	N/A	N/A
		4+	58	100
	ImmuClone Anti-B	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-AB	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-D rapid	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-CDE	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABD6CDE_N	NOVACLONE Diluent Control	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	NOVACLONE Anti-A	0	0	30
		?	30	58

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	NOVACLONE Anti-B	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	NOVACLONE Anti-AB	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-D rapid	0	0	30
		?	30	76

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-CDE	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABD6K_I	ImmuClone Rh-Hr Control	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		4+	76	100
	ImmuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	ImmuClone Anti-B	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-AB	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		4+	76	100
	ImmuClone Anti-D rapid	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	Automated immuClone Anti-Kell	0	0	23
		?	23	50
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	50	80
		4+	80	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABD6K_N	NOVACLONE Diluent Control	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	NOVACLONE Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	NOVACLONE Anti-B	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	NOVACLONE Anti-AB	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-D rapid	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	Automated immuClone Anti-Kell	0	0	23
		?	23	50
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	50	80
		4+	80	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABO_REV	A1-Cell	0	0	23

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	A2-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	B-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	O-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABODFULL	NOVACLONE Diluent Control	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	NOVACLONE Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	NOVACLONE Anti-B	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		4+	76	100
	ImmuClone Anti-D rapid	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	NOVACLONE Anti-D	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	A1-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	B-Cell	0	0	23

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	O-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABODFULL2	ImmuClone Rh-Hr Control	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-A	0	0	30
		?	30	58

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	ImmuClone Anti-B	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	ImmuClone Anti-D rapid	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	NOVACLONE Anti-D	0	0	30
		?	30	76

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	A1-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	B-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100
	O-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100

Assay Reagent Component Grid

Reagents and Microplates	ABDLONG	ABDLONG2	ABDLONG3	ABDLONG4	ABDLONGK	ABDLONG2K	ABD6_I	ABD6_N	ABD6CDE_I	ABD6CDE_N	ABD6K_I	ABD6K_N	ABO_Rev	ABODFULL	ABODFULL2
Untreated Microplates (barcoded)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Reagent Red Blood cells (Referencells – Group A1)	X	X	X	X	X	X							X	X	X
Reagent Red Blood cells (Referencells – Group A2)	X	X	X	X	X	X							X		
Reagent Red Blood cells (Referencells – Group B)	X	X	X	X	X	X							X	X	X
Reagent Red Blood cells (Referencells – Group O)	X	X	X	X	X	X							X	X	X
NOVACLONE Anti-A	X		X		X			X		X		X		X	
NOVACLONE Anti-B	X		X		X			X		X		X		X	
NOVACLONE Anti-AB	X		X		X			X		X		X			
NOVACLONE Anti-D	X	X	X	X	X	X	X	X						X	X
ImmuClone Anti-A		X		X		X	X		X		X				X
ImmuClone Anti-B		X		X		X	X		X		X				X

Reagents and Microplates	ABDLONG	ABDLONG2	ABDLONG3	ABDLONG4	ABDLONGK	ABDLONG2K	ABD6_I	ABD6_N	ABD6CDE_I	ABD6CDE_N	ABD6K_I	ABD6K_N	ABO_Rev	ABODFULL	ABODFULL2
ImmuClone Anti-AB		X		X		X	X		X		X				
ImmuClone Anti-D rapid	X	X	X	X	X	X	X	X	X	X	X	X		X	X
ImmuClone Rh-Hr Control	X	X	X	X	X	X	X		X		X				X
NOVACLONE Diluent Control								X		X		X		X	
ImmuClone Anti-CDE			X	X					X	X					
Automated immuClone Anti-Kell					X	X					X	X			
Autocontrol	X	X	X	X	X	X									

Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert.

Assay Button Abbreviation	**Brief Synopsis of Assay Procedural Steps**

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
ABDLONG ABDLONG2 ABDLONG3 ABDLONG4 ABDLONGK ABDLONG2K ABD6_I ABD6_N ABD6CDE_I ABD6CDE_N ABD6K_I ABD6K_N ABO_REV ABODFULL ABODFULL2	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. If applicable, add one stirball to each new vial of Referencells A1, B and O to be used. Gently agitate each vial to resuspend the red blood cells. 5. Load reagents, microplates, and blood samples, onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 6. Assign the appropriate assay to the blood samples either manually or following the upload worklist procedure. 7. Start the appropriate assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the assays, and records and interprets blood sample results. 8. At the completion of the NEO Iris assay, click the Results button on the main menu bar to access the blood samples results.

Results and Interpretations

Introduction

The NEO Iris™ generates a result for each well read by the instrument and an interpretation of the results. Each NEO Iris assay has predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported as Negative, Positive, Equivocal or Invalid. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for assays include:

Indicator	Name	Description
+	Positive	The reaction value is greater than the cutoff value.
-	Negative	The reaction value is less than or equal to the cutoff value.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater than the negative cutoff value or equal or less than the positive cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

The described assays are designed to be read automatically by the instrument, and even though you cannot edit reactions or results, you can still view the images of the assay reactions by using the instrument software. Reaction features are described in the associated reagent package inserts.

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO Iris process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	Possible Well Results	Possible Test Interpretations
ABDLONG ABDLONG2 ABODFULL ABODFULL2	+, -, ?, X	ABO Interpretations: A, B, AB, O, NTD / Mixed field ?, *INV* Rh Interpretations: RH+, RH-, NTD / Mixed field ?, *INV*
ABDLONG3 ABDLONG4	+, -, ?, X	ABO Interpretations: A, B, AB, O, NTD / Mixed field ?, *INV* Rh/CDE Interpretations: RH+ CDE+, RH- CDE-, RH- CDE+, NTD / Mixed field ?, *INV*
ABDLONGK ABDLONG2K	+, -, ?, X	ABO Interpretations: A, B, AB, O, NTD/Mixed field ?, *INV* Rh Interpretations: RH+, RH-, NTD / Mixed field ?, *INV* Kell Interpretations: K+, K-, NTD / Mixed field ?, *INV*
ABD6_I ABD6_N	+, -, ?, X	ABO Interpretations: A, B, AB, O, NTD/Mixed field ?, *INV* Rh Interpretations: RH+, RH-, NTD / Mixed field ?, *INV*
ABD6CDE_I ABD6CDE_N	+, -, ?, X	ABO Interpretations: A, B, AB, O, NTD/Mixed field ?, *INV* Rh/CDE Interpretations: RH+ CDE+, RH- CDE-, RH- CDE+, NTD / Mixed field ?, *INV*
ABD6K_I ABD6K_N	+, -, ?, X	ABO Interpretations: A, B, AB, O, NTD/Mixed field ?, *INV* Rh Interpretations: RH+, RH-, NTD / Mixed field ?, *INV* Kell Interpretations: K+, K-, NTD / Mixed field ?, *INV*

ABO_REV	+, -, ?, X	ABO Interpretations: A, B, AB, NTD/Mixed field ?, *INV*

Attachment VII: NEO Iris Operator Manual

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results and interpretations used for the S3_Cell assay.

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All operating instructions must be followed. In no event shall Immucor be held responsible for failures, errors, or other liabilities resulting from a customer’s noncompliance with the procedures and precautions outlined in this manual.

The sample screen displays and sample printouts in this Attachment VI for NEO Iris Operator Manual are for information and illustration purposes only. Immucor makes no representations or warranties about the accuracy or reliability of the information presented on the screen displays, and this information is not to be used for clinical or maintenance evaluation.

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How this Attachment is Organized

In This Section

This section describes the organization of this attachment, including:

- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons

Notational Conventions

This attachment uses a page numbering system that includes a prefix of the attachment number (VII) hyphenated with the page number. Sequential lists that describe step-by-step procedures are included as numbered lists.

The footer of each page contains the current attachment version identified using a nine character hyphenated format combined with a five character attachment alpha-numeric identifier (AVII) in parentheses. The first three characters (NEO Iris) identify the instrument. The second set of three characters identifies this document as an attachment to the operator manual (001). The final set of three characters identifies the version of the attachment associated with the operator manual. 100 designates version 1; 200 designates a full version 2 update; and so on.

Limitations of Use and Warnings

Limitations of use and warnings are located in this attachment, specifically in the body of the text where they are most relevant to the information. An icon draws your attention to limitations of use and warnings.

Use of Icons

The following icons appear in this attachment to alert you of warnings or limitations of use.

Icon	Type of Warning	Related to…
	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Consult instructions for use	

Assay Description

Introduction

Intended Use

The S3_Cell is an automated assay used for the detection of unexpected IgG antibodies to red blood cells for samples with low or no amount of albumin. This assay has to run in addition to the quality control assay QC3_Cell before routine testing of blood specimens and can only function as an add-on test to the QC. Sample addition is NOT verified when using the S3_Cell assay.

List of assays

The following table lists the described assay on the NEO Iris in a vertical assay configuration.

Assay Description	Assay short name	Used reagents	Microplates Used
	Capture-R Ready Screen		
RBC antibody screen	S3_Cell	1. Capture LISS 2. Capture-R Ready Indicator Red Cells	Capture-R Ready Screen 3

Limitations, Warnings and Notes

Icon	Description
	Limitation: Sample addition is NOT verified when using the S3_Cell assay as the Range Check of the Well filled verification step is turned off. Therefore each negative result requires confirmation by additional methodology. The S3_Cell assay is NOT intended as a stand-alone QC assay and does not replace the QC3_Cell Assay, the QC3_Cell assay must be run as the instrument quality control assay. This assay is not intended to be used for routine blood sample testing.

All further limitations, warnings and notes that relate to the described assay are defined in the Operator Manual Chapter 12: Limitations of Use and Warnings and in Attachment I of the NEO Iris instrument.

Cutoffs and Reagent Components

List of Cutoffs

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
S3_Cell	Screening wells	0	0	20
		?	20	30
		1+	30	45
		2+	45	65

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+	65	90
		4+	90	100
	IgG coated positive control well	0	0	30
		?	-	-
		1+	30	45
		2+	45	65
		3+	65	90
		4+	90	100

Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
S3_Cell	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the blood samples from the red blood cells/clot. Remove the caps from the blood sample tubes. 3. Remove the Capture-R® Ready-Screen® (3) microplate frame and the desired number of Capture-R® Ready-Screen® (3) strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the S3_Cell assay to the blood samples, either manually or following the upload worklist procedure. 8. Start the S3_Cell assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the S3_Cell assay, and records and interprets the blood sample results. 9. At the completion of the NEO Iris S3_Cell assay, click the Results button on the main menu bar to access the blood samples results.

Results and Interpretations

Introduction

The NEO Iris™ generates a result for each well read by the instrument and an interpretation of the results. Each NEO Iris assay has predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported as Negative, Positive, Equivocal or Invalid. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for the S3_Cell assay includes:

Indicator	Name	Description
+	Positive	The reaction value is greater than the positive cutoff value.
-	Negative	The reaction value is less than or equal to the negative control value.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater than the negative cutoff value or equal to or less than the positive cutoff value.
X	Invalid	The invalid symbol indicates an error status for a given well. An Invalid test well results in generated if the instrument detects a processing error or process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.)

The described assays are designed to be read automatically by the instrument, and even though you cannot edit reactions or results, you can still view the images of the assay reactions by using the instrument software. Reaction features are described in the associated reagent package inserts.

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO Iris process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	Possible Well Results	Possible Test Interpretations
S3_Cell	+, -, ?, X	Positive, Negative, No_Int, Ctrl Fail, *INV* Note: Ctrl Fail indicates that the per sample positive control well (4th well in S3_Cell) has failed. This control well must react at least 3+ in order for the sample test result to be valid. If the control well is less than 3+, the the interpretation given will be Ctrl Fail.

Attachment VIII: NEO Iris Operator Manual

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results and interpretations used for the Phenotyping assays.

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How this Attachment is Organized

In This Section

This section describes the organization of this attachment, including:

- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons

Notational Conventions

This attachment uses a page numbering system that includes a prefix of the attachment number (VIII) hyphenated with the page number. Sequential lists that describe step-by-step procedures are included as numbered lists.

The footer of each page contains the current attachment version identified using a nine character hyphenated format combined with a five character attachment alpha-numeric identifier (AVIII) in parentheses. The first three characters (NEO Iris) identify the instrument. The second set of three characters identifies this document as an attachment to the operator manual (001). The final set of three characters identifies the version of the attachment associated with the operator manual. 100 designates version 1; 200 designates a full version 2 update; and so on.

Limitations of Use and Warnings

Limitations of use and warnings are located in this attachment, specifically in the body of the text where they are most relevant to the information. An icon draws your attention to limitations of use and warnings.

Use of Icons

The following icons appear in this attachment to alert you of warnings or limitations of use.

Icon	Type of Warning	Related to...
	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Consult instructions for use	

Assay Description

Introduction

Intended Use

The described assays are designed to provide phenotyping status on RhCE, D and Kell. Assays are based on direct agglutination technology for the NEO Iris™ automated analyzer.

List of assays

The following table lists the described assays on the NEO Iris. The assays exist in a horizontal and/or vertical configuration.

Assay Description	Assay short name	Used reagents	Microplates Used
	Blood grouping	**Horizontal/12 wells per strip**	
Rh Blood Group	RHFORM_D	1. immuClone Anti-C(1) 2. immuClone Anti-C(2) 3. immuClone Anti-c(1) 4. immuClone Anti-c(2) 5. immuClone Anti-E(1) 6. immuClone Anti-E(2) 7. immuClone Anti-e(1) 8. immuClone Anti-e(2) 9. immuClone Anti-Kell 10. automated ImmuClone Anti-Kell 11. immuClone Anti-D rapid 12. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay short name	Used reagents	Microplates Used
Rh Blood Group	RHFORM_Cw	1. immuClone Anti-C(1) 2. immuClone Anti-C(2) 3. immuClone Anti-c(1) 4. immuClone Anti-c(2) 5. immuClone Anti-E(1) 6. immuClone Anti-E(2) 7. immuClone Anti-e(1) 8. immuClone Anti-e(2) 9. immuClone Anti-Kell 10. automated ImmuClone Anti-Kell 11. immuClone Anti-Cw 12. immuClone Rh-Hr Control	Untreated microplates
Rh Blood Group	PHENO16_2	1. immuClone Anti-C(2) 2. immuClone Anti-c(2) 3. immuClone Anti-E(2) 4. immuClone Anti-e(2) 5. immuClone Anti-Kell 6. immuClone Rh-Hr Control	Untreated microplates
Rh Blood Group	PHENO16_3	1. immuClone Anti-C(2) 2. immuClone Anti-c(2) 3. immuClone Anti-E(2) 4. immuClone Anti-e(2) 5. automated ImmuClone Anti-Kell 6. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay short name	Used reagents	Microplates Used
Rh Blood Group	PHENO16_4	1. immuClone Anti-C(1) 2. immuClone Anti-c(1) 3. immuClone Anti-E(1) 4. immuClone Anti-e(1) 5. automated ImmuClone Anti-Kell 6. immuClone Rh-Hr Control	Untreated microplates
Rh Blood Group	CcEe	1. immuClone Anti-C(1) 2. immuClone Anti-c(1) 3. immuClone Anti-E(1) 4. immuClone Anti-e(1) 5. immuClone Rh-Hr Control	Untreated microplates
Rh Blood Group	CcEe2	1. immuClone Anti-C(2) 2. immuClone Anti-c(2) 3. immuClone Anti-E(2) 4. immuClone Anti-e(2) 5. immuClone Rh-Hr Control	Untreated microplates
Rh Blood Group	CDE	1. immuClone Anti-CDE 2. immuClone Rh-Hr Control	Untreated microplates
	Blood grouping	**Vertical/8 wells per strip**	
Rh Blood Group	PHENO12_2	1. immuClone Anti-C(2) 2. immuClone Anti-c(2) 3. immuClone Anti-E(2) 4. immuClone Anti-e(2) 5. immuClone Anti-Kell 6. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay short name	Used reagents	Microplates Used
Rh Blood Group	PHENO12_3	1. immuClone Anti-C(2) 2. immuClone Anti-c(2) 3. immuClone Anti-E(2) 4. immuClone Anti-e(2) 5. automated ImmuClone Anti-Kell 6. immuClone Rh-Hr Control	Untreated microplates
Rh Blood Group	CcEe	1. immuClone Anti-C(1) 2. immuClone Anti-c(1) 3. immuClone Anti-E(1) 4. immuClone Anti-e(1) 5. immuClone Rh-Hr Control	Untreated microplates
Rh Blood Group	CcEe2	1. immuClone Anti-C(2) 2. immuClone Anti-c(2) 3. immuClone Anti-E(2) 4. immuClone Anti-e(2) 5. immuClone Rh-Hr Control	Untreated microplates
Rh Blood Group	CDE	1. immuClone Anti-CDE 2. immuClone Rh-Hr Control	Untreated microplates

Limitations, Warnings and Notes

All limitations, warnings and notes that relate to the described assays are defined in the Operator Manual Chapter 12: Limitations of Use and Warnings and in Attachment I of the NEO Iris instrument. No additional limitations that relate to the described assays were identified.

Cutoffs and Reagent Components

List of Cutoffs

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
RHFORM_D	ImmuClone Anti-C(1)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-C(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-c(1)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-c(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-E(1)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-E(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-e(1)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-e(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+	75.0	80.0
		4+	80.0	99.9
	immuClone Anti-Kell	0	0.0	23.0
		?	23.0	35.0
		1+(not reported)	N/A	N/A
		2+	35.0	50.0
		3+	50.0	80.0
		4+	80.0	99.9
	Automated ImmuClone Anti-Kell	0	0.0	23.0
		?	23.0	50.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	50.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-D rapid	0	0.0	30.0
		?	30.0	76.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	76.0	76.0
		4+	76.0	99.9
	ImmuClone Rh-Hr Control	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		4+	80.0	99.9

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
RHFORM_Cw	ImmuClone Anti-C(1)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-C(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-c(1)	0	0.0	23..0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-c(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-E(1)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-E(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	ImmuClone Anti-e(1)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-e(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	immuClone Anti-Kell	0	0.0	23.0
		?	23.0	35.0
		1+(not reported)	N/A	N/A
		2+	35.0	50.0
		3+	50.0	80.0
		4+	80.0	99.9
	Automated ImmuClone	0	0.0	23.0
		?	23.0	50.0

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Anti-Kell	1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	50.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-Cw	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	immuClone Rh-Hr Control	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
PHENO12_2	ImmuClone	0	0.0	23.0

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Anti-C(2)	?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-c(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-E(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-e(2)	0	0.0	23.0
		?	23.0	75.0

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	immuClone Anti-Kell	0	0.0	23.0
		?	23.0	35.0
		1+(not reported)	N/A	N/A
		2+	35.0	50.0
		3+	50.0	80.0
		4+	80.0	99.9
	immuClone Rh-Hr Control	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
PHENO12_3	ImmuClone Anti-C(2)	0	0.0	23.0
		?	23.0	75.0

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-c(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-E(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-e(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	Automated ImmuClone Anti-Kell	0	0.0	23.0
		?	23.0	50.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	50.0	80.0
		4+	80.0	99.9
	immuClone Rh-Hr Control	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
PHENO16_2	ImmuClone Anti-C(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-c(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-E(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-e(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+	75.0	80.0
		4+	80.0	99.9
	immuClone Anti-Kell	0	0.0	23.0
		?	23.0	35.0
		1+(not reported)	N/A	N/A
		2+	35.0	50.0
		3+	50.0	80.0
		4+	80.0	99.9
	immuClone Rh-Hr Control	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
PHENO16_3	ImmuClone Anti-C(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		4+	80.0	99.9
	ImmuClone Anti-c(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-E(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-e(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	Automated	0	0.0	23.0

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	ImmuClone Anti-Kell	?	23.0	50.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	50.0	80.0
		4+	80.0	99.9
	immuClone Rh-Hr Control	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
PHENO16_4	ImmuClone Anti-C(1)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone	0	0.0	23.0

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Anti-c(1)	?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-E(1)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-e(1)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	Automated ImmuClone	0	0.0	23.0
		?	23.0	50.0

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Anti-Kell	1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	50.0	80.0
		4+	80.0	99.9
	immuClone Rh-Hr Control	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
CcEe	ImmuClone Anti-C(1)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-c(1)	0	0.0	23.0
		?	23.0	75.0

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-E(1)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-e(1)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	immuClone Rh-Hr Control	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
CcEe2	ImmuClone Anti-C(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-c(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-E(2)	0	0.0	23.0
		?	23.0	75.0

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	ImmuClone Anti-e(2)	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9
	immuClone Rh-Hr Control	0	0.0	23.0
		?	23.0	75.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75.0	80.0
		4+	80.0	99.9

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
CDE	immuClone	0	0.0	30.0

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Anti-CDE	?	30.0	76.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76.0	99.9
	immuClone Rh-Hr Control	0	0.0	30.0
		?	30.0	76.0
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76.0	99.9

Assay Reagent Component Grid

Reagents and Microplates	RHFORM_D	RHFORM_Cw	PHENO12_2	PHENO12_3	PHENO16_2	PHENO16_3	PHENO16_4	CcEe	CcEe2	CDE
Untreated Microplates (barcoded)	X	X	X	X	X	X	X	X	X	X
ImmuClone Anti-C(1)	X	X					X	X		
ImmuClone Anti-C(2)	X	X	X	X	X	X			X	
ImmuClone Anti-c(1)	X	X					X	X		
ImmuClone Anti-c(2)	X	X	X	X	X	X			X	
ImmuClone Anti-E(1)	X	X					X	X		
ImmuClone Anti-E(2)	X	X	X	X	X	X			X	
ImmuClone Anti-e(1)	X	X					X	X		
ImmuClone Anti-e(2)	X	X	X	X	X	X			X	
ImmuClone Anti-Kell	X	X	X		X					
Automated ImmuClone Anti-Kell	X	X		X		X	X			
ImmuClone Anti-Cw		X								
ImmuClone Anti-CDE										X
ImmuClone Anti-D rapid	X									
ImmuClone Rh-Hr Control	X	X	X	X	X	X	X	X	X	X

Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
RHFORM_D RHFORM_Cw PHENO12_2 PHENO12_3 PHENO16_2 PHENO16_3 PHENO16_4 CcEe CcEe2 CDE	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples, onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 5. Assign the appropriate assay to the blood samples either manually or following the upload worklist procedure. 6. Start the appropriate assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the assays, and records and interprets blood sample results. 7. At the completion of the NEO Iris assay, click the Results button on the main menu bar to access the blood samples results.

Results and Interpretations

Introduction

The NEO Iris™ generates a result for each well read by the instrument and an interpretation of the results. Each NEO Iris assay has predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported as Negative, Positive, Equivocal or Invalid. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for assays include:

Indicator	Name	Description
+	Positive	The reaction value is greater than the cutoff value.
-	Negative	The reaction value is less than or equal to the cutoff value.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater that the negative cutoff value or equal o or less than the positive cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

The described assays are designed to be read automatically by the instrument, and even though you cannot edit reactions or results, you can still view the images of the assay reactions by using the instrument software. Reaction features are described in the associated reagent package inserts.

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	Possible Well Results	Possible Test Interpretations
RHFORM_D	+, -, ?, X	CDE Interpretations: ccD.ee, CCD.ee, CcD.ee, ccD.Ee, CCD.Ee, CcD.Ee, ccD.EE, CcD.EE, CCD.EE, ccddee, CCddee, Ccddee, ccddEe, CCddEe, CcddEe, ccddEE, CcddEE, CCddEE, NTD / Mixed field ?, *INV* Kell Interpretations: K+, K-, NTD / Mixed field ?, *INV*
RHFORM_Cw	+, -, ?, X	CE and Cw Interpretations: cc ee Cw+, CC ee Cw+, Cc ee Cw+, cc Ee Cw+, CC Ee Cw+, Cc Ee Cw+, cc EE Cw+, Cc EE Cw+, CC EE Cw+, cc ee Cw-CC ee Cw-, Cc ee Cw-, ccEe Cw-, CC Ee Cw-, Cc Ee Cw-, cc EE Cw-, CcEE Cw-, CC EE Cw-, NTD / Mixed field ?, *INV* Kell Interpretations: K+, K-, NTD / Mixed field ?, *INV*
RHFORM_Cw *Alternative Aurora File	+, -, ?, X	CE Interpretations: cc ee, CC ee, Cc ee, cc Ee Cw+, CC Ee, Cc Ee, cc EE, Cc EE, CC EE, NTD / Mixed field ?, *INV* Cw Interpretations: Cw+, Cw-, NTD / Mixed field ?, *INV* Kell Interpretations: K+, K-, NTD / Mixed field ?, *INV*

PHENO12_2 PHENO12_3 PHENO16_2 PHENO16_3 PHENO16_4	+, -, ?, X	CE Interpretations: Kell Interpretations:	CC EE, Cc EE, cc EE, CC Ee, Cc Ee, cc Ee, CC ee, Cc ee, cc ee, NTD / Mixed field ?, *INV* K+, K-, NTD / Mixed field ?, *INV*
CcEe CcEe2	+, -, ?, X	CE Interpretations:	CC EE, Cc EE, cc EE, CC Ee, Cc Ee, cc Ee, CC ee, Cc ee, ccee, NTD / Mixed field ?, *INV*
CDE	+, -, ?, X	CDE Interpretations:	CDE+, CDE-, NTD / Mixed field ?, *INV*

*Alternative result interpretation depending on installed aurora file version

Attachment IX: NEO Iris Operator Manual

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results and interpretations used for the S2_Cell and SAb_ID assays.

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No responsibility is assumed by Immucor for the use or reliability of software or equipment that is not supplied by Immucor or its affiliated dealers. All warnings and cautions must be reviewed by the Operator prior to using the NEO Iris for the first time.

How this Attachment is Organized

In This Section

This section describes the organization of this attachment, including:

- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons

Notational Conventions

This attachment uses a page numbering system that includes a prefix of the attachment number (VIX) hyphenated with the page number. Sequential lists that describe step-by-step procedures are included as numbered lists.

The footer of each page contains the current attachment version identified using a nine character hyphenated format combined with a five character attachment alpha-numeric identifier (AVIX) in parentheses. The first three characters (NEO Iris) identify the instrument. The second set of three characters identifies this document as an attachment to the operator manual (001). The final set of three characters identifies the version of the attachment associated with the operator manual. 100 designates version 1; 200 designates a full version 2 update; and so on.

Limitations of Use and Warnings

Limitations of use and warnings are located in this attachment, specifically in the body of the text where they are most relevant to the information. An icon draws your attention to limitations of use and warnings.

Use of Icons

The following icons appear in this attachment to alert you of warnings or limitations of use.

Icon	Type of Warning	Related to...
	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Consult instructions for use	

Assay Description

Introduction

Intended Use

The S2_Cell assay is an automated screen assay used for the detection of unexpected IgG antibodies to red blood cells. The SAb_ID assay is used as an antibody panel to identify unexpected IgG antibodies. Both, the S2_Cell assay and the SAb_ID assay contain an internal Negative control and an internal Positive control (containing a mixture of antibodies). Therefore an additional daily QC is not required for those as it is built into the test system.

List of assays

The following table lists the described assay on the NEO Iris in a vertical assay configuration.

Assay Description	Assay short name	Used reagents	Microplates Used
	Capture-R Ready Screen		
RBC antibody screen	S2_Cell	1. Capture LISS 2. Capture-R Ready Indicator Red Cells 3. Capture-R Positive Control Serum (Weak) 4. Capture-R Negative Control Serum	Capture-R Ready-Screen (I and II)
RBC antibody panel	SAb_ID	1. Capture LISS 2. Capture-R Ready Indicator Red Cells 3. Capture-R Positive Control Serum (Weak) 4. Capture-R Negative Control Serum	Capture-R Ready-ID

Limitations, Warnings and Notes

Icon	Description
	Limitation: Sample addition is NOT verified when using the S2_Cell or SAb_ID assay as the Range Check of the Well filled verification step is turned off. Therefore each negative result requires confirmation by additional methodology. The assays contain internal Positive and Negative controls that need to pass in order to validate the run of the blood samples. This assay is not intended to be used for routine blood sample testing.

All further limitations, warnings and notes that relate to the described assay are defined in the Operator Manual Chapter 12: Limitations of Use and Warnings and in Attachment I of the NEO Iris instrument.

Cutoffs and Reagent Components

List of Cutoffs

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
S2_Cell	All	0	0	20
		?	20	30
		1+	30	45
		2+	45	65
		3+	65	90
		4+	90	100
SAb_ID	Sample	0	0	20
		?	20	30
		1+	30	45
		2+	45	65
		3+	65	90
		4+	90	100
	Positive control	0	0	30
		?	-	-
		1+	30	45
		2+	45	65
		3+	65	90
		4+	90	100
	Negative control	0	0	30
		?	-	-
		1+	30	45
		2+	45	65
		3+	65	90
		4+	90	100

Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
S2_Cell	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the blood samples from the red blood cells/clot. Remove the caps from the blood sample tubes. 3. Remove the Capture-R® Ready-Screen® (I and II) microplate frame and the desired number of Capture-R® Ready-Screen® (I and II) strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the S2_Cell assay to the blood samples, either manually or following the upload worklist procedure. 8. Start the S2_Cell assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the S2_Cell assay, and records and interprets the blood sample results. 9. At the completion of the NEO Iris S2_Cell assay, click the Results button on the main menu bar to access the blood sample results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
SAb_ID	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the blood samples from the red blood cells/clot. Remove the caps from the blood sample tubes. 3. Remove the Capture-R® Ready-ID® microplate frame and the desired number of Capture-R® Ready-ID® strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the SAb_ID assay to the blood samples, either manually or following the upload worklist procedure. 8. Start the SAb_ID assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the SAb_ID assay, and records the blood sample results. 9. At the completion of the NEO Iris SAb_ID assay, click the Results button on the mainmenu bar to access the blood sample results. If any wells are reported positive, you must cross-reference this data with the lot-specific Capture-R® Ready-ID® Master List to determine the antibody identification (if any exists).

Results and Interpretations

Introduction

The NEO Iris™ generates a result for each well read by the instrument and an interpretation of the results. Each NEO Iris assay has predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported as Negative, Positive, Equivocal or Invalid. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for the S2_Cell and SAb_ID assay include:

Indicator	Name	Description
+	Positive	The reaction value is greater than the positive cutoff value.
-	Negative	The reaction value is less than or equal to the negative control value.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater than the negative cutoff value or equal to or less than the positive cutoff value.
X	Invalid	The invalid symbol indicates an error status for a given well. An Invalid test well results in generated if the instrument detects a processing error or process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.)

The described assays are designed to be read automatically by the instrument, and even though you cannot edit reactions or results, you can still view the images of the assay reactions by using the instrument software. Reaction features are described in the associated reagent package inserts.

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO Iris process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	Possible Well Results	Possible Test Interpretations
S2_Cell	+, -, ?*, X	Positive, Negative, No_Int, *INV*
SAb_ID	+, -, ?*, X	Positive, Negative, No_Int, *INV*, Ctrl Fail Note: Ctrl Fail indicates that the per sample positive control well (15th well in SAb_ID) has failed. This control well must react at least 3+ in order for the sample test result to be valid. If the control well is less than 3+, then the interpretation given will be Ctrl Fail.

Attachment X: NEO Iris Operator Manual

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results, interpretations used for the Antigen screening assays.

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How this Attachment is Organized

In This Section

This section describes the organization of this attachment, including:

- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons

Notational Conventions

This attachment uses a page numbering system that includes a prefix of the attachment number (X) hyphenated with the page number. Sequential lists that describe step-by-step procedures are included as numbered lists.

The footer of each page contains the current attachment version identified using a nine character hyphenated format combined with a five character attachment alpha-numeric identifier (A-X) in parentheses. The first set of characters (NEO Iris_EU) identify the instrument. The second set of three characters identifies this document as an attachment to the operator manual (001). The final set of three characters identifies the version of the attachment associated with the operator manual. 100 designates version 1; 200 designates a full version 2 update; and so on.

Limitations of Use and Warnings

Limitations of use and warnings are located in this attachment, specifically in the body of the text where they are most relevant to the information. An icon draws your attention to limitations of use and warnings.

Use of Icons

The following icons appear in this attachment to alert you of warnings or limitations of use.

Icon	Type of Warning	Related to...
	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Consult instructions for use	

Antigen Screening Assay Description

Introduction

Intended Use

Antigen screening assays are intended for the detection of rare antigens on red blood cells. Three categories of screening assays are available :

- Agglutination based antigen screening assay that incubates at room temperature.
- Agglutination based antigen screening assay that incubates at 37°C.
- Solid phase based antigen screening assay.

The Antigen screening assays make use of antisera selected by the customer, and the instrument system performs the assay processing steps using a standard set of parameters. Performance Characteristics have not been established. Because the type of antisera used in the assay is not prescribed by Immucor, the user must establish that the performance level is appropriate for their intended application.

List of assays

Assay Description	Assay Button Abbreviation	Microplates Used
Agglutination based antigen screening assay that incubates at room temperature.	mAgScrRT	Untreated microplates
Agglutination based antigen screening assay that incubates at 37°C.	mAgScr37	Untreated microplates
Solid phase based antigen screening assay.	pAgScrAHG	Capture-R® Select

Limitations, Warnings and Notes

Icon	Description
	Limitation: The **mAgScrRT**, **mAgScr37** and **pAgScrAHG** assays use antisera selected by end users, therefore Immucor has not established the performance characteristics of the customer selected antisera with the Iris system. It is the user's responsibility to identify and validate the antisera for use in conjunction with these assay test methods. As the user selects the antisera, Immucor has not performed any verification or validation to establish the specific performance characteristics with the antisera. Therefore, the users must establish the performance level and ensure it is appropriate for their specific application of the assay. Unless the end user has validated that the performance level is suitable for their use, additional measures should be considered to establish results are valid.
	Limitation: For the **mAgScrRT**, **mAgScr37** and **pAgScrAHG** assays: The barcode number used on the antisera vial will appear as the antisera ID in reports/results rather than the product name (e.g. Fy^{a}). You can choose to manually enter the product ID (e.g. Fy^{a}) and lot rather than scanning in the barcode or create a barcode with that name.
	Limitation: For the **mAgScrRT**, **mAgScr37** and **pAgScrAHG** assays: **You will need to aliquot the correct amount of antisera into a test tube as directed in the Assay Procedural Steps. If insufficient volume of antisera is loaded, then a portion of the tests ordered will be invalidated due to insufficient liquid**.
	Limitation: The maximum number of samples that can be antigen typed per microplate is 92 for the pAgScrAHG assay and 94 for the mAgScrRT and mAgScr37assays.
	Limitation: DAT positive red blood cells will give false positive results when used with the pAgScrAHG assay.
	Limitation: Capture-R® Ready Indicator Red Cells should be used no more than 24 hours after a stir ball has been added to the vial. Vials of reagents, other than Indicator Red Cells, that have remained continuously on the NEO Iris for 72 hours (3 days) should be removed and replaced with fresh vials. Vials of reagents, other than Indicator Red Cells, that are removed from the NEO Iris when not in use and refrigerated can be used up to their expiration dates. Users must determine the on-board usage time and stability for the antisera they apply for this assay.

Antigen Screening Assay Cutoffs

List of Cutoffs

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
mAgScrRT mAgScr37	All	0	0	30
		?	30	35
		1+	35	55
		2+	55	70
		3+	70	80
		4+	80	99
pAgScrAHG	All	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	99

Antigen Screening Assay Reagent Component Grid

Reagents & Microplates	mAgScrRT	mAgScr37	pAgScrAHG
Rh-Control	X	X	
Anti-D Rapid (ImmuClone)	X	X	
corQC™ EXTEND Standard	X	X	X
Untreated microplates	X	X	
Capture® LISS			X
Capture-R® Ready Indicator Red Cells			X
Capture-R® Positive Control Serum			X
Capture-R® Negative Control Serum			X
Capture-R® Select			X

Antigen Screening Assay Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert. Package inserts are also the source of information for limitations of the reagents in use.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
mAgScrRT	Qualification of Screening Material 1. Select the desired screening antiserum for the antigen of interest. 2. Prepare serial dilutions of the antiserum in test tubes with 6% BSA (Bovine Serum Albumin) in PBS. 3. Choose a red blood cell sample with heterozygous expression of the antigen of interest. 4. Test this red blood cell sample against each of the antiserum dilutions using the test tube method. The target dilution to be used for the agglutination based antigen screening assays (**mAgScrRT** and **mAgScr37**) is the highest dilution that gives at least a 2+ reaction in tube. However, a lower dilution may be used if desired. Note**:** If commercial antiserum is to be used, refer to the package insert for instructions on using the reagent for tube testing. If non-reagent material is to be used, refer to the following steps as a guide for tube testing. 5. If not using a commercially prepared red blood cell suspension, prepare a 2-5% suspension of red blood cells. 6. Add 1 drop of each antiserum dilution to separate test tubes 7. Add 1 drop of the red blood cell suspension to each tube 8. Mix the contents of each tube and centrifuge for 15-45s at 900-1000 x g. 9. Gently agitate each tube to suspend the red blood cell buttons. Examine for agglutination. Assay Procedural Steps 1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Aliquot the correct amount of diluted screening antisera into a test tube. The **mAgScrRT** assay uses a value of 45µl of antisera for each reaction plus 150 µl of antisera required as dead volume in the test tube. (e.g. if 20 samples are being screened for one antigen using the **mAgScrRT** assay, 1.05 ml of antisera. (45µl x 20 + 150µl) would be required.) 4. Remove reagent vial caps. 5. Load the diluted screening antiserum test tube*, reagents, microplates, and blood samples (and/or donor samples), onto the NEO following the procedures in **Chapter 6 – Instrument Testing Operation**. Note**:** The barcode number printed on the original antiserum vial, if scanned or typed into the ID field, will appear as the antiserum ID in the reports/results rather than the product name (e.g. Fy^a).

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
	You can choose to manually enter the product ID (e.g. Fy^a), or create and scan a barcode with that name ID, rather than scanning in the barcode printed on the vial label. 6. Assign the **mAgScrRT** assay to the screening antiserum. This will bring up the Crossmatch dialog box. Enter the ID of each sample to be screened by using the hand held scanner or by manual entry. The **mAgScrRT** assay can also be ordered following the Worklist procedure. 7. Start the **mAgScrRT** assay following the procedures in **Chapter 6 – Instrument Testing Operation**. The NEO automatically performs the **mAgScrRT** assay, and records and interprets the screening results. 8. At the completion of the NEO **mAgScrRT** assay, press the **Results** button on the Main Menu Bar to access the screening results.
mAgScr37	Qualification of Screening Material 1. Select the desired screening antiserum for the antigen of interest. 2. Prepare serial dilutions of the antiserum in test tubes with 6% BSA (Bovine Serum Albumin) in PBS. 3. Choose a red blood cell sample with heterozygous expression of the antigen of interest. 4. Test this red blood cell sample against each of the antiserum dilutions using the test tube method. The target dilution to be used for the agglutination based antigen screening assays (**mAgScrRT** and **mAgScr37**) is the highest dilution that gives at least a 2+ reaction in tube. However, a lower dilution may be used if desired. Note**:** If commercial antiserum is to be used, refer to the package insert for instructions on using the reagent for tube testing. If non-reagent material is to be used, refer to the following steps as a guide for tube testing. 5. If not using a commercially prepared red blood cell suspension, prepare a 2-5% suspension of red blood cells. 6. Add 1 drop of each antiserum dilution to separate test tubes. 7. Add 1 drop of the red blood cell suspension to each tube. 8. Mix the contents of each tube and centrifuge for 15-45s at 900-1000 x g. 9. Gently agitate each tube to suspend the red blood cell buttons. Examine for agglutination. Assay Procedural Steps 1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Aliquot the correct amount of diluted screening antisera into a test tube. The **mAgScr37** assay uses a value of 45µl of antisera for each reaction plus 150 µl of antisera required as dead volume in the test tube. (e.g. if 20 samples are being screened for one antigen using the **mAgScr37** assay, 1.05 ml of antisera. (45µl x 20 + 150µl) would be required.) 4. Remove reagent vial caps. 5. Load the diluted screening antiserum test tube*, reagents, microplates, and blood samples (and/or donor samples), onto the NEO following the procedures in **Chapter 6 – Instrument Testing Operation**. Note**:** The barcode number printed on the original antiserum vial, if scanned or typed into the ID field, will appear as the antiserum ID in the reports/results rather than the product name (e.g. Fy^a). You can choose to manually enter the product ID (e.g. Fy^a), or create and scan a barcode with that

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
	name ID, rather than scanning in the barcode printed on the vial label. 6. Assign the **mAgScr37** assay to the screening antiserum. This will bring up the Crossmatch dialog box. Enter the ID of each sample to be screened by using the hand held scanner or by manual entry. The **mAgScr37** assay can also be ordered following the Worklist procedure. 7. Start the **mAgScr37** assay following the procedures in **Chapter 6 – Instrument Testing Operation**. The NEO automatically performs the **mAgScr37** assay, and records and interprets the screening results. 8. At the completion of the NEO **mAgScr37** assay, press the **Results** button on the Main Menu Bar to access the screening results.
pAgScrAHG	Qualification of Screening Material 1. Select the desired screening antiserum for the antigen of interest. 2. Prepare serial dilutions of the antiserum in test tubes with 6% BSA (Bovine Serum Albumin) in PBS. 3. Choose a red blood cell sample with heterozygous expression of the antigen of interest. 4. Test this red blood cell sample against each of the antiserum dilutions using the test tube method. 5. The target dilution to be used for the antiglobulin based antigen screening assays (**pAgScrAHG**) is the highest dilution that gives at least a weak positive (w+) reaction in tube. However, a lower dilution may be used if desired. Note**:** If commercial antiserum is to be used, refer to the package insert for instructions on using the reagent for tube testing. If non-reagent material is to be used, refer to the following steps as a guide for tube testing. 6. If not using a commercially prepared red blood cell suspension, prepare a 2-5% suspension of red blood cells. 7. Add 1 drop of each antiserum dilution to separate test tubes. 8. Add 1 drop of the red blood cell suspension to each tube. 9. Mix the contents of each tube and incubate at 36-38°C for 20 minutes. 10. Wash the red blood cells in each tube at least three times with large volumes of saline. Decant thoroughly after each wash. 11. Add Anti-Human Globulin in the amount specified by the manufacturer's package insert. Mix the contents of each tube thoroughly. 12. Centrifuge for 15-45 seconds at 900-1000 x g, or as described in the manufacturer's package insert. 13. Gently agitate each tube to suspend the red blood cell buttons. Examine for agglutination. Assay Procedural Steps 1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Aliquot the correct amount of diluted screening antisera into a test tube. The **pAgScrAHG** assay uses a value of 55µl of antisera for each reaction plus 150 µl of antisera required as dead volume in the test tube. (e.g. if 20 samples are being screened for one antigen using the **pAgScrAHG** assay, 1.25 ml of antisera. (55µl x 20 + 150µl) would be required.) 4. Remove reagent vial caps. 5. Load the diluted screening antiserum test tube*, reagents, microplates, and blood samples (and/or donor samples), onto the NEO following the procedures in **Chapter 6 – Instrument Testing**

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
	Operation. Note**:** The barcode number printed on the original antiserum vial, if scanned or typed into the ID field, will appear as the antiserum ID in the reports/results rather than the product name (e.g. Fy^a). You can choose to manually enter the product ID (e.g. Fy^a), or create and scan a barcode with that name ID, rather than scanning in the barcode printed on the vial label. 6. Assign the **pAgScrAHG** assay to the screening antiserum. This will bring up the Crossmatch dialog box. Enter the ID of each sample to be screened by using the hand held scanner or by manual entry. The **pAgScrAHG** assay can also be ordered following the Worklist procedure. 7. Start the **pAgScrAHG** assay following the procedures in **Chapter 6 – Instrument Testing Operation**. The NEO automatically performs the **pAgScrAHG** assay, and records and interprets the screening results. 8. At the completion of the NEO **pAgScrAHG** assay, press the **Results** button on the Main Menu Bar to access the screening results.

Antigen Screening Assay Results and Interpretations

Introduction

The NEO Iris generates a result for each well read by the instrument and an interpretation of the results. The Antigen screening assays have predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported Positive, Negative, Invalid or Equivocal. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for Antigen Screening Assays include:

Well Result	Name	Description
+	Positive	The reaction value can be considered as positive.
-	Negative	The reaction value can be considered as negative.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater than the negative cutoff value or equal to or less than the positive cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO Iris process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	Possible Well Results	Possible Test Interpretations
mAgScrRT mAgScr37 pAgScrAHG	+,-,?,X	Sample Interpretations: Negative, Positive, No_Int, *INV* Control Interpretations: Negative, Positive, No_Int, *INV**

Key for Table of Well Results and Test Interpretations by Assay

The two (2) tables below describe the possible well test results per the Result Interpretations section of this attachment.

Well Result	Description
+	Positive
-	Negative
?	Equivocal
X	Invalid

Test Interpretation	Description
INV	Invalid
No_Int	No Interpretation

Attachment XI: NEO Iris Operator Manual

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results, interpretations and interface data used for the Non-ABO Titration assays.

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All operating instructions must be followed. In no event shall Immucor be held responsible for failures, errors, or other liabilities resulting from a customer’s noncompliance with the procedures and precautions outlined in this manual.

The sample screen displays and sample printouts in this Attachment XI for NEO Iris Operator Manual are for information and illustration purposes only. Immucor makes no representations or warranties about the accuracy or reliability of the information presented on the screen displays, and this information is not to be used for clinical or maintenance evaluation.

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No responsibility is assumed by Immucor for the use or reliability of software or equipment that is not supplied by Immucor or its affiliated dealers. All warnings and cautions must be reviewed by the Operator prior to using the NEO Iris for the first time.

How this Attachment is Organized

In This Section

This section describes the organization of this attachment, including:

- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons

Notational Conventions

This attachment uses a page numbering system that includes a prefix of the attachment number (XI) hyphenated with the page number. Sequential lists that describe step-by-step procedures are included as numbered lists.

The footer of each page contains the current attachment version identified using a string hyphenated format combined with a four character attachment alpha-numeric identifier (A-XI) in parentheses. The first set of characters (NEO Iris_EU) identifies the instrument. The second set of three characters identifies this document as an attachment to the operator manual (001). The final set of three characters identifies the version of the attachment associated with the operator manual. 100 designates version 1; 200 designates a full version 2 update; and so on.

Limitations of Use and Warnings

Limitations of use and warnings are located in this attachment, specifically in the body of the text where they are most relevant to the information. An icon draws your attention to limitations of use and warnings.

Use of Icons

The following icons appear in this attachment to alert you of warnings or limitations of use and to indicate where additional information is provided.

Icon	Type of Warning	Related to…
	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Consult instructions for use	
	Note	

Non-ABO Titration Assay Description

Introduction

The assays are for the determination of IgG alloantibody titers from plasma or serum on the NEO Iris automated analyzer.
The clinical interpretation and clinical cutoffs will be established by the user.
The assays are designed for the determination of the IgG antibody titers using Capture® solid phase red cell adherence technology against an antigen present on the chosen cells used to perform the tests.
The instrument will display the reaction strength of each well.

Description of assays

The following table lists the Non-ABO Titration assays available on the NEO Iris. The assays employ Capture-R® Select technology using the red cell products Panoscreen®/Panoscreen® C^w and Panoscreen® EXTEND as antigen expressing cells. The assays determine IgG alloantibody titers ranging from 2 to 256.

Assay Button Abbreviation	Red Cell reagent used for the test	Assay group
T_IgG_P1	Panoscreen I	Titration assays using Panoscreen/Panoscreen C^w cells
	Panoscreen C^w I	
T_IgG_P2	Panoscreen II	
	Panoscreen C^w II	
T_IgG_P3	Panoscreen III	
	Panoscreen C^w III	
T_IgG_E1	Panoscreen EXTEND I	Titration assays using Panoscreen EXTEND cells
T_IgG_E2	Panoscreen EXTEND II	
T_IgG_E3	Panoscreen EXTEND III	
T_IgG_E4	Panoscreen EXTEND IV	
T_IgG_E5	Panoscreen EXTEND V	

Limitations, Warnings and Notes

Icon	Description
	Samples tested positive on an antibody screen or antibody identification method and determined as <2 or negative in a titration assay should be considered to have a titer of 1.
	Limitation**:** Capture-R® Select plates: Strips removed from pouches should be used within 16 hours. Capture-R® Ready Indicator Red Cells should be used no more than 24 hours after a stir ball has been added to the vial. Vials of reagents other than Indicator red cells, that have remained continuously on the NEO Iris for 72 hours (3 days) should be removed and replaced with fresh vials. Vials of reagents, other than Indicator red cells, that are removed from the NEO Iris when not in use and refrigerated can be used up to their expiry dates.
	Warning: Inspect all reagents for the presence of foam before placing on the instrument when performing any assay. Do not vigorously agitate reagents. Shaking will produce foam in the vial that can cause the Liquid Level Detection (LLD) function of the pipetting system to erroneously aspirate foam and/or air rather than reagent. This will produce incorrect results or an error.
	Warning: If you are using two or more instruments, then the specific reagent vials for each instrument must be dedicated for use on that single instrument to ensure correct reagent volume tracking. If the actual reagent volume (less than the software numeric volume) is not sufficient for the number of tests scheduled, the instrument will produce invalid results and samples will need to be rescheduled for testing.
	Warning: If you do not add the stirballs to the Capture-R® Indicator Red Cells suspensions, the Panoscreen/ Panoscreen C^{w} Cells or Panoscreen EXTEND Cells, the results may be invalid or incorrect. Do not touch the stirballs. You should add them directly to the cellular reagent vials using the dispenser provided. Contamination of cellular reagents can occur if the stirballs are touched. You must only add one stirball per vial of cellular reagent. Do not add more than one stirball per vial.
	Warning: In rare occasions a possible result for a sample tested on a titration assay is “check for inconsistent grading”. The instrument will not provide a titer result. Inconsistent grading implies that one or more well grading result within the dilution series of a sample are higher than the previous well grading result despite higher dilution (refer to table “List of Cutoffs”). A sample that shows the grading failure needs to be repeated.
	Warning: To prevent contamination of specimens that are to be tested multiple times over an extended period of time it is recommended to aliquot and freeze samples instead of loading one aliquot serveral times on and off the instrument.

Icon	Description
	Limitation: Samples that exhibit excessive hemolysis or lipemia, or are icteric, should not be tested on the instrument. Samples that exhibit a hemolysis concentration of more than 108 mg/dl in IgG assays must not be tested on the instrument, because they may generate erroneous results. Color check in IgG assays can detect excessive hemolysis and invalids the result. Samples that exhibit a triglyceride concentration of more than 273 mg/dl in IgG assays must not be tested on the instrument, because they may generate erroneous results. Icteric samples (conjugated bilirubin) are tested until a concentration of 52.4 mg/dl in IgG assays without showing erroneous results. Icteric samples (unconjugated bilirubin) are tested until a concentration of 26.3 mg/dl in IgG assays without showing erroneous results.
	Warning: The antigen expression on red cells used for the assays can be heterozygous or homozygous depending on the chosen cell. As the number of bound IgG antibodies per red cell is expected to be higher for cells which express the relevant antigen homozygously, the titer of an antibody determined on a homozygous cell might be higher than the titer determined on a heterozygous cell due to the nature of the cells.
	Warning: The antigens of red cell donors are displayed on the Panoscreen/ Panoscreen C^w Master List accompanying each lot and are listed the Package insert for Panoscreen EXTEND. The correct cells expressing the antigen of interest need to be chosen for the test.

This list of notes, warnings and limitations is not intended as a substitute for the detailed package insert of the reagents used with the Non-ABO Titration assays.

Non-ABO Titration Cutoffs and Reagent Components

List of Cutoffs

Assay Abbreviation	Grade	Lower Limit >	Upper Limit <=
T_IgG_P1 T_IgG_P2 T_IgG_P3 T_IgG_E1 T_IgG_E2 T_IgG_E3 T_IgG_E4 T_IgG_E5	0	0.0	20.0
	1+	20.0	50.0
	2+	50.0	72.0
	3+	72.0	90.0
	4+	90.0	99.9

All non-ABO Titration assays include an on-plate run control using Capture-R control sera. Cutoffs for the control wells are as displayed below:

Control cutoffs	Grade	Lower Limit >	Upper Limit <=
Capture-R Weak Positive and Negative Control	0	0.0	17.5
	1+	17.5	50.0
	2+	50.0	72.0
	3+	72.0	90.0
	4+	90.0	99.9

Assay Reagent Component Grid

Reagents and Microplates	T_IgG_P1	T_IgG_P2	T_IgG_P3	T_IgG_E1	T_IgG_E2	T_IgG_E3	T_IgG_E4	T_IgG_E5
Capture-R® Weak Positive Control Serum	X	X	X	X	X	X	X	X
Capture-R® Negative Control Serum	X	X	X	X	X	X	X	X
Capture-R® Select	X	X	X	X	X	X	X	X
Panoscreen® I / Panoscreen® C^w I	X							
Panoscreen® II / Panoscreen® C^w II		X						
Panoscreen® III / Panoscreen® C^w III			X					
Panoscreen® Extend I				X				
Panoscreen® Extend II					X			
Panoscreen® Extend III						X		
Panoscreen® Extend IV							X	
Panoscreen® Extend V								X
Capture-R® Ready Indicator Red Cells	X	X	X	X	X	X	X	X
Capture® LISS	X	X	X	X	X	X	X	X

Non-ABO Titration Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
T_IgG_P1 T_IgG_P2 T_IgG_P3 T_IgG_E1 T_IgG_E2 T_IgG_E3 T_IgG_E4 T_IgG_E5	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells. Remove the caps from the blood sample tubes. (50µl per sample is used for Non-ABO Titration Assays) 3. Remove reagent vial caps. 4. Select the red cell expressing the antigen of interest from the provided lot Masterlist (for Panoscreen/ Panoscreen C^w) or Package insert (Panoscreen EXTEND). 5. Add one stirball to each new vial of Panoscreen/Panoscreen C^w or Panoscreen EXTEND cells to be used. Add one stirball to each vial of Capture-R Indicator Red Cells. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples onto the NEO Iris following the 1. procedures in **Chapter 6 – Instrument Testing Operation**. 7. Assign the appropriate assay(s) to the blood samples, either manually or following the upload worklist procedure. 8. Start the appropriate assay(s) following the procedures in **Chapter 6 – Instrument Testing Operation**. The NEO Iris automatically performs the assay(s), and records and interprets blood sample results. 9. Upon completion of the NEO Iris Non-ABO Titrations assay(s), click the Results button on the main menu bar to access the blood sample results. 10. Assay endpoint: This is determined automatically as the last result above the cutoff, which is set at 20 for Non-ABO titration assays.

Non-ABO Titration Results and Interpretations

Introduction

The NEO Iris generates a result for each well read by the instrument and provides an interpretation of the results.

A test well result is the reaction result for a given test well. Test well results are reported Positive, Negative or Invalid. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for Non-ABO Titration assay includes:

Indicator	Name	Description
+	Positive	The reaction value is greater than the cutoff value.
-	Negative	The reaction value is less than or equal to the cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

The Non-ABO Titration assays are designed to be read automatically by the instrument, and even though you cannot edit reactions or results, you can still view the images of the assay reactions by using the instrument software. Reaction features are described in the associated reagent package inserts.

Result Interpretations

The result interpretation is based on the reaction pattern of test well results. Final titer interpretation is the same for each Non-ABO Titration assay (T_IgG_E1, …) and is listed in the table below.

Non-ABO Titration assay		Dilution (per well)							
		2	4	8	16	32	64	128	≥256
Titer	<2 or negative	-	-	-	-	-	-	-	-
	2	+	-	-	-	-	-	-	-
	4	+	+	-	-	-	-	-	-
	8	+	+	+	-	-	-	-	-
	16	+	+	+	+	-	-	-	-
	32	+	+	+	+	+	-	-	-
	64	+	+	+	+	+	+	-	-
	128	+	+	+	+	+	+	+	-
	≥256	+	+	+	+	+	+	+	+

Performance Characteristics

Specific Performance Characteristics

Method comparison studies were performed at two (2) external sites and at Immucor, Inc. as an internal site. Specimens were tested on NEO Iris. Test results were compared for agreement between the automated titer assays and results for manually prepared dilutions.

Comparison Non-ABO Titrations vs. Manual Doubling Dilutions	Equal or within ±1 Doubling Dilution			Equal or within ±2 Doubling Dilutions		
N	n	Agreement (%)	LCI* (%)	n	Agreement (%)	LCI* (%)
66	62	93.9	86.7	66	100	95.6

* Agreement at the 95% one-sided lower confidence interval

Reproducibility

The reproducibility of the Non-ABO Titration Assays was evaluated at two (2) external sites and at Immucor, Inc. as an internal site. Each site tested three (3) samples per assay, representing low, medium and high titers covering the range of the assay. The samples were tested in triplicate per run, two (2) runs per day, for five (5) nonconsecutive days.

Reproducibility Summary of All Assay Results		Equal or within ±1 Doubling Dilution			Equal or within ±2 Doubling Dilutions		
Assay	N	n	Agreement (%)	LCI* (%)	n	Agreement (%)	LCI* (%)
T_IgG_P1	90	90	100	95.9	90	100	95.9
T_IgG_P2	90	90	100	95.9	90	100	95.9
T_IgG_E2	90	90	100	95.9	90	100	95.9
T_IgG_E5	90	90	100	95.9	90	100	95.9

* Agreement at the 95% one-sided lower confidence interval

Interface Specification Information

Non-ABO Titration assays information for the interface specification, detailed below, is supplemental information to **Attachment 2 for the NEO Iris Operator Manual**. Refer to **Attachment 2 for the NEO Iris Operator Manual** for a full description of the interface specification.

Result Record and Field 4 Measurement Values

<table>
<tr><th>Field</th><th>Description</th><th colspan="2">Possible Values</th></tr>
<tr><td>R 3.4</td><td>Assay Name</td><td colspan="2">T_IgG_P1, T_IgG_P2, T_IgG_P3, T_IgG_E1, T_IgG_E2, T_IgG_E3, T_IgG_E4, T_IgG_E5</td></tr>
<tr><td>R 4.1</td><td>Original graded result</td><td colspan="2">-, 1, 2, 3, 4, X</td></tr>
<tr><td rowspan="2">R 4.2</td><td rowspan="2">Interpreted Result 1</td><td>Corresponding Assay</td><td>Possible Values</td></tr>
<tr><td>T_IgG_P1
T_IgG_P2
T_IgG_P3
T_IgG_E1
T_IgG_E2
T_IgG_E3
T_IgG_E4
T_IgG_E5</td><td><2 or negative, 2, 4, 8, 16, 32, 64, 128, ≥256, Check for inconsistent grading, *INV*</td></tr>
</table>

LIS Well Result Identification for Field 4 Measurement Values (R 4.1)

<table>
<tr><th>Assay</th><th colspan="2">Test phase</th></tr>
<tr><td rowspan="8">T_IgG_P1
T_IgG_P2
T_IgG_P3
T_IgG_E1
T_IgG_E2
T_IgG_E3
T_IgG_E4
T_IgG_E5</td><td>1</td><td>Dilution 1:2</td></tr>
<tr><td>2</td><td>Dilution 1:4</td></tr>
<tr><td>3</td><td>Dilution 1:8</td></tr>
<tr><td>4</td><td>Dilution 1:16</td></tr>
<tr><td>5</td><td>Dilution 1:32</td></tr>
<tr><td>6</td><td>Dilution 1:64</td></tr>
<tr><td>7</td><td>Dilution 1:128</td></tr>
<tr><td>8</td><td>Dilution 1:256</td></tr>
</table>

Attachment XIV: Capture-R Select based Screening Assays

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results and interpretations used for the Capture-R Select based Screening assays.

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All operating instructions must be followed. In no event shall Immucor be held responsible for failures, errors, or other liabilities resulting from a customer's noncompliance with the procedures and precautions outlined in this manual.

The sample screen displays and sample printouts in this Attachment XIV for NEO Iris Operator Manual are for information and illustration purposes only. Immucor makes no representations or warranties about the accuracy or reliability of the information presented on the screen displays, and this information is not to be used for clinical or maintenance evaluation.

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No responsibility is assumed by Immucor for the use or reliability of software or equipment that is not supplied by Immucor or its affiliated dealers. All warnings and cautions must be reviewed by the Operator prior to using the NEO Iris for the first time.

How this Attachment is Organized

In This Section

This section describes the organization of this attachment, including:

- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons

Notational Conventions

This attachment uses a page numbering system that includes a prefix of the attachment number (XIV) hyphenated with the page number. Sequential lists that describe step-by-step procedures are included as numbered lists.

The footer of each page contains the current attachment version identified using a nine character hyphenated format combined with a five character attachment alpha-numeric identifier (A-XIV) in parentheses. The first three characters (NEO Iris) identify the instrument. The second set of three characters identifies this document as an attachment to the operator manual (001). The final set of three characters identifies the version of the attachment associated with the operator manual. 100 designates version 1; 200 designates a full version 2 update; and so on.

Limitations of Use and Warnings

Limitations of use and warnings are located in this attachment, specifically in the body of the text where they are most relevant to the information. An icon draws your attention to limitations of use and warnings.

Use of Icons

The following icons appear in this attachment to alert you of warnings or limitations of use.

Icon	Type of Warning	Related to…
	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Limitation	
	Note	
	Consult instructions for use	

Description for Assays

Introduction

Intended Use

The Capture-R Select based Screening Assays are intended for detection and identification of IgG red blood cell antibodies on the NEO Iris® and NEO® v2.0 automated systems.

Principles of the Assays

The described assays are designed to provide customers the option to select specific red cell reagents or characterized red cells from other sources, such as donor red blood cells, for automated 2 or 4 cell IgG antibody screening at 37°C to meet regional specific needs. The assays are intended to provide the customer the ability to select characterized red cells based on customer defined criteria. Since reagent red cells may come in different formulations, 2 and 4 cell antibody screening assays will be available for use of red cell suspensions with a concentration of 2-5% or with a lower concentration of 0.8% (+/-0.2%).

The IgG detection assays are based on Immucor's patented Capture-R® Select technology and are designed for use on the NEO Iris® and NEO® v2.0 automated analyzers.

List of assays

The following table lists the described assays on the NEO Iris. The assays exist in a vertical configuration.

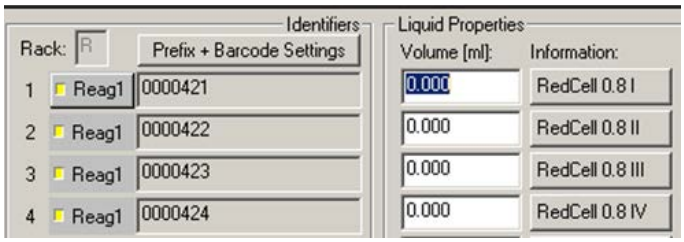
Assay Description	Assay short name	Used reagents	Microplates Used
	Blood grouping	**Vertical/8 wells per strip**	
Antibody screening (2-5%)	SC_2C	1. RedCell I* 2. RedCell II* 3. corQC® EXTEND Standard 4. Capture® LISS 5. Capture-R® Positive Control Serum (Weak) 6. Capture-R® Negative Control Serum 7. Capture-R® Ready Indicator Red Cells	Capture-R® Select plates
Antibody screening (0.8%)	SC_2C_I	1. RedCell 0.8 I* 2. RedCell 0.8 II* 3. corQC® EXTEND Standard 4. Capture® LISS 5. Capture-R® Positive Control Serum (Weak) 6. Capture-R® Negative Control Serum 7. Capture-R® Ready Indicator Red Cells	Capture-R® Select plates

Assay Description	Assay short name	Used reagents	Microplates Used
Antibody screening (2-5%)	SC_4C	1. RedCell I* 2. RedCell II* 3. RedCell III* 4. RedCell IV* 5. corQC® EXTEND Standard 6. Capture® LISS 7. Capture-R® Positive Control Serum (Weak) 8. Capture-R® Negative Control Serum 9. Capture-R® Ready Indicator Red Cells	Capture-R® Select plates
Antibody screening (0.8%)	SC_4C_I	1. RedCell 0.8 I* 2. RedCell 0.8 II* 3. RedCell 0.8 III* 4. RedCell 0.8 IV* 5. corQC® EXTEND Standard 6. Capture® LISS 7. Capture-R® Positive Control Serum (Weak) 8. Capture-R® Negative Control Serum 9. Capture-R® Ready Indicator Red Cells	Capture-R® Select plates

***NOTE:** The reagents described as "RedCell (0.8) I-IV" refer to the red cell reagents selected and validated by the customer for use in their laboratory. Immucor will provide 7-digit barcodes for each of the listed RedCell reagents. Those barcodes shall be attached to the selected red cells to enable their use on the NEO Iris® and NEO® v2.0 instruments. They will not contain any further information on lot numbers and expiry dates. Recording the relevant reagent information will be within the responsibility of the customer. A reagent tracking sheet provided with this Operator Manual Attachment shall facilitate simple tracking of used reagent lots and corresponding expiry dates.

Limitations, Warnings and Notes

Icon	Description
	Warning: Red cell reagents suitable for the proposed test are required to be selected by the user. Select reagents based on the corresponding red cell Masterlist and further reagent information provided by the reagent's supplier and based on any applicable regulatory requirements. It is the users responsibility to select red cells with the phenotypes matching those specified in local regulations and guidelines applicable to red cell antibody screening techniques.
	Warning: Assays SC_2C and SC_4C are designed for the use of *RedCell* suspensions with a concentration of 2-5% while 0.8% (+/-0.2%) *RedCell* suspensions can be tested using the SC_2C_l and SC_4C_l assays. Deviation from the recommended concentrations may lead to false positive, false negative or invalid results. If red blood cells need to be diluted to meet the above requirements, dilute red blood cell concentrate in buffered saline. Red blood cells should be free of hemolysis. Fragmented RBC membranes will interfere with cell monolayer formation. If the red blood cell sample shows signs of degradation, i.e., slight to moderate (1+ - 2 +) hemolysis, wash sample red blood cells at least 2 times with buffered saline before preparing the desired red cell suspension. Samples exhibiting severe hemolysis (≥3+) cannot be used.
	Warning: On board time and reagent expiry of the *RedCell* reagents cannot be automatically tracked by the system as barcode labels do not contain the relevant information. The operator is required to track lot number, expiry date and first on board time/date for each *RedCell* vial used on the instrument. A *RedCell* labeling sheet is provided with this Operator Manual Attachment.
	Warning: Immucor does not provide an on board stability claim for any red cell reagents other than Immucor red cell products released for automated use on the NEO Iris®/NEO® v2.0. Immucor reagents for automated detection of IgG antibodies on NEO Iris® have a 72 hours on board stability claim. Use of Immucor reagent red cells is therefore recommended.

Icon	Description
⚠	Warning: Reagent fill volume for *RedCell* reagents is not automatically recognized or tracked in the NEO software. When the *RedCell* reagent is loaded onto the instrument, the operator is required to manually enter the correct fill volume in the field next to the reagent name. Note that a dead volume of 1 mL needs to be subtracted from the actual fill volume when entering the reagent information, i.e. when the actual vial fill volume is 10 mL, manually type 9 mL in the corresponding data field. To edit the fill volume, click on the relevant loading bay and reagent rack and enter the correct fill volume minus the dead volume under Liquid Properties Volume (see image below). 
⚠	Warning: *RedCells* used on the Screening assays need to be vialed in 10 mL glass vials with the following specifications: 22 x 60 mm, thread 18 mm, flat bottom. Use of vials with differing specifications may lead to abortion of assay runs due to insufficient red cell volume or pipettor crashes.
⚠	Warning: Store all reagents used on the Capture-R Select based Screening Assays according to the suppliers' specifications to prevent compromising of reagent performance.
⚠	Warning: Do not pool red cell reagents from different vials or transfer red cell reagents from their original vial to prevent bacterial or chemical contamination.
⚠	Warning: In a case where both positive control wells obtain reaction scores below the positive cutoff the result for the Capture-R® Positive Control is "negative" or in a case where both negative control wells obtain 3+ reactions the result for the Capture-R® Negative Control is "positive" due to the definition in the DMS results text. Although the failed control does not display the Ctrl_Fail notice, the run will be invalidated by the system and no results interpretation will be provided.
⚠	Limitation: Capture-R Select based Screening Assays do only detect IgG antibodies at a temperature of 37°C.

Icon	Description
	**Note: It is recommended to qualify the use of the chosen *RedCells* by running a sample on the system with a known IgG antibody once per day.**
	Note: The RedCell Labeling Sheet that is provided in this Operator Manual Attachment shall help the operator to track relevant *RedCell* reagent data and ensure correct labeling and usage of the red cell products

All further limitations, warnings and notes that relate to the described assay are defined in the Operator Manual Chapter 12: Limitations of Use and Warnings and in Attachment I of the NEO Iris® instrument.

Cutoffs and Reagent Components

List of Cutoffs

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
SC_2C SC_2C_I	Positive/ Negative Control	0	0.0	17.5
		?	17.5	17.5
		1+	17.5	50.0
		2+	50.0	72.0
		3+	72.0	90.0
		4+	90.0	99.9
	RedCell (0.8) I/ RedCell (0.8) II	0	0.0	20.0
		?	20.0	30.0
		1+	30.0	45.0
		2+	45.0	65.0
		3+	65.0	90.0
		4+	90.0	99.9
SC_4C SC_4C_I	Positive/ Negative Control	0	0.0	17.5
		?	17.5	17.5
		1+	17.5	50.0
		2+	50.0	72.0
		3+	72.0	90.0
		4+	90.0	99.9
	RedCell (0.8) I/ RedCell (0.8) II/ RedCell (0.8) III/ RedCell (0.8) IV	0	0.0	20.0
		?	20.0	30.0
		1+	30.0	45.0
		2+	45.0	65.0
		3+	65.0	90.0
		4+	90.0	99.9

Assay Reagent Component Grid

Reagents and Microplates	**SC_2C**	**SC_2C_I**	**SC_4C**	**SC_4C_I**
Capture-R® Select plate	x	x	x	x
corQC® EXTEND Standard	x	x	x	x
Capture-R® Indicator Red Cells	x	x	x	x
Capture-R® Positive Control Serum (Weak)	x	x	x	x
Capture-R® Negative Control Serum	x	x	x	x
Capture® LISS	x	x	x	x
RedCell I*	x		x	
RedCell II*	x		x	
RedCell III*			x	
RedCell IV*			x	
RedCell 0.8 I*		x		x
RedCell 0.8 II*		x		x
RedCell 0.8 III*				x
RedCell 0.8 IV*				x

***NOTE:** The reagents described as "RedCell (0.8) I-IV" refer to the red cell reagents selected and validated by the customer for use in their laboratory.

Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements.

Information on *RedCell* reagent labeling

Immucor provides barcode labels to enable the use of customer validated red cell reagents with concentrations of 2-5% or 0.8% for antibody screening purposes using the Capture-R Select based 2 and 4 Cell Screening assays. The following table lists the assignment of barcodes to the corresponding *RedCell* reagent.

***RedCell* reagent name**	**Barcode**
RedCell I*	0000411
RedCell II*	0000412
RedCell III*	0000413
RedCell IV*	0000414
RedCell 0.8 I*	0000421
RedCell 0.8 II*	0000422
RedCell 0.8 III*	0000423
RedCell 0.8 IV*	0000424

To ensure that barcodes are correctly identified by the instrument, they shall only be used on reagent vials that align with the vial specifications described in the "Limitations, Warnings and Notes" section.

The listed barcodes do not automatically provide information on the lot, expiry dates and on board time of the *RedCell* reagent. For this purpose, a *RedCell* Labeling Sheet is attached to this Operator Manual Attachment. By filling in this sheet, tracking of lot numbers, expiry dates and further reagent information shall be ensured.

Assay Procedural Steps

This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
SC_2C SC_2C_I SC_4C SC_4C_I	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Select suitable red cell reagents to be used for antibody screening on the Capture-R Select based Screening assays based on their antigen profile, red cell concentration and suitability to run on the automated NEO Iris®/ NEO® v2.0 platform. If red cells are required to be diluted for use on the Screening assays, prepare 2-5% or 0.8% (+/-0.2%) suspensions in buffered saline. 3. Attach barcode labels provided by Immucor to the chosen red cell reagent vials and track lot number, expiry date and further reagent information using the RedCell Labeling Sheet. 4. Centrifuge the blood samples to separate the plasma from the red blood cells. Remove the caps from the blood sample tubes. 5. Remove the Capture-R® Select microplate frame and the desired number of Capture-R® Select strips from the pouch. 6. Remove reagent vial caps. 7. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells, corQC® EXTEND cells and *RedCell* reagents to be used. Gently agitate each vial to resuspend the red blood cells. 8. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 9. Manually enter the fill volumes of the *RedCell* reagents by clicking on the lane bay on which the reagents are loaded and manually entering the fill volume minus the vial deadvolume (1ml) under "Liquid Properties". 10. Assign the SC_2C, SC_2C_I, SC_4C and/ or SC_4C_I assay to the blood samples, either manually or following the upload worklist procedure. 11. Start the SC_2C, SC_2C_I, SC_4C and/ or SC_4C_I assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the SC_2C, SC_2C_I, SC_4C and/ or SC_4C_I assay, and records and interprets the blood sample results. 12. At the completion of the NEO Iris SC_2C, SC_2C_I, SC_4C and/ or SC_4C_I assay, click the Results button on the main menu bar to access the blood sample results.

Results and Interpretations

Introduction

The NEO Iris® generates a result for each well read by the instrument and an interpretation of the results. Each NEO Iris® assay has predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported as Negative, Positive, Equivocal or Invalid. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for assays include:

Indicator	Name	Description
+	Positive	The reaction value is greater than the cutoff value.
-	Negative	The reaction value is less than or equal to the cutoff value.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater than the negative cutoff value or equal or less than the positive cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

The described assays are designed to be read automatically by the instrument, and even though you cannot edit reactions or results, you can still view the images of the assay reactions by using the instrument software. Reaction features are described in the associated reagent package inserts.

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	Possible Well Results	Possible Test Interpretations
SC_2C SC_2C_I SC_4C SC_4C_I	+, -, ?, X	Run control interpretations: Positive, Negative, *INV*, Ctrl_Fail Result interpretations: Positive, Negative, No_Int, *INV*

RedCell Labeling Sheet

Original red cell reagent information			**Information for use on NEO Iris**			
Red cell reagent product name	Lot number	Cell concentration	Immucor barcode number (enter manually)	Instrument SN	Comments	Operator
	Expiry date	Vial fill volume	Fill volume entered in NEO software? (fill volume - 1ml)	First on board date and time		
			☐ (✓)			
Red cell reagent product name	Lot number	Cell concentration	Immucor barcode number (enter manually)	Instrument SN	Comments	Operator
	Expiry date	Vial fill volume	Fill volume entered in NEO software? (fill volume - 1ml)	First on board date and time		
			☐ (✓)			
Red cell reagent product name	Lot number	Cell concentration	Immucor barcode number (enter manually)	Instrument SN	Comments	Operator
	Expiry date	Vial fill volume	Fill volume entered in NEO software? (fill volume - 1ml)	First on board date and time		
			☐ (✓)			
Red cell reagent product name	Lot number	Cell concentration	Immucor barcode number (enter manually)	Instrument SN	Comments	Operator
	Expiry date	Vial fill volume	Fill volume entered in NEO software? (fill volume - 1ml)	First on board date and time		
			☐ (✓)			

Attachment XV: NEO Iris Operator Manual

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results and interpretations used for the ABO Rh assays.

Copyrights and Disclaimers

No warranties of any nature are extended by this document. You should be very careful to ensure that the use of this information and/or hardware and software material complies with the laws, rules, and regulations of the jurisdictions with respect to which it is used.

All operating instructions must be followed. In no event shall Immucor be held responsible for failures, errors, or other liabilities resulting from a customer's noncompliance with the procedures and precautions outlined in this manual.

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How this Attachment is Organized

In This Section

This section describes the organization of this attachment, including:

- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons

Notational Conventions

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Limitations of Use and Warnings

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Use of Icons

The following icons appear in this attachment to alert you of warnings or limitations of use.

Icon	Type of Warning	Related to...
	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Consult instructions for use	

Description for ABODFULLH, ABORH_V and Baby_BG3 Assays

Introduction

Intended Use

The described assays are designed to provide basic blood type and Rh status which can include both forward testing (of red blood cell) and reverse testing (of plasma/serum). Assays are based on direct agglutination technology for the NEO Iris™ automated analyzer.

List of assays

The following table lists the described assays on the NEO Iris. The assays exist in a horizontal or vertical configuration.

Assay Description	Assay short name	Used reagents	Microplates Used
	Blood grouping	**Horizontal/12 wells per strip**	
Forward and Reverse ABORh Blood Grouping	ABODFULLH	1. ImmuClone Rh-Hr Control 2. immuClone Anti-A 3. immuClone Anti-B 4. immuClone Anti-D rapid 5. NOVACLONE Anti-D 6. Referencells A1 7. Referencells B 8. Referencells O	Untreated microplates

Assay Description	Assay short name	Used reagents	Microplates Used
	Blood grouping	**Vertical/8 wells per strip**	
Forward and Reverse ABORh Blood Grouping	ABORH_V	1. ImmuClone Rh-Hr Control 2. NOVACLONE Anti-A 3. NOVACLONE Anti-B 4. NOVACLONE Anti-A,B 5. NOVACLONE Anti-D 6. Referencells A1 7. Referencells B 8. Referencells O	Untreated microplates
Forward ABORh Blood Grouping	Baby_BG3	1. immuClone Rh-Hr Control 2. NOVACLONE Anti-A 3. NOVACLONE Anti-B 4. NOVACLONE Anti-A,B 5. NOVACLONE Anti-D	Untreated microplates

Limitations, Warnings and Notes

All limitations, warnings and notes that relate to the described assays are defined in the Operator Manual Chapter 12: Limitations of Use and Warnings are in Attachment I of the NEO Iris instrument.

No additional limitations that relate to the described assays were identified.

Cutoffs and Reagent Components

List of Cutoffs

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABODFULLH	ImmuClone Rh-Hr Control	0	0.0	30.0
		? (not reported)	N/A	N/A
		1+	30.0	35.0
		2+	35.0	50.0
		3+	50.0	76.0
		4+	76.0	99.9
	immuClone Anti-A	0	0.0	30.0
		?	30.0	58.0
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58.0	99.9
	immuClone Anti-B	0	0.0	30.0
		?	30.0	76.0
		1+(not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76.0	99.9
	immuClone Anti-D rapid	0	0.0	30.0
		?	30.0	76.0
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+ (not reported)	N/A	N/A
		4+	76.0	99.9
	NOVACLONE Anti-D	0	0.0	30.0
		?	30.0	76.0
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76.0	99.9
	Referencells A1, B, O	0	0.0	23.0
		?	23.0	28.0
		1+	28.0	35.0
		2+	35.0	50.0
		3+	50.0	76.0
		4+	76.0	99.9

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABORH_V	ImmuClone Rh-Hr Control	0	0.0	30.0
		? (not reported)	N/A	N/A
		1+	30.0	35.0
		2+	35.0	50.0
		3+	50.0	76.0
		4+	76.0	99.9
	NOVACLONE	0	0.0	30.0

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Anti-A	?	30.0	58.0
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58.0	99.9
	NOVACLONE Anti-B	0	0.0	30.0
		?	30.0	76.0
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76.0	99.9
	NOVACLONE Anti-A,B	0	0.0	30.0
		?	30.0	76.0
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76.0	99.9
	NOVACLONE	0	0.0	30.0

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Anti-D	?	30.0	76.0
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76.0	99.9
	Referencells A1, B, O	0	0.0	23.0
		?	23.0	28.0
		1+	28.0	35.0
		2+	35.0	50.0
		3+	50.0	76.0
		4+	76.0	99.9

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
Baby_BG3	immuClone Rh-Hr Control	0	0.0	30.0
		? (not reported)	N/A	N/A
		1+	30.0	35.0
		2+	35.0	50.0
		3+	50.0	76.0
		4+	76.0	99.9
	NOVACLONE Anti-A	0	0.0	30.0
		?	30.0	58.0

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58.0	99.9
	NOVACLONE Anti-B	0	0.0	30.0
		?	30.0	76.0
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76.0	99.9
	NOVACLONE Anti-A,B	0	0.0	30.0
		?	30.0	76.0
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76.0	99.9
	NOVACLONE Anti-D	0	0.0	30.0
		?	30.0	76.0

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76.0	99.9

Assay Reagent Component Grid

Reagents and Microplates	ABODFULLH	ABORH_V	Baby_BG3
Untreated Microplates (barcoded)	x	x	x
immuClone Rh-Hr Control	x	x	x
immuClone Anti-A	x		
immuClone Anti-B	x		
immuClone Anti-D rapid	x		
NOVACLONE Anti-A		x	x
NOVACLONE Anti-B		x	x
NOVACLONE Anti-A,B		x	x
NOVACLONE Anti-D	x	x	x
Referencells A1	x	x	
Referencells B	x	x	
Referencells O	x	x	

Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
ABODFULLH, ABORH_V	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. 3. Remove reagent vial caps. 4. Add one stirball to each new vial of Referencells A1, B and O to be used. Gently agitate each vial to resuspend the red blood cells. 5. Load reagents, microplates, and blood samples, onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 6. Assign the appropriate assay to the blood samples either manually or following the upload worklist procedure. 7. Start the appropriate assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the assays, and records and interprets blood sample results. 8. At the completion of the NEO Iris assay, click the Results button on the main menu bar to access the blood samples results.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
Baby_BG3	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples, onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 5. Assign the appropriate assay to the blood samples either manually or following the upload worklist procedure. 6. Start the appropriate assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the assays, and records and interprets blood sample results. 7. At the completion of the NEO Iris assay, click the Results button on the main menu bar to access the blood samples results.

Results and Interpretations

Introduction

The NEO Iris™ generates a result for each well read by the instrument and an interpretation of the results. Each NEO Iris assay has predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported as Negative, Positive, Equivocal or Invalid. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for assays include:

Indicator	Name	Description
+	Positive	The reaction value is greater than the cutoff value.
-	Negative	The reaction value is less than or equal to the cutoff value.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater that the negative cutoff value or equal o or less than the positive cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

The described assays are designed to be read automatically by the instrument, and even though you cannot edit reactions or results, you can still view the images of the assay reactions by using the instrument software. Reaction features are described in the associated reagent package inserts.

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	Possible Well Results	Possible Test Interpretations
ABODFULLH	+, -, ?, X	ABO Interpretations: A, B, AB, O, NTD / Mixed field ?, *INV* Rh Interpretations: RH+, RH-, NTD / Mixed field ?, *INV*
ABORH_V	+, -, ?, X	ABO Interpretations: A, B, AB, O, NTD / Mixed field ?, *INV* Rh Interpretations: RH+, RH-, NTD / Mixed field ?, *INV*
Baby_BG3	+, -, ?, X	ABO Interpretations: A, B, AB, O, NTD / Mixed field ?, *INV* Rh Interpretations: RH+, RH-, NTD / Mixed field ?, *INV*

Attachment XVI: NEO Iris Operator Manual

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results, interpretations and interface data used for the Monoclonal assays for the detection of S, s, Fya, Fyb and k.

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How this Attachment is Organized

In This Section

This section describes the organization of this attachment, including:

- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons

Notational Conventions

This attachment uses a page numbering system that includes a prefix of the attachment number (XVI) hyphenated with the page number. Sequential lists that describe step-by-step procedures are included as numbered lists.

The footer of each page contains the current attachment version identified using a nine character hyphenated format combined with a five character attachment alpha-numeric identifier (A-XVI) in parentheses. The first set of characters (NEO Iris_EU) identify the instrument. The second set of three characters identifies this document as an attachment to the operator manual (001). The final set of three characters identifies the version of the attachment associated with the operator manual. 100 designates version 1; 200 designates a full version 2 update; and so on.

Limitations of Use and Warnings

Limitations of use and warnings are located in this attachment, specifically in the body of the text where they are most relevant to the information. An icon draws your attention to limitations of use and warnings.

Use of Icons

The following icons appear in this attachment to alert you of warnings or limitations of use.

Icon	Type of Warning	Related to…
	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Consult instructions for use	

Description for monoclonal S/s, Fya, Fyb, k Assays

Introduction

Intended Use

Anti-S (Monoclonal) Gamma-clone®, Anti-s (Monoclonal) Gamma-clone®and Anti-Fy^b (Monoclonal) Gamma-clone® blood grouping reagents are intended for the detection of S, s, and Fy^b antigens, respectively, on red blood cells by direct hemagglutination on the NEO Iris® automated analyzer.

Anti-Fy^a (Monoclonal) Gamma-clone® and Anti-k (Monoclonal) Gamma-clone® blood grouping reagents are intended for the detection of Fy^a and k antigens, respectively, on red blood cells by Capture-R® Select-based indirect agglutination on the NEO Iris® automated analyzer.

List of assays

The following table lists the monoclonal assays for the detection of S and s (AG_Ssli_m), Fy^a (AG_Fya_m), Fy^b (AG_Fyb_m) and k (AG_k_li_m) on the NEO Iris. The AG_Ssli_m and AG_Fyb_m assays exist in a horizontal and in a vertical configuration.

Version 1.00:

Assay Description	Assay short name	Used reagents	Microplates Used
	Blood grouping	**Horizontal/12 wells per strip**	
Monoclonal S/s	AG_Ssli_m	1. Monoclonal Control 2. Anti-S (Monoclonal) Gamma-clone® 3. Anti-s (Monoclonal) Gamma-clone®	Untreated microplates
Monoclonal Fy^b	AG_Fyb_m	1. Monoclonal Control 2. Anti-Fy^b (Monoclonal) Gamma-clone®	Untreated microplates
	Blood grouping	**Vertical/8 wells per strip**	
Monoclonal S/s	AG_Ssli_m	1. Monoclonal Control 2. Anti-S (Monoclonal) Gamma-clone® 3. Anti-s (Monoclonal) Gamma-clone®	Untreated microplates
Monoclonal Fy^b	AG_Fyb_m	1. Monoclonal Control 2. Anti-Fy^b (Monoclonal) Gamma-clone®	Untreated microplates
Monoclonal Fy^a	AG_Fya_m	1. Monoclonal Control 2. Anti-Fy^a (Monoclonal) Gamma-clone®	Capture-R® Select plates

Assay Description	Assay short name	Used reagents	Microplates Used
Monoclonal Cellano (k)	AG_k_li_m	1. Monoclonal Control 2. Anti-k (Monoclonal) Gamma-clone®	Capture-R® Select plates

Limitations, Warnings and Notes

Icon	Description
	Note: The purpose of the Monoclonal Control for AG_Ssli_m, AG_Fya_m, AG_Fyb_m and AG_k_li_m assay is to serve as a sample control for Immucor low protein blood grouping reagents. It is expected to indicate those sample related conditions that could lead to spontaneous agglutination with low protein reagents and, therefore, a false positive interpretation for the test. When the Monoclonal Control well yields a positive result, then the instrument would not report the blood type.
	Limitation: Vials of reagents, that have remained continuously on the NEO Iris for 72 hours (3 days) should be removed and replaced with fresh vials. Vials of reagents that are removed from the NEO Iris when not in use and refrigerated can be used up to their expiration dates.
	Limitation: The NEO Iris cannot reliably detect hemagglutination reactions that are graded as 1+ or less in test tube methodology. The NEO Iris does not generate an interpretation of mixed-field. Such a mixed-field reaction will be interpreted as positive, negative, or equivocal.
	Limitation for AG_Fyb_m: The expression of certain red blood cell antigens may diminish in strength during storage, particularly in EDTA samples. Better results will be obtained with fresh samples.
	Limitation: The grading of reactions on the NEO Iris must only be regarded as an approximation when compared to off-line visual grading by laboratory technical staff.
	Limitation for AG_Ssli_m and AG_k_li_m: Samples that exhibit excessive hemolysis or lipemia, or are icteric, should not be tested on the instrument. Samples that exhibit a hemolysis concentration of more than 1034.4 mg/dl must not be tested on the assays, because they may generate erroneous results. Samples that exhibit a triglyceride concentration of more than 1536.0 mg/dl in the assays must not be tested on the instrument, because they may generate erroneous results. Icteric samples (conjugated bilirubin) are tested until a concentration of 41.6 mg/dl without showing erroneous results. Icteric samples (unconjugated bilirubin) are tested until a concentration of 40.0 mg/dl without showing erroneous results.

Icon	Description
	Limitation for AG_Fya_m and AG_Fyb_m: Samples that exhibit excessive hemolysis or lipemia, or are icteric, should not be tested on the instrument. Samples that exhibit a hemolysis concentration of more than 1008.0 mg/dl must not be tested on the assays, because they may generate erroneous results. Samples that exhibit a triglyceride concentration of more than 1794.0 mg/dl in the assays must not be tested on the instrument, because they may generate erroneous results. Icteric samples (conjugated bilirubin) are tested until a concentration of 44.8 mg/dl without showing erroneous results. Icteric samples (unconjugated bilirubin) are tested until a concentration of 40.8 mg/dl without showing erroneous results.
	Limitation for AG_Fyb_m: The Fyx phenotype may not be detected by the Immucor Anti-Fy^{b} (Monoclonal) Gamma-clone reagent.

Monoclonal S/s, Fy^a, Fy^b, k Assay Cutoffs and Reagent Components

List of Cutoffs

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
AG_Ssli_m	Monoclonal control	0	0	25
		? (not reported)	N/A	N/A
		1+	25	35
		2+	35	50
		3+	50	80
		4+	80	99
	Anti-S (Monoclonal) Gamma-clone® Anti-s (Monoclonal) Gamma-clone®	0	0	25
		?	25	28
		1+	28	35
		2+	35	50
		3+	50	80
		4+	80	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
AG_Fyb_m	Monoclonal control	0	0	25
		? (not reported)	N/A	N/A
		1+	25	35
		2+	35	50
		3+	50	72
		4+	72	99
	Anti-Fyb (Monoclonal) Gamma-clone®	0	0	25
		?	25	28
		1+	28	35
		2+	35	50
		3+	50	72
		4+	72	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
AG_Fya_m	Positive and negative control	0	0	17.5
		? (not reported)	N/A	N/A
		1+	17.5	50
		2+	50	72
		3+	72	90
		4+	90	99
	Monoclonal Control	0	0	20
		? (not reported)	N/A	N/A
		1+	20	50
		2+	50	72
		3+	72	90
		4+	90	99
	Anti-Fya (Monoclonal) Gamma-clone®	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
AG_k_li_m	Positive and negative control	0	0	17.5
		? (not reported)	N/A	N/A
		1+	17.5	50
		2+	50	72
		3+	72	90
		4+	90	99
	Monoclonal Control	0	0	20
		? (not reported)	N/A	N/A
		1+	20	50
		2+	50	72

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+	72	90
		4+	90	99
	Anti-k (Monoclonal) Gamma-clone®	0	0	20
		?	20	40
		1+	40	50
		2+	50	72
		3+	72	90
		4+	90	99

Assay Reagent Component Grid

Reagents and Microplates	AG_Ss_Ii_m	AG_Fyb_m	AG_Fya_m	AG_k_Ii_m
Untreated Microplates (barcoded)	x	x		
Capture-R® Select plates			x	x
Specimen Diluent	x	x		
Monoclonal Control	x	x	x	x
Anti-S IgM (Monoclonal) Gamma-clone®	x			
Anti-s IgM (Monoclonal) Gamma-clone®	x			
Anti-Fyb IgM (Monoclonal) Gamma-clone®		x		
Anti-Fya IgG (Monoclonal) Gamma-clone®			x	
Anti-k IgG (Monoclonal) Gamma-clone®				x
corQC® Extend Standard			x	x
Capture-R® Positive and Negative Control Sera			x	x
Capture® LISS			x	x
Capture-R® Ready Indicator Red Cells			x	x

Monoclonal S/s, Fya, Fyb, k Assay Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert. Package inserts are also the source of information for limitations of the reagents in use.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
AG_Ss_li_m, AG_Fyb_m	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples, onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 5. Assign the assay (AG_Ssli_m / AG_Fyb_m) to the blood samples either manually or following the upload worklist procedure. 6. Start the AG_Ssli_m / AG_Fyb_m assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the AG_Ssli_m / AG_Fyb_m assay, and records and interprets blood sample results. 7. At the completion of the NEO Iris assays, click the Results button on the main menu bar to access the blood samples results.
AG_Fya_m, AG_k_li_m	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove the Capture-R® Select microplate frame and the desired number of Capture-R® Select strips from the pouch. 4. Remove reagent vial caps. 5. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells or CorQC® Extend cells to be used. Gently agitate each vial to resuspend the red blood cells. 6. Load reagents, microplates, and blood samples, onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 7. Assign the assay (AG_Fya_m / AG_k_li_m) to the blood samples either manually or following the upload worklist procedure. 8. Start the AG_Fya_m / AG_k_li_m assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the AG_Fya_m / AG_k_li_m assay, and records and interprets blood sample results. 9. At the completion of the NEO Iris assays, click the Results button on the main menu bar to access the blood samples results.

Monoclonal S/s, Fya, Fyb, k Assay Results and Interpretations

Introduction

The NEO Iris® generates a result for each well read by the instrument and an interpretation of the results. The Monoclonal S/s, Fya, Fyb, k Assays have predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported Positive, Negative, Invalid or Equivocal. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for Monoclonal S/s, Fya, Fyb, k Assays include:

Indicator	Name	Description
+	Positive	The reaction value can be considered as positive.
-	Negative	The reaction value can be considered as negative.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater than the negative cutoff value or equal to or less than the positive cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO Iris process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	Possible Well Results	Possible Test Interpretations
AG_Ssli_m	Monoclonal Control: +(1, 2, 3, 4), -, X S/s: +(1, 2, 3, 4), -, ?[1], X	S/s interpretations: S+, S-, s+, s-, NTD, Ctrl failure, *INV*
AG_Fyb_m	Monoclonal Control: +(1, 2, 3, 4), -, X Fyb: +(1, 2, 3, 4), -, ?[1], X	Fyb interpretations: Fyb+, Fyb-, NTD, Ctrl failure, *INV*

Assay	Possible Well Results	Possible Test Interpretations
AG_Fya_m	Monoclonal Control: +(1, 2, 3, 4), -, X Fya: +(1, 2, 3, 4), -, ?[1], X	Fya interpretations: Fya+, Fya-, NTD, Mono ctrl failure, *INV* Control interpretations: positive, negative, Ctrl failure, *INV*
AG_k_li_m	Monoclonal Control: +(1, 2, 3, 4), -, X k (Cellano): +(1, 2, 3, 4), -, ?[1], X	Cellano interpretations: Cellano+, Cellano-, NTD, Mono ctrl failure, *INV* Control interpretations: positive, negative, Ctrl failure, *INV*

[1] Equivocal results of antibody wells may be edited. There cannot be an equivocal result for Monoclonal Control wells, wherefore negative control results are not editable.

Key for Table of Well Results and Test Interpretations by Assay

The two (2) tables below describe the possible well test results per the Result Interpretations section of this attachment.

Well Result	Description
+	Positive
-	Negative
?	Equivocal
X	Invalid

Test Interpretation	Description
INV	Invalid
NTD	No Type Determined
Ctrl failure	Control failure
Mono ctrl failure	Negative control failure

Interface Specification Information

The Monoclonal S/s, Fya, Fyb and k assay information for the interface specification, detailed below, is supplemental information to **Attachment II for the NEO Iris Operator Manual (EU).** Refer to **Attachment II for the NEO Iris Operator Manual (EU)** for a full description of the interface specification.

Result Record Field 4 Measurement Values

SUB-COMPONENT 1		
Assay	**Possible Values for Reaction Pattern**	
All Assays	-, 1, 2, 3, 4, ?, X	
SUB-COMPONENT 2		
Assay	**Interpretation Values**	
AG_Ssli_m	**S Interpretation**	**s Interpretation**
	S+, S-, NTD, Ctrl failure, *INV*	s+, s-, NTD, Ctrl failure, *INV*
AG_Ssli_m[1]	S+ s+, S- s+, S+ s-, S- s-, NTD, Ctrl failure, *INV*	
AG_Fya_m	Fya+, Fya-, NTD, Mono ctrl failure, *INV*	
AG_Fyb_m	Fyb+, Fyb-, NTD, Ctrl failure, *INV*	
AG_k_li_m	Cellano+, Cellano-, NTD, Mono ctrl failure, *INV*	

[1] Applicable for alternative Aurora file with one Element

LIS Well Result Identification for Result Field 4 Measurement Values

Assay	**Test phase**	
AG_Ssli_m	1	Monoclonal Control
	2	Anti-S (Monoclonal) Gamma-clone®
	3	Anti-s (Monoclonal) Gamma-clone®
AG_Fyb_m	1	Anti-Fyb (Monoclonal) Gamma-clone®
	2	Monoclonal Control
AG_Fya_m	1	Anti-Fya (Monoclonal) Gamma-clone®
	2	Monoclonal Control
AG_k_li_m	1	Anti-k (Monoclonal) Gamma-clone®
	2	Monoclonal Control

Performance Characteristics

Specific Performance Characteristics

Method Comparison Studies:

Method comparison studies were performed at two (2) external sites and one (1) internal site. Immucor, Inc., as the manufacturer, was the internal site. The external sites were representative of blood collection establishments, hospital-based transfusion services, and/or clinical laboratories. Samples were tested with the reagent and also a comparator reagent. Test results were evaluated for agreement between reagents. Combined results from all sites are summarized in the following tables:

Note: Agreement between methods does not indicate which method is correct.

Assay performance represents NEO Iris and Galileo NEO (software version 3.1 or higher).

Anti-S (Monoclonal) Gamma-clone:

Initial Results N=975		Comparator Reagent			
		Positive	Negative		
Anti-S	Positive	545	2*	Positive Percent Agreement	99.81%
				PPA (95% 1-Sided LCI)	99.13%
	Negative	1**	427	Negative Percent Agreement	99.53%
				NPA (95% 1-Sided LCI)	98.54%

Discordant samples were further genotyped by DNA molecular testing (PreciseType™ HEA BeadChip). *One (1) sample gave mixed-field reaction with comparator reagent; one (1) sample gave mixed-field reaction on NEO Iris. **Sample gave mixed-field reaction with comparator reagent. If these three (3) samples are excluded from the analysis, resolved PPA 99.58% (95% 1-sided LCI) and NPA 98.90% (95% 1-sided LCI).).

Anti-little s (Monoclonal) Gamma-clone:

Initial Results N=975		Comparator Reagent			
		Positive	Negative		
Anti-s	Positive	793	3*	Positive Percent Agreement	100%
				PPA (95% 1-Sided LCI)	99.71%
	Negative	0	179	Negative Percent Agreement	98.35%
				NPA (95% 1-Sided LCI)	95.80%†

Discordant samples were further genotyped by DNA molecular testing (PreciseType™ HEA BeadChip). *Two (2) samples initially typed s– with comparator reagent; repeat test with comparator reagent and DNA were s+. One (1) sample initially type s– with comparator reagent; repeat tests with comparator reagent and NEO Iris were s–, DNA was s+. Resolved NPA 99.44% (97.39%† 95% 1-sided LCI). †The Lower 99% CI was not met due to the lower number of s– samples in the population, N=179.

Anti-k (Cellano) (Monoclonal) Gamma-clone:

Initial Results N=834		Comparator Reagent			
		Positive	Negative		
Anti-k	Positive	819	0	Positive Percent Agreement	100%
				PPA (95% 1-Sided LCI)	99.72%
	Negative	0	15	Negative Percent Agreement	100%
				NPA (95% 1-Sided LCI)	85.77%*

*The Lower 99% CI was not met due to the lower number of k– samples in the population, N=15.

Anti-Fya (Monoclonal) Gamma-clone:

Initial Results N=974		Comparator Reagent			
		Positive	Negative		
Anti-Fy^a	Positive	673	5*	Positive Percent Agreement	100%
				PPA (95% 1-Sided LCI)	99.66%
	Negative	0	296	Negative Percent Agreement	98.34%
				NPA (95% 1-Sided LCI)	96.54%

Discordant samples were further genotyped by DNA molecular testing (PreciseType™ HEA BeadChip). All five (5) samples initially typed Fy(a–) with comparator reagent; repeat test with comparator reagent and DNA were Fy(a+). Resolved NPA 100% (99.23% 95% 1-side LCI).

Anti-Fyb (Monoclonal) Gamma-clone:

Initial Results N=1236		Comparator Reagent			
		Positive	Negative		
Anti-Fy^b	Positive	624	7*	Positive Percent Agreement	98.89%
				PPA (95% 1-Sided LCI)	97.93%
	Negative	7†	598	Negative Percent Agreement	98.84%
				NPA (95% 1-Sided LCI)	97.84%

Discordant samples were further genotyped by DNA molecular testing (PreciseType™ HEA BeadChip). *† one (1) sample in each category resolved in favor of the instrument result. Resolved PPA 99.05% (98.13% 95% 1-side LCI) and NPA 99.01% (98.05% 95% 1-side LCI).
†Three (3) samples typed as Fy(a+b+^{w}) [Fy$_{mod}$ (Fy^x)] due to the 265C>T SNP. Three (3) samples were unresolved as DNA testing gave low signal results (2) or was QNS for testing (1).
*One (1) sample had debris in the well and tested Fy(b–) upon retest. Four (4) samples were falsely positive due to misaligned instrument ROIs (Region of Interest); three (3) samples were Fy(b–) upon retest, one (1) sample remained Fy(b+) upon retest. One (1) sample was unresolved as DNA testing gave low signal results.

Precision Studies:

Anti-S, Anti-s, Anti-k, Anti-Fya and Anti-Fyb (Monoclonal) Gamma-clone reagents:

Repeatability and Reproducibility were performed at three (3) sites by testing identical sample panels, containing positive and negative panel members in triplicate, testing two runs per day for five non-consecutive days. Results demonstrated 100% agreement for all positive and negative panel members.

Attachment XVIII: NEO Iris Operator Manual

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results, interpretations and interface data used for the RHFORMEL and PHENO12 assays for the detection of phenotyping status on RhCE and Kell.

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How this Attachment is Organized

In This Section

This section describes the organization of this attachment, including:

- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons

Notational Conventions

This attachment uses a page numbering system that includes a prefix of the attachment number (XVIII) hyphenated with the page number. Sequential lists that describe step-by-step procedures are included as numbered lists.

The footer of each page contains the current attachment version identified using a nine character hyphenated format combined with a five character attachment alpha-numeric identifier (A-XVIII) in parentheses. The first set of characters (NEO Iris_EU) identify the instrument. The second set of three characters identifies this document as an attachment to the operator manual (001). The final set of three characters identifies the version of the attachment associated with the operator manual. 100 designates version 1; 200 designates a full version 2 update; and so on.

Limitations of Use and Warnings

Limitations of use and warnings are located in this attachment, specifically in the body of the text where they are most relevant to the information. An icon draws your attention to limitations of use and warnings.

Use of Icons

The following icons appear in this attachment to alert you of warnings or limitations of use.

Icon	Type of Warning	Related to…
	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Consult instructions for use	

Description for RHFORMEL and PHENO12

Introduction

Intended Use

The described assays are designed to provide phenotyping status on RhCE and Kell. Assays are based on direct agglutination technology for the NEO Iris™ automated analyzer.

List of assays

The following table lists the described assays on the NEO Iris. The assays exist in a horizontal or vertical configuration.

Assay Description	Assay short name	Used reagents	Microplates Used
	Blood grouping	**Horizontal/12 wells per strip**	
Rh Blood Group	RHFORMEL	1. immuClone Anti-C(1) 2. immuClone Anti-C(2) 3. immuClone Anti-c(1) 4. immuClone Anti-c(2) 5. immuClone Anti-E(1) 6. immuClone Anti-E(2) 7. immuClone Anti-e(1) 8. immuClone Anti-e(2) 9. immuClone Anti-Kell (1) 10. Automated ImmuClone Anti-Kell 11. immuClone Rh-Hr Control	Untreated microplates
	Blood grouping	**Vertical/8 wells per strip**	
Rh Blood Group	PHENO12	1. immuClone Anti-C(1) 3. immuClone Anti-c(1) 5. immuClone Anti-E(1) 7. immuClone Anti-e(1) 9. immuClone Anti-Kell (1) 11. immuClone Rh-Hr Control	Untreated microplates

Limitations, Warnings and Notes

All limitations, warnings and notes that relate to the described assays are defined in the Operator Manual Chapter 12: Limitations of Use and Warnings and in Attachment I of the NEO Iris instrument.
No additional limitations that relate to the described assays were identified.

Cutoffs and Reagent Components

List of Cutoffs

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
RHFORMEL	ImmuClone Anti-C(1)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-C(2)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-c(1)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-c(2)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-E(1)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	ImmuClone Anti-E(2)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-e(1)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-e(2)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	immuClone Anti-Kell (1)	0	0	23
		?	23	35
		1+ (not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	Automated ImmuClone Anti-Kell	0	0	23
		?	23	50
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	50	80
		4+	80	99
	ImmuClone Rh-Hr Control	0	0	23
		? (not reported)	N/A	N/A
		1+	23	35

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		2+	35	50
		3+	50	76
		4+	76	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
PHENO12	ImmuClone Anti-C(1)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-c(1)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-E(1)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-e(1)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	immuClone Anti-Kell (1)	0	0	23
		?	23	35
		1+(not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	immuClone Rh-Hr Control	0	0	23
		? (not reported)	N/A	N/A
		1+	23	75
		2+	75	50
		3+	50	76
		4+	76	99

Assay Reagent Component Grid

Reagents and Microplates	RHFORMEL	PHENO12
Untreated Microplates (barcoded)	X	X
ImmuClone Anti-C(1)	X	X
ImmuClone Anti-C(2)	X	
ImmuClone Anti-c(1)	X	X
ImmuClone Anti-c(2)	X	
ImmuClone Anti-E(1)	X	X
ImmuClone Anti-E(2)	X	
ImmuClone Anti-e(1)	X	X
ImmuClone Anti-e(2)	X	
ImmuClone Anti-Kell (1)	X	X
Automated ImmuClone Anti-Kell	X	
ImmuClone Rh-Hr Control	X	X

Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert. Package inserts are also the source of information for limitations of the reagents in use.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
RHFORMEL PHENO12	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples, onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 5. Assign the appropriate assay to the blood samples either manually or following the upload worklist procedure. 6. Start the appropriate assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the assays, and records and interprets blood sample results. 7. At the completion of the NEO Iris assay, click the Results button on the main menu bar to access the blood samples results.

Results and Interpretations

Introduction

The NEO Iris®generates a result for each well read by the instrument and an interpretation of the results. Each NEO Iris assay has predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported Positive, Negative, Invalid or Equivocal. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for assays include:

Indicator	Name	Description
+	Positive	The reaction value can be considered as positive.
-	Negative	The reaction value can be considered as negative.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater than the negative cutoff value or equal to or less than the positive cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

The described assays are designed to be read automatically by the instrument, and even though you cannot edit reactions or results, you can still view the images of the assay reactions by using the instrument software. Reaction features are described in the associated reagent package inserts.

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO Iris process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	Possible Well Results	Possible Test Interpretations

Assay	Possible Well Results	Possible Test Interpretations
RHFORMEL PHENO12	ImmuClone Rh-Hr Control: +(1, 2, 3, 4), -, X Other reagents: +(1, 2, 3, 4), -, ?[1], X	CE Interpretations: cc ee, CC ee, Cc ee, cc Ee, CC Ee, Cc Ee, cc EE, Cc EE, CC EE, NTD / Mixed field ?, NTD, *INV* Kell Interpretations: K+, K-, NTD / Mixed field ?, NTD, *INV*

[1] Equivocal results of antibody wells may be edited. There cannot be an equivocal result for ImmuClone Rh-Hr Control wells, wherefore negative control results are not editable.

Key for Table of Well Results and Test Interpretations by Assay

The two (2) tables below describe the possible well test results per the Result Interpretations section of this attachment.

Well Result	Description
+	Positive
-	Negative
?	Equivocal
X	Invalid

Test Interpretation	Description
INV	Invalid
NTD	No Type Determined
NTD / Mixed field ?	No Type Determined / Mixed field ?
NTD NTD	No Type Determined No Type Determined

Interface Specification Information

The RHFORMEL and PHENO12 assay information for the interface specification, detailed below, is supplemental information to **Attachment II for the NEO Iris Operator Manual (EU).** Refer to **Attachment II for the NEO Iris Operator Manual (EU)** for a full description of the interface specification.

Result Record Field 4 Measurement Values

SUB-COMPONENT 1		
Assay	**Possible Values for Reaction Pattern**	
RHFORMEL PHENO12	-, 1, 2, 3, 4, ?, X	
SUB-COMPONENT 2		
Assay	**Interpretation Values**	
	CE Interpretation	**Kell Interpretation**
RHFORMEL PHENO12	CC EE, Cc EE, cc EE, CC Ee, Cc Ee, cc Ee, CC ee, Cc ee, cc ee NTD, *INV*, NTD / Mixed field ?	K+, K-, NTD, *INV*, NTD / Mixed field ?

LIS Well Result Identification for Result Field 4 Measurement Values

Assay	**Test phase**	
RHFORMEL	1	ImmuClone Anti-C(1)
	2	ImmuClone Anti-C(2)
	3	ImmuClone Anti-c(1)
	4	ImmuClone Anti-c(2)
	5	ImmuClone Anti-E(1)
	6	ImmuClone Anti-E(2)
	7	ImmuClone Anti-e(1)
	8	ImmuClone Anti-e(2)
	9	ImmuClone Anti-Kell (1)
	10	Automated Anti-Kell
	11	ImmuClone Rh-Hr Control
PHENO12	1	ImmuClone Anti-C(1)
	2	ImmuClone Anti-c(1)
	3	ImmuClone Anti-E(1)
	4	ImmuClone Anti-e(1)
	5	ImmuClone Anti-Kell (1)
	6	ImmuClone Rh-Hr Control

Performance Characteristics

Specific Performance Characteristics

Method Comparison Studies:

A method comparison study was performed at one (1) internal site at Immucor Medizinische Diagnostik GmbH. Result concordance of the updated RHFORMEL and PHENO12 assays (i.e. RHF_PEO and PH12_PEO) on the NEO Iris (methods under test) were compared to the validated CcEe assay (reference method 1) and AG_K assay (reference method 2) on the NEO Iris.

To verify the result consistency of the method under test and the reference method the concordance of all test results was calculated by comparing the number of results in agreement with the total number of results. Minitab 20 was used for concordance calculations employing the 1-proportion exact method at the 95% lower bound confidence interval (LCI). The following tables display the result concordance.

Assay performance represents NEO Iris and Galileo NEO (software version 3.1 or higher).

Data analysis for method under test RHF_PEO:

2x2 Contingency Table		Reference method		Analysis
		Positive	Negative	
Method under test	Positive	34	0	Number of tests 258 Concordance 95% Lower Confidence interval 99.1% Positive percent agreement 100% (LCI: 93.5%*) Negative percent agreement 100% (LCI: 99.0%)
	Negative	0	224	

* The PPA (95% 1-sided LCI) was 93.5% due to the low frequency of Kell positive antigens in the Caucausian population (9%). The percent agreement (point estimate) was 100%.

Data analysis for method under test PH12_PEO:

2x2 Contingency Table	Reference method		Analysis
	Positive	Negative	Number of tests

Method under test	Positive	30	0	253 Concordance 95% Lower Confidence interval 99.1% Positive percent agreement 100% (LCI: 92,6%*) Negative percent agreement 100% (LCI: 99.0%)
	Negative	0	223	

* The PPA (95% 1-sided LCI) was 92.6% due to the low frequency of Kell positive antigens in the Caucausian population (9%). The percent agreement (point estimate) was 100%.

Attachment XIX: Capture-R Select based Identification Assays

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results and interpretations used for the Capture-R Select based Identification assays.

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How this Attachment is Organized

In This Section

This section describes the organization of this attachment, including:

- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons

Notational Conventions

This attachment uses a page numbering system that includes a prefix of the attachment number (XIX) hyphenated with the page number. Sequential lists that describe step-by-step procedures are included as numbered lists.

The footer of each page contains the current attachment version identified using a nine character hyphenated format combined with a five character attachment alpha-numeric identifier (A-XIX) in parentheses. The first three characters (NEO Iris) identify the instrument. The second set of three characters identifies this document as an attachment to the operator manual (001). The final set of three characters identifies the version of the attachment associated with the operator manual. 100 designates version 1; 200 designates a full version 2 update; and so on.

Limitations of Use and Warnings

Limitations of use and warnings are located in this attachment, specifically in the body of the text where they are most relevant to the information. An icon draws your attention to limitations of use and warnings.

Use of Icons

The following icons appear in this attachment to alert you of warnings or limitations of use.

Icon	Type of Warning	Related to…
	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Limitation	

	Note	
	Consult instructions for use	

Description for 8-Cell ID Assays

Introduction

Intended Use

The Capture-R Select based Identification Assays are intended for the identification of unexpected IgG red blood cell antibodies on the NEO Iris automated systems.

Principles of the Assays

The assays are designed to provide customers the option to select specific red cell reagents for automated 8 cell IgG antibody identification at 37 °C to meet regional specific needs. The assays are intended to provide the customer the ability to select characterized red cells based on customer defined criteria. Since reagent red cells may come in different formulations, the 8 cell antibody identification assays will be available for use of red cell suspensions with a concentration of 2-5 % or with a lower concentration of 0.8 % (+/-0.2 %).

The IgG identification assays are based on Immucor's patented Capture-R® Select technology and are designed for use on the NEO Iris® and NEO® v2.0 automated analyzers.

List of assays

The following table lists the described assays on the NEO Iris. The assays exist in a vertical configuration.

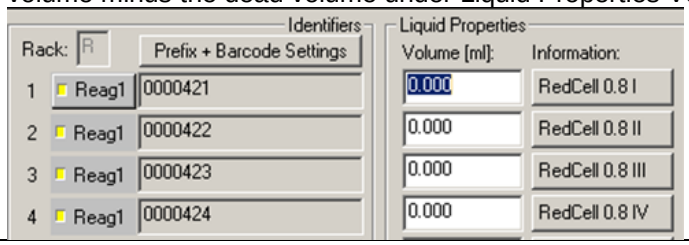
Assay Description	Assay short name	Used reagents	Microplates Used
	Capture-R Select		
Antibody identification (2-5 %)	SC_8C	1. RedCell III* 2. RedCell IV* 3. RedCell V* 4. RedCell VI* 5. RedCell VII* 6. RedCell VIII* 7. RedCell IX* 8. RedCell X*	Capture-R® Select plates

Assay Description	Assay short name	Used reagents	Microplates Used
Antibody identification (0.8 %)	SC_8C_I	1. RedCell 0.8 III* 2. RedCell 0.8 IV* 3. RedCell 0.8 V* 4. RedCell 0.8 VI* 5. RedCell 0.8 VII* 6. RedCell 0.8 VIII* 7. RedCell 0.8 IX* 8. RedCell 0.8 X*	Capture-R® Select plates

***NOTE:** The reagents described as "RedCell (0.8) III-X" refer to the red cell reagents selected and validated by the customer for use in their laboratory. Immucor will provide 7-digit barcodes for each of the listed RedCell reagents. Those barcodes shall be attached to the selected red cells to enable their use on the NEO Iris® and NEO® v2.0 instruments. They will not contain any further information on lot numbers and expiry dates. Recording the relevant reagent information will be within the responsibility of the customer. A reagent tracking sheet provided with this Operator Manual Attachment shall facilitate simple tracking of used reagent lots and corresponding expiry dates.

Limitations, Warnings and Notes

Icon	Description
	Warning: Red cell reagents suitable for the proposed test are required to be selected by the user. Select reagents based on the corresponding red cell Masterlist and further reagent information provided by the reagent's supplier and based on any applicable regulatory requirements. It is the users responsibility to select red cells with the phenotypes matching those specified in local regulations and guidelines applicable to red cell antibody identification techniques.
	Warning: Proper suspension of cellular reagents is essential for unimpeded performance of the assay. For this reason, all cellular reagents, including the customer-chosen red cell reagents (0.8) III – X need to be resuspended by gentle agitation and equipped with a stir ball prior to use. The user needs to make sure that all cellular reagents are placed in the magnetic stirrer positions on the loading bay.
	Warning: The assay SC_8C is designed for the use of *RedCell* suspensions with a concentration of 2-5% while 0.8% (+/-0.2%) *RedCell* suspensions can be tested using the SC_8C_I assay. Deviation from the recommended concentrations may lead to false positive, false negative or invalid results. If red blood cells need to be diluted refer to the Instructions for Use of the selected red cells.
	Warning: On board time and reagent expiry of the *RedCell* reagents cannot be automatically tracked by the system as barcode labels do not contain the relevant information. The operator is required to track lot number, expiry date and first on board time/date for each *RedCell* vial used on the instrument. A *RedCell* labeling sheet is provided with this Operator Manual Attachment.
	Warning: Immucor does not provide an on board stability claim for any red cell reagents other than Immucor red cell products released for automated use on the NEO Iris®/NEO® v2.0. Immucor reagents for automated detection of IgG antibodies on NEO Iris® have a 72 hours on board stability claim. Use of Immucor reagent red cells is therefore recommended.

Icon	Description
	Warning: Reagent fill volume for *RedCell* reagents is not automatically recognized or tracked in the NEO software. When the *RedCell* reagent is loaded onto the instrument, the operator is required to manually enter the correct fill volume in the field next to the reagent name. Note that a dead volume of 1 mL needs to be subtracted from the actual fill volume when entering the reagent information, i.e. when the actual vial fill volume is 10 mL, manually type 9 mL in the corresponding data field. To edit the fill volume, click on the relevant loading bay and reagent rack and enter the correct fill volume minus the dead volume under Liquid Properties Volume (see image below): 
	Warning: *RedCells* used on the Identification assays need to be vialed in 10 mL glass vials with the following specifications: 22 x 60 mm, thread 18 mm, flat bottom. Use of vials with differing specifications may lead to abortion of assay runs due to insufficient red cell volume or pipettor crashes.
	Warning: Store all reagents used on the Capture-R Select based Identification Assays according to the suppliers' specifications to prevent compromising of reagent performance.
	Warning: Do not pool red cell reagents from different vials or transfer red cell reagents from their original vial to prevent bacterial or chemical contamination.
	Warning: In a case where both positive control wells obtain reaction scores below the positive cutoff the result for the Capture-R® Positive Control is "negative" or in a case where both negative control wells obtain 3+ reactions the result for the Capture-R® Negative Control is "positive" due to the definition in the DMS results text. Although the failed control does not display the Ctrl_Fail notice, the run will be invalidated by the system and no results interpretation will be provided.
	Limitation: It is recommended to use commercially available red cells which have been manufactured specifically for antibody detection and/or identification. Follow the Instructions for Use of the selected red cells.
	Limitation: It is recommended to place the control strip (first strip) in the first column of the Capture-R® Select microplate frame. If the control strip is placed into a different column three negative control results will be displayed on the result reports.
	Limitation: The 8 cell antibody identification assays are not intended for use with plasma samples originating from RhIg donors. As samples from this origin are often seen to contain additional antibodies of unknown specifity, false positive results are likely to occur.
	Limitation: Capture-R Select based Screening Assays do only detect IgG antibodies at a temperature of 37°C.
	Note: It is recommended to qualify the use of the chosen *RedCells* by running a sample with a known IgG antibody once per day if the red cell reagents have not been qualified by other QC methods.

Icon	Description
	Note: The RedCell Labeling Sheet that is provided in this Operator Manual Attachment shall help the operator to track relevant *RedCell* reagent data and ensure correct labeling and usage of the red cell products

All further limitations, warnings and notes that relate to the described assays are defined in the Operator Manual Chapter 12: Limitations of Use and Warnings and in Attachment I of the NEO Iris® instrument.

Cutoffs and Reagent Components

List of Cutoffs

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
SC_8C SC_8C_I	Positive/ Negative Control	0	0.0	17.5
		? (not reported)	N/A	N/A
		1+	17.5	50.0
		2+	50.0	72.0
		3+	72.0	90.0
		4+	90.0	99.9
	RedCell (0.8) III/ RedCell III RedCell (0.8) IV/ RedCell IV RedCell (0.8) V/ RedCell V RedCell (0.8) VI/ RedCell VI RedCell (0.8) VII/ RedCell VII RedCell (0.8) VIII/	0	0.0	20.0
		?	20.0	30.0
		1+	30.0	45.0

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	RedCell VIII RedCell (0.8) IX/ RedCell IX RedCell (0.8) X RedCell X	2+	45.0	65.0
		3+	65.0	90.0
		4+	90.0	99.9

Assay Reagent Component Grid

Reagents and Microplates	SC_8C	SC_8C_I
Capture-R® Select plate	x	x
corQC® EXTEND Standard	x	x
Capture-R® Indicator Red Cells	x	x
Capture-R® Positive Control Serum (Weak)	x	x
Capture-R® Negative Control Serum	x	x
Capture® LISS	x	x
RedCell III*	x	
RedCell IV*	x	
RedCell V*	x	
RedCell VI*	x	
RedCell VII*	x	
RedCell VIII*	x	
RedCell IX*	x	

Reagents and Microplates	**SC_8C**	**SC_8C_I**
RedCell X*	x	
RedCell 0.8 III*		x
RedCell 0.8 IV*		x
RedCell 0.8 V*		x
RedCell 0.8 VI*		x
RedCell 0.8 VII*		x
RedCell 0.8 VIII*		x
RedCell 0.8 IX*		x
RedCell 0.8 X*		x

***NOTE:** The reagents described as “RedCell (0.8) III-X” refer to the red cell reagents selected and validated by the customer for use in their laboratory.

Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements.

Information on *RedCell* reagent labeling

Immucor provides barcode labels to enable the use of customer validated red cell reagents with concentrations of 2-5 % or 0.8 % for antibody identification purposes using the Capture-R Select based 8 Cell Identification assays. The following table lists the assignment of barcodes to the corresponding *RedCell* reagent.

***RedCell* reagent name**	**Barcode**
RedCell III*	0000413
RedCell IV*	0000414
RedCell V*	0000415
RedCell VI*	0000416
RedCell VII*	0000417
RedCell VIII*	0000418
RedCell IX*	0000419
RedCell X*	0000410
RedCell 0.8 III*	0000423
RedCell 0.8 IV*	0000424
RedCell 0.8 V*	0000425
RedCell 0.8 VI*	0000426
RedCell 0.8 VII*	0000427
RedCell 0.8 VIII*	0000428
RedCell 0.8 IX*	0000429
RedCell 0.8 X*	0000420

To ensure that barcodes are correctly identified by the instrument, they shall only be used on reagent vial that align with the vials specifications described in the “Limitations, Warnings and Notes” section.
The listed barcodes do not automatically provide information on the lot, expiry dates and on board time of the RedCell reagent. For this purpose, a RedCell Labeling Sheet is attached to this Operator Manual Attachment. By filling in this sheet, tracking of lot numbers, expiry dates and further reagent information shall be ensured.

Assay Procedural Steps

This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
SC_8C SC_8C_I	1. Bring all reagents and blood samples to 18–30 °C before testing. 2. Select suitable red cell reagents to be used for antibody identification on the Capture-R Select based Identification assays based on their antigen profile, red cell concentration and suitability to run on the automated NEO Iris®/ NEO® v2.0 platform. 3. Attach barcode labels provided by Immucor to the chosen red cell reagent vials and track lot number, expiry date and further reagent information using the RedCell Labeling Sheet. 4. Centrifuge the blood samples to separate the plasma from the red blood cells. Remove the caps from the blood sample tubes. 5. Remove the Capture-R® Select microplate frame and the desired number of Capture-R® Select strips from the pouch. 6. Remove reagent vial caps. 7. Add one stirball to each new vial of Capture-R® Ready Indicator Red Cells, corQC® EXTEND Standard cells and *RedCell* reagents to be used. Gently agitate each vial to resuspend the red blood cells. 8. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 9. Manually enter the fill volumes of the *RedCell* reagents by clicking on the lane bay on which the reagents are loaded and manually entering the fill volume minus the vial deadvolume (1 ml) under “Liquid Properties”. 10. Assign the SC_8C and/ or SC_8C_I assay to the blood samples, either manually or following the upload worklist procedure. 11. Start the SC_8C and/ or SC_8C_I assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the SC_8C and/ or SC_8C_I assay, and records and interprets the blood sample results. 12. At the completion of the NEO Iris SC_8C and/ or SC_8C_I assay, click the Results button on the main menu bar to access the blood sample results.

Results and Interpretations

Introduction

The NEO Iris® generates a result for each well read by the instrument and an interpretation of the results. Each NEO Iris® assay has predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported as Negative, Positive, Equivocal or Invalid. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for assays include:

Indicator	Name	Description
+	Positive	The reaction value is greater than the cutoff value.
-	Negative	The reaction value is less than or equal to the cutoff value.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater than the negative cutoff value or equal or less than the positive cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

The described assays are designed to be read automatically by the instrument, and even though you cannot edit reactions or results, you can still view the images of the assay reactions by using the instrument software. Reaction features are described in the associated reagent package inserts.

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	Possible Well Results	Possible Test Interpretations

SC_8C SC_8C_I	+, -, ?, X	Run control interpretations: Positive, Negative, *INV*, Ctrl_Fail Result interpretations: Positive, Negative, No_Int, *INV*

RedCell Labeling Sheet

Original red cell reagent information			**Information for use on NEO Iris**			
Red cell reagent product name	Lot number	Cell concentration	Immucor barcode number (enter manually)	Instrument SN	Comments	Operator
	Expiry date	Vial fill volume	Fill volume entered in NEO software? (fill volume - 1ml)	First on board date and time		
			☐ (✓)			
Red cell reagent product name	Lot number	Cell concentration	Immucor barcode number (enter manually)	Instrument SN	Comments	Operator
	Expiry date	Vial fill volume	Fill volume entered in NEO software? (fill volume - 1ml)	First on board date and time		
			☐ (✓)			
Red cell reagent product name	Lot number	Cell concentration	Immucor barcode number (enter manually)	Instrument SN	Comments	Operator
	Expiry date	Vial fill volume	Fill volume entered in NEO software? (fill volume - 1ml)	First on board date and time		
			☐ (✓)			
Red cell reagent product name	Lot number	Cell concentration	Immucor barcode number (enter manually)	Instrument SN	Comments	Operator
	Expiry date	Vial fill volume	Fill volume entered in NEO software? (fill volume - 1ml)	First on board date and time		
			☐ (✓)			

Attachment XX: NEO Iris Operator Manual

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results, interpretations and interface data used for the AG_M_m assay for the detection of M antigen.

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How this Attachment is Organized

In This Section

This section describes the organization of this attachment, including:

- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons

Notational Conventions

This attachment uses a page numbering system that includes a prefix of the attachment number (XVI) hyphenated with the page number. Sequential lists that describe step-by-step procedures are included as numbered lists.

The footer of each page contains the current attachment version identified using a nine character hyphenated format combined with a five character attachment alpha-numeric identifier (A-XVI) in parentheses. The first set of characters (NEO Iris_EU) identify the instrument. The second set of three characters identifies this document as an attachment to the operator manual (001). The final set of three characters identifies the version of the attachment associated with the operator manual. 100 designates version 1; 200 designates a full version 2 update; and so on.

Limitations of Use and Warnings

Limitations of use and warnings are located in this attachment, specifically in the body of the text where they are most relevant to the information. An icon draws your attention to limitations of use and warnings.

Use of Icons

The following icons appear in this attachment to alert you of warnings or limitations of use.

Icon	Type of Warning	Related to…
	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Consult instructions for use	

Description for monoclonal M antigen Assay

Introduction

Intended Use

Anti-M IgG (Monoclonal) blood group reagent used to detect the M (MNS1) erythorocyte antigen of donors and recipients by direct hemagglutination test on the NEO Iris® automated analyzer using the AG_M_m assay.

List of assays

The following table lists the monoclonal assays for the detection of Anti-M (AG_M_m) on the NEO Iris. The AG_M_m assay exist in a horizontal and in a vertical configuration.

Version 1.00:

Assay Description	Assay short name	Used reagents	Microplates Used
	Blood grouping	**Horizontal/12 wells per strip**	
Monoclonal M	AG_M_m	1. Anti-M (Monoclonal) 2. Monoclonal Control	Untreated microplates
	Blood grouping	**Vertical/8 wells per strip**	
Monoclonal M	AG_M_m	1. Anti-M (Monoclonal) 2. Monoclonal Control	Untreated microplates

Limitations, Warnings and Notes

Icon	Description
	Note: The purpose of the Monoclonal Control for AG_M_m assay is to serve as a sample control for Immucor low protein blood grouping reagents. It is expected to indicate those sample related conditions that could lead to spontaneous agglutination with low protein reagents and, therefore, a false positive interpretation for the test. When the Monoclonal Control well yields a positive result, then the instrument would not report the blood type.
	Limitation: Vials of reagents, that have remained continuously on the NEO Iris for 72 hours (3 days) should be removed and replaced with fresh vials. Vials of reagents that are removed from the NEO Iris when not in use and refrigerated can be used up to their expiration dates.
	Limitation: The NEO Iris does not generate an interpretation of mixed-field. Such a mixed-field reaction will be interpreted as positive, negative, or equivocal.
	Limitation for AG_M_m: Samples that exhibit excessive hemolysis or lipemia, or are icteric, should not be tested on the instrument. Hemolytic samples are tested until a concentration of 1065.3 mg/dl without showing erroneous results. Lipemic samples (Tryglyceride) are tested until a concentration of 1674.0 mg/dl without showing erroneous results. Icteric samples (conjugated bilirubin) are tested until a concentration of 47.6 mg/dl without showing erroneous results. Icteric samples (unconjugated bilirubin) are tested until a concentration of 50.0 mg/dl without showing erroneous results

Monoclonal M Assay Cutoffs and Reagent Components

List of Cutoffs

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
AG_M_m	Anti-M IgG (Monoclonal)	0	0	25
		? (Query)	25	28
		1+	28	35
		2+	35	50
		3+	50	80
		4+	80	99
	Monoclonal control	0	0	25
		?(Query)	25	25
		1+	25	35
		2+	35	50
		3+	50	80
		4+	80	99

Assay Reagent Component Grid

Reagents and Microplates For AG_M_m	• Untreated Microplates (barcoded) • Specimen Diluent • Monoclonal Control • Anti-M IgG (monoclonal)

Monoclonal M Assay Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert. Package inserts are also the source of information for limitations of the reagents in use.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
AG_M_m	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples, onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 5. Assign the assay (AG_M_m) to the blood samples either manually or following the upload worklist procedure. 6. Start the AG_M_m assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the AG_M_m assay, and records and interprets blood sample results. 7. At the completion of the NEO Iris assays, click the Results button on the main menu bar to access the blood samples results.

Monoclonal M Assay Results and Interpretations

Introduction

The NEO Iris® generates a result for each well read by the instrument and an interpretation of the results. The Monoclonal M Assay have predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported Positive, Negative, Invalid or Equivocal. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for Monoclonal M antigen Assay include:

Indicator	Name	Description
+	Positive	The reaction value can be considered as positive.
-	Negative	The reaction value can be considered as negative.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater than the negative cutoff value or equal to or less than the positive cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO Iris process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	Possible Well Results	Possible Test Interpretations
AG_M_m	Monoclonal Control: +(1, 2, 3, 4), -, X M: +(1, 2, 3, 4), -, ?[1], X	Monoclonal Control interpretations: positive, negative, Ctrl failure M interpretations: M+, M-, NTD, *INV*

[1] Equivocal results of antibody wells may be edited. There cannot be an equivocal result for Monoclonal Control wells, wherefore negative control results are not editable.

Key for Table of Well Results and Test Interpretations by Assay

The two (2) tables below describe the possible well test results per the Result Interpretations section of this attachment.

Well Result	Description
+	Positive
-	Negative
?	Equivocal
X	Invalid

Test Interpretation	Description
INV	Invalid
NTD	No Type Determined
Ctrl failure	Control failure
Mono ctrl failure	Negative control failure

Interface Specification Information

The Monoclonal M assay information for the interface specification, detailed below, is supplemental information to **Attachment II for the NEO Iris Operator Manual (EU).** Refer to **Attachment II for the NEO Iris Operator Manual (EU)** for a full description of the interface specification.

Result Record Field 4 Measurement Values

SUB-COMPONENT 1	
Assay	**Possible Values for Reaction Pattern**
All Assays	-, 1, 2, 3, 4, ?, X
SUB-COMPONENT 2	
Assay	**Interpretation Values**
AG_M_m	M+, M-, NTD, Ctrl failure, *INV*

LIS Well Result Identification for Result Field 4 Measurement Values

Assay	**Test phase**	
AG_M_m	1	Anti-M (Monoclonal)
	2	Monoclonal Control

Performance Characteristics

Specific Performance Characteristics

Sensitivity/Specificity Studies:

Result concordance of Anti-M IgG used on the AG_M_m assay on the NEO Iris was compared to results of manual tube test:

The following tables display the result concordance:

Anti-M (Monoclonal) Gamma-clone:

Initial Results N=1023		Comparator Reagent			
		Positive	Negative		
Anti-M	Positive	805	1*	Positive Percent Agreement	99.9%
				PPA (95% 1-Sided LCI)	99.7%
	Negative	0	217	Negative Percent Agreement	99.5%
				NPA (95% 1-Sided LCI)	97.8%

* One (1) sample showed discrepancy between M_PEO and the reference method. The sample remained discrepant after performing genotyping. The root cause of the discrepancy was found to be related to the specimen that was derived from a patient obtaining at least one transfusion before blood drawing which is the propable cause of the inconclusive phenotyping results.

Sensitivity and Specificity were calculated with the initial testing data and displayed in the following table:

Sensitivity	Specificity
100% (805/805)	99.5% (216/217)

Repeatability and Reproducibility Studies:

Anti-M (Monoclonal) reagent:

Repeatability and Reproducibility were performed with five (5) samples in triplicates, on three (3) intstruments, on five (5) non-consecutive days, two (2) runs per day, over a time period of ten (10) days.. Results demonstrated 100% agreement for all positive and negative test samples

Attachment XXI NEO Iris Operator Manual

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results, interpretations and interface data used for the AG_N_m assay for the detection of N antigen.

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How this Attachment is Organized

In This Section

This section describes the organization of this attachment, including:

- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons

Notational Conventions

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The footer of each page contains the current attachment version identified using a nine character hyphenated format combined with a five character attachment alpha-numeric identifier (A-XVI) in parentheses. The first set of characters (NEO Iris_EU) identify the instrument. The second set of three characters identifies this document as an attachment to the operator manual (001). The final set of three characters identifies the version of the attachment associated with the operator manual. 100 designates version 1; 200 designates a full version 2 update; and so on.

Limitations of Use and Warnings

Limitations of use and warnings are located in this attachment, specifically in the body of the text where they are most relevant to the information. An icon draws your attention to limitations of use and warnings.

Use of Icons

The following icons appear in this attachment to alert you of warnings or limitations of use.

Icon	Type of Warning	Related to…
	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Consult instructions for use	

Description for monoclonal N antigen Assay

Introduction

Intended Use

Anti-N IgM (Monoclonal) blood group reagent used to detect the N (MNS1) erythorocyte antigen of donors and recipients by direct hemagglutination test on the NEO Iris® automated analyzer using the AG_N_m assay.

List of assays

The following table lists the monoclonal assays for the detection of Anti-N (AG_N_m) on the NEO Iris. The AG_N_m assay exist in a horizontal and in a vertical configuration.

Version 1.00:

Assay Description	Assay short name	Used reagents	Microplates Used
	Blood grouping	**Horizontal/12 wells per strip**	
Monoclonal N	AG_N_m	1. Anti-N (Monoclonal) 2. Monoclonal Control	Untreated microplates
	Blood grouping	**Vertical/8 wells per strip**	
Monoclonal N	AG_N_m	1. Anti-N (Monoclonal) 2. Monoclonal Control	Untreated microplates

Limitations, Warnings and Notes

Icon	Description
	Note: The purpose of the Monoclonal Control for AG_N_m assay is to serve as a sample control for Immucor low protein blood grouping reagents. It is expected to indicate those sample related conditions that could lead to spontaneous agglutination with low protein reagents and, therefore, a false positive interpretation for the test. When the Monoclonal Control well yields a positive result, then the instrument would not report the blood type.
	Limitation: Vials of reagents, that have remained continuously on the NEO Iris for 72 hours (3 days) should be removed and replaced with fresh vials. Vials of reagents that are removed from the NEO Iris when not in use and refrigerated can be used up to their expiration dates.
	Limitation: The NEO Iris cannot reliably detect hemagglutination reactions that are graded as 1+ or less in test tube methodology. The NEO Iris does not generate an interpretation of mixed-field. Such a mixed-field reaction will be interpreted as positive, negative, or equivocal.
	Limitation: The grading of reactions on the NEO Iris must only be regarded as an approximation when compared to off-line visual grading by laboratory technical staff.

Icon	Description
	Limitation for AG_N_m: Samples that exhibit excessive hemolysis or lipemia, or icteric, should not be tested on the instrument. Hemolytic samples are tested until a concentration of 1065.3 mg/dl without showing erroneous results. Lipemic samples are tested until a concentration of 1674.0 mg/dl without showing erroneous results. Icteric samples (conjugated bilirubin) are tested until a concentration of 47.6 mg/dl without showing erroneous results. Icteric samples (unconjugated bilirubin are tested until a concentration of 50.0 mg/dl without showing erroneous results

Monoclonal N Assay Cutoffs and Reagent Components

List of Cutoffs

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
AG_N_m	Anti-N IgG (Monoclonal)	0	0	25
		? (Query)	25	28
		1+	28	35
		2+	35	50
		3+	50	80
		4+	80	99
	Monoclonal control	0	0	25
		?(Query)	25	25
		1+	25	35
		2+	35	50
		3+	50	80
		4+	80	99

Assay Reagent Component Grid

Reagents and Microplates For AG_N_m	• Untreated Microplates (barcoded) • Specimen Diluent • Monoclonal Control • Anti-N IgM (monoclonal)

Monoclonal N Assay Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert. Package inserts are also the source of information for limitations of the reagents in use.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
AG_N_m	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples, onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 5. Assign the assay (AG_N_m) to the blood samples either manually or following the upload worklist procedure. 6. Start the AG_N_m assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the AG_N_m assay, and records and interprets blood sample results. 7. At the completion of the NEO Iris assays, click the Results button on the main menu bar to access the blood samples results.

Monoclonal N Assay Results and Interpretations

Introduction

The NEO Iris® generates a result for each well read by the instrument and an interpretation of the results. The Monoclonal N Assay have predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported Positive, Negative, Invalid or Equivocal. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for Monoclonal N antigen Assay include:

Indicator	Name	Description
+	Positive	The reaction value can be considered as positive.
-	Negative	The reaction value can be considered as negative.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater than the negative cutoff value or equal to or less than the positive cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO Iris process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	Possible Well Results	Possible Test Interpretations
AG_N_m	Monoclonal Control: +(1, 2, 3, 4), -, X N: +(1, 2, 3, 4), -, ?[1], X	Monoclonal Control interpretations: positive, negative, Ctrl failure N interpretations: N+, N-, NTD, *INV*

[1] Equivocal results of antibody wells may be edited. There cannot be an equivocal result for Monoclonal Control wells, wherefore negative control results are not editable.

Key for Table of Well Results and Test Interpretations by Assay

The two (2) tables below describe the possible well test results per the Result Interpretations section of this attachment.

Well Result	Description
+	Positive
-	Negative
?	Equivocal
X	Invalid

Test Interpretation	Description
INV	Invalid
NTD	No Type Determined
Ctrl failure	Control failure
Mono ctrl failure	Negative control failure

Interface Specification Information

The Monoclonal N assay information for the interface specification, detailed below, is supplemental information to **Attachment II for the NEO Iris Operator Manual (EU).** Refer to **Attachment II for the NEO Iris Operator Manual (EU)** for a full description of the interface specification.

Result Record Field 4 Measurement Values

SUB-COMPONENT 1	
Assay	**Possible Values for Reaction Pattern**
All Assays	-, 1, 2, 3, 4, ?, X
SUB-COMPONENT 2	
Assay	**Interpretation Values**
AG_N_m	N+, N-, NTD, Ctrl failure, *INV*

LIS Well Result Identification for Result Field 4 Measurement Values

Assay	**Test phase**	
AG_N_m	1	Monoclonal Control
	2	Anti-N (Monoclonal)

Performance Characteristics

Specific Performance Characteristics

Sensitivity/Specificity Studies:

Result concordance of Anti-N IgM used on the AG_N_m assay on the NEO Iris was compared to results of manual tube test:

The following tables display the result concordance:

Anti-N (Monoclonal) Gamma-clone:

Initial Results N=1023		Comparator Reagent			
		Positive	Negative		
Anti-N	Positive	705	2*	Positive Percent Agreement	100%
				PPA (95% 1-Sided LCI)	99.6%
	Negative	0	316	Negative Percent Agreement	99.4%
				NPA (95% 1-Sided LCI)	98.0%

* Two (2) samples were discrepant at initial test. Both were N negative in the tube but positive on the automated method at initial testing. Two (2) re-tests were conducted and have that the initial tube (reference method) test showed a discrepant result. After re-test, the tube test results were N positive in the tube test. Therefore, the discrepancies were resolved.

Sensitivity and Specificity were calculated with the initial testing data and displayed in the following table:

Sensitivity	Specificity
100% (705/705)	99.4% (314/316)

Repeatability and Reproducibility Studies:

Anti-N (Monoclonal) reagent:

Repeatability and Reproducibility were performed with five (5) samples in triplicates, on three (3) intstruments, on five (5) non-consecutive days, two (2) runs per day, over a time period of ten (10) days.. Results demonstrated 100% agreement for all positive and negative test samples

Attachment XXII: NEO Iris Operator Manual

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results, interpretations and interface data used for the AG_K (H), PHENO12_2, PHENO16 and PHENO16_2 assays for the detection of phenotyping status on RhCE and/or Kell.

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How this Attachment is Organized

In This Section

This section describes the organization of this attachment, including:

- Notational Conventions
- Limitations of Use and Warnings
- Use of Icons

Notational Conventions

This attachment uses a page numbering system that includes a prefix of the attachment number (XXII) hyphenated with the page number. Sequential lists that describe step-by-step procedures are included as numbered lists.

The footer of each page contains the current attachment version identified using a nine character hyphenated format combined with a five character attachment alpha-numeric identifier (A- XXII) in parentheses. The first set of characters (NEO Iris_EU) identify the instrument. The second set of three characters identifies this document as an attachment to the operator manual (001). The final set of three characters identifies the version of the attachment associated with the operator manual. 100 designates version 1; 200 designates a full version 2 update; and so on.

Limitations of Use and Warnings

Limitations of use and warnings are located in this attachment, specifically in the body of the text where they are most relevant to the information. An icon draws your attention to limitations of use and warnings.

Use of Icons

The following icons appear in this attachment to alert you of warnings or limitations of use.

Icon	Type of Warning	Related to…
	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Consult instructions for use	

Description for AG_K (H), PHENO12_2, PHENO16 and PHENO16_2 assays

Introduction

Intended Use

The described assays are designed to provide phenotyping status on RhCE and/or Kell. Assays are based on direct agglutination technology for the NEO Iris™ automated analyzer.

List of assays

The following table lists the described assays on the NEO Iris. The assays exist in a horizontal or vertical configuration.

Assay Description	Assay short name	Used reagents	Microplates Used
	Blood grouping	**Horizontal/12 wells per strip**	
Rh Blood Group	AG_K	1. immuClone Anti-Kell (1) 2. immuClone Rh-Hr Control	Untreated microplates
	Blood grouping	**Vertical/8 wells per strip**	
Rh Blood Group	PHENO12_2	1. immuClone Anti-C(2) 2. immuClone Anti-c(2) 3. immuClone Anti-E(2) 4. immuClone Anti-e(2) 5. immuClone Anti-Kell (1) 6. immuClone Rh-Hr Control	Untreated microplates

	Blood grouping	**Horizontal/12 wells per strip**	
Rh Blood Group	PHENO16	1. immuClone Anti-C(1) 2. immuClone Anti-c(1) 3. immuClone Anti-E(1) 4. immuClone Anti-e(1) 5. immuClone Anti-Kell (1) 6. immuClone Rh-Hr Control	Untreated microplates
	Blood grouping	**Horizontal/12 wells per strip**	
Rh Blood Group	PHENO16_2	1. immuClone Anti-C(2) 2. immuClone Anti-c(2) 3. immuClone Anti-E(2) 4. immuClone Anti-e(2) 5. immuClone Anti-Kell (1) 6. immuClone Rh-Hr Control	Untreated microplates

Limitations, Warnings and Notes

All limitations, warnings and notes that relate to the described assays are defined in the Operator Manual Chapter 12: Limitations of Use and Warnings and in Attachment I of the NEO Iris instrument. No additional limitations that relate to the described assays were identified.

Cutoffs and Reagent Components

List of Cutoffs

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
AG_K	immuClone Anti-Kell (1)	0	0	23
		?	23	35
		1+(not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	immuClone Rh-Hr Control	0	0	23
		? (not reported)	N/A	N/A
		1+	23	35
		2+	35	50
		3+	50	80
		4+	80	99
PHENO12_2	ImmuClone Anti-C(2)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		4+	80	99
	ImmuClone Anti-c(2)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-E(2)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-e(2)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	immuClone	0	0	23

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Anti-Kell (1)	?	23	35
		1+(not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	immuClone Rh-Hr Control	0	0	23
		? (not reported)	23	23
		1+	23	35
		2+	35	50
		3+	50	80
		4+	80	99
PHENO16	ImmuClone Anti-C(1)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-c(1)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-E(2)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-e(2)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	immuClone Anti-Kell (1)	0	0	23
		?	23	35
		1+(not reported)	N/A	N/A
		2+	35	50
		3+	50	80

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		4+	80	99
	immuClone Rh-Hr Control	0	0	23
		? (not reported)	N/A	N/A
		1+	23	35
		2+	35	50
		3+	50	80
		4+	80	99
PHENO16_2	ImmuClone Anti-C(2)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-c(2)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-E(2)	0	0	23
		?	23	75

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-e(2)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	immuClone Anti-Kell (1)	0	0	23
		?	23	35
		1+(not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	immuClone Rh-Hr Control	0	0	23
		? (not reported)	N/A	N/A
		1+	23	35
		2+	35	50

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+	50	80
		4+	80	99

Assay Reagent Component Grid

Reagents and Microplates	AG_K	PHENO12_2	PHENO16	PHENO16_2
Untreated Microplates (barcoded)	X	X	X	X
ImmuClone Anti-C(1)			X	
ImmuClone Anti-C(2)		X		X
ImmuClone Anti-c(1)			X	
ImmuClone Anti-c(2)		X		X
ImmuClone Anti-E(1)			X	
ImmuClone Anti-E(2)		X		X
ImmuClone Anti-e(1)			X	
ImmuClone Anti-e(2)		X		X
ImmuClone Anti-Kell (1)	X	X	X	X
ImmuClone Rh-Hr Control	X	X	X	X

Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert. Package inserts are also the source of information for limitations of the reagents in use.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
AG_K PHENO12_2 PHENO16 PHENO16_2	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples, onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 5. Assign the appropriate assay to the blood samples either manually or following the upload worklist procedure. 6. Start the appropriate assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the assays, and records and interprets blood sample results. 7. At the completion of the NEO Iris assay, click the Results button on the main menu bar to access the blood samples results.

Results and Interpretations

Introduction

The NEO Iris®generates a result for each well read by the instrument and an interpretation of the results. Each NEO Iris assay has predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported Positive, Negative, Invalid or Equivocal. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for assays include:

Indicator	Name	Description
+	Positive	The reaction value can be considered as positive.
-	Negative	The reaction value can be considered as negative.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater than the negative cutoff value or equal to or less than the positive cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

The described assays are designed to be read automatically by the instrument, and even though you cannot edit reactions or results, you can still view the images of the assay reactions by using the instrument software. Reaction features are described in the associated reagent package inserts.

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO Iris process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	Possible Well Results	Possible Test Interpretations
AG_K	ImmuClone Rh-Hr Control: +(1, 2, 3, 4), -, X ImmuClone Anti-Kell (1): +(1, 2, 3, 4), -, ?[1], X	Kell Interpretations: K+, K-, NTD / Mixed field ?, NTD, *INV*
PHENO12_2 PHENO16 PHENO16_2	ImmuClone Rh-Hr Control: +(1, 2, 3, 4), -, X Other reagents: +(1, 2, 3, 4), -, ?[1], X	CE Interpretations: cc ee, CC ee, Cc ee, cc Ee, CC Ee, Cc Ee, cc EE, Cc EE, CC EE, NTD / Mixed field ?, NTD, *INV* Kell Interpretations: K+, K-, NTD / Mixed field ?, NTD, *INV*

[1] Equivocal results of antibody wells may be edited. There cannot be an equivocal result for ImmuClone Rh-Hr Control wells, wherefore negative control results are not editable.

Key for Table of Well Results and Test Interpretations by Assay

The two (2) tables below describe the possible well test results per the Result Interpretations section of this attachment.

Well Result	Description
+	Positive
-	Negative
?	Equivocal
X	Invalid

Test Interpretation	**Description**
INV	Invalid
NTD	No Type Determined
NTD / Mixed field ?	No Type Determined / Mixed field ?
NTD NTD	No Type Determined No Type Determined

Interface Specification Information

The AG_K (H), PHENO12_2, PHENO16 and PHENO16_2 assays information for the interface specification, detailed below, is supplemental information to **Attachment II for the NEO Iris Operator Manual (EU).** Refer to **Attachment II for the NEO Iris Operator Manual (EU)** for a full description of the interface specification.

Result Record Field 4 Measurement Values

SUB-COMPONENT 1		
Assay	**Possible Values for Reaction Pattern**	
AG_K PHENO12_2 PHENO16 PHENO16_2	-, 1, 2, 3, 4, ?, X	
SUB-COMPONENT 2		
Assay	**Interpretation Values**	
AG_K	**Kell Interpretation**	
	K+, K-, NTD, *INV*, NTD / Mixed field ?	
PHENO12_2 PHENO16 PHENO16_2	**CE Interpretation**	**Kell Interpretation**
	CC EE, Cc EE, cc EE, CC Ee, Cc Ee, cc Ee, CC ee, Cc ee, cc ee NTD, *INV*, NTD / Mixed field ?	K+, K-, NTD, *INV*, NTD / Mixed field ?

LIS Well Result Identification for Result Field 4 Measurement Values

Assay	**Test phase**	
AG_K	1	ImmuClone Anti-Kell (1)
	2	ImmuClone Rh-Hr Control
PHENO12_2	1	ImmuClone Anti-C(2)
	2	ImmuClone Anti-c(2)
	3	ImmuClone Anti-E(2)
	4	ImmuClone Anti-e(2)
	5	ImmuClone Anti-Kell (1)

	6	ImmuClone Rh-Hr Control
PHENO16	1	ImmuClone Anti-C(1)
	2	ImmuClone Anti-c(1)
	3	ImmuClone Anti-E(1)
	4	ImmuClone Anti-e(1)
	5	ImmuClone Anti-Kell (1)
	6	ImmuClone Rh-Hr Control
PHENO16_2	1	ImmuClone Anti-C(2)
	2	ImmuClone Anti-c(2)
	3	ImmuClone Anti-E(2)
	4	ImmuClone Anti-e(2)
	5	ImmuClone Anti-Kell (1)
	6	ImmuClone Rh-Hr Control

Performance Characteristics

Specific Performance Characteristics

Method Comparison Studies:

A method comparison study was performed at one (1) internal site at Immucor Medizinische Diagnostik GmbH. Result concordance of the updated AG_K (H), PHENO12_2, PHENO16 and PHENO16_2 assays (i.e. AGK_PEO, PH122_PEO, PH16_PEO and PH162_PEO) on the NEO Iris (methods under test) were compared to the validated PHENO12 assay (reference method) on the NEO Iris.
To verify the result consistency of the method under test and the reference method the concordance of all test results was calculated by comparing the number of results in agreement with the total number of results. Minitab 20 was used for concordance calculations employing the 1-proportion exact method at the 95% lower bound confidence interval (LCI).

Assay performance represents NEO Iris (software version 3.1 or higher).

Result concordance of AG_K, PHENO12_2, PHENO16 and PHENO16_2 on the NEO Iris/v2.0 were compared to results obtained on PHENO12 on the NEO Iris/v2.0. The following tables display the result concordance.

Data analysis for method under test AGK_PEO:

<table>
<tr><th colspan="2" rowspan="2">2x2 Contingency Table</th><th colspan="2">Reference method</th><th>Analysis</th></tr>
<tr><th>Positive</th><th>Negative</th><td rowspan="3">Number of tests
300

Concordance 95% Lower Confidence interval
99.2%

Positive percent agreement
100% (LCI: 97.0%*)

Negative percent agreement
100% (LCI: 99.0%)</td></tr>
<tr><td rowspan="2">Method under test</td><td>Positive</td><td>76</td><td>0</td></tr>
<tr><td>Negative</td><td>0</td><td>224</td></tr>
</table>

* The PPA (95% 1-sided LCI) was 97.0% due to the low frequency of Kell positive antigens in the Caucausian population (9%). The percent agreement (point estimate) was 100%.

Result Concordance (True positive)	**Result Concordance (True negative)**
100% (76/76)	100% (224/224)

Data analysis for method under test PH122_PEO:

2x2 Contingency Table		**Reference method**		**Analysis**
		Positive	**Negative**	Number of tests 300 Concordance 95% Lower Confidence interval 99.2% Positive percent agreement 100% (LCI: 97.0%*) Negative percent agreement 100% (LCI: 99.0%)
Method under test	**Positive**	76	0	
	Negative	0	224	

* The PPA (95% 1-sided LCI) was 97.0% due to the low frequency of Kell positive antigens in the Caucausian population (9%). The percent agreement (point estimate) was 100%.

Result Concordance (True positive)	**Result Concordance (True negative)**
100% (76/76)	100% (224/224)

Data analysis for method under test PH16_PEO:

2x2 Contingency Table		Reference method		Analysis
		Positive	**Negative**	Number of tests 300 Concordance 95% Lower Confidence interval 99.2% Positive percent agreement 100% (LCI: 97.0%*) Negative percent agreement 100% (LCI: 99.0%)
Method under test	**Positive**	76	0	
	Negative	0	224	

* The PPA (95% 1-sided LCI) was 97.0% due to the low frequency of Kell positive antigens in the Caucausian population (9%). The percent agreement (point estimate) was 100%.

Result Concordance (True positive)	**Result Concordance (True negative)**
100% (76/76)	100% (224/224)

Data analysis for method under test PH162_PEO:

2x2 Contingency Table		Reference method		Analysis
		Positive	**Negative**	Number of tests 300 Concordance 95% Lower Confidence interval 99.2% Positive percent agreement 100% (LCI: 97.0%*) Negative percent agreement 100% (LCI: 99.0%)
Method under test	**Positive**	76	0	
	Negative	0	224	

* The PPA (95% 1-sided LCI) was 97.0% due to the low frequency of Kell positive antigens in the Caucausian population (9%). The percent agreement (point estimate) was 100%.

Result Concordance (True positive)	**Result Concordance (True negative)**
100% (76/76)	100% (224/224)

Attachment XXIV: NEO Iris Operator Manual

In This Attachment

This attachment describes the reagents, cutoff values, basic assay procedural steps, possible well results, interpretations and interface data used for the updated assays using the immuClone (2) Anti-K (Kell) Automated IgM reagent.

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Use of Icons

The following icons appear in this attachment to alert you of warnings or limitations of use.

Icon	Type of Warning	Related to...

	Warning	Potentially damaging or dangerous outcomes if certain critical procedural steps are ignored or incorrectly executed.
	Limitation	
	Consult instructions for use	

Assay Description

Introduction

Intended Use

The described assays are designed to provide basic blood type, Rh status and/or Kell which can include both forward testing (of red blood cell) and reverse testing (of plasma/serum). Assays are based on direct agglutination technology for the NEO Iris™ and NEO® v2.0 automated analyzer.

List of assays

The following table lists the described assays on the NEO Iris.

Assay Description	Assay short name	Used reagents	Microplates Used
	Blood grouping	**Horizontal/12 wells per strip**	
Rh Blood Group	RHFORMEL	1. immuClone Anti-C(1) 2. immuClone Anti-C(2) 3. immuClone Anti-c(1) 4. immuClone Anti-c(2) 5. immuClone Anti-E(1) 6. immuClone Anti-E(2) 7. immuClone Anti-e(1) 8. immuClone Anti-e(2) 9. immuClone Anti-Kell (1) 10. ImmuClone (2) Anti-K Automated IgM 11. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay short name	Used reagents	Microplates Used
Rh Blood Group	RHFORM_D	1. immuClone Anti-C(1) 2. immuClone Anti-C(2) 3. immuClone Anti-c(1) 4. immuClone Anti-c(2) 5. immuClone Anti-E(1) 6. immuClone Anti-E(2) 7. immuClone Anti-e(1) 8. immuClone Anti-e(2) 9. immuClone Anti-Kell (1) 10. immuClone (2) Anti-K Automated IgM 11. immuClone Anti-D rapid 12. immuClone Rh-Hr Control	Untreated microplates
Rh Blood Group	RHFORM_Cw	1. immuClone Anti-C(1) 2. immuClone Anti-C(2) 3. immuClone Anti-c(1) 4. immuClone Anti-c(2) 5. immuClone Anti-E(1) 6. immuClone Anti-E(2) 7. immuClone Anti-e(1) 8. immuClone Anti-e(2) 9. immuClone Anti-Kell (1) 10. ImmuClone (2) Anti-K Automated IgM 11. immuClone Anti-Cw 12. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay short name	Used reagents	Microplates Used
Rh Blood Group	PHENO16_3	1. immuClone Anti-C(2) 2. immuClone Anti-c(2) 3. immuClone Anti-E(2) 4. immuClone Anti-e(2) 5. ImmuClone (2) Anti-K Automated IgM 6. immuClone Rh-Hr Control	Untreated microplates
Rh Blood Group	PHENO16_4	1. immuClone Anti-C(1) 2. immuClone Anti-c(1) 3. immuClone Anti-E(1) 4. immuClone Anti-e(1) 5. ImmuClone (2) Anti-K Automated IgM 6. immuClone Rh-Hr Control	Untreated microplates
Rh Blood Group	KELL	1. immuClone Anti-Kell (1) 2. ImmuClone (2) Anti-K Automated IgM 3. immuClone Rh-Hr Control	Untreated microplates
Forward and Reverse ABO Blood Grouping incl. Kell	ABDLONGK	1. NOVACLONE Anti-A 2. NOVACLONE Anti-B 3. NOVACLONE Anti-AB 4. A1-Cell 5. A2-Cell 6. B-Cell 7. O-Cell 8. Autocontrol 9. NOVACLONE Anti-D 10. immuClone Anti-D rapid 11. ImmuClone (2) Anti-K Automated IgM 12. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay short name	Used reagents	Microplates Used
Forward and Reverse ABO Blood Grouping incl. Kell	ABDLONG2K	1. immuClone Anti-A 2. immuClone Anti-B 3. immuClone Anti-AB 4. A1-Cell 5. A2-Cell 6. B-Cell 7. O-Cell 8. Autocontrol 9. NOVACLONE Anti-D 10. immuClone Anti-D rapid 11. ImmuClone (2) Anti-K Automated IgM 12. immuClone Rh-Hr Control	Untreated microplates
Forward ABO Blood Grouping incl. Kell	ABD6K_I	1. ImmuClone Rh-Hr Control 2. immuClone Anti-A 3. immuClone Anti-B 4. immuClone Anti-AB 5. immuClone Anti-D rapid 6. ImmuClone (2) Anti-K Automated IgM	Untreated microplates
Forward ABO Blood Grouping incl. Kell	ABD6K_N	1. NOVACLONE Diluent Control 2. NOVACLONE Anti-A 3. NOVACLONE Anti-B 4. NOVACLONE Anti-AB 5. immuClone Anti-D rapid 6. ImmuClone (2) Anti-K Automated IgM	Untreated microplates
	Blood grouping	**Vertical/8 wells per strip**	
Rh Blood Group	AG_K	1. ImmuClone (2) Anti-K Automated IgM 2. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay short name	Used reagents	Microplates Used
Rh Blood Group	PHENO	1. immuClone Rh-Hr Control 2. immuClone Anti-C(1) 3. immuClone Anti-E(1) 4. immuClone Anti-c(1) 5. immuClone Anti-e(1) 6. ImmuClone (2) Anti-K Automated IgM	Untreated microplates
Rh Blood Group	PHENO12_3	1. immuClone Anti-C(2) 2. immuClone Anti-c(2) 3. immuClone Anti-E(2) 4. immuClone Anti-e(2) 5. ImmuClone (2) Anti-K Automated IgM 6. immuClone Rh-Hr Control	Untreated microplates

Assay Description	Assay short name	Used reagents	Microplates Used
	QC		
QC	QC	According to customer specific requirements	Untreated microplates

Limitations, Warnings and Notes

All limitations, warnings and notes that relate to the described assays are defined in the Operator Manual Chapter 12: Limitations of Use and Warnings and in Attachment I of the NEO Iris instrument. No additional limitations that relate to the described assays were identified.

Cutoffs and Reagent Components

List of Cutoffs

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
RHFORMEL	ImmuClone Anti-C(1)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-C(2)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-c(1)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-c(2)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-E(1)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-E(2)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-e(1)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-e(2)	0	0	23
		?	23	75
		1+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		2+ (not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-Kell (1)	0	0	23
		?	23	35
		1+ (not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	ImmuClone (2) Anti-K Automated IgM	0	0	23
		?	23	35
		1+ (not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	ImmuClone Rh-Hr Control	0	0	23
		? (not reported)	N/A	N/A
		1+	23	35
		2+	35	50
		3+	50	76
		4+	76	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
RHFORM_D	ImmuClone Anti-C(1)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-C(2)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-c(1)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-c(2)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	ImmuClone Anti-E(1)	0	0.	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-E(2)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-e(1)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-e(2)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		4+	80	99
	ImmuClone Anti-Kell (1)	0	0	23
		?	23	35
		1+(not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	ImmuClone (2) Anti-K Automated IgM	0	0	23
		?	23	35
		1+(not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	ImmuClone Anti-D rapid	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	99
	ImmuClone Rh-Hr Control	0	0	23
		? (not reported)	N/A	N/A
		1+	23	35
		2+	35	50
		3+	50	76

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		4+	76	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
RHFORM_Cw	ImmuClone Anti-C(1)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-C(2)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-c(1)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+	75	80
		4+	80	99
	ImmuClone Anti-c(2)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-E(1)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-E(2)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	ImmuClone Anti-e(1)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-e(2)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-Kell (1)	0	0	23
		?	23	35
		1+(not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	ImmuClone (2) Anti-K	0	0	23
		?	23	35

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Automated IgM	1+(not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	ImmuClone Anti-Cw	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Rh-Hr Control	0	0	23
		? (not reported)	N/A	N/A
		1+	23	35
		2+	35	50
		3+	50	76
		4+	76	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
PHENO16_3	ImmuClone Anti-C(2)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-c(2)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-E(2)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-e(2)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone (2) Anti-K Automated IgM	0	0	23
		?	23	35
		1+(not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	ImmuClone Rh-Hr Control	0	0	23
		? (not reported)	N/A	N/A
		1+	23	35
		2+	35	50
		3+	50	76
		4+	76	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
PHENO16_4	ImmuClone Anti-C(1)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+	75	80
		4+	80	99
	ImmuClone Anti-c(1)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-E(1)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-e(1)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		4+	80	99
	ImmuClone (2) Anti-K Automated IgM	0	0	23
		?	23	35
		1+(not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	ImmuClone Rh-Hr Control	0	0	23
		? (not reported)	N/A	N/A
		1+	23	35
		2+	35	50
		3+	50	76
		4+	76	99
Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
KELL	ImmuClone Anti-Kell (1)	0	0	23
		?	23	35
		1+(not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	ImmuClone (2) Anti-K	0	0	23
		?	23	35

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Automated IgM	1+(not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	ImmuClone Rh-Hr Control	0	0	23
		? (not reported)	N/A	N/A
		1+	23	35
		2+	35	50
		3+	50	76
		4+	76	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABDLONGK	NOVACLONE Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	99
	NOVACLONE Anti-B	0	0	30
		?	30	76

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	99
	NOVACLONE Anti-AB	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	99
	A1-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	99
	A2-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+	50	76
		4+	76	99
	B-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	99
	O-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	99
	Autocontrol	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	99
	NOVACLONE Anti-D	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	99
	ImmuClone Anti-D rapid	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	99
	ImmuClone (2) Anti-K Automated IgM	0	0	23
		?	23	35
		1+ (not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	ImmuClone Rh-Hr Control	0	0	30
		? (not reported)	N/A	N/A
		1+	30	35
		2+	35	50

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		3+	50	76
		4+	76	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABDLONG2K	ImmuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	99
	ImmuClone Anti-B	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	99
	ImmuClone Anti-AB	0	0	30
		?	30	76

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	99
	A1-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	99
	A2-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	99
	B-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	O-Cell	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	99
	Autocontrol	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	99
	NOVACLONE Anti-D	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	99
	ImmuClone Anti-D rapid	0	0	30
		?	30	76

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	99
	ImmuClone (2) Anti-K Automated IgM	0	0	23
		?	23	35
		1+ (not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	ImmuClone Rh-Hr Control	0	0	30
		? (not reported)	N/A	N/A
		1+	30	35
		2+	35	50
		3+	50	76
		4+	76	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABD6K_I	ImmuClone Rh-Hr Control	0	0	30
		? (not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+	30	35
		2+	35	50
		3+	50	76
		4+	76	99
	ImmuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	99
	ImmuClone Anti-B	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	99
	ImmuClone Anti-AB	0	0	30
		?	30	76

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	99
	ImmuClone Anti-D rapid	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	99
	ImmuClone (2) Anti-K Automated IgM	0	0	23
		?	23	35
		1+ (not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
ABD6K_N	NOVACLONE	0	0	30

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Diluent Control	? (not reported)	N/A	N/A
		1+	30	35
		2+	35	50
		3+	50	76
		4+	76	99
	NOVACLONE Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	99
	NOVACLONE Anti-B	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	99
	NOVACLONE	0	0	30

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Anti-AB	?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	99
	ImmuClone Anti-D rapid	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	99
	ImmuClone (2) Anti-K Automated IgM	0	0	23
		?	23	35
		1+ (not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
AG_K	ImmuClone (2) Anti-K Automated IgM	0	0	23
		?	23	35
		1+(not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99
	ImmuClone Rh-Hr Control	0	0	23
		? (not reported)	N/A	N/A
		1+	23	35
		2+	35	50
		3+	50	80
		4+	80	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
PHENO	ImmuClone Rh-Hr Control	0	0	23
		? (not reported)	N/A	N/A
		1+	23	35
		2+	35	50
		3+	50	76
		4+	76	99
	ImmuClone	0	0	23

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
	Anti-C(1)	?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-E(1)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-c(1)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-e(1)	0	0	23
		?	23	75

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone (2) Anti-K Automated IgM	0	0	23
		?	23	35
		1+(not reported)	N/A	N/A
		2+	35	50
		3+	50	80
		4+	80	99

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
PHENO12_3	ImmuClone Anti-C(2)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-c(2)	0	0	23
		?	23	75

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-E(2)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone Anti-e(2)	0	0	23
		?	23	75
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+	75	80
		4+	80	99
	ImmuClone (2) Anti-K Automated IgM	0	0	23
		?	23	35
		1+(not reported)	N/A	N/A

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
		2+	35	50
		3+	50	80
		4+	80	99
	immuClone Rh-Hr Control	0	0	23
		? (not reported)	N/A	N/A
		1+	23	35
		2+	35	50
		3+	50	76
		4+	76	99

Assay Reagent Component Grid

Reagents and Microplates	RHFORMEL	RHFORM_D	RHFORM_Cw	PHENO16_3	PHENO16_4	KELL	AG_K	PHENO	PHENO12_3
Untreated Microplates (barcoded)	X	X	X	X	X	X	X	X	X
ImmuClone Anti-C(1)	X	X	X		X			X	
ImmuClone Anti-C(2)	X	X	X	X					X
ImmuClone Anti-c(1)	X	X	X		X			X	
ImmuClone Anti-c(2)	X	X	X	X					X
ImmuClone Anti-E(1)	X	X	X		X			X	
ImmuClone Anti-E(2)	X	X	X	X					X
ImmuClone Anti-e(1)	X	X	X		X			X	
ImmuClone Anti-e(2)	X	X	X	X					X
ImmuClone Anti-Kell (1)	X	X	X			X			
ImmuClone (2) Anti-K Automated IgM	X	X	X	X	X	X	X	X	X
ImmuClone Anti-Cw			X						
ImmuClone Anti-D rapid		X							
ImmuClone Rh-Hr Control	X	X	X	X	X	X	X	X	X

Reagents and Microplates	ABDLONGK	ABDLONG2K	ABD6K_I	ABD6K_N
Untreated Microplates (barcoded)	X	X	X	X
Reagent Red Blood cells (Referencells – Group A1)	X	X		
Reagent Red Blood cells (Referencells – Group A2)	X	X		
Reagent Red Blood cells (Referencells – Group B)	X	X		
Reagent Red Blood cells (Referencells – Group O)	X	X		
NOVACLONE Anti-A	X			X
NOVACLONE Anti-B	X			X
NOVACLONE Anti-AB	X			X
NOVACLONE Anti-D	X	X		
ImmuClone Anti-A		X	X	
ImmuClone Anti-B		X	X	
ImmuClone Anti-AB		X	X	
ImmuClone Anti-D rapid	X	X	X	X
ImmuClone Rh-Hr Control	X	X	X	
NOVACLONE Diluent Control				X
ImmuClone (2) Anti-K Automated IgM	X	X	X	X
Autocontrol	X	X		

Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert. Package inserts are also the source of information for limitations of the reagents in use.

Assay Button Abbreviation	**Brief Synopsis of Assay Procedural Steps**

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
QC RHFORMEL RHFORM_D RHFORM_Cw PHENO16_3 PHENO16_4 KELL ABDLONGK ABDLONG2K ABD6K_I ABD6K_N AG_K PHENO PHENO12_3	1. Bring all reagents and blood samples to 18–30°C before testing. 2. Centrifuge the blood samples to separate the plasma from the red blood cells and then remove the caps from those tubes. Process the donor segment blood samples, but do not centrifuge those samples. 3. Remove reagent vial caps. 4. Load reagents, microplates, and blood samples, onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 5. Assign the appropriate assay to the blood samples either manually or following the upload worklist procedure. 6. Start the appropriate assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the assays, and records and interprets blood sample results. 7. At the completion of the NEO Iris assay, click the Results button on the main menu bar to access the blood samples results.

Results and Interpretations

Introduction

The NEO Iris® generates a result for each well read by the instrument and an interpretation of the results. Each NEO Iris assay has predefined interpretations for test well results.

A test well result is the reaction result for a given test well. Test well results are reported Positive, Negative, Invalid or Equivocal. These results are determined by comparing the well reaction value to assay-specific cutoff values. Assay cutoff values are listed in this attachment.

Possible Test Well Results

Possible test well results for assays include:

Indicator	Name	Description
+	Positive	The reaction value can be considered as positive.
-	Negative	The reaction value can be considered as negative.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater than the negative cutoff value or equal to or less than the positive cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

The described assays are designed to be read automatically by the instrument, and even though you cannot edit reactions or results, you can still view the images of the assay reactions by using the instrument software. Reaction features are described in the associated reagent package inserts.

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO Iris process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	Possible Well Results	Possible Test Interpretations
RHFORMEL	ImmuClone Rh-Hr Control: +(1, 2, 3, 4), -, X Other reagents: +(1, 2, 3, 4), -, ?[1], X	CE Interpretations: cc ee, CC ee, Cc ee, cc Ee, CC Ee, Cc Ee, cc EE, Cc EE, CC EE, NTD / Mixed field ?, NTD, *INV* Kell Interpretations: K+, K-, NTD / Mixed field ?, NTD, *INV*

RHFORM_D	+, -, ?, X	CDE Interpretations: ccD.ee, CCD.ee, CcD.ee, ccD.Ee, CCD.Ee, CcD.Ee, ccD.EE, CcD.EE, CCD.EE, ccddee, CCddee, Ccddee, ccddEe, CCddEe, CcddEe, ccddEE, CcddEE, CCddEE, NTD / Mixed field ?, *INV* Kell Interpretations: K+, K-, NTD / Mixed field ?, *INV*
RHFORM_Cw	+, -, ?, X	CE and Cw Interpretations: cc ee Cw+, CC ee Cw+, Cc ee Cw+, cc Ee Cw+, CC Ee Cw+, Cc Ee Cw+, cc EE Cw+, Cc EE Cw+, CC EE Cw+, cc ee Cw-CC ee Cw-, Cc ee Cw-, ccEe Cw-, CC Ee Cw-, Cc Ee Cw-, cc EE Cw-, CcEE Cw-, CC EE Cw-, NTD / Mixed field ?, *INV* Kell Interpretations: K+, K-, NTD / Mixed field ?, *INV*
RHFORM_Cw *Alternative Aurora File	+, -, ?, X	CE Interpretations: cc ee, CC ee, Cc ee, cc Ee Cw+, CC Ee, Cc Ee, cc EE, Cc EE, CC EE, NTD / Mixed field ?, *INV* Cw Interpretations: Cw+, Cw-, NTD / Mixed field ?, *INV* Kell Interpretations: K+, K-, NTD / Mixed field ?, *INV*
PHENO16_3 PHENO16_4 PHENO12_3	+, -, ?, X	CE Interpretations: CC EE, Cc EE, cc EE, CC Ee, Cc Ee, cc Ee, CC ee, Cc ee, cc ee, NTD / Mixed field ?, *INV* Kell Interpretations: K+, K-, NTD / Mixed field ?, *INV*
PHENO	+, -, ?, X	CE Interpretations: CC EE, Cc EE, cc EE, CC Ee, Cc Ee, cc Ee, CC ee, Cc ee, cc ee, IND / DP, *INV* Kell Interpretations: Kell +, Kell -, IND / DP, *INV*
KELL AG_K	+, -, ?, X	K+, K-, NTD / Mixed field ?, *INV*

ABDLONGK ABDLONG2K	+, -, ?, X	ABO Interpretations: A, B, AB, O, NTD/Mixed field ?, *INV* Rh Interpretations: RH+, RH-, NTD / Mixed field ?, *INV* Kell Interpretations: K+, K-, NTD / Mixed field ?, *INV*
ABD6K_I ABD6K_N	+, -, ?, X	ABO Interpretations: A, B, AB, O, NTD/Mixed field ?, *INV* Rh Interpretations: RH+, RH-, NTD / Mixed field ?, *INV* Kell Interpretations: K+, K-, NTD / Mixed field ?, *INV*

[1] Equivocal results of antibody wells may be edited. There cannot be an equivocal result for ImmuClone Rh-Hr Control wells, wherefore negative control results are not editable.

*Alternative result interpretation depending on installed aurora file version

Key for Table of Well Results and Test Interpretations by Assay

The two (2) tables below describe the possible well test results per the Result Interpretations section of this attachment.

Well Result	**Description**
+	Positive
-	Negative
?	Equivocal
X	Invalid

Test Interpretation	**Description**
INV	Invalid
NTD	No Type Determined
NTD / Mixed field ?	No Type Determined / Mixed field ?
IND / DP	No Type Determined / Mixed field ?

NTD NTD	No Type Determined No Type Determined

Performance Characteristics

Specific Performance Characteristics

Method Comparison Studies:

A method comparison study was conducted internally at Immucor Inc. to evaluate the performance of the immuClone(2) Anti-K (Kell) Automated IgM reagent.

Result concordance of the updated assays was determined by verifying that the results generated on the NEO Iris and Galileo NEO System (software version 3.1 or higher) with assays using the immuClone(2) Anti-K (Kell) Automated IgM are equivalent to the results generated for the same samples tested in reference assays using immuClone(1) Anti-K (Kell). Both vertical and horizontal assay configurations were tested for equivalency to ensure representation of all assays that are configured to use the immuClone(2) Anti-K Automated IgM product.

The following acceptance criterion was met for the immuClone (2) Anti-K (Kell) Automated IgM reagent within all assays under test (AG_K, PHENO12_3, ABDLONG2K, Kell, PHENO16_4, RHFORMEL):

- Result interpretations for phenotyping reactions by the System shall be at least 99% (PE) overall concordant, 99% (PE) PPA concordant, and 99% (PE) NPA concordant to the expected result of the test well.

Reagent Concordance Summary for immuClone (2) Anti-K						
Assay	Overall Concordance		PPA		NPA	
	PE	Test Count	PE	Test Count	PE	Test Count
AG_K	100%	301/301	100%	109/109	100%	192/192
PHENO12_3	100%	303/303	100%	109/109	100%	194/194
ABDLONG2K	100%	300/300	100%	107/107	100%	193/193
Kell	100%	309/309	100%	108/108	100%	201/201
PHENO16_4	100%	309/309	100%	108/108	100%	201/201
RHFORMEL	100%	309/309	100%	108/108	100%	201/201

Sensitivity and specificity were calculated from all of the test wells generated with the immuClone(2) Anti-K product compared to the true result.

Sensitivity	Specificity
100% (649/649)	100% (1182/1182)

Precision Studies

Reproducibility and Repeatability Studies:

This reproducicility and repeatability study was conducted internally at Immucor Inc. to evaluate performance of the immuClone(2) Anti-K (Kell) Automated IgM reagent using the vertical AG_K assay on the NEO Iris and Galileo NEO System (software version 3.1 or higher). Three (3) samples were tested in quadruplicate (12 total replicates) on four (4) consecutive days and one (1) nonconsecutive day spanning a total of six (6) days.

Twelve (12) replicates/tubes were run with the AG_K assay two (2) times per day with at least two (2) hours separating the two (2) runs on three (3) NEO Iris / Galileo NEO Systems.

All expected-positive samples tested in replicates generated positive results, and all expected-negative samples tested in replicates generated negative results with the AG_K assay using the immuClone(2) Anti-K (Kell) Automated IgM reagent. Results generated met all acceptance criteria and demonstrated 100% agreement:

Agreement Analysis	Concordance
Day	100% (PE)
System	100% (PE)
Run (by system)	100% (PE)
Sample	100% (PE)
PPA	100% (PE)

Agreement Analysis	Concordance
NPA	100% (PE)
Overall concordance	100% (PE)

NEO Iris® ASSAY GUIDE:

Open Channel Anti-D Group Assays

In This Chapter:

About this Assay Guide

This assay guide is supplementary instructions for use to the NEO Iris® Operation Manual. The guide provides specific information about the intended use, operation instructions, assay parameters, limitations and warnings that are unique to the Open Channel Anti-D Assays. Users must still comply with the general instructions provided by the NEO Iris® Operator manuals and corresponding reagent package inserts when using this assay, unless others indicated within this guide.

Intended Use

The Open Channel Anti-D Assays on the NEO Iris® fully automates standard direct microplate-based methods for ABO Grouping and Rh(D) typings. The assays are intended to provide the customer the ability to choose alternative Anti-D reagents, potentially beyond those provided by Immucor. The assays employ other Immucor reagents. By leaving a single open channel explicitly for customer selection of an Anti-D reagent, customers may choose a reagent that allows detection of specific Rh(D) categories of special interest (for example, D Category VI). Therefore, depending on the specifics of which Anti-D reagent is selected by the customer, the assay(s) may only be used for donor and/or patient testing as indicated and validated.

The NEO Iris® OCABDCHK2 and OCABD6_I assays are intended to be used for confirmation of ABO and RhD antigens on human erythrocytes from previously characterized samples (patient and/or donor in origin), as long as the end user selects an Anti-D reagent manufactured for and verified by the customer upon the intended population from which the samples arise.

The NEO Iris® OCABDLNG2 assay is intended to be used for characterization of ABO and RhD antigens on human erythrocytes of samples (patient and/or donor in origin), as long as the end user selects an Anti-D reagent manufactured for and verified by the customer upon the intended population from which the samples arise.

The ABO portion of the Open Channel assays are intended for use only with the reagents described in **List of Assays section.** The reagent described as OC Anti-D refers to the Anti-D reagent that the customer selects and fully validates its use for each and every customer selected Anti-D reagent prior to any use in their laboratory.

List of Assays and Reagents for the NEO Iris®

Assay Description	Assay Short Name	Used Reagents	Microplates used
	Open channel (Agglutination)	**Horizontal/4 wells per strip**	
Forward ABO Blood Grouping	OCABDCHK2	1. immuClone Rh-Hr Control 2. immuClone Anti-A 3. immuClone Anti-B 4. OC Anti-D	Untreated microplates
	Open channel (Agglutination)	**Horizontal/6 wells per strip**	
Forward ABO Blood Grouping	OCABD6_I	1. immuClone Rh-Hr Control 2. immuClone Anti-A 3. immuClone Anti-B 4. immuClone Anti-AB 5. OC Anti-D 6. Novaclone Anti-D	Untreated microplates
	Open channel (Agglutination)	**Horizontal/12 wells per strip**	
Forward and reverse ABO Blood Grouping	OCABDLNG2	1. immuClone Rh-Hr Control 2. immuClone Anti-A 3. immuClone Anti-B 4. immuClone Anti-AB 5. OC Anti-D 6. NOVACLONE Anti-D 7. Referencells A1 8. Referencells A2 9. Referencells B 10. Referencells O	Untreated microplates

Warning:

The Open Channel Anti-D Assay is a direct hemagglutination method. When selecting an Anti-D for use in the open channel, a low protein anti-D reagent capable of direct agglutination should be selected. Reagents that are not capable of direct agglutination may give unexpected negative results. High protein reagents may lead to false positive reactions that are not detected by the Rh-Hr control.

The degree to which reagent Anti-D clones can detect D antigen variants and quantitative weak D antigens in a direct test varies greatly. The open channel Anti-D assays are direct test methods. Results of an indirect test should be evaluated before assigning an RhD negative status.

Assay Procedural Steps

Before you begin

You must prepare all of the necessary reagents and samples for each assay according to the detailed reagent package insert requirements. This brief synopsis of assay procedural steps relating to sample and reagent preparation is intended as summarized steps only and is not intended as a substitute for the detailed package insert. Package inserts are also the source of information for limitations of the reagents in use. To confirm the correct reactivity of the reagents, it is recommended that the reagents are to be tested each day of use by running the Quality Control (QC). For QC frequency, minimum requirements refer to national guidelines.

Assay Button Abbreviation	Brief Synopsis of Assay Procedural Steps
OCABDCHK2 OCABD6_I OCABDLNG2	Customers must validate these assays and document their validation prior to employing them for clinical use! 1. Bring all reagents, and blood samples to 18–30°C before testing 2. Centrifuge the blood sample collection tubes to separate the plasma from the red blood cells and then remove the caps from those tubes. 3. Select the necessary number of untreated microplates for use. 4. For OC Anti-D reagent only: Before first use of a vial, stick a new barcode provided by Immucor to the vial (NOTE: Only vials that fit onto the NEO Iris instrument are allowed to be used. Contact your local Application Specialist for further information.) Document the labelling on the open channel labelling sheet. 5. Remove reagent vial caps. 6. If needed, add one stirball to each new vial of Referencells®. Gently agitate each vial to resuspend the red blood cells. 7. Load reagents, microplates, and blood samples onto the NEO Iris following the procedures in Chapter 6 – Instrument Testing Operation. 8. Assign the corresponding assay to the blood samples, either manually or following the upload worklist procedure. 9. Start the corresponding assay following the procedures in Chapter 6 – Instrument Testing Operation. The NEO Iris automatically performs the assay, and records and interprets the blood sample results. 10. At the completion of the assay, click the Results button on the main menu bar to access the blood sample results.

Test Results and Interpretations

Possible Test Well Results

Possible test well results for all assays include:

Indicator	Name	Description
+	Positive	The reaction value is greater than the positive cutoff value.
-	Negative	The reaction value is less than or equal to the negative cutoff value.
?	Equivocal	The Equivocal symbol indicates that the reaction well cannot be definitively considered negative or positive. The reaction value is greater than the negative cutoff value or equal to or less than the positive cutoff value.
X	Invalid	The Invalid symbol indicates an error status for a given well. An Invalid test well result is generated if the instrument detects a processing error or a process control parameter out of range (e.g. liquid level detection error, clot detection, incubator temperature out of range, etc.).

Result Interpretations

The interpretation of the test well results is based on the reaction or reaction pattern of individual test well results, applicable control well results, and NEO Iris® process control monitoring. Possible interpretations generated by each assay are listed in the table below.

Assay	Possible Well Results	Possible Test Interpretations
OCABDCHK2 OCABD6_I OCABDLNG2	+, - , ?, X	ABO Interpretations: A, B, AB, O, NTD / Mixed Field?, *INV* Rh Interpretations: Positive, Negative, NTD / Mixed Field?, *INV*.

Note: Assays that include the use of two different Anti-D reagents and yield a positive result with one Anti-D reagent, but a negative result with the other Anti-D reagent for a given sample, will generate an NTD result related to the Rh (D) testing. This can be due to, but is not limited to, reduced D antigen epitope representation on the red blood cell membrane, or the presence of a D variant. Clinical determinations are the purview of the lab director, physicians involved in the care of the patient(s) and should fully understand the work up, including all limitations to any selected tests, that may be required as confirmation, before any result is provided or clinical decisions made regarding the result.

Assay Cutoffs for NEO Iris®

Assay Abbreviation	**Reaction**	**Grade**	**Lower Limit >**	**Upper Limit <=**
OCABDCHK2	immuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	immuClone Anti-B OC Anti-D immuClone Rh-Hr Control	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+(not reported)	N/A	N/A
		4+	76	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
OCABD6_I	immuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	immuClone Anti-B immuClone Anti-A,B OC Anti-D, Novaclone Anti-D immuClone Rh-Hr Control	0	0	30
		?	30	76
		1+(not reported)	N/A	N/A
		2+(not reported)	N/A	N/A
		3+(not reported)	N/A	N/A
		4+	76	100

Assay Abbreviation	Reaction	Grade	Lower Limit >	Upper Limit <=
OCABDLNG2	immuClone Anti-A	0	0	30
		?	30	58
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	58	100
	immuClone Anti-B immuClone Anti-A,B OC Anti-D, Novaclone Anti-D immuClone Rh-Hr Control	0	0	30
		?	30	76
		1+ (not reported)	N/A	N/A
		2+ (not reported)	N/A	N/A
		3+ (not reported)	N/A	N/A
		4+	76	100
	Referencells A1, A2, B, O Autocontrol	0	0	23
		?	23	28
		1+	28	35
		2+	35	50
		3+	50	76
		4+	76	100

Reagent Barcodes

These NEO Iris® assays use barcodes to identify reagents and samples in the loading modules. Using barcode technology increases the number of steps that can be automated, thus decreasing handling errors. Immucor manufactured reagents are provided with a barcode.

Immucor Standard Reagent Barcodes

Immucor manufactured reagents are provided with a barcode that is encoded with the following information:

- **Reagent ID** – The type of reagent
- **Expiration date** – The last date that the reagent may be used
- **Lot number** – Batch identifier
- **Serial number** – Unique identifier for each vial

The serial number identifies each reagent vial as unique and allows the system to track consumption of the reagent during use on the system. This provides a process control to monitor fill levels of the vial. The system assumes vials with 10mL reagent are being used.

Customer Selected OC Anti-D Reagent

Since the OC Anti-D is selected by the customer and may not bear a barcode, or a barcode that is formatted to meet the NEO Iris® system requirements, Immucor has available a secondary barcode label that can be applied to the customer validated OC Anti-D Reagent. The barcode provided includes the barcode elements described above with the following key limitations:

- **Reagent ID** – an ID character corresponding to the OC Anti-D
- **Expiration date** – A series of barcodes will possess an expiration date corresponding to the last day of the indicated month and year.
- **Lot number** – This will be a sequential number, but will not be the exact lot number applied by the reagent manufacturer. Immucor has provided a log sheet as a part of this assay guide so that end users can maintain documented between the NEO recognized lot and the manufacturers lot.
- **Serial number** – Unique identifier for each vial

Limitations and Warnings

The specific performance characteristics are described in the package inserts of each reagent. The expected results are specific to the reagent or test wells in use.

The limitations and warnings published in the NEO Iris® Operation Manual must be observed when using these assays.

Warning:

As the Open Channel Anti-D is designed to allow customer selection of an appropriate Anti-D reagent for their use, Immucor has not fully evaluated any specific anti-D performance characteristics for reagents not labeled and sold by Immucor, and as such, cannot provide any assurances as to functionality of the reagent or the combined reagent assay pairing.

The end user must validate open channel assays for their use based upon the customer's intended purpose, Immucor cannot be responsible for the choice of reagent. The open channel assays are to be used in combination with the open channel label provided by Immucor as described. Labelling of Anti-D reagents shall be documented on the open channel labelling sheet (see below) or in laboratory determined methodology. Only vials that fit onto the NEO Iris® may be used (contact your local application specialist for hardware support) and Immucor does not provide any guidance other than a 10 ml vial compatible with the instrument rack system.

As with all reagents, it is necessary to avoid contaminating the reagents during use. Signs of potentially unusable reagents include but are not limited to: marked turbidity, precipitate, fibrin gel or particles present. Do not use contaminated reagents. Do not use leaking vials. Vsiually inspect reagent before use. Discard reagent if there is any concern.

Example Labelling Sheet for Open Channel Assays

The specific performance characteristics are described in the package inserts of each reagent or test well. The expected results are specific to the reagent or test wells in use.

Reagent name	Lot no.	Expiry date	Labelling date	NEO Iris® barcode	Date/Signature	Barcode expiry matches reagent expiry? (Y/N)

Index

In This Index

This index contains an alphabetical listing of subject matter referenced in the NEO Iris Operator Manual with associated page numbers. This enables you to quickly locate specific information about the NEO within this manual.

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