Intellectual Property

The intellectual property rights of this Operation Manual and its corresponding products belong to Zybio Inc. (hereinafter referred to as "Zybio").

No one may use, disclose or allow others to obtain all or part of the information in this manual by any means without the prior written permission of Zybio. No one is allowed to take photos, copy, duplicate or translate all or part of this manual into other languages.

Zybio reserves the final right to interpret this manual.

Zybio reserves the right to modify the contents of the manual without prior notice.

Zybio reserves the right to change the technology without prior notice.

Zybio reserves the right to modify the Operation Manual without prior notice.

zybio is a registered trademark or trademark of Zybio.

Statement

The version of this manual is 1.0, and the release date is 2020.1. The manual may be amended without prior notice.

Zybio reserves the final right to interpret this Operation Manual.

The illustrations provided in the Operation Manual are only examples and may not be completely consistent with the actual display on the product. The actual items shall prevail and shall not be used for other purposes.

Only when all the following requirements are met can Zybio consider itself responsible for the safety, reliability and performance of the product, namely:

1) Assembly operation, re-commissioning, extensions, improvement and maintenance shall be carried out by personnel recognized by Zybio.

2) All replacement parts used in the repairs and all accessories and consumables used are products of or approved by Zybio.

3) The operation of the product shall be carried out according to this Operation Manual.

4) Relevant electrical equipment meets the requirements of national standard values and this Operation Manual.

After-Sales Service

Contact: Zybio Inc.

Address: Floor 1 to Floor 4, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, China 400082.

Website: www.zybio.com

Tel.: +86(0)23 6865 5509

Fax: +86(0)23 6869 9779

E-mail: info@zybio.com

EC- Representative: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Warning

1) This instrument can only be used by professionals, doctors and testers trained by Zybio or its Agents.
2) If each hospital or institution using this instrument cannot prepare a complete set of repair/maintenance plan, abnormal instrument failure may occur and personal safety may be endangered.
3) Please ensure that the analyzer is used under the operating conditions specified in the Operation Manual. If the operating conditions are exceeded, the analyzer may not operate normally, the measurement results will not be reliable, and the analyzer components may be damaged and personal safety may be endangered.

Attention

1) The readers of this Operation Manual are the following operators:
   - Personnel operating the system;
   - Personnel who maintain the system and handle system failures;
   - Personnel who learns the operating system.
2) When the instrument reaches the expiration date, it is recommended to stop using it or use it after comprehensive overhaul and maintenance by Zybio.

Product Description

Thank you for purchasing Chemistry Analyzer by Zybio Inc. Hereby we would like to express our gratitude.

Before using the product, please read the contents of this Operation Manual carefully so that you can use it correctly.

The pictures in this instruction book are for illustration or example only and shall not be used for other purposes. The actual pictures are subject to the product.

Please keep this Operation Manual properly after reading, so that you can check it at any time in case of needing.

Product Name: Chemistry Analyzer

Model and Specification: EXC200, EXC220

Management Classification: The management category is Class II

Production License No.: YSYJXSCX20150016

Registration Certificate No. / Product Technical Requirement No.: YXZZ20202220024

The product structure consists of a reagent sample processing unit, a stirring unit, a reaction unit, a photoelectric detection unit, a control and data processing unit and software.

Scope of application: The product is based on the principle of spectrophotometry and is used with matched reagents in clinical applications for the quantitative detection of human serum, plasma, urine, cerebrospinal fluid and whole blood.

Name of registered person/manufacturer: Zybio Inc.

Registered Person's Residence/Production Address: Floor 1 to Floor 4, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, Chongqing, China 400082.

Service life: 10 years. This service life is determined according to the lifespan test performed on the instrument. In the process of use, the user shall carry out maintenance and repair of the product according to the requirements of the Operation Manual. After maintenance and repair, the product that is confirmed to still maintain its basic safety and effectiveness can be used normally.

Warranty and Maintenance Services

The warranty period of purchased products shall be subject to the sales contract.

Consumables: it refers to disposable consumable materials that need to be replaced after each use or vulnerable materials that need to be replaced regularly. Consumables have no warranty.

During the warranty period, faults caused by quality problems or design defects of products can be treated with free maintenance services. All you need to do is provide the "Warranty Card" to maintenance specialist of Zybio. The warranty period starts from the "Date of Installation" filled in the "Warranty Card" attached to the product. **The "Warranty Card" is your only warranty certificate and must not be lost.** If the "Warranty Card" and other relevant provisions of Zybio products conflict with relevant national laws and regulations, the provisions of relevant national laws and regulations shall be followed.

If the repair work required during the warranty period due to the following non-product problems does not fall within the scope of the free warranty:

- Voltage mismatch;
- Improper human use;
- Maintenance not approved by Zybio;
- Force majeure factors such as natural disasters;
- Other repair works caused by instrument or part itself.

We promise to provide corresponding technical support and technical cooperation for the products sold and guarantee after-service.

Preface

This manual mainly helps users to understand the safety, installation, structure and function, analysis principle, operation process, maintenance, alarm and treatment of EXC2X Series Chemistry Analyzer (hereinafter referred to as EXC2X). In order to ensure its correct use, please strictly follow the instructions.

Scope of Application of Operation Manual

This manual is suitable for medical inspection professionals or trained doctors, nurses or testers to read, and is used for:

- Understanding EXC2X hardware and software;
- Setting system parameters;
- Performing routine operations;
- Performing system maintenance and troubleshooting.

Guide to Operation Manual

When you need ...	**Please refer to ...**
Learn about EXC2X safety information	Chapter 1 Safety Information
Learn about EXC2X system overview	Chapter 2 System Overview
Understand the basic test operation method of EXC2X	Chapter 3 Basic Operation Methods
Understand EXC2X software operation and software parameter setting	Chapter 4 Software System Operation
Understand the setting of EXC2X parameters and the principle of instrument analysis	Chapter 5 Analysis Principle and Calculation Method
Know how to maintain EXC2X	Chapter 6 Maintenance and Service
Understand the cause and treatment of EXC2X fault	Chapter 7 Alarm and Management
Understand the transportation and storage methods of EXC2X	Chapter 8 Transportation and Storage

Table of Contents

Product Description

1. Safety Information

1.1. Overview

This chapter introduces the significance of the safety symbols, the labels related to the product, and silkscreen printing used in the Operation Manual, as well as the potential safety hazards and precautions when using the instrument.

Note: the following symbols are for reference only. For details, please refer to the Operation Manual.

1.2. Symbols used in the operation manual

Symbol	Meaning
 Warning	Prompt the operator to follow the instructions below the symbol. Failure to do so may result in personal injury.
 Caution	Prompt the operator to follow the instructions below the symbol, otherwise it may cause product failure, damage or affect the test results.
 Attention	Prompt the operator to follow the instructions below the symbol and emphasize important information or contents requiring special attention of the operator in the operation steps.
 Biological hazard	Prompt the operator to follow the instructions below the symbol, otherwise there is a risk of potential biological infectivity.

1.3. Silkscreen printing and labeling related to products

Various warning labels and silkscreen printing are used on the instrument to identify the characteristics of the instrument and remind operators to pay attention. Other marks related to the use of the instrument are also explained below. Please check the warning labels frequently to keep them clean and complete. If the label cannot be read normally due to blurring or falling off, please contact our customer service department for replacement.

Note: The following signs or symbols are for reference only, and the specific pictures are subject to the actual objects.

Symbol	Meaning
	Please refer to the specific files delivered with the instrument.
	Moving parts prompt label
	**Electric shock** When the power is on, unauthorized maintenance personnel must not open the analyzer panel. Splashing liquid shall be avoided on the table. If liquid flows into the analyzer, please immediately turn off the analyzer and contact Zybio in time.
	**Biohazard** The background color of this symbol is yellow, and the symbol and outline are black. 1) All test samples, calibrators, quality control, etc. Shall be considered infectious and gloves shall be worn when contacting; 2) All waste liquid should be considered infectious and gloves should be worn when contacting. Parts in contact with the test sample, such as suction nozzle and measuring cuvette, shall be considered infectious, and gloves shall be worn during contact; 3) All wastes are considered infectious and should be treated as medical wastes according to current regulations; 4) When the instrument reaches its service life, it should be treated according to the requirements of the local environmental protection department, and should not be treated and discarded as ordinary wastes.

Symbol	Meaning
	**High temperature** It may cause injury to human body.
	**Corrosion** Cleaning fluid is chemically corrosive, and protective gloves should be worn during operation.
	**Moving parts** Do not reach in when working
	Disassembly is strictly prohibited by non-professionals.
	Alternating current symbol
	USB Interface
RS232	RS-232 communication serial port
	Net port
	This electronic information product contains some toxic and harmful substances. The environmental protection service period is 20 years, within which it can be used safely. After the environmental protection service period, it should be put into the recycling system.
IVD	Only for in vitro diagnostic use

Symbol	Meaning
	Serial number
	Date of production
	Manufacturer
	Please refer to the Operation Manual
	On (power)
	Off (power)
100V-240V～ 50/60Hz	Power input condition
DW1	Purified water inlet
DW2	Purified water outlet
HW	Concentrated waste liquid outlet
LW	Diluted waste liquid outlet
CW	Concentrated detergent inlet
CL	Condensate water outlet
DW-D	Purified water float sensor
CW-D	Float sensor for concentrated detergent
W-D	Waste liquid float sensor

1.4. Matters needing attention

1.4.1. Scope of application

Caution

1) EXC2X series Chemistry Analyzer is mainly used in medical institutions for quantitative examination of human serum, plasma, urine and other samples.
2) When making clinical judgment according to the test results, please consider the clinical examination results or other test results.

1.4.2. Operator

Caution

EXC2X series Chemistry Analyzer is only applicable to personnel trained by Zybio or its agents.

1.4.3. Application environment

Attention

1) Please install correctly according to the installation environment specified in this Operation Manual. Installing or using not under the specified conditions may lead to unreliable results and may damage the instrument.
2) If you need to change the working environment of the analyzer, please contact Zybio or the agent in your region.

1.4.4. Data backup

Attention

The system itself carries out backup processing on the data and stores the data in the industrial control board. If the industrial control board data is deleted or damaged due to some reasons, the data will be lost. Please back up the analysis data and analysis parameters to other mobile storage devices on a regular basis.

1.4.5. Analysis parameters

Attention

Incorrect analysis parameters will lead to incorrect test results, please consult Zybio or reagent supplier.

1.4.6. Electromagnetic interference

Attention

1) The analyzer is vulnerable to electromagnetic interference during operation, which may affect the test results and lead to misoperation. Please do not use electric drills, mobile phones, interphones and other devices that generate electromagnetic waves during operation.
2) During the operation of the analyzer, electromagnetic waves will be radiated to the outside. Do not install or use electromagnetic sensitive equipment near the analyzer.

1.4.7. Imperfect grounding

Attention

3) The power supply must be grounded correctly, otherwise there is danger of electric shock.
4) The grounding impedance must be less than 10mΩ. Poor grounding may lead to unstable test results and leakage of electricity from the casing, thus posing a risk of electric shock.

1.4.8. Label falling off

Attention

When the label of the instrument is fuzzy or falls off, please contact Zybio for replacement.

1.4.9. Leakage

Attention

1) Before testing, carefully check the manually tighted joints of each pipe to see if there is liquid leakage, which will lead to inaccurate suction and discharge capacity.
2) Do not place reagents or samples on the analyzer table to avoid liquid splashing and leakage.

1.4.10. Probe blocking

Attention

Carefully check the reagent and sample, which cannot contain insoluble floaters, such as cellulose, fibrin, etc. Otherwise, the reagent-sample probe will be blocked.

1.4.11. Ultraviolet transparent plastic cuvette

Attention

Ultraviolet transparent plastic cuvette (referred to as colorimetric cup or plastic cuvette) used by EXC2X series Chemistry Analyzer. Please use cuvette specified by Zybio, otherwise the expected use effect may not be obtained.

1.4.12. Water quality

Attention

The water quality shall meet the requirements of ISO3696 Class II, otherwise it will easily lead to valve and pump damage and not thorough cleaning.

1.4.13. System applicable

1) Please use the system according to the instructions in the Operation Manual. Incorrect use may lead to incorrect measurement results, and may even lead to system damage or personal injury.
2) Before using the system for the first time, calibration should be carried out before quality control to confirm that the system works normally.
3) When using the system on a daily basis, it is recommended to carry out quality control to ensure the reliability of the results.
4) Before analysis, please cover the reaction tray and reagent-sample tray.

Warning

5) Do not uncover the reaction tray during the analysis.
6) During the analysis, please ensure that there are no obstacles in the movement track of the probe and stirring rod.
7) When the reaction tray and reagent-sample tray rotate, do not touch them to prevent scratches.
8) Do not install any software or hardware other than those specified by Zybio on this system, or it may hinder the normal operation of this system. Please do not run other software during the operation of this system.
9) Do not use this system for other purposes. Incorrect use may cause the instrument to be infected with virus. Computer viruses may spread through USB, programs, networks, etc.

1.4.14. System maintenance

1) Please follow the instructions in this Operation Manual for system maintenance. Incorrect maintenance may lead to incorrect analysis results and even system damage or personal injury.

2) After replacing the main components, such as light source lamp, reagent-sample probe and syringe piston assembly, please carry out calibration analysis.

Warning

3) If you stop using the instrument due to malfunction or other reasons and needs repair or disposal, please contact Zybio or local agent in time. At the same time:

- Please take other measures, such as replacing the unfinished tests with other instruments or methods, so as not to cause delay in the results.
- Please take out the reagent on the instrument and store it separately according to the instructions for using the reagent in the kit. Put the reagent back in the refrigerator for cold storage to prevent it from deteriorating.

1.4.15. Sample

1) Please use a completely separated serum sample and a urine sample without suspended substances. If the serum sample contains fibrin or the urine sample contains suspended substances, the reagent-sample probe may be blocked, thus affecting the accuracy of the analysis results.

2) Drugs, anticoagulants, preservatives, etc. Present in the sample may interfere with some analysis results.

Warning

3) Lipemia, jaundice, hemolysis, etc. in the sample may affect the analysis results, and it is recommended to make blank analysis of the sample.

4) Please store the sample correctly. Incorrect sample storage conditions may change the composition content of samples, thus affecting the accuracy of analysis results.

5) Do not leave the sample tube open for a long time to prevent the sample from volatilizing, otherwise the accuracy of analysis results may be affected.

6) There is a requirement on sample volume in the analysis of this system. When sampling, please take appropriate sample volume according to the relevant instructions in this Operation Manual.

1.4.16. Reagent, calibrator and control

1) When using this system for analysis, please use appropriate reagents, calibrator and QC.
2) Please select suitable reagents according to this system. If you are not sure whether the reagent is available, please consult the manufacturer, agent of the reagent or manufacturer, agent of Zybio.

Warning

3) For the use and storage of reagents, calibrator and QC, please refer to the instructions of reagent manufacturers or distributors.
4) If reagents, calibrator and QC are not stored properly, even within the validity period, correct test results may not be obtained.
5) Please calibrate after replacing the reagent. Without calibration and quality control, correct analysis results may not be obtained.
6) Cross contamination of reagents may affect analysis results during analysis. For information on reagent cross-contamination, please consult the relevant reagent manufacturer or distributor.

1.4.17. Instrument discard

Warning

Some substances of waste analyzers are controlled by pollution regulations. Please follow the local waste disposal standard to dispose of the waste analyzer.

1.5. Picture

All the pictures in this Operation Manual are for illustration or example only and shall not be used for other purposes.

2. System Overview

This chapter gives a detailed introduction to the instrument about the installation, hardware, software and specifications, mainly including the following contents:

- Installation requirements and methods of instruments
- System structure of hardware
- Optional module
- Introduction and use of software interface

2.1. Installer

The installation of the instrument can only be carried out by Zybio's technicians or technicians authorized by Zybio.

Warning

EXC2X series Chemistry Analyzer can only be installed by Zybio or its authorized agent, and users need to provide corresponding environment and space. When the analyzer needs to be relocated, please contact Zybio or the local agent.

When you receive the analyzer, please inform Zybio and the local agent immediately.

2.2. Damage examination

All analyzers have passed the strict inspection of Zybio before packaging and transportation. When you receive the analyzer, please check carefully before unpacking and pay attention to the following damages:

1) The outer package is inverted or deformed;
2) The outer package has obvious traces of being wetted by water;
3) The outer package has obvious marks of impact;
4) There are signs that the outer packing has been opened.

Once the above damages are found, please inform Zybio or its authorized local agent immediately. If the outer package is in good condition, please open the packing case and check it after unpacking in the presence of the designated staff of Zybio:

1) Check whether all components are complete according to the packing list in the packing box;
2) Carefully check the appearance of all devices for cracks, bumps or deformation.

After unpacking, please carefully inspect the appearance of the instrument and check the packing list. If there is any handling damage or the configuration is found to be incomplete, please immediately declare it to Zybio or its authorized local agent.

2.3. Installation requirements

2.3.1. Site

- For indoor installation only;
- The installation table should be flat (inclination is less than 1/200);
- The mounting table can bear at least about 80kg of weight;
- Good ventilation;
- The environment should be as dust-free as possible;
- Avoid direct sunlight;
- Avoid heat sources and wind sources;
- No corrosive and flammable gases;
- No vibration on the table surface;
- No loud noise source and power interference;
- Keep away from brush-type engines and electrical contact equipment that are frequently switched on and off;
- Keep away from devices that emit electromagnetic waves, such as cell phones, radio transceivers, etc.

2.3.2. Power

- 100-240 V~, 50/60 Hz, properly grounded with grounding resistance of less than 10 mΩ
- Input power: ≤500 VA

Warning

Please ground the power socket correctly. Incorrect grounding may cause electric shock and system damage. Please confirm that the power outlet output voltage meets the system requirements.

2.3.3. Humidity and temperature

- Ambient temperature: 10℃-30℃
- Ambient humidity: 30%~85%, no frost

Caution

The system must be operated within the specified ambient temperature and humidity range, otherwise the test results may be unreliable. If the ambient temperature and humidity exceed the specified range, use air conditioning equipment.

2.3.4. Atmospheric pressure

■ Atmospheric pressure: 70.0 kPa~106.0 kPa

2.3.5. Space

Please install the instrument according to the space requirements shown in the figure below.

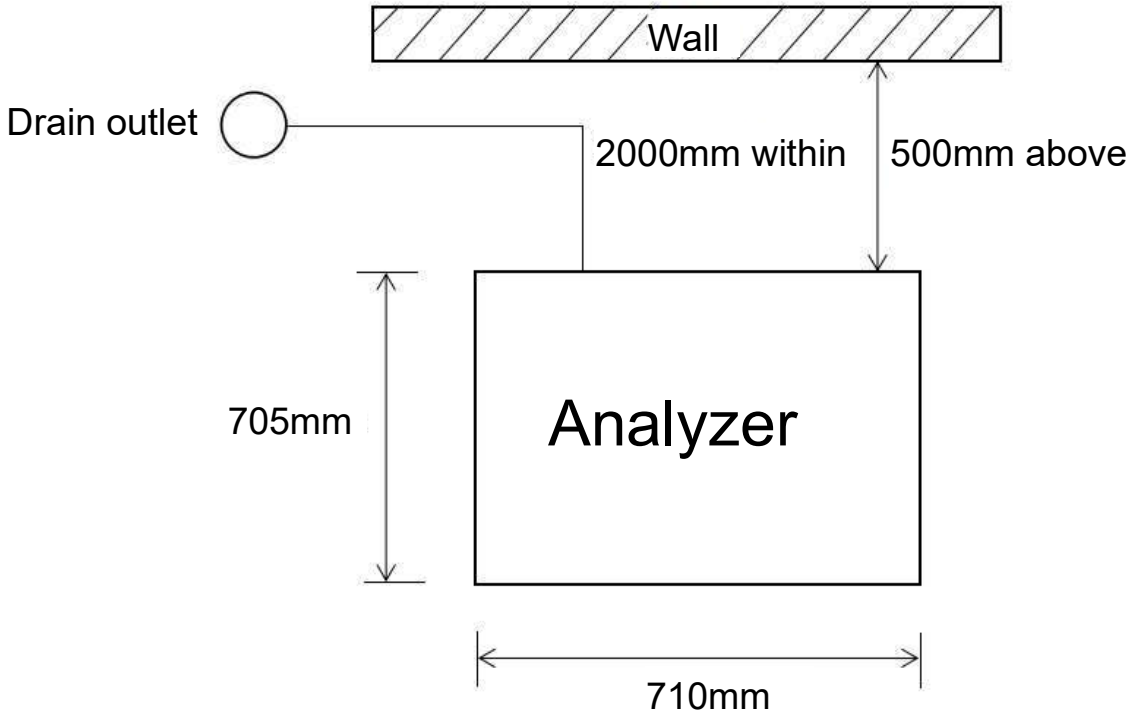


Figure 2-1 Installation Space Requirements

2.3.6. Water supply and drainage requirements

- The water quality of the water supply must meet the requirements of ISO3696 Class II;

Caution

The water quality must meet the water supply requirements. Otherwise, the water purity may affect the test results.

- Water supply volume: not less than 5L/h;
- The distance between the water supply device and the water inlet of the chemistry analyzer shall not exceed 10 meters;
- Waste container connection: the waste container shall be placed at the same level as the instrument or lower than the level of the instrument, and it must be ensured that its mouth is lower than the waste container outlet on the rear plate of the machine;
- Sewer connection: the height of waste liquid outlet from the ground shall not be higher than 12cm;
- The length of waste liquid pipe shall not be longer than 2m.

Biological hazard

Biological pollution

Please wear gloves, work clothes to prevent infection and protective glasses as needed when operating.

After installing the instrument, please connect the fluidic component correctly according to the following figure:

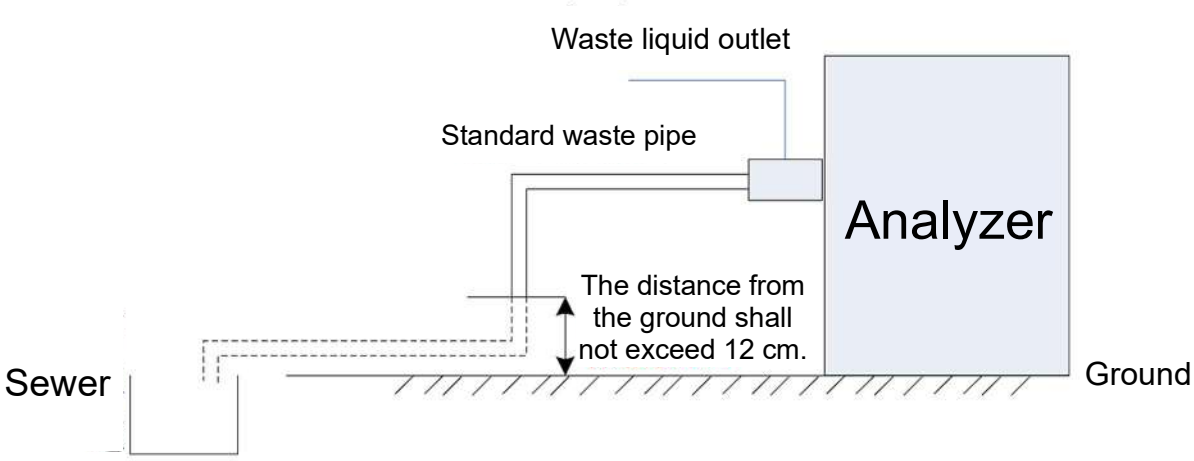


Figure 2-2 Requirements for Fluidic Component Connection

Please treat the discharged waste liquid according to the local discharge standard.

When connecting the drain pipes, be careful not to fold or flatten them.

Attention

Biological pollution

Waste liquid is mainly consists of blood. Please treat the waste liquid discharged by the instrument according to the local discharge standard.

Biological hazard

2.4. Product composition

The Chemistry Analyzer consists of a reagent-sample processing unit, a mixing unit, a reaction unit, a photoelectric detection unit, a control and data processing unit and software.

2.4.1. Reagent-sample processing unit

The reagent-sample processing unit mainly completes the whole operation process of loading reagent and sample, including adding the first reagent, adding the sample, adding the second reagent, etc.

2.4.2. Mixing unit

The mixing unit mainly completes the mixing operation of reagents and samples.

2.4.3. Reaction unit

The reaction unit mainly completes the reaction of reagent and sample, incubation and automatic cleaning of the cuvette.

2.4.4. Photoelectric detection unit

The photoelectric detection unit is mainly used to collect photoelectric signals and other functions.

2.4.5. Control and data processing unit

The control and data processing unit mainly consists of touch screen, built-in main control board and industrial control board. It can be operated on the touch screen interface to control the operation of the instrument. The main control board and the industrial control board can process the photoelectric signal value and convert it into various results required for detection.

2.4.6. Software

The name of the software is Chemistry Analyzer software, with functions of sample, result, reagent, status, calibration, quality control, setup and maintenance. Users can operate the software for sample application, results query, reagent management, online status checking, calibration application, quality control application, instrument setup, and various maintenance operations.

2.4.7. Accessories and consumables

Accessories and consumables refer to the components necessary for sample testing of the instrument, which shall be checked frequently to ensure sufficient quantity, supplemented and replaced when necessary. Among them, the attachment is the content in A.4 except the host computer; consumables include the contents in A.3 and the matching reagents.

2.5. Instrument structure

2.5.1. Front view of instrument

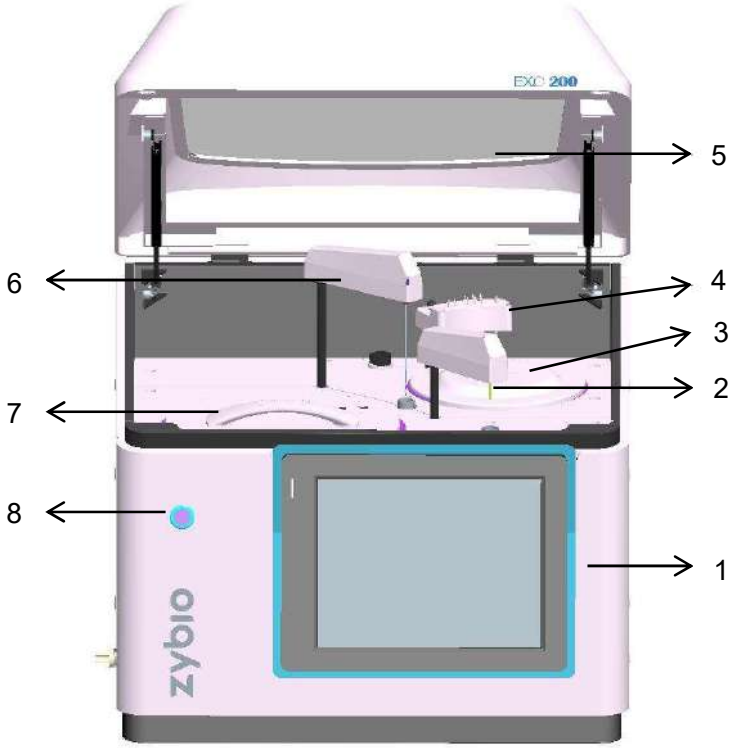


Figure 2-3 Front Structure

1-Touch Screen; 2-Stirring Rod; 3-Reaction Tray;

4-Automatic Cleaning Mechanism; 5-Top Cover; 6-Reagent - Sample Probe;

7-Reagent - Sample Tray; 8-Analysis Switch

2.5.2. Rear view of instrument

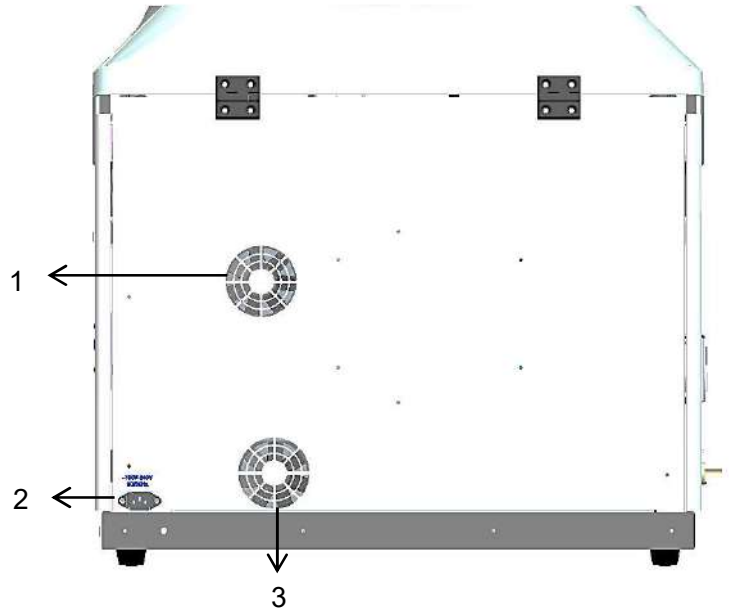


Figure 2-4 Rear Structure

1-Fan; 2-Power Socket; 3-Fan

2.5.3. Side view of instrument

- Left side

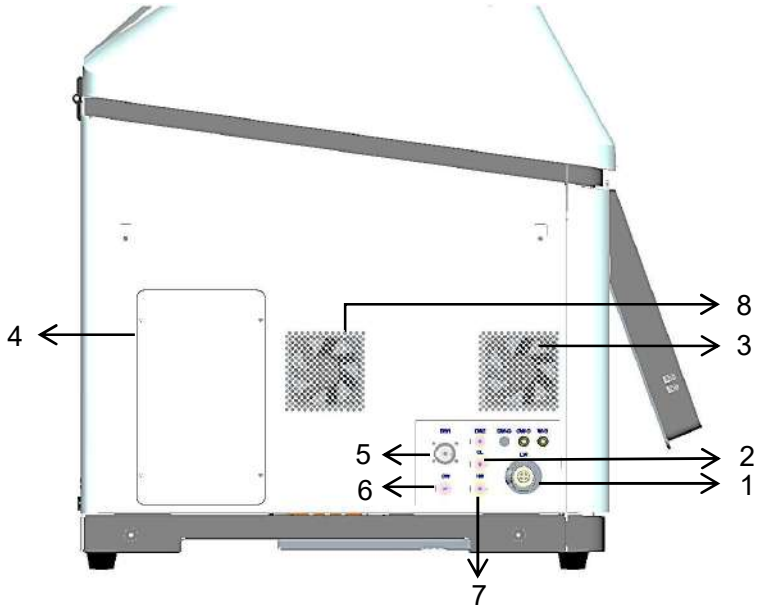


Figure 2-5 Left Side Structure

1-Diluted Waste Liquid Pipe Interface; 2-Condensate Water Interface;

3-Air Inlet; 4-Maintenance Window; 5-Purified Water Inlet Pipe Interface;

6-Concentrated Detergent Inlet Pipe Interface;

7-Concentrated Waste Liquid Pipe Interface; 8-Air Inlet

- Right side

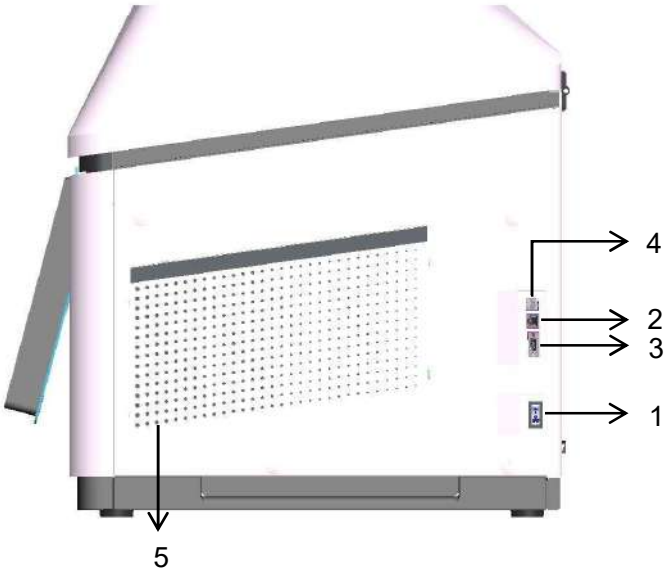


Figure 2-6 Right Side Structure

1-Main Power Switch; 2-Serial Port Interface; 3-Network Port Interface;

4-USB Interface; 5-Air Inlet;

The functions of each communication interface are as follows:

Network port: use a network cable to connect the router for LIS data transmission.

Serial port: can connect to printer or perform serial communication.

USB interface: can be connected to a USB printer, or for U disk to insert data to copy.

2.5.4. Reagent-sample processing unit

The reagent-sample processing unit is used for loading reagents and samples, sending each reagent and sample to a corresponding reagent absorption position and a sample absorption position respectively for absorption, then injecting into a cuvette for reaction, and measuring the absorbance of the reaction liquid by the photoelectric detection unit. The reagent sample processing unit is mainly composed of the following components:

- Reagent-sample tray assembly
- Reagent-sample probe assembly
- Reagent cooling system
- Sample tube
- Reagent bottle

2.5.4.1. Reagent-sample tray assembly

The reagent-sample tray assembly includes a reagent-sample tray (including a reagent-sample tray cover) and a reagent refrigeration system.

The reagent-sample tray is designed with a disc structure and is located on the left side of the analyzer table, which is used for loading sample tubes and reagent bottle. Each sample tube and reagent bottle is rotated to the corresponding sample suction position and reagent suction position respectively, waiting for the reagent-sample probe to suck.

The reagent refrigeration system is used to ensure that the reagents in the reagent bottle are always kept in a low temperature environment to keep the properties of the reagents stable and reduce volatilization. The reagent-sample tray has a 24-hour uninterrupted cooling function, which can ensure that the reagents in the reagent bottle are always stored in a low-temperature environment, ensure stable properties of the reagents, and reduce volatilization.

The following is the picture of reagent-sample tray:

Figure 2-7 Reagent-sample Tray

The reagent-sample tray is divided into inner, middle and outer circles, with a total of 80 reagent/sample positions. Among them:

- The inner circle contains 19 R1/R2 reagent positions +1 acid-base cleaning site
- The middle circle contains 19 R1/R2 reagent positions +1 acid-base cleaning site
- The outer circle is 40 sample positions

2.5.4.2. Installation of reagent-sample tray

1) Hold the handle in the middle of the reagent-sample tray by hand, and vertically lower the alignment hole under the handle to the pin position of the base.

2) Press the 2 panel fasteners on the reagent-sample tray.

2.5.4.3. Disassembly of reagent-sample tray

1) Pull out the 2 panel fasteners on the reagent-sample tray.

2) Lift the handle of the reagent-sample tray up vertically and take it out.

Warning

Before loading or removing the reagent-sample tray, it must be confirmed that all moving parts of the analyzer have stopped, such as reagent-sample probe, stirring rod, cleaning mechanism, reaction tray and reagent-sample tray.

Biological hazard

Biological pollution

Please wear gloves, work clothes to prevent infection and protective glasses as needed when operating.

2.5.4.4. Reagent-sample probe assembly

The reagent-sample probe assembly consists of a probe, a probe rocker arm, a drive shaft, a probe syringe, a cleaning basin and related fluidic components. It is mainly used to suck a specified amount of sample or reagent from a sample tube or reagent bottle and inject it into a cuvette to participate in the reaction.

2.5.4.5. Reagent-sample probe

The reagent-sample probe integrates the functions of the sample probe, the first reagent probe and the second reagent probe, and the amount of sample or reagent to be sucked depends on the type of item.

Figure 2-8 Reagent-sample Probe

1) Function

Absorb a specified amount of sample from the sample tube or R1/R2 reagent from the reagent bottle and place it in a cuvette (colorimetric cuvette).

2) Specifications

Samples: 2 ~ 50 μL, increasing by 0.5 μL each time;

Reagent: 10 ~ 400 μL, increasing by 0.5 μL each time.

3) Action

Move down and up at the following positions.

- Sample suction:

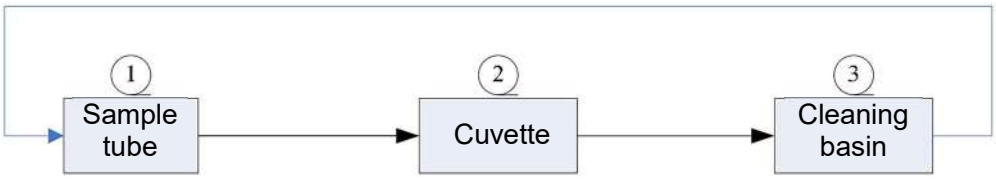


Figure 2-9 Sampling Position

- Suction reagent:

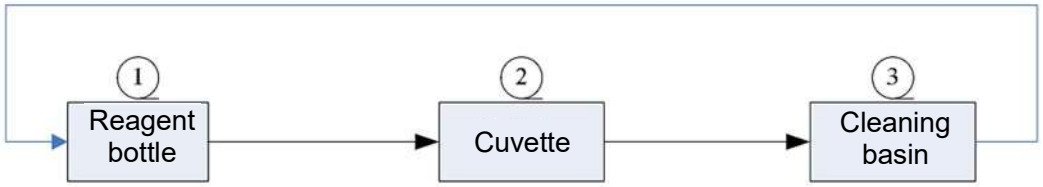


Figure 2-10 Reagent Aspiration Position

4) Fluidic component diagram

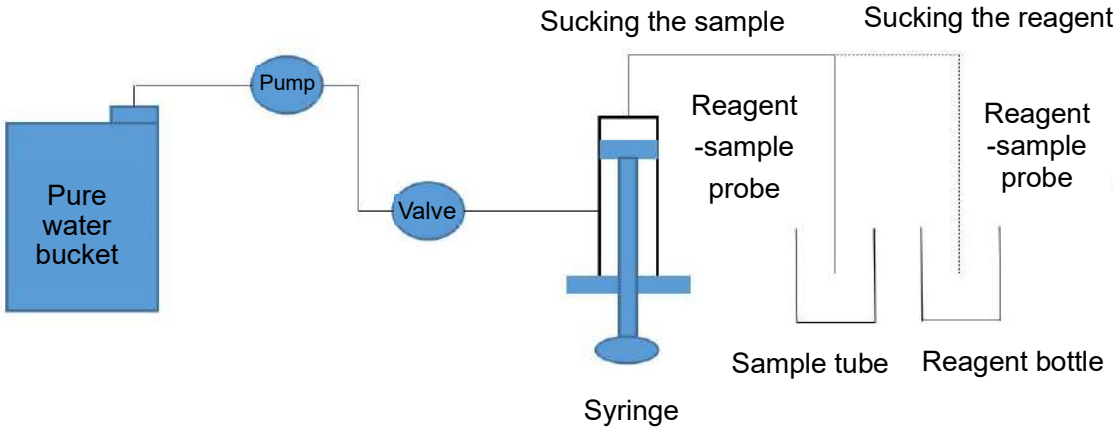


Figure 2-11 Fluidic Component Diagram

In addition to the basic sample /reagent suction functions, the reagent-sample probe also has the following functions:

- Vertical collision avoidance: it can detect obstacles in the vertical direction. In case of collision, the automatic protection system will be activated to prevent the reagent-sample probe from being damaged.
- Liquid level detection and tracking with quantity: the liquid level in the sample tube can be automatically detected and the depth falling below the liquid level can be determined according to the amount of liquid absorbed.

Warning

When the system is running, do not place your hands, other parts of your body or any obstacles on the swing path of the reagent-sample probe rocker arm, otherwise personal injury or system damage may occur.

2.5.4.6. Cleaning of reagent-sample probe

Clean the interior and outer wall of the reagent-sample probe in the cleaning basin, and the reagent-sample probe syringe can be seen by opening the maintenance window at the left rear of the analyzer.

2.5.4.7. Reagent cooling system

A cooling plate is installed at the bottom of the reagent sample cabin, which can absorb the heat inside the reagent sample cabin and radiate the heat to the outside through the air duct to achieve the cooling effect. There is a temperature sensor at the cooling plate, which will monitor the temperature of the cooling plate in real time. When the temperature drops to (2 ± 0.1) ° C, the control system will appropriately reduce the current flowing through the cooling plate according to the control algorithm, thereby reducing the power of the cooling plate. When the temperature rises, the control system will increase the current flowing through the cooling fins, thereby increasing the power of the cooling plate and stabilizing the temperature of the cooling plate at (2 ± 0.1) ° C. At the same time, insulation foam is adhered around and at the bottom of the reagent sample pot for thermal insulation. As a result, the temperature around the reagent sample tray can be maintained at 2-8 ° C, which ensures that the detection reagents are always stored in a low temperature environment, so that the environmental temperature will not affects the reagent performance if the test time is long.

2.5.4.8. Sample tube

The sample tube is used for holding samples. The sample tray supports the following sample tube types.

- Micro measuring cuvette: Φ14*25 mm, Φ12*37 mm
- Original blood collection tube/plastic test tube: Φ12*68.5 mm, Φ12*99 mm, Φ12.7*75 mm, φ12.7*100 mm, Φ13*75 mm, Φ13*95 mm, Φ13*100 mm;

Different specifications of sample tubes require different minimum sample volume. The minimum sample volume of each sample tube must be guaranteed, otherwise sample suction errors may result. If the sample volume is less than the dead volume, transfer the sample to a smaller sample tube before testing. The minimum sample volume of the sample

tube is the sum of the minimum sample volume required for the test and the dead volume of the sample tube.

2.5.4.9. Reagent bottle

Reagent bottle is used to contain reagents and is divided into 35mL and 20mL specifications.

2.5.5. Reaction unit

The reaction unit mainly consists of a reaction system and an automatic cleaning system.

2.5.5.1. Reaction system

It comprises reaction tray, cuvette and heater, wherein the reaction tray is used for placing the cuvette, and plastic cuvette is used as the cuvette, which is used as a reaction container and used for colorimetric measurement.

The heater is used to provide a constant temperature environment for the reaction. The driving part turns the cuvette to the corresponding reagent adding position, sample adding position, stirring position and cleaning position respectively.

1 Reaction tray

In the analysis process of the reaction tray, place the designated cuvette at the reagent adding position, sample adding position, stirring position or cleaning position.

The reaction tray is a single circle and can accommodate 63 plastic cuvettes.

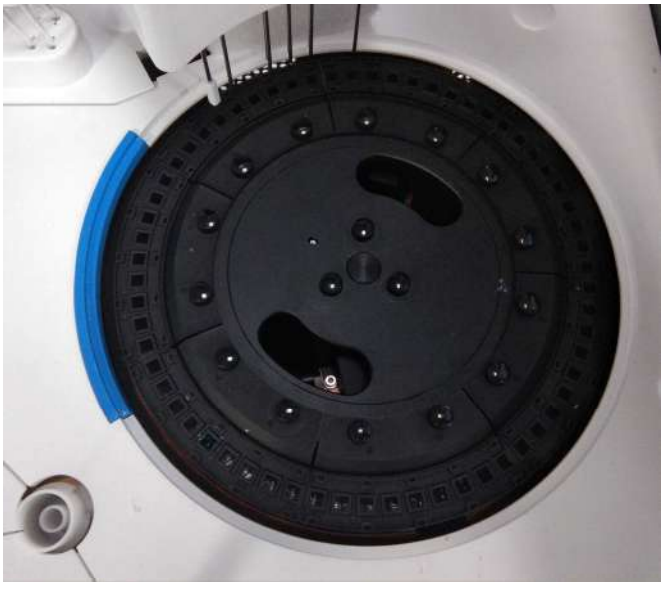


Figure 2-12 Reaction Tray

1) Function

   Load cuvette, allowing a sample and a reagent to react in a constant temperature bath at 37℃, and directly conduct colorimetric measurement through the plastic cuvette.

2) Specifications

Number of cuvette: 63

Material of cuvette: Ultraviolet transparent plastic cuvette

3) Action

Rotate anti-clockwisely

2 Cuvette

The material is plastic, and the optical diameter of each cuvette is 5 mm±0.03 mm.

After each test, the system automatically 6-steps cleans and dries the cuvette for the next test.

3 Temperature control tank

There is a heater in the temperature control tank. The heater will heat the temperature control tank before the test. There is also a temperature sensor. When the temperature is too high, the heater will automatically stop heating. When the temperature is too low, the heater will automatically continue to heat. In order to ensure that the entire temperature control tank maintains a constant temperature of 37 ° C, it provides a constant temperature platform for the reaction, effectively simulates the temperature of the human body, and ensures the accuracy of the test results.

1) Function

Keep the reaction temperature at 37°C

2) Specifications

Setting temperature: 37°C

Temperature accuracy: 37°C±0.2°C

Temperature fluctuation: ±0.1°C

2.5.5.2. Automatic cleaning system

The system supports 6-step automatic cleaning. After the test is finished, the cuvette is automatically cleaned through 6-step cleaning.

The automatic cleaning system consists of a cleaning probe, a lifting motor and related fluidic components. The lifting motor controls the cleaning probe to move up and down in each cleaning stage to complete the cleaning of the cuvette.

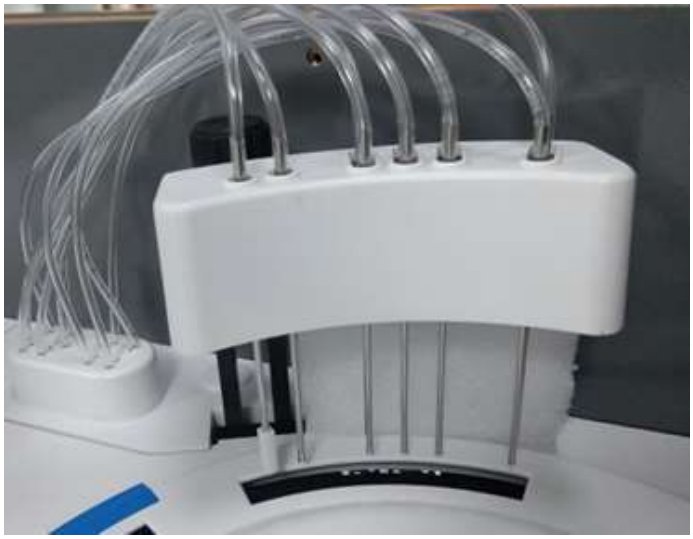


Figure 2-13 Cleaning System

1) Function

Clean the plastic cuvette after the test, suck out the reaction solution, inject purified water and concentrated detergent, and drain it.

2) Specifications

There are six cleaning heads in total, of which:

- Section 1 sucks the reaction liquid and injects purified water mixed with concentrated cleaning liquid;
- Sections 2 to 4 suck the purified water injected in the previous section and inject purified water again;
- Sections 5 and 6 suck out the remaining water droplets in the plastic cuvette.

3) Action

Move up and down in cuvette to complete the action of sucking the reaction liquid and fill concentrated cleaning liquid and purified water.

2.5.6. Mixing unit

It is mainly composed of a stirring rod and a stirring rod cleaning basin. The stirring rod is driven by the motor to stir the mixed reaction liquid in the cuvette to ensure a complete reaction. The stirring rod cleaning basin provides stirring after the reaction. The function of the rod cleaning avoids carrying pollution in the reaction or affects the accuracy of the measurement results.

1) Function

Mix the reagent and sample in the plastic cuvette (colorimetric cuvette).

2) Action

Move down, rotate and move up at the undermentioned positions.

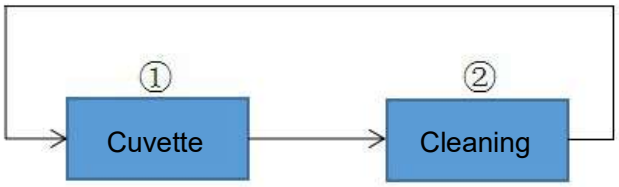


Figure 2-14 Mixing Position

Figure 2-15 Stirring Rod

2.5.7. Photoelectric detection unit

The photoelectric detection unit is used for measuring the absorbance of the reaction liquid in the cuvette and consists of an optical system and a signal detection system. Its main function is to detect the change of light intensity of light-transmitting reactant, convert the optical change signal caused by chemical reaction into electrical signal by photoelectric conversion method, and reflect the change of light intensity by detecting the change of electrical signal.

The optical system consists of a light source, an optical diameter colorimetric system and a light splitting component, and is used for providing monochromatic light with sufficient intensity and a stable and reliable colorimetric optical path structure.

The signal detection system includes photoelectric conversion part and AD acquisition and processing part. Its main function is to convert the light intensity signal of monochromatic light absorbed by the reactant and focused on the photoelectric conversion device into an electrical signal. The electrical signal is amplified and then collected by A/D to output photoelectric data reflecting the light intensity, which is then transmitted to the corresponding control unit for absorbance calculation.

1) Function

The absorbance of the reaction solution in the plastic cuvette was measured during the rotation of the reaction tray.

2) Specifications

Wavelength: 340 nm ~ 800 nm, optional wavelength

Simultaneous determination of wavelengths: simultaneous determination of one or more wavelengths

Wavelength accuracy: ±2 nm

Half wave width: 8±2 nm

Inspector: photoelectric diode

Light source: tungsten halogen lamp, 12 V 20 W, 2000 h

3) Schematic diagram

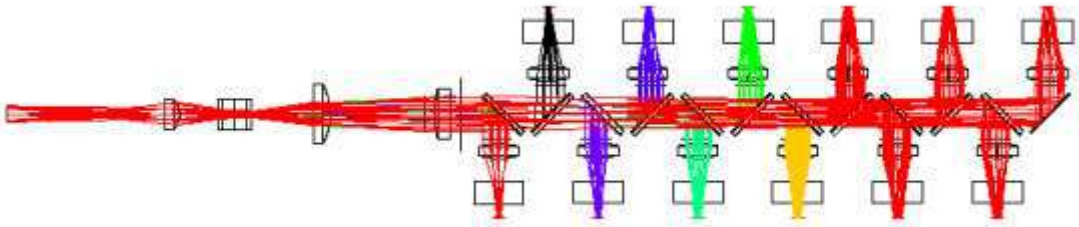


Figure 2-16 Optical Path Diagram

2.6. Software interface

2.6.1. Interface

The operation interface of EXC2X series Chemistry Analyzer includes toolbar, status bar and function display area, as shown in the following figure:

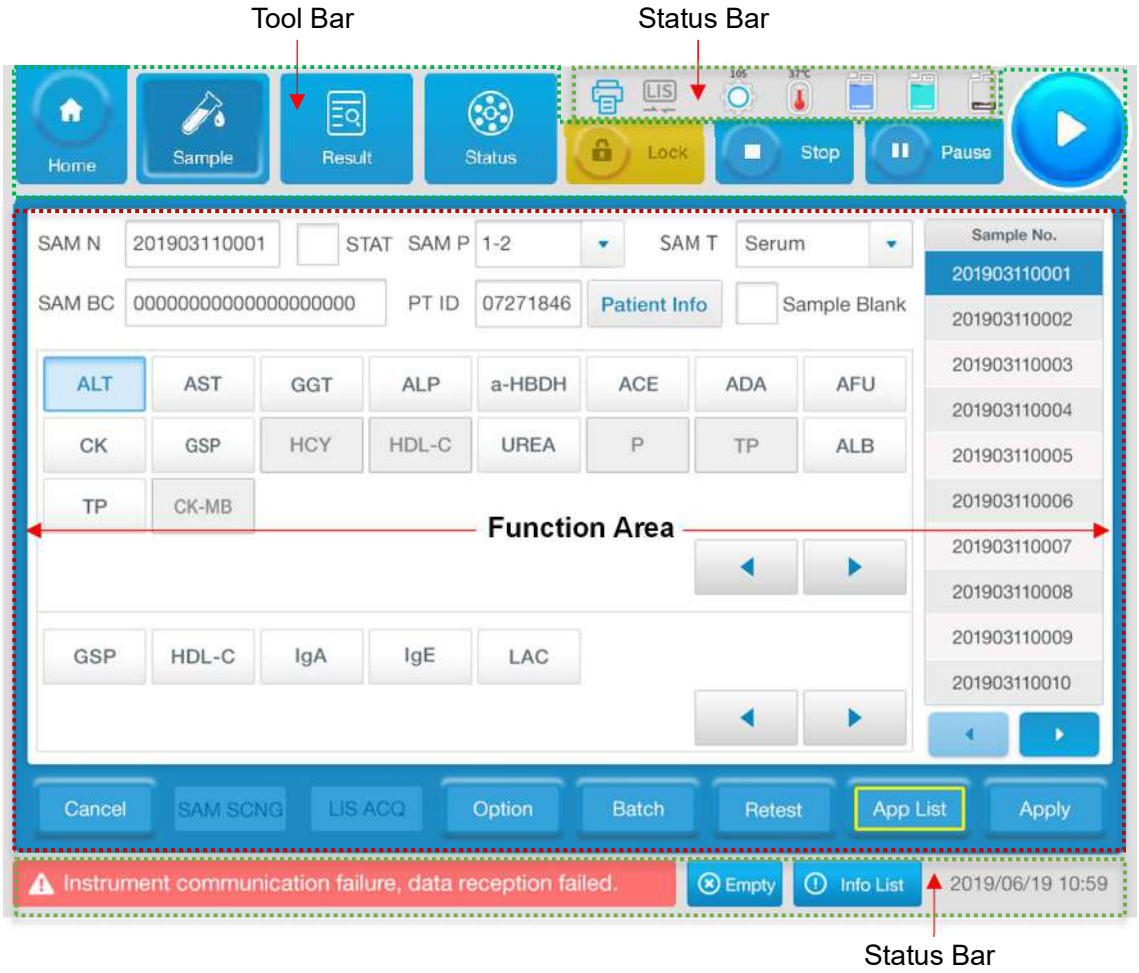


Figure 2-17 Software Operation Interface

■ Status bar

Includes status display area and alarm information display area.

(1) Status display area

It displays system status, test period, reaction tray temperature, cleaning container status, pure container status, waste container status and system time.

1) System status: When the analyzer is in the test state, the gear in the upper right corner rotates, and the number on the gear indicates the total number of running cycles of the reaction tray in the most recent test (or ongoing test);

2) Reaction tray temperature: Indicates the actual temperature of the reaction tray;

3) Printer connection status: highlighted as connected printer and gray as

unconnected printer;

4) LIS connection status: highlighted as connected LIS system, and grayed out as unconnected LIS system;

5) Cleaning container, pure water container and waste liquid container: display the state of water container;

6) System date and time: date and time are displayed in the lower right corner;

7) User: The logged-in user name is displayed in the upper left corner of the home page.

(2) Alarm information display area

When the system has error information, error information or alarm information will be displayed in the error information column. Click "**Empty**" in the function button area to clear the current error message or alarm message, and directly click "**Info List**" to enter the alarm information details page.

- Toolbar

Includes various function buttons and shortcut buttons.

(1) Function button

Used to open various function pages of the system, mainly including the following buttons:

1) Sample: Carry out patient sample test (including batch application) and support functions such as patient information input, sample position setting and sample position release.

2) Calibration: You can set calibrator information, apply for calibration test and reagent blank test, and review calibration results and reagent blank results.

3) Quality control: You can set up QC information, apply for quality control tests, review quality control results and other operations.

4) Status: Displays information about the sample tray, reagent tray, and reaction tray. In sample tray interface, you can view the sample information, release the sample position, view the reaction curve, etc. In reagent tray interface, you can set the reagent position, check the reagent information, detect the reagent volume, etc. In reaction tray interface, you can check the state of the reaction tray, the test information, the reaction curve, etc. (Note: structurally, the sample tray and the reagent tray are combined into a reagent-sample tray, which is separated in software for easy operation. The sample tray on the software interface corresponds to 40 sample positions on the outer circle of the instrument reagent-sample tray; the reagent tray corresponds to 40 reagent positions in the middle circle and the inner circle. If there is something similar below, it will not be explained again).

5) Reagent: It can be used to query reagent information, scan reagent, detect remaining volume, load and unload reagent, etc.

6) Results: Patient sample results can be reviewed, reaction curves can be viewed,

and patient information can be viewed and edited.

7) Setup: Including test setup, system setup, user setup and item setup.

8) Maintenance: Including daily maintenance and engineering maintenance. Daily maintenance consisting of periodic maintenance, trouble shooting, data backup, temperature curve, consumable status and unit status and engineering maintenance consisting of maintenance and debugging.

(2) Shortcut button

1) Start: Start all tests that have been applied for.

2) Pause: Pause the sample adding action.

3) Stop: Stop adding R1 reagent.

4) Lock: Lock the interface, and clicking other function keys is invalid.

5) Home page: Return to the home page interface with one key.

This figure shows the current alarm information before and after viewing.

This figure is to enter the fault processing and view the fault information

- Function display area

  The function interface displays after clicking the function button.

3. Basic Operation Method

3.1. Overview

This chapter describes the basic operation and daily operation process of the instrument, mainly including the following steps:

- Pre-startup check
- Startup
- Instrument status checking
- Reagent loading
- Calibration
- Quality control
- Routine testing
- Start
- Query
- Stop
- Daily maintenance
- Shutdown
- Operation after shutdown

3.2. Operation process

Operational flow

Table 3-1

Operating steps	Description
1. Pre-startup check	Check the water source, power supply, waste liquid connection, reagent-sample probe/stirring rod, and the remaining amount of concentrated cleaning liquid.
2. Startup	Turn on the power switch and start the operating software.
3. Instrument status checking	Check system status, alarm status, reagent/calibration status and maintenance status.
4. Reagent loading	Prepare chemistry reagents, detergent and diluent.
5. Calibration	Apply for calibration items, prepare calibrator and start calibration tests.
6. Quality control	Apply for QC items, prepare QC and start QC test.
7. Routine testing	Apply for routine sample tests, prepare samples and start sample tests.
8. Start	Start testing the applied items.
9. Query	Query testing status and result
10.Stop	Stop testing the applied items.
11. Daily maintenance	Clean reagent-sample tray, analyzer panel, etc.
12.Shutdown	Perform shutdown operation.
13. Operation after shutdown	Turn off power supply, dispose chemistry samples, clean instruments, clean waste liquid, etc. to ensure safe operation.

3.3. Pre-startup check

3.3.1. Water source check

1) Check whether there is enough deionized water in the external water storage container to ensure continuous water supply; if not, inject deionized water first;
2) Check that the water pipes between the water source, water inlet module and analyzer are firmly connected;
3) Check and confirm that the melt delivery tube is unblocked and free from bending, twisting, leakage, etc.

3.3.2. Power supply check

1) Check the power supply to ensure it works and can provide correct voltage;
2) Check the power cord of the instrument to make sure it is firmly connected.

3.3.3. Probe and stirring rod check

1) Check the reagent-sample probe to make sure it is free of dirt and bending.
   - If there is dirt, clean the reagent-sample probe.
   - If there is bending, replace the reagent-sample probe.
2) Check the stirring rod to make sure there is no dirt or bending.
   - If there is dirt, clean the stirring rod.
   - If there is bending, replace the stirring rod.

3.3.4. Detergent volume check

1) For the remaining amount of cleaning liquid in the acid-base cleaning position, if it is insufficient, please add or replace it in time;
2) Open the external 5L concentrated cleaning liquid barrel and check the remaining amount of concentrated cleaning liquid. If the remaining amount is insufficient, please add or replace it in time.

3.3.5. Waste connection check

1) Check whether the waste container is empty, if not, please empty the waste container;
2) Make sure that the waste pipe is not bent and the drain outlet of the sewer is not higher than 12cm.

Please dispose the waste according to the local discharge standard.

Biological hazard

3.3.6. Moving parts check

The movement of moving parts such as reagent-sample probe, stirring rod, cleaning mechanism, reaction tray, reagent-sample tray, syringe, etc. has no other interferenceand can operate smoothly and locate accuratelysmooth operation and accurate positioning.

3.4. Startup

3.4.1. Power on

Before plugging in the power cord, check whether the main switch of the instrument power supply is in the "off" state. If not, turn the switch state to the "off" state before plugging in the power cord safely.

After powering on, switch the main power switch to the “on” status, then after pressing the analysis switch, the indicator lamp will light up, and the system will be started and initialization and self-checking will be conducted. After the completion of the system startup, you will enter the login interface.

3.4.2. Login

1) Enter the user name and password in the login dialog box, and click **Login**.

Caution

1) The user name of the system administrator is "Admin" and the password is "Zybio" by default. It is recommended to change the password when using it for the first time to prevent others from using administrator privileges at will.
2) If the operator forgets his password, please contact Zybio User Services or the agent in the region.

2) Log in correctly and display the home page interface of the operating software after the instrument is normally turned on and tested. At this point, the startup process completes.

Caution

In order to ensure accurate test results, please start the test operation 30 minutes after startup to ensure stable light source and temperature control.

3.5. Instrument status check

After the startup is completed, please check the states of the instrument when necessary. Such as reagent status and maintenance alarm status. When the status of the instrument is abnormal, refer to "Maintenance and Service" and "Alarm and Treatment" for system maintenance and troubleshooting.

3.5.1. Reagent status check

1) Click the **Status**-**Reagent Tray** button in the homepage interface, then open the covers

of all reagents, and click **Residual Detection** on the software to select the corresponding reagent positions for detection.

2) When the reagent is deficient or exhausted, the corresponding reagent position is rosy.

Figure 3-1 Reagent Tray Status

3) Replace or replenish reagent according to the reagent state, and then refresh it.

3.5.2. Maintenance alarm status check

After starting up every day, it is necessary to check the maintenance status of the instrument to confirm whether any items have expired. If it expires, maintenance needs to be performed immediately to ensure the normal operation of the instrument.

Click **Maintenance-Daily Maintenance-Periodic Maintenance** to confirm whether any items have expired.

3.6. Reagent preparation

After checking the status of the instrument and performing the pre-test inspection, it is necessary to prepare the reagents used for the very day. Items that are not loaded with reagents can be applied for, but cannot participate in the test. In the standby mode, the instrument must be woken up before loading reagents.

3.6.1. Reagent preparation

When loading reagent, first open the reagent-sample tray, and then put the reagent in correct position. There is no special requirements for reagents and the instrument is suitable for all biochemical reagents on the market. With the open system, users can set or import items by themselves.

Biological hazard

Please be sure to wear gloves and work clothes to prevent infection, wear protective glasses when necessary, and do not directly contact with reagents, otherwise skin damage or inflammation may occur.

3.7. Concentrated detergent preparation

The concentrated detergent is normally alkali with the PH more than 8.5 and is used to clean the cuvette and can only be loaded manually. When loading it, the bottle cap should be opened, the float sensor should be removed, and then the cap and sensor should be installed in the newly opened concentrated cleaning liquid barrel.

3.8. Probe detergent preparation

The probe detergent is normally alkali with the PH more than 8.5 and is used to clean the reagent-sample probe and can only be loaded manually. When the detergent exceeds the validity period or the volume is insufficient, please add or replace the detergent immediately.

Attention

Before loading the probe detergent, make sure there are no bubbles in the reagent bottle to avoid affecting the cleaning effect.

3.9. Diluent preparation

For dilution items, sample diluent is required and can only be loaded manually. The sample diluent is normally saline. You only need to set the dilution ratio according to the dilution factor when testing.

3.10. Calibration

Calibration tests are used to calculate calibration parameters, thus participating in the calculation of sample results.

In general, calibration tests are recommended when any of the following occurs:

- Add a new item
- When reagents, calibrators and QC are still within the validity period, the QC test fails
- Change reagent lot number or bottle number

- The items has exceeded the validity period of calibration
- The calibration rules have been modified, including calibration method, number of repetitions, concentration of calibrators and calibrators used
- The light source lamp, syringe, reagent-sample probe, etc. have been replaced

Calibration must be performed if the following parameters are modified:

- Primary wavelength
- Sub-wavelength
- Blank time
- Reaction time
- Reagent volume
- Sample volume
- Analytical method
- Reaction direction
- Sample blank and result unit
- Intercept
- Two items tested in the same test

Warning

Repeated calibration tests are impossible to damage equipment and reduce protection against danger.

3.10.1. Calibrator preparation

Prepare the calibrator in advance and only load it manually. The calibrator has no special requirements and is suitable for calibrator produced by all manufacturers on the market. Note that the calibrator must be within the validity period of the bottle opening.

3.10.2. Calibration application

Apply calibration according to the items

When any of the above occurs, please apply for calibration according to the following steps.

Before applying for calibration of chemistry items, ensure that the calibrators have been set correctly.

3.10.2.1. Setting of calibrator

In the homepage interface, select **Calibration**-**Cal Setting** to enter the setting interface shown in the figure below, and set the information such as the location, concentration, validity period and batch number of calibrator.

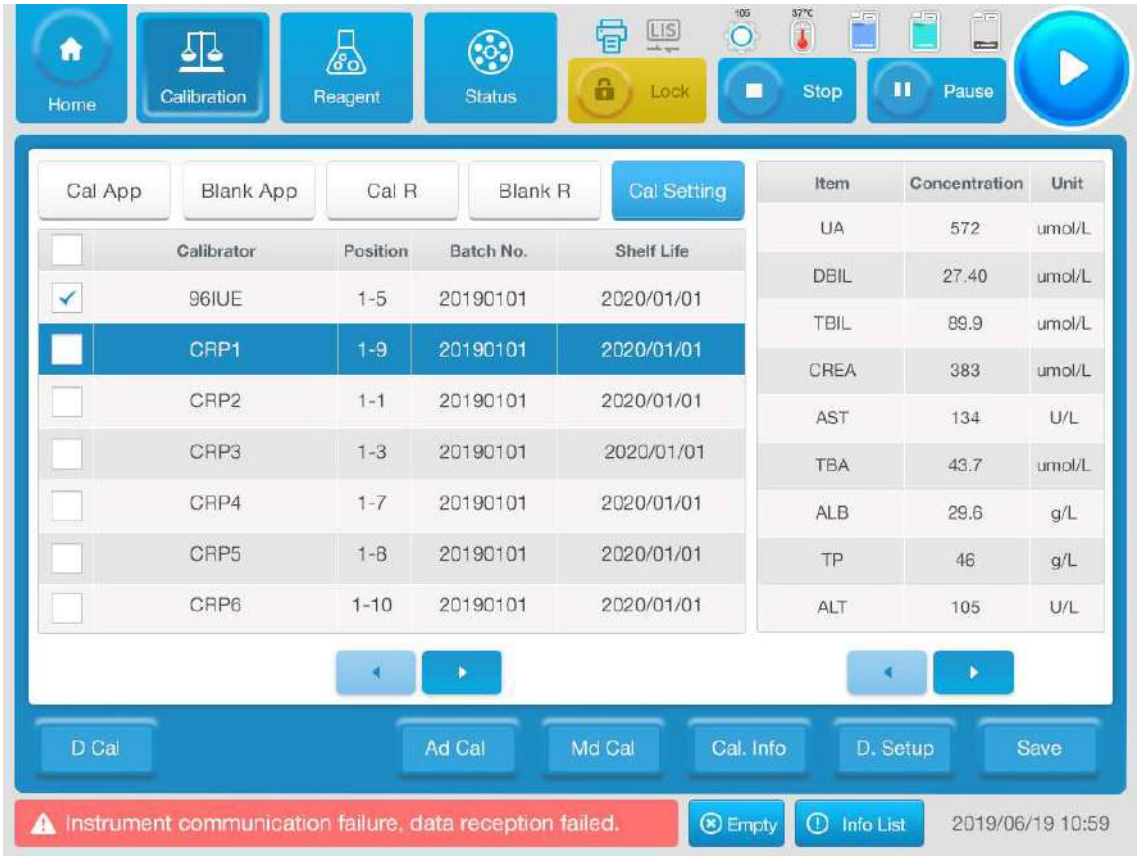


Figure 3-2 Calibration Setting

Basic interpretation of parameters

Parameter	Meaning	Operation
Cal App	Apply for calibration	Click to enter the "Calibration Application" interface
Blank App	Apply for reagent blank	Click to enter the "Blank Application" interface
Cal R	Review calibration results	Click to enter the "Calibration Result Review" interface
Blank R	Review blank test results	Click to enter the "Blank Result Review" interface
Cal Setting	Set the parameter of calibrator	Click to enter the “Calibrator Setting” interface
Select	Select calibrator	Click once to select and click again to repeal
Calibrator	Name of calibrator	No operation required
Position	Tray number and position of calibrator	No operation required
Batch No.	Batch number of calibrator	No operation required

Parameter	Meaning	Operation
Shelf Life	Effective date of calibrator	No operation required
Item	Item name	No operation required
Concentration	Set the concentration of calibrator corresponding to the current item	Directly input
Unit	Concentration unit	No operation required
Ad Cal	Add calibrator	Click to enter the "Add Calibrator" interface
Md Cal	Modify calibrator setting information	Click to enter the "Modify Calibrator" interface
D Cal	Remove the calibrator from the list	Directly click
Cal. Info	Set calibrator information	Click to enter the "Calibration Information" interface
D. Setup	Set calibration dilution parameters	Click to enter the "Calibration Dilution Setup" interface

Basic operation

- Add calibrator

  1) Click **Ad Cal** to open the "Add Calibrator" interface;

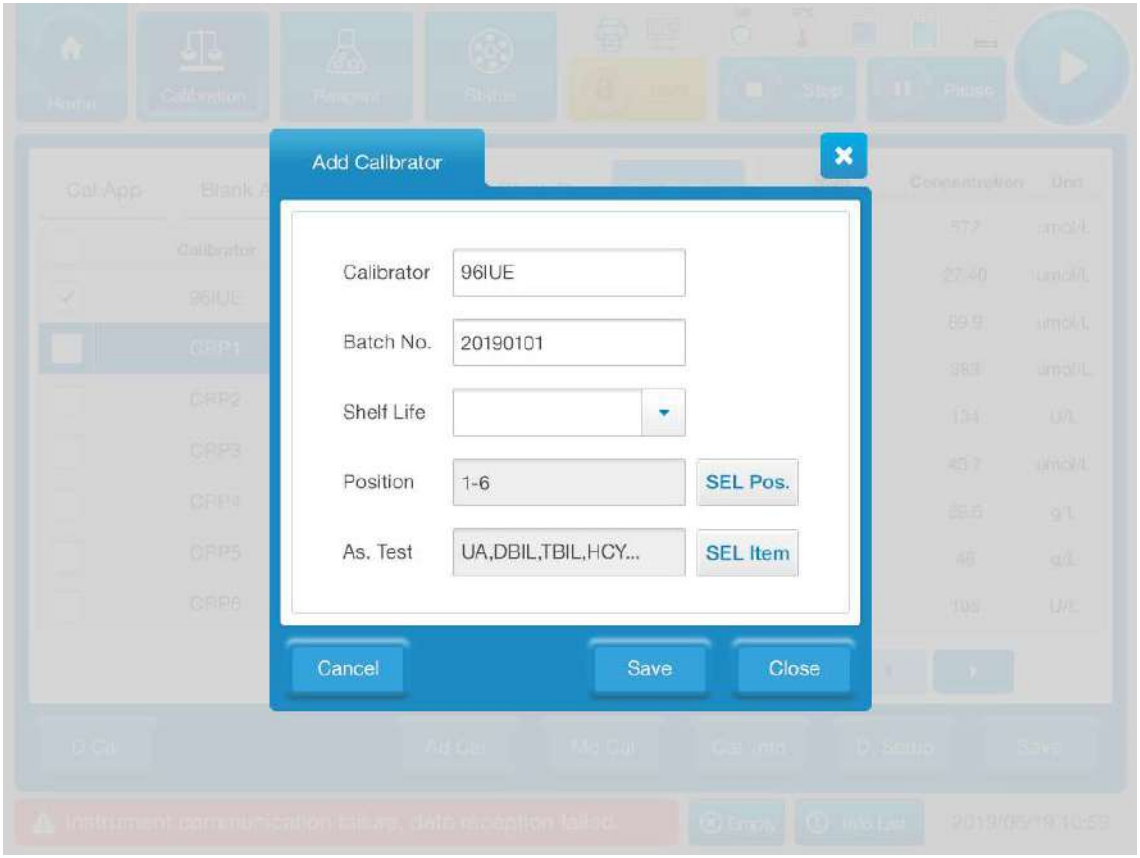


Figure 3-3 Add Calibrator

2) Enter the name and batch number of calibrator;

3) Drop down to select the validity period of calibrator;

4) Click **SEL Pos.** , select the tray number and cuvette number in the pop-up dialog box, and click **OK**;

5) Click **Item**, select the corresponding item in the pop-up dialog box, and then click **OK**;

6) To save the added calibrator, click **Save**, otherwise, click **Cancel**.

■ Set the concentration of calibrator

1) Select (click to select a row, not select some of them) the calibrator which needs to set concentration in the "Calibrator List";

2) Enter the concentration value of calibrator in the concentration column behind the corresponding item name in the "Concentration List";

3) To save the set calibrator concentration, click the **Save** button.

■ Modify calibrator

1) Select the calibrator to be modified in the calibrator list, and calibrator information is not allowed to be modified during testing;

2) Click **Md Cal** and enter the corresponding contents in the pop-up dialog box. The

operation method is the same as "Add Calibrator";

3) To save the modified content, click **OK**, otherwise, click **Cancel**.

- Delete calibrator

1) Check the calibrator to be deleted in the "Calibrator List";

2) Click **D Cal** to open a prompt box;

3) If you are sure to delete it, click **OK**, otherwise click **Cancel**.

- Calibration information

1) Click **Cal. Info** to open the "Calibration Information" interface;

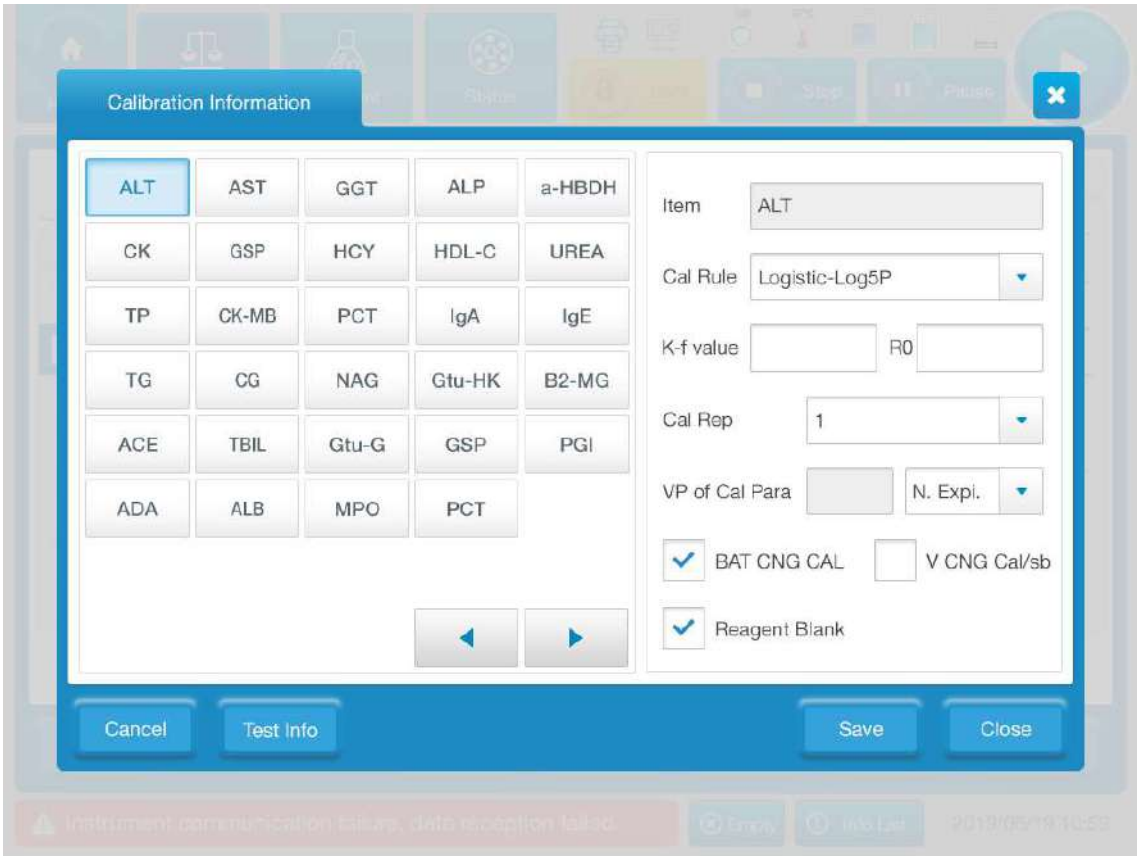


Figure 3-4 Calibration Information

2) Select the item to set calibration information in the item list;

3) Select the corresponding calibration rule from the "Cal Rule" drop-down list, and select "V CNG Cal", "V CNG Cal/sb" or “Reagent Blank” as required;

4) Click the **Test Info** button to set calibration detection information;

5) After confirming that the information is correct, click **Save**, otherwise click **Cancel**.

3.10.2.2. Calibration application

Click **Cal App** button to enter the calibration application interface shown in the figure below

to perform calibration test application, reagent blank application and other operations.

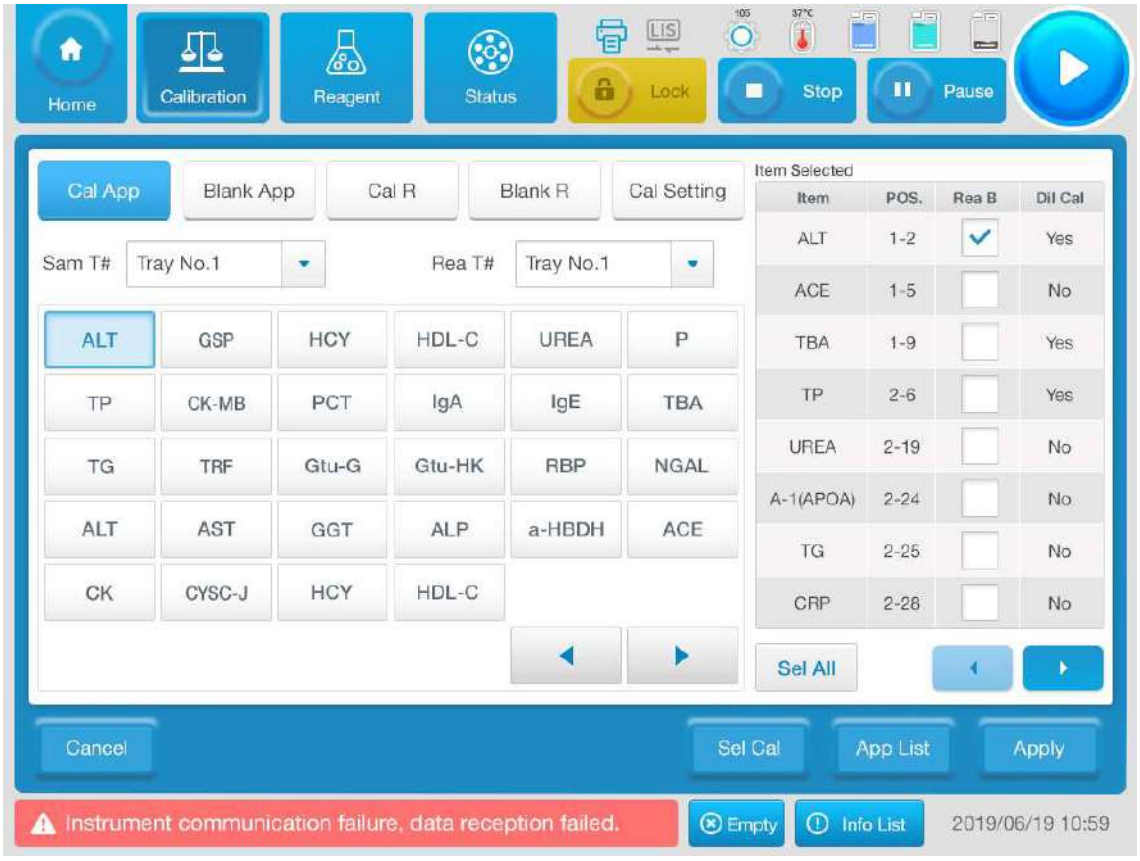


Figure 3-5 Calibration Application

Basic interpretation of parameters

Parameter	Meaning	Operation
Sam T#	Select the tray number where the sample is located	Drop-down selection
Rea T#	Select the tray number where the reagent is located	Drop-down selection
Item	The name of the item selected in the “Item List”	No operation required
Rea B	Check for reagent blank	Click to check or uncheck
Dil Cal	Calibrate the diluent or not	No operation required

Parameter	Meaning	Operation
Sel Cal	Select the calibrator corresponding to a certain item	Click to enter the "Select Calibrator" interface
App List	View the list of items for which calibration has been applied	Click to enter the "Calibration Application List" interface

Basic operation

- Apply for calibration

  1) Click **Calibration-Cal App**;

  2) Drop down to select the tray numbers where the calibrator and reagent are located, respectively;

  3) Select the item to be calibrated in the list of items on the left. If the reagent blank test is required at the same time,check the reagent blank in the "Item Selected" on the right and select as ;

  4) Select a row in "Item Selected" and click **Sel Cal** to open the "Select Calibrator" interface. You can check the calibrator required for calibration of this item and click **Save-Close** to return to the calibration application main interface;

  5) To save the applied calibration, click **Apply**, otherwise, click **Cancel**.

- Delete calibration application

  1) Click **App List** to open the "Calibration Application List" interface:

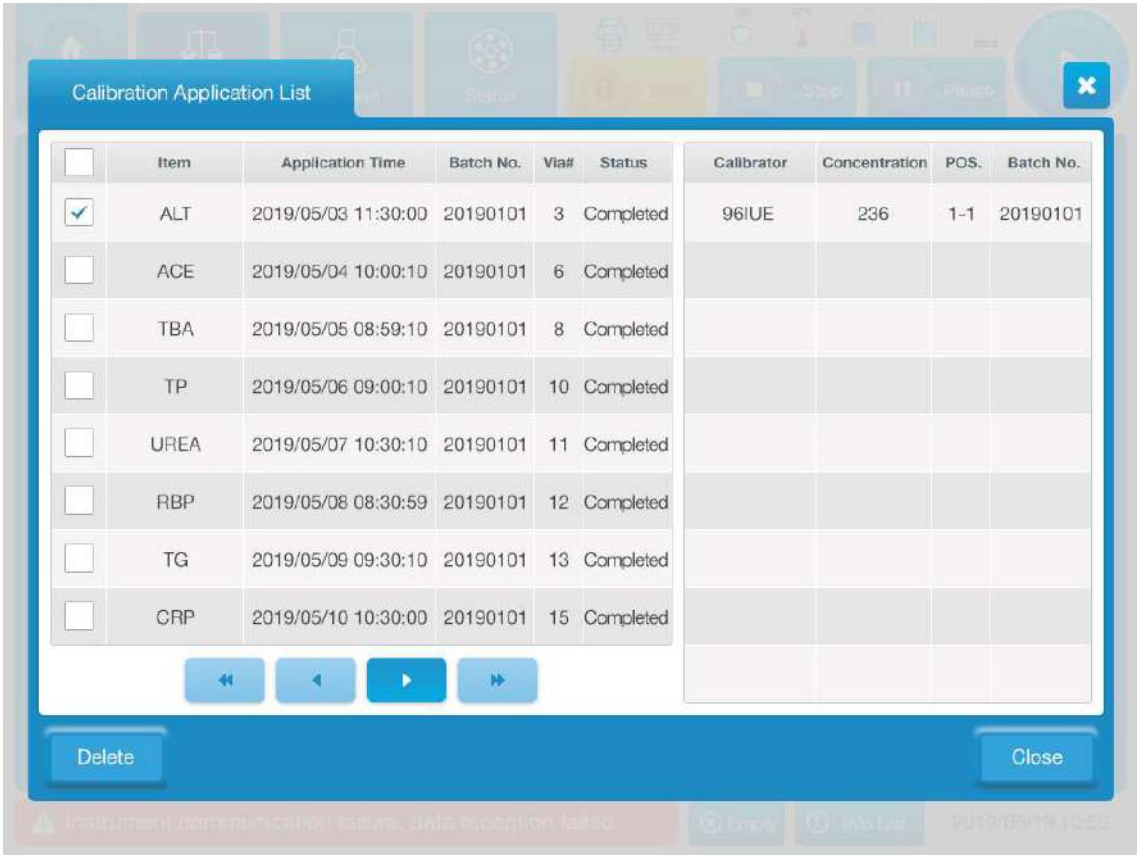


Figure 3-6 Calibration Application List

2) Select the calibration items to be delete, click **Delete**, otherwise, click **Close**.

3.10.2.3. Calibration results

Click the **Cal R** button to enter the calibration result interface, and perform operations such as querying calibration results and querying calibration curves.

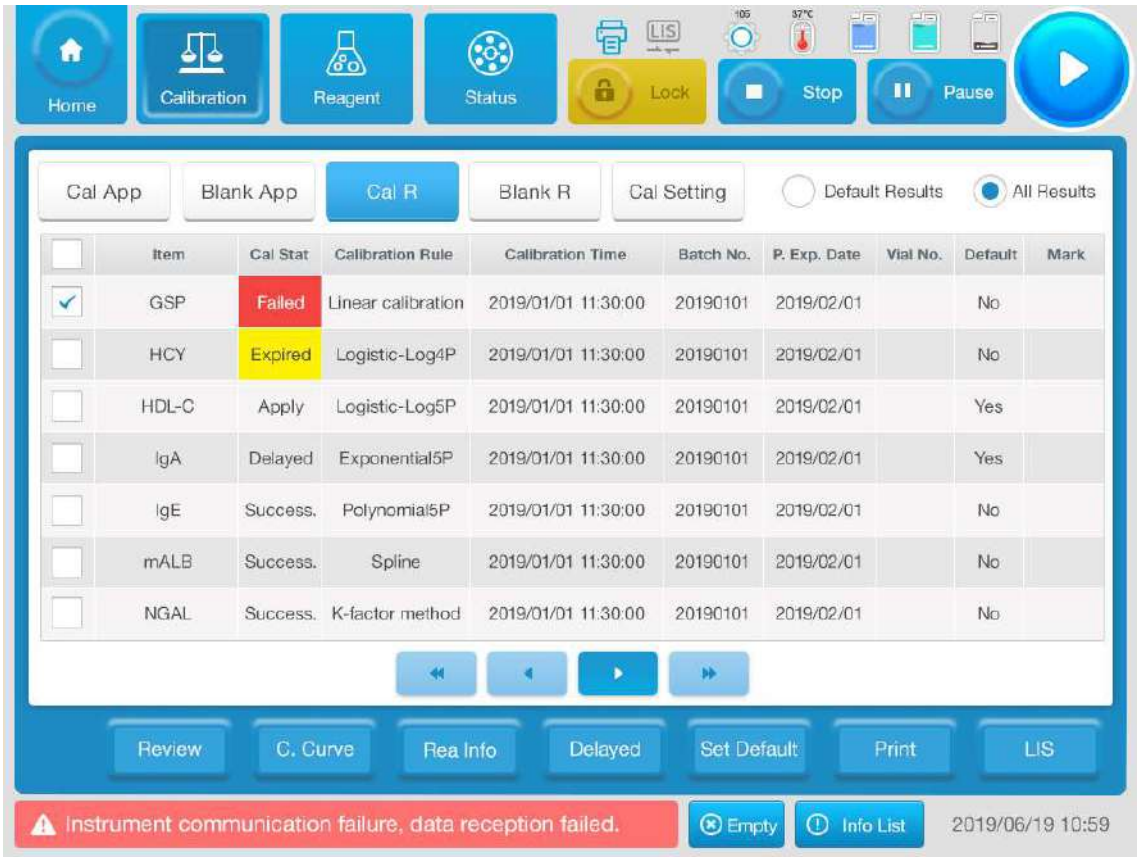


Figure 3-7 Calibration Results

Basic interpretation of parameters

Parameter	Meaning	Operation
Item	Name of calibration item	No operation required
Cal Stat	Calibration status, including success, failure, expiration and extension	No operation required
Calibration Rule	Mainly includes linear calibration, Logistic-Log4P, Logistic-Log5P, Exploratory 5P, Polynomial5P, Spline and K factor method	No operation required
Calibration Time	The time when the calibration starts	No operation required

Parameter	Meaning	Operation
VP of Cal Para	Shelf life of calibration parameters	No operation required
Default	The calibration result is default	No operation required
Mark	Marking of calibration items, including expired calibrator "ECF", expired reagent "ER"and recalculation of calibration results "#"	No operation required

Basic operation

- Review calibration results

  1) Click **Review** to pop up the calibration result review interface;

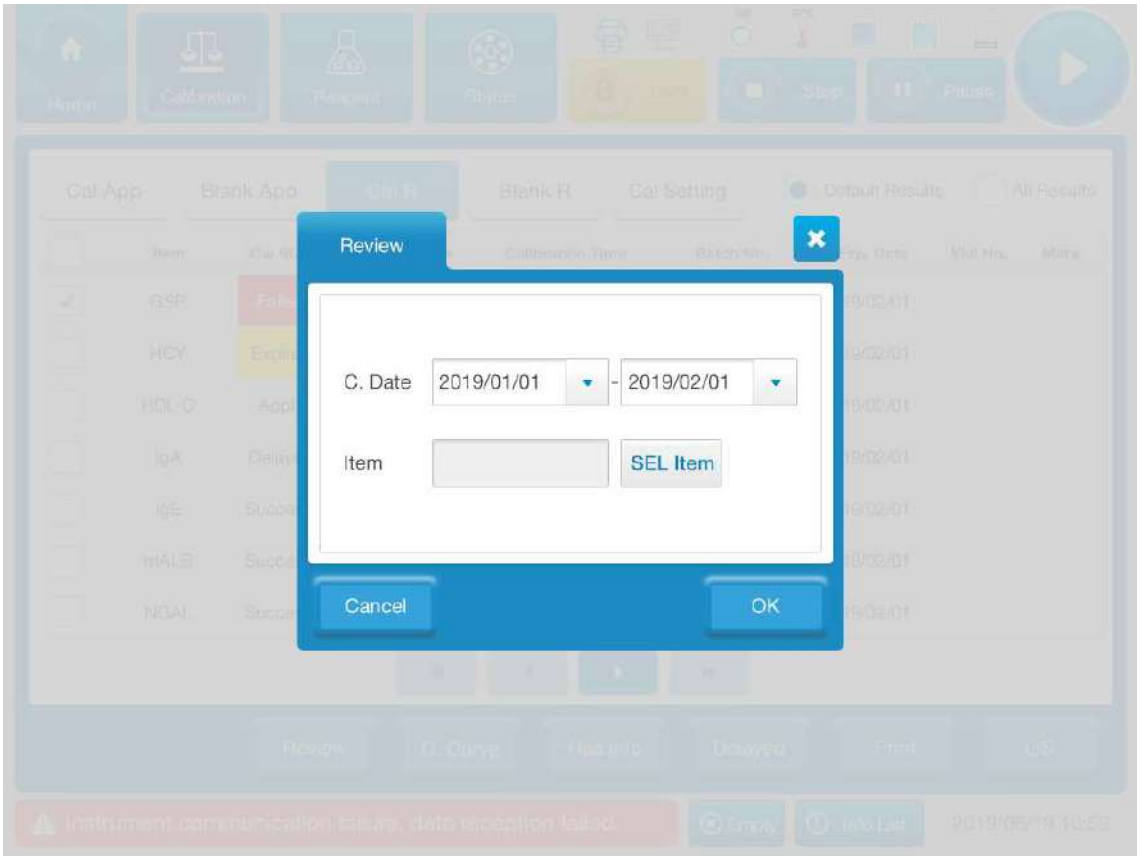


Figure 3-8 Calibration Result Review

  2) Select the items to review results, and drop down to select the calibration date;

  3) Click the **OK** button.

- View calibration curve

  1) Check the items need to view in the “calibration result” interface, and lick **C. Curve** to enter the "Calibration Curve" interface, as shown in the following figure;

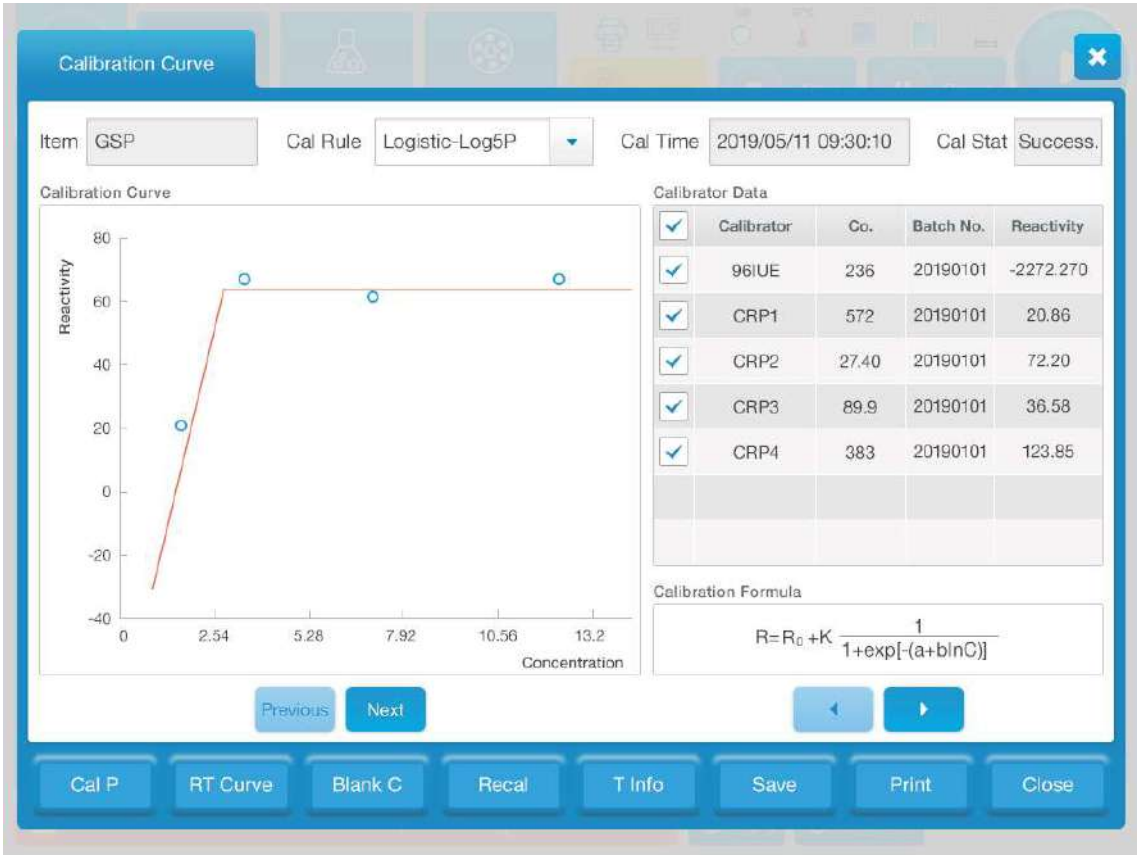


Figure 3-9 Calibration Curve

2) Check the calibration liquid in the "Calibrator Data" on the right and click the **RT Curve** button to view the reaction curve of the calibration liquid;

3) Click **Cal P** to view or modify the calibration parameters in the pop-up window;

4) Click **Blank C** to open the "Blank Correction" interface, drop down to select the test date, click **Query**, then select the reagent blank required for the item, click **Correction** to complete the correction, otherwise click **Close**;

5) After the calibration rule is changed or the selected calibrator is changed in "Calibrator Data", click the **Recal** button to refresh the calibration curve and recalculate the calibration parameters at the same time;

6) If you want to view the calibration detection information, click the **T Info** button;

7) Click the **Save** button to save the changes;

8) Click the **Print** button to print the calibration curve;

9) Click the **Close** button to close the calibration curve interface.

■ View reagent information

1) Select an item in the calibration results list;

2) Click **Rea Info** to view the reagent type, batch number, vial number and other information of the item.

- Delayed

  1) Check one or more items;

  2) Click **Delayed** to open the "Delay of Calibration Parameters" interface:

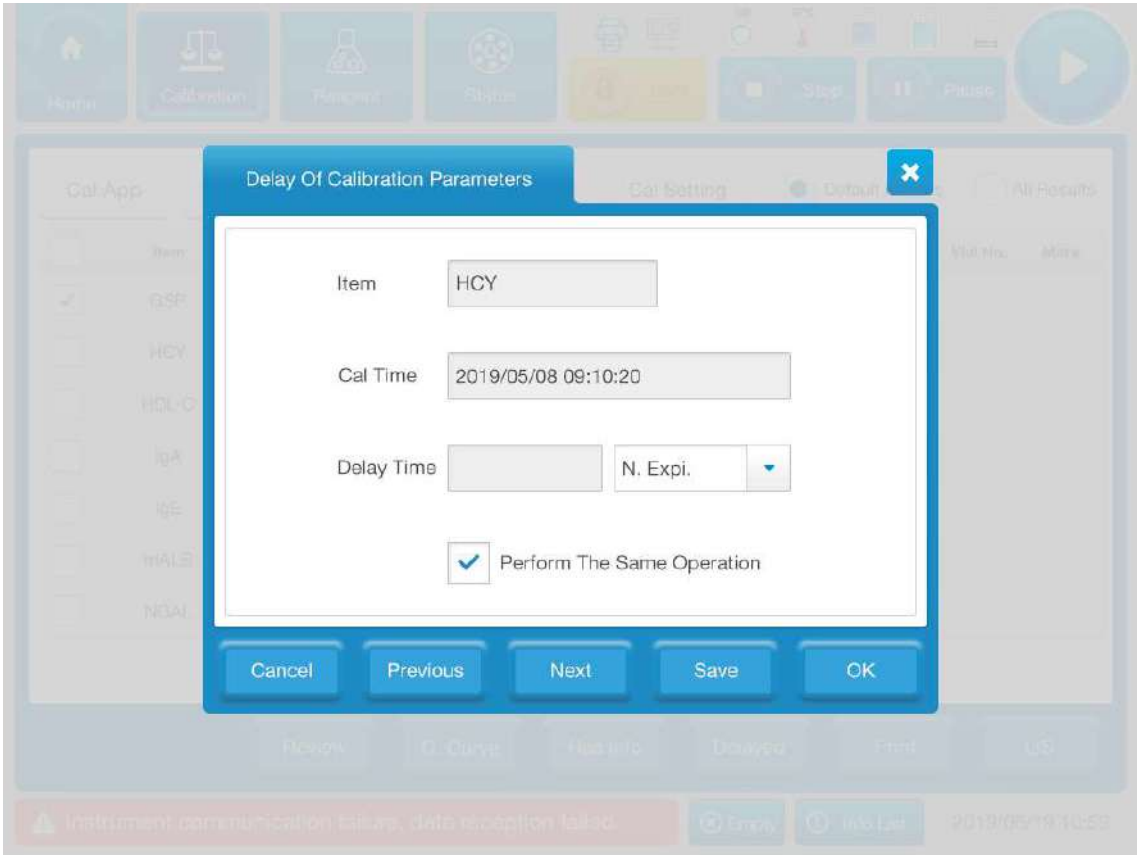


Figure 3-10 Calibration Parameter Extension

  3) The extension time can be set by dropping down. The ‘‘Delay Time’’ plus the previously set "VP of Cal Para" is the latest calibration parameter validity period.

- Set default

  1) Click "All Results" to switch to "All results" interface

  2) Select an item in the calibration results list;

  3) Click **Set Default** to set the calibration result as the default results.

- Print

  1) Select an item;

  2) Click **Print** to print the selected result or all the results in the pop-up dialog box.

- LIS transmit

  1) Select an item;

  2) Click **LIS** to send selected results or all results in the pop-up dialog box.

3.10.2.4. Reagent blank

Basic operation

■ Apply reagent blank

1) Select **Calibration-Blank App** to enter the "Blank Application" interface, as shown in the following figure;

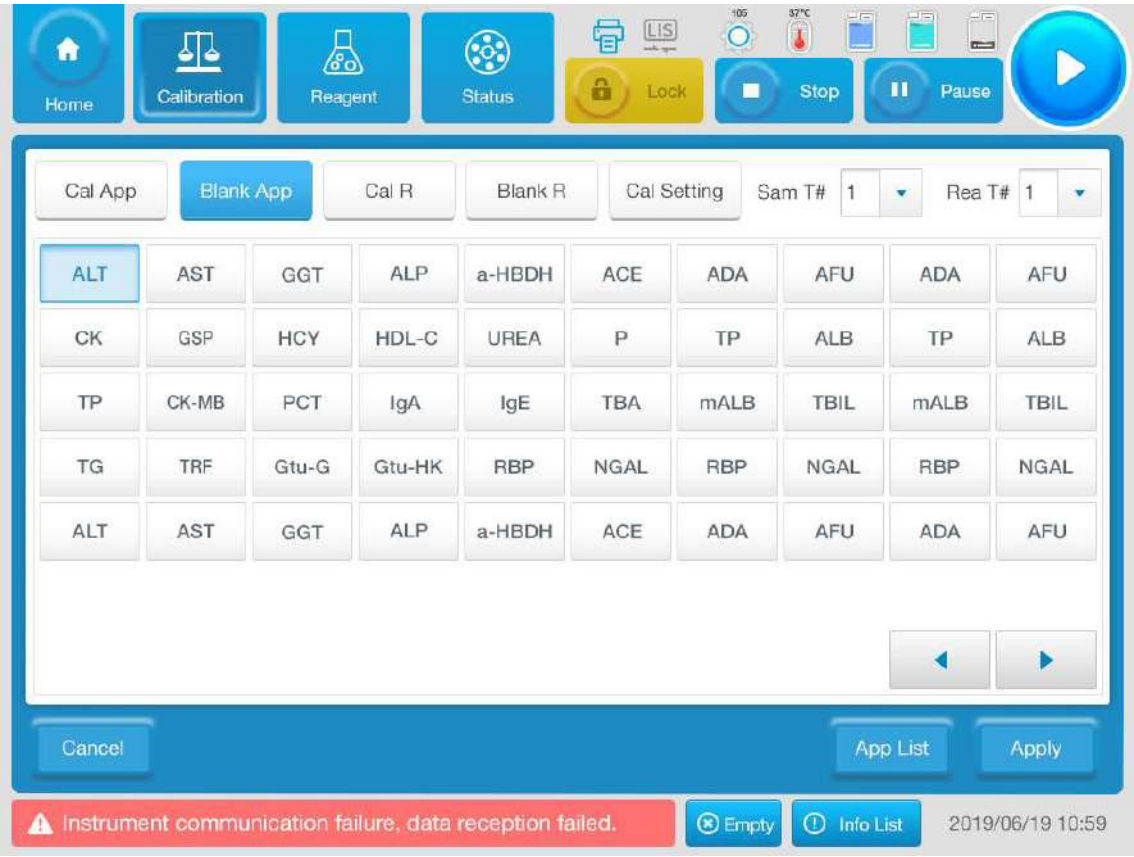


Figure 3-11 Blank Application

2) Select reagent blank test items from the list;

3) To save the applied reagent blank test, click **Apply**, otherwise, click **Cancel**.

■ Delete reagent blank

1) Click **Blank App-App List** to open the following dialog box;

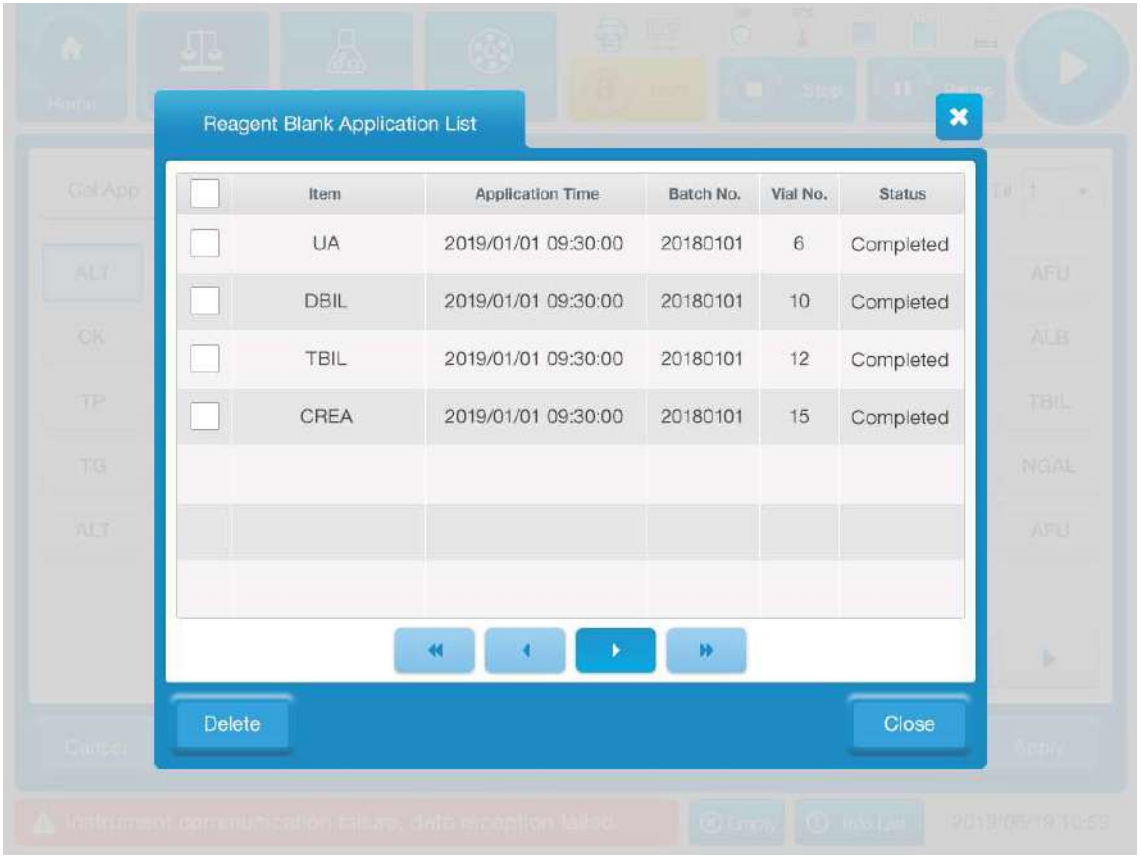


Figure 3-12 Reagent Blank Application List

2) Select the reagent blank items to be deleted;

3) If you are sure to delete the selected reagent blank items, click **Delete**, otherwise, click **Close**.

3.10.2.5. Blank result

Click **Blank R** to enter the blank result interface for querying reagent blank results and querying reagent blank reaction curves.

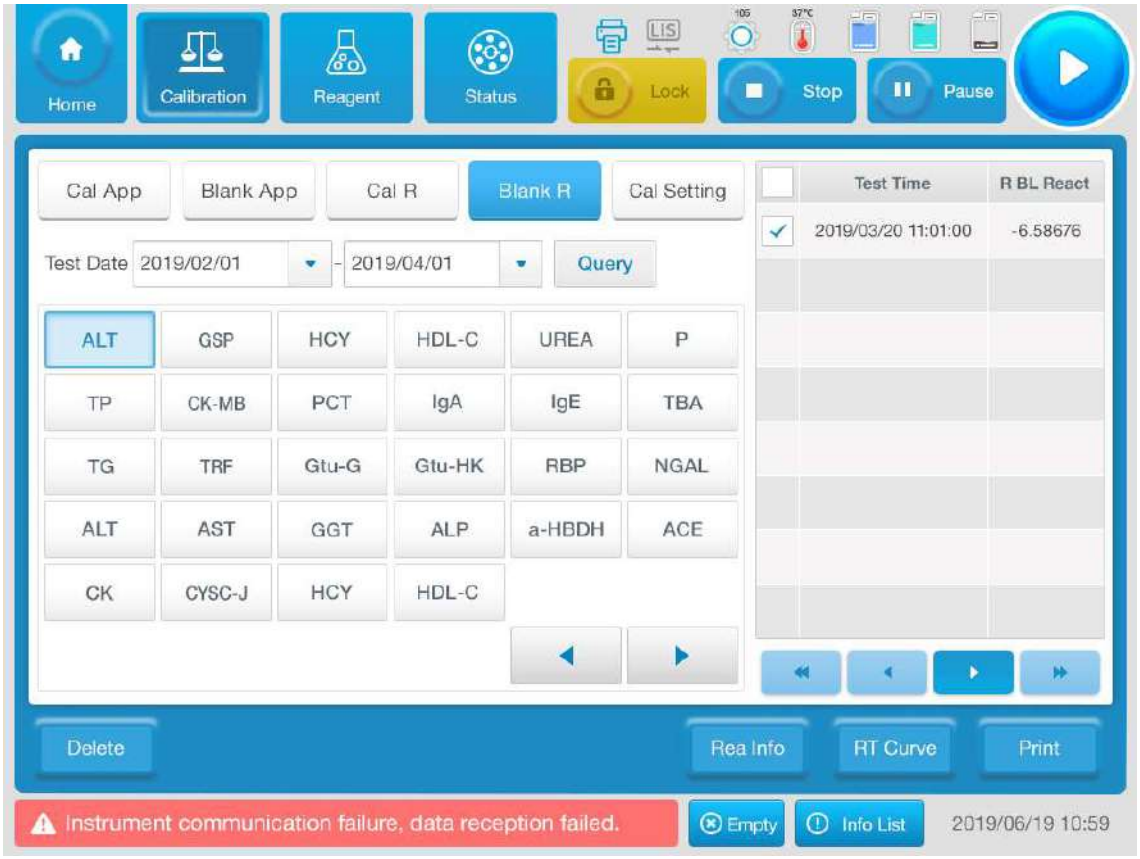


Figure 3-13 Blank Result

Basic operation

- Review blank result

  1) Select the test date from the drop-down list, and click **Query**;

  2) If an item is selected in the list on the left, the test time and reagent blank reactivity of the item will be displayed on the right.

- Reagent information

  1) Check one item in the list on the right of blank result;

  2) Click **Rea Info** to view the reagent type, batch number, and bottle number of the item in the pop-up reagent information interface;

  3) Click **Previous** or **Next** to switch to display different reagent information.

- Review blank reaction curve

  1) Check the blank result of a reagent on the right;

  2) Click **RT Curve** to open the blank reaction curve interface.

Figure 3-14 Blank Reaction Curve

- Delete reagent blank results

  1) Select the blank result of a reagent on the right;

  2) Click the **Delete** button.

- Print reagent blank results

  1) Select the blank result of a reagent on the right;

  2) Click the **Print** button.

3.11. Quality control

As the quality control results can ensure the accuracy of the sample test results, it is recommended to carry out quality control tests every day.

3.11.1. Quality control preparation

Prepare quality control in advance and it can be only be loaded manually. There is no special requirement for the quality control, and it is suitable for the quality control produced by all manufacturers on the market. Note that the quality control must be used within its expiration date.

3.11.2. Quality control application

It is allowed to apply for quality control tests according to the QC. You can apply for quality control tests through items or combined items. You may select at least one item, otherwise it is not allowed to apply. If you don't set the mean and standard deviation, it is not allowed for QC test.

3.11.2.1. Setting of control

Select **QC**- **QC Setting** to enter the following interface:

Figure 3-15 Quality Control Setting

Basic interpretation of parameters

Parameter	Meaning	Operation
QC	Name of QC	No operation required
Batch No.	Batch number of QC	No operation required
POS.	The tray number and cuvette number of the sample	No operation required
Sample type	Type of sample	No operation required
Shelf Life	Shelf life of QC	No operation required
Item	Item name	No operation required
M	The QC corresponds to the mean value of each item that QC corresponds to	Enter directly in the box
SD	Standard deviation of each item that QC corresponds to	Enter directly in the box
Unit	A unit of quality control results	No operation required
Save	Save QC information	Directly click
Ad QC	Add QC	Directly click
Md QC	Modify QC setting	Directly click
D QC	Remove the QC from the list	Directly click
QC Rrules	Setup QC rules for the item	Directly click

Basic operation

- Add new QC

  1) Click **Ad QC** to open the ‘Add QC‘ interface:

Figure 3-16 Add QC

2) Enter the name and batch number of the QC;

3) Drop down to select the sample type and validity period of the QC;

4) Click **SEL Pos.** , select the tray number and cuvette number in the pop-up dialog box, and click **OK**;

5) Click **SEL Item**, select the corresponding items in the pop-up dialog box, and then click **OK**;

6) To save the added QC, click **Save**, otherwise, click **Cancel**.

■ Set the mean and standard deviation of the QC

1) Select a row in the "QC List" on the left;

2) Enter the mean value of the QC in the mean value column after the corresponding item name in the "Concentration List" on the right, and enter the standard deviation of the QC in the standard deviation column;

3) To save the set QC mean and standard deviation information, click the **Save** button.

■ Modify quality control

1) Select the QC to be modified in the "QC List" and it is not allowed to modify the information of the QC during the instrument test;

2) Click **Md QC** and enter the corresponding contents in the pop-up dialog box. The operation method is the same as "Add QC";

3) To save the modified content, click the **Save** button.

- Delete QC

1) Select the QC to be deleted from the QC List;

2) Click the **D QC** button to pop up a prompt box;

3) If you are sure to delete, click **OK**, otherwise, click **Cancel**.

- Set quality control rules

1) Click **QC Rules** to enter the quality control rules setting interface:

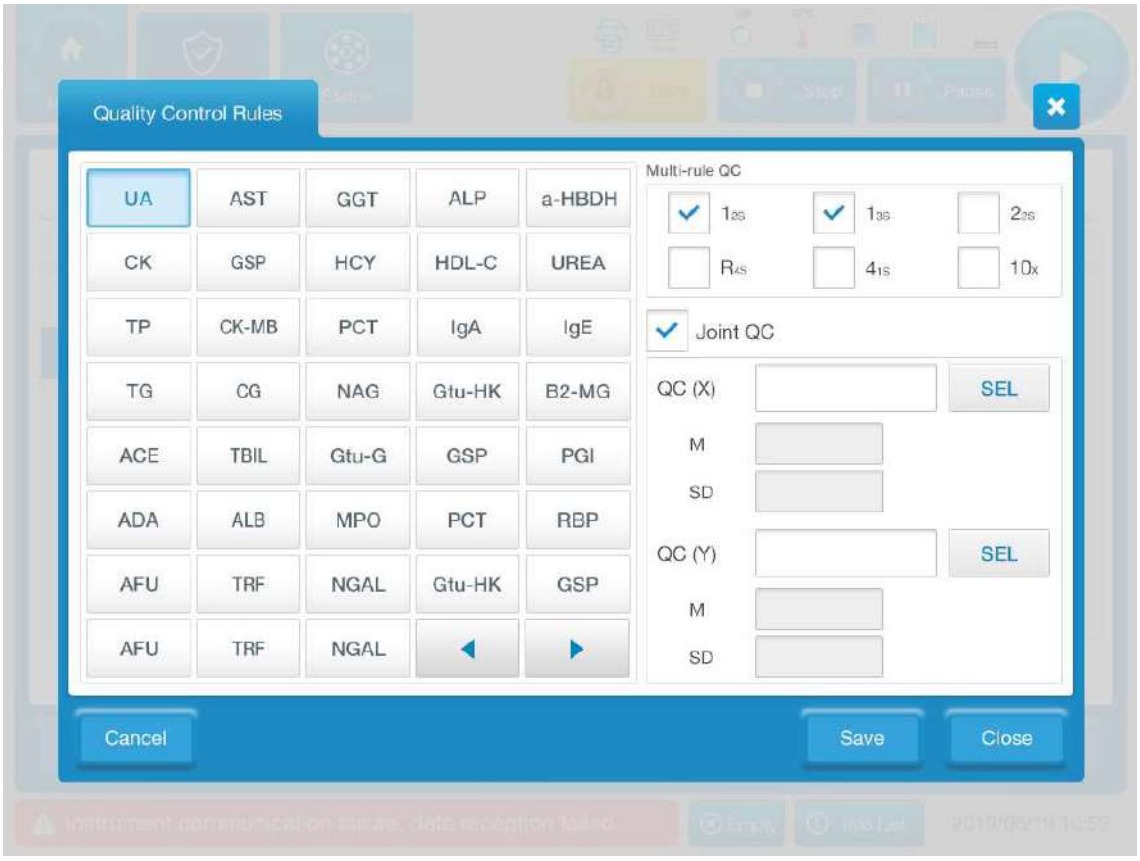


Figure 3-17 QC Rule

2) Click to select an item on the left, and check the quality control rules in the "Multi-rule QC" on the right;

3) If you want to carry out joint quality control, you need to select both QC (X) and QC (Y);

4) If you don't want to carry out joint quality control, you don't need to select either QC (X) or QC (Y), and you can directly click the **Save** button;

5) Click **Close** to exit the interface.

3.11.2.2. Application for quality control

Click the **QC App** button to enter the following quality control application interface:

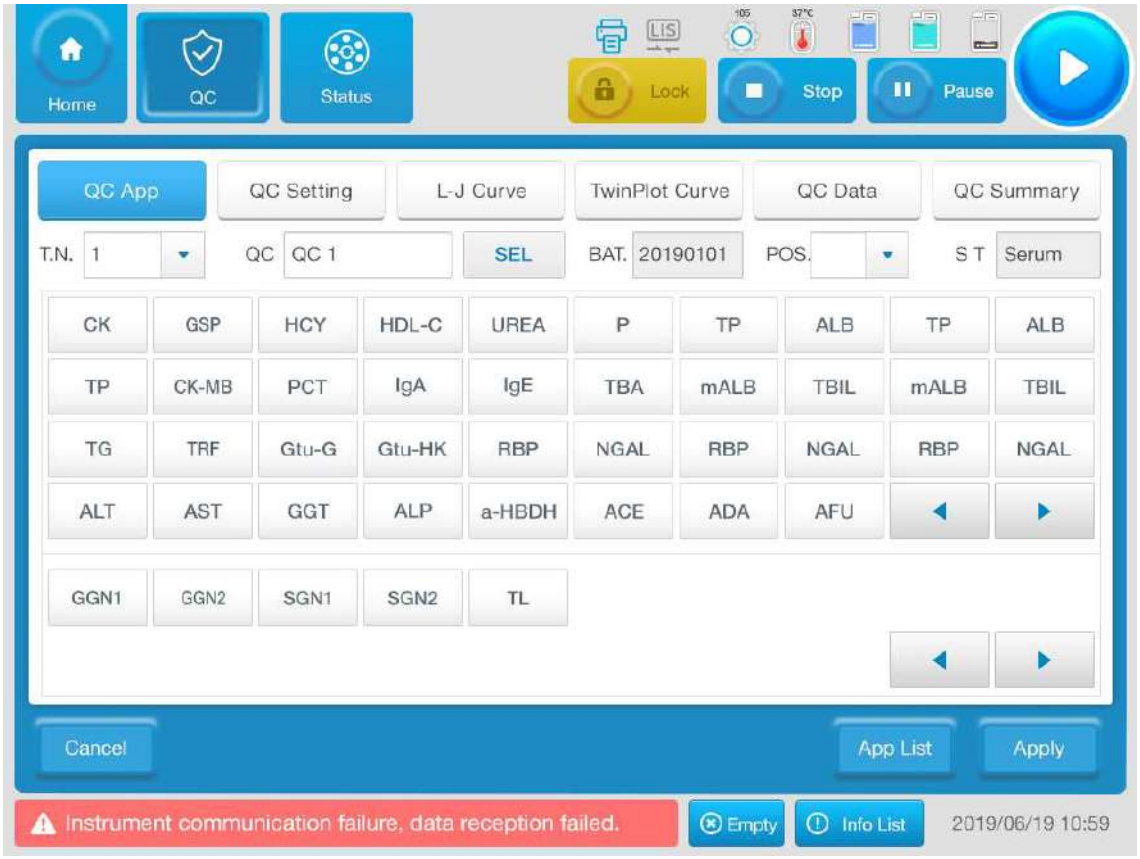


Figure 3-18 Quality Control Application

Basic interpretation of parameters

Parameter	Meaning	Operation
QC	Name of QC set up	Click **SEL** to enter the "Select QC" interface
T.N.	Sample tray number	Select from the drop-down box
BAT.	Batch number of QC has been selected	No operation required
POS.	The tray number and cuvette number of the QC	Select from the drop-down box
S T	Selected sample type	No operation required
App List	List of QC samples applied	Directly click
Cancel	Cancel quality control application	Click to return to the previous menu

Parameter	Meaning	Operation
Apply	Apply for quality control after selecting items	Directly click

Basic operation

- Apply for quality control

  1) Click **QC App** to enter the "Quality Control Application" interface;

  2) Click **SEL** QC to confirm its batch number and sample type;

  3) If the position of QC has not been selected, the tray number and cuvette number can be determined in the **POS.** drop-down menu;

  4) Select the quality control item in "Regular Item" or "Combined Items";

  5) Click the **Apply** button.

- Delete QC apply

  1) Click **App List** to enter the "QC Application List" interface:

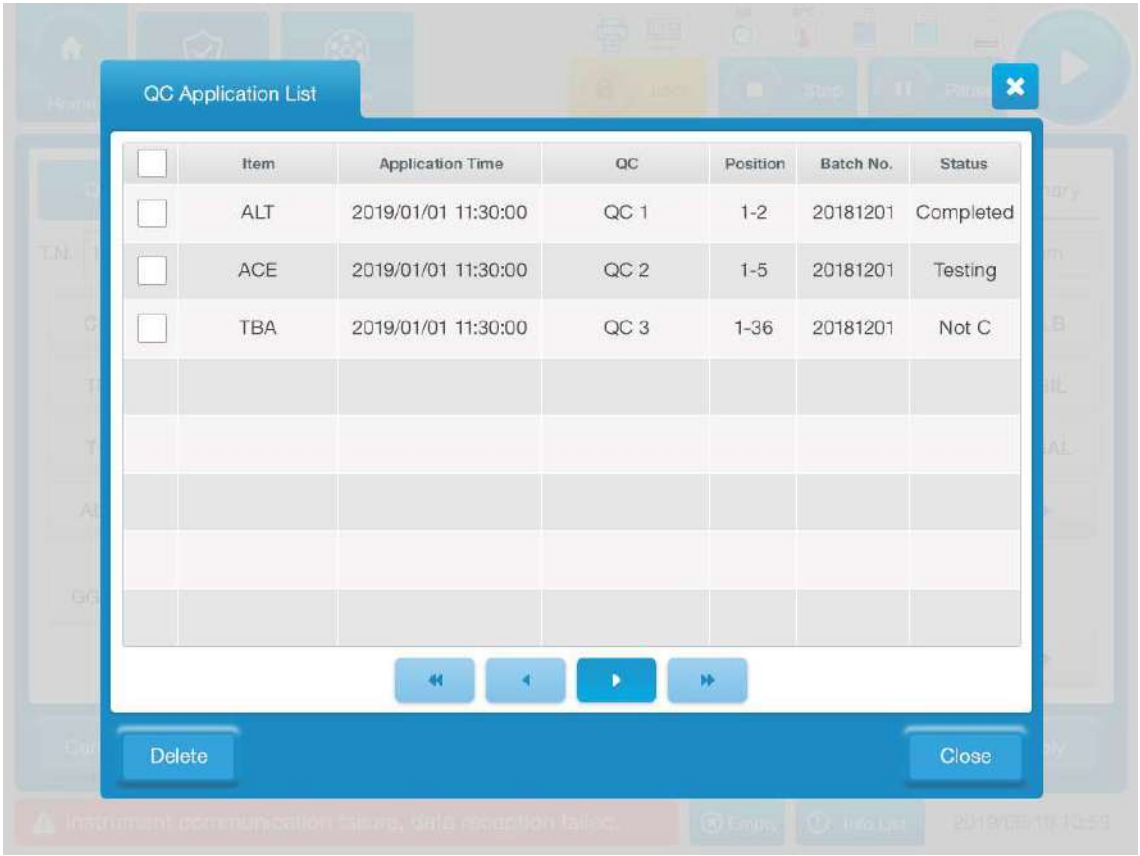


Figure 3-19 Control Application List

  2) Check the control application to be deleted;

  3) Select the quality control application that needs to be deleted, and click the **Delete** button to confirm deletion; otherwise, click the **Close** button.

3.11.2.3. Quality control data

Click **QC Data** to enter the quality control data interface, as the following:

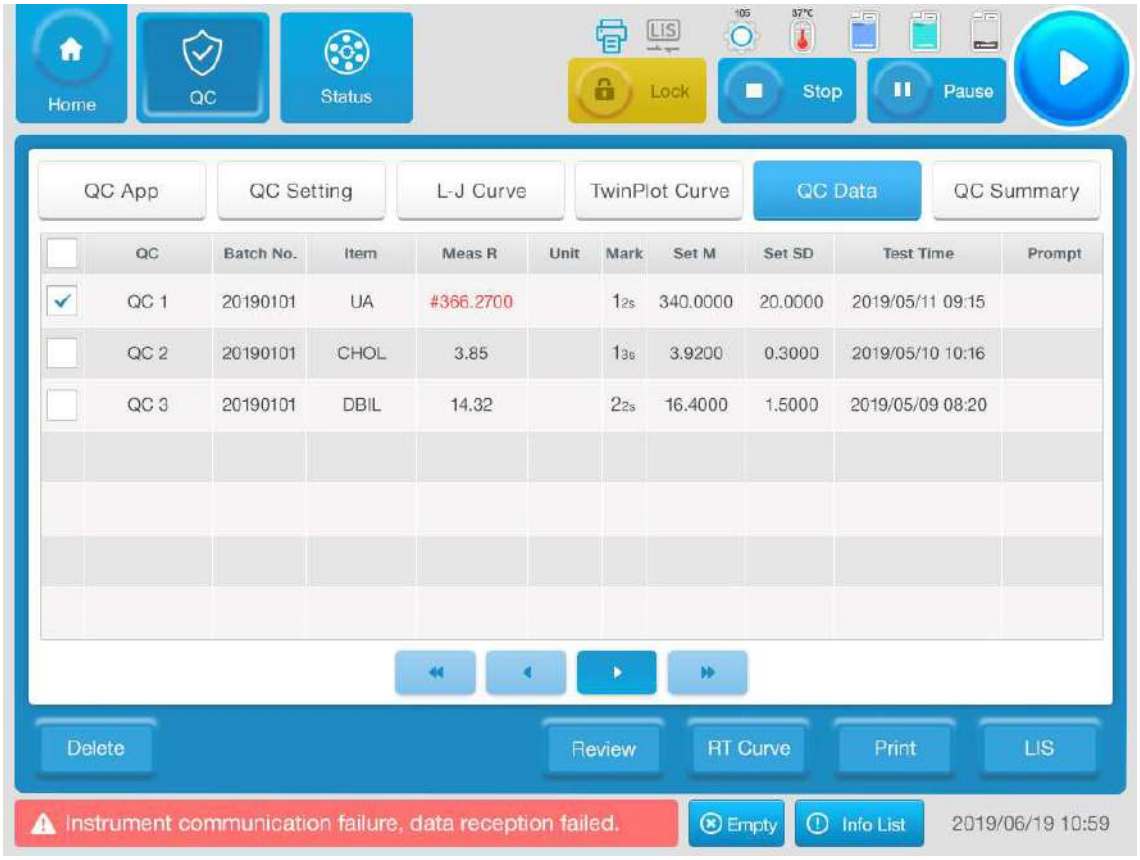


Figure 3-20 Quality Control Data

Basic interpretation of parameters

Parameter	Meaning	Operation
QC	Name of QC	No operation required
Batch No.	Batch number of QC	No operation required
Item	The items corresponding to the QC	No operation required
Meas R	Quality control results and out-of-control symbols	No operation required
Unit	A unit of QC results	No operation required
Set M	Mean value set in quality control setting	No operation required
Set SD	Standard deviation set in quality control setting	No operation required
Mark	Marking symbols, including: use of quality control rules "12s, 13s, 22s, R4s, 41s, 10x"	No operation required
Prompt	Marking symbols, including: use of expired QC "EQC", use of expired reagent "ER"	No operation required
Test time	The time when the quality control test starts	No operation required

Basic operation

1) Click the **Review** button, in the pop-up dialog box to select items and QC, and drop-down to select quality control date, click **OK** to view the quality control results;
2) Select a certain quality control result and click **RT Curve** to view the reaction curve of the quality control result;
3) Select a certain quality control result and click **Delete** to delete the quality control result;
4) Select a certain quality control result and click the **Print** button. In the pop-up dialog box, you can choose to print only the selected quality control result or all the quality control results;
5) Select a certain quality control result and click the **LIS** button. In the pop-up dialog box, you can choose to send only the selected quality control result or all the quality control results.

3.11.2.4. Quality control summary

Click **QC Summary** to enter the quality control summary interface, as the following:

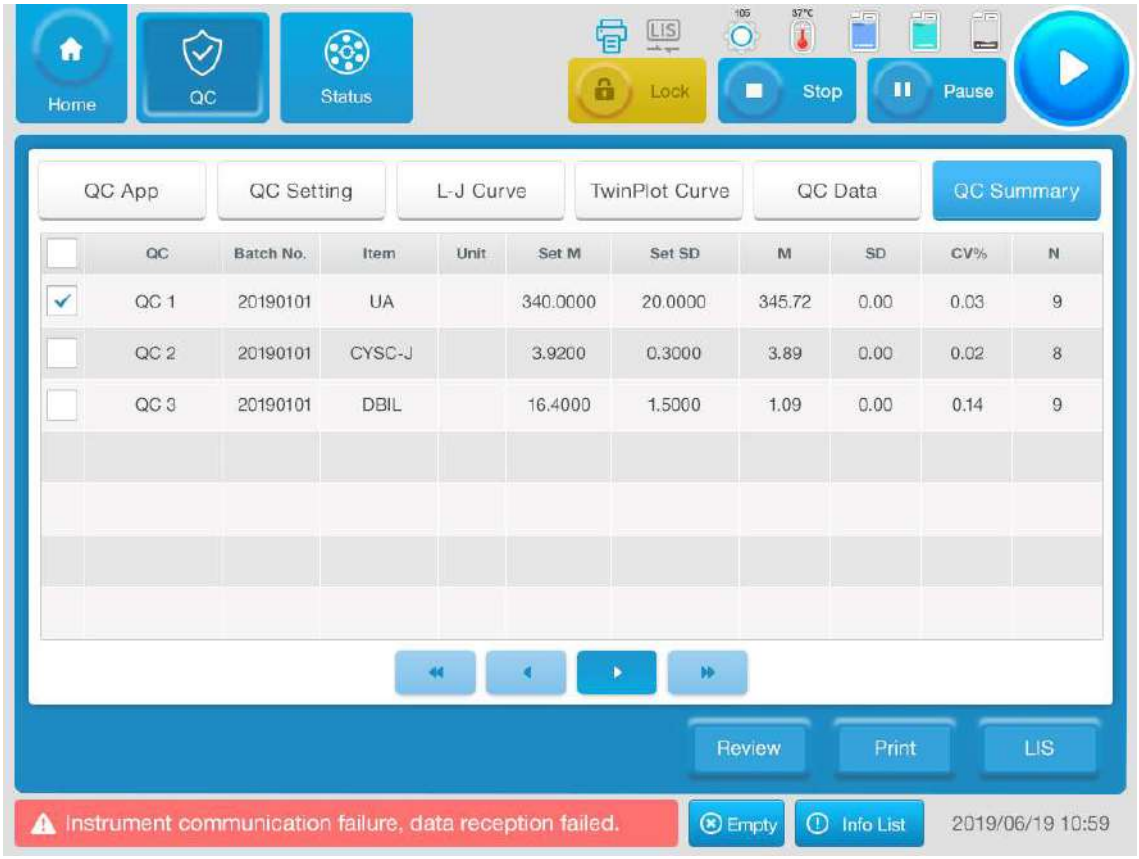


Figure 3-21 QC Summary

Basic interpretation of parameters

Parameter	Meaning	Operation
M	The arithmetic mean value of all control results of the same QC and the same item	No operation required
SD	Standard deviation of all control results of the same QC and the same item	No operation required
CV%	Repeatability CV of all control results of the same QC and the same item	No operation required
N	The total number of quality control tests conducted for the same item in the same QC	No operation required

Basic operation

1) Click the **Review** button, in the pop-up dialog box to select items and QC, and drop-down to select quality control date, click OK to view the quality control results;

2) Select a certain quality control result and click the **Print** button in the pop-up dialog

box, you can choose to print only the selected quality control result or all the quality control results;

3) Select a certain quality control result and click the **LIS** button. In the pop-up dialog box, you can choose to send only the selected quality control result or all the quality control results.

3.11.2.5. L-J curve

Figure 3-22 L-J Curve

Basic operation

1) Click to select item , drop down to select quality control date, click select QC 1, and then click **Review** to view the L-J chart of quality control results;

2) To view the quality control results of other QC at the same time, click to select QC 2 and QC 3;

3) To display the deleted quality control results in "QC Data", click "Display D V";

4) Click **Previous** or **Next** to view the quality control result of the previous item or the quality control result of the next item in the item list;

5) Click **Print** to print the quality control results;

3.11.2.6. Twinplot

Figure 3-23 TwinPlot Curve

Basic operation

1) Click to select item, drop down to select the quality control date, and click the **Review** button to view the quality control results. At the same time, the names, mean and standard deviation of QC (X) and QC (Y) will be displayed at the bottom left;

2) Other operations are the same as "L-J chart".

3.12. Routine test

This section describes how to apply for routine testing of samples.

3.12.1. Sample application

In the sample application menu, users can apply for samples, and can choose test applications for functions such as STAT, batch application, and retest according to actual needs; they can also view the application list and enter patient information.

Click **Sample** in the main interface. The sample application interface is as follows:

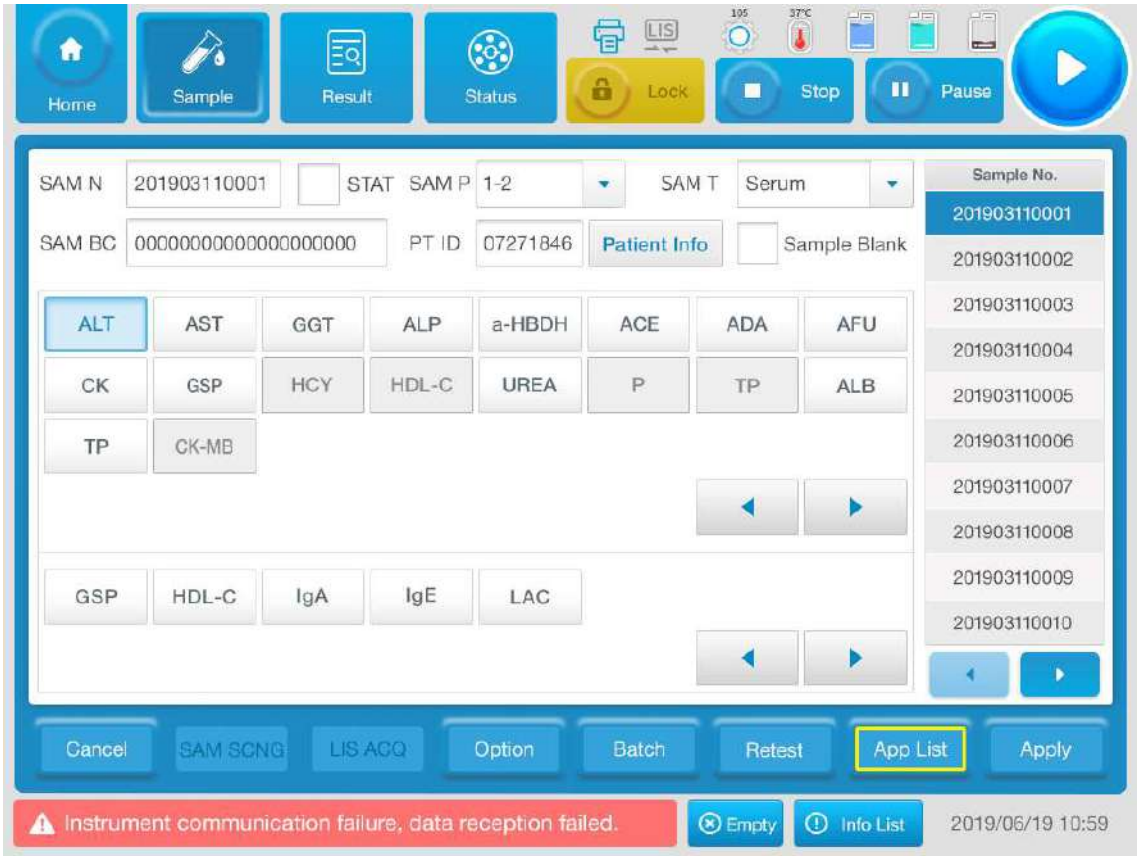


Figure 3-24 Sample Application

Basic interpretation of parameters

Parameter	Meaning	Operation
SAM N	Number of test sample	Enter directly in the box
STAT	Set the current sample as STAT	Selecting the previous radio box indicates that the STAT is selected
SAM P	Select the location of the sample	Select the tray number and cuvette number from the drop-down box
SAM T	Select sample type	Select from the drop-down box
SAM BC	Bar code of test sample	Enter directly in the box
PT ID	Enter patient information	Click **Patient Info** to enter the "Patient Information" interface
Sample Blank	Test sample blank	Click to choose and click again to cancel

Parameter	Meaning	Operation
SAM SCNG	Perform sample barcode scanning	Click to pop up the sample scan dialog box
LIS ACQ	LIS acquisition content selection	Click to enter" LIS Acquisition" interface
Option	Select test method	Click to enter the "Option" interface
Batch	Apply for batches of sample test	Click to enter the "Batch Application" interface
Retest	Retest sample	Click to enter the "Retest" interface
App List	Check the list of applied samples and items	Click to enter the "Application List" interface
Cancel	Cancel this sample application	Click **Cancel**
Apply	Apply for testing	Click **Apply**

Note:

1) The sample position consists of "Tray No." and "Cuvette No.". Conventional samples support virtual tray setting, which can be set up to 5 at most. The default for the current day is from the 1st position of the 1st tray. The occupied sample position cannot be used for reapplication before release.

2) The numbering can be composed of numbers. The sample numbering is prefixed by time. For each sample number starting from 0001, the user can enter 1-9999, and the system will automatically jump to the default format. If the input data exceeds this range, an error will be reported. You can re-enter it again. You cannot set a duplicate sample number after releasing the sample position. You can set it only after deleting the sample.

Basic sequence of operations

- Apply for a single sample

  1) Select the sample tray number and cuvette number from the sample position drop-down box;

  2) Drop down to select sample type;

  3) If it is an STAT test, select the STAT radio box, otherwise not select;

  4) Enter interface contents such as sample number;

  5) Click the item to be measured in the measurement item selection area, click once

for selection, and click again to cancel;

6) Click the **Apply** button.

- Batches application

1) Select the sample tray number and cuvette number from the sample position drop-down box;

2) Drop down to select sample type;

3) If it is an STAT test, select the STAT radio box, otherwise not select;

4) Click the **Batch** button, enter the start number and end number in the pop-up window, or enter the start number and batch number, and then click **OK** to close the popup window;

5) Click the item to be measured in the measurement item selection area, click once for selection, and click again to cancel;

6) Click the **Apply** button.

Attention

1) During batch application, the sample number and cuvette position on the sample tray are increased in sequence according to the number of the starting sample and the cuvette position of the starting sample.

2) The starting sample for batch application must be the sample that has not yet been applied. If the sequentially increasing sample positions contain samples with the status of "Application", "Under Test", "Incomplete" or "Complete", the sample positions will be skipped and will continue to be set from the next sample position.

3) Batch application and single application can be carried out at the same time.

- Delete sample application

1) Click **App List** to enter the "Application List" interface:

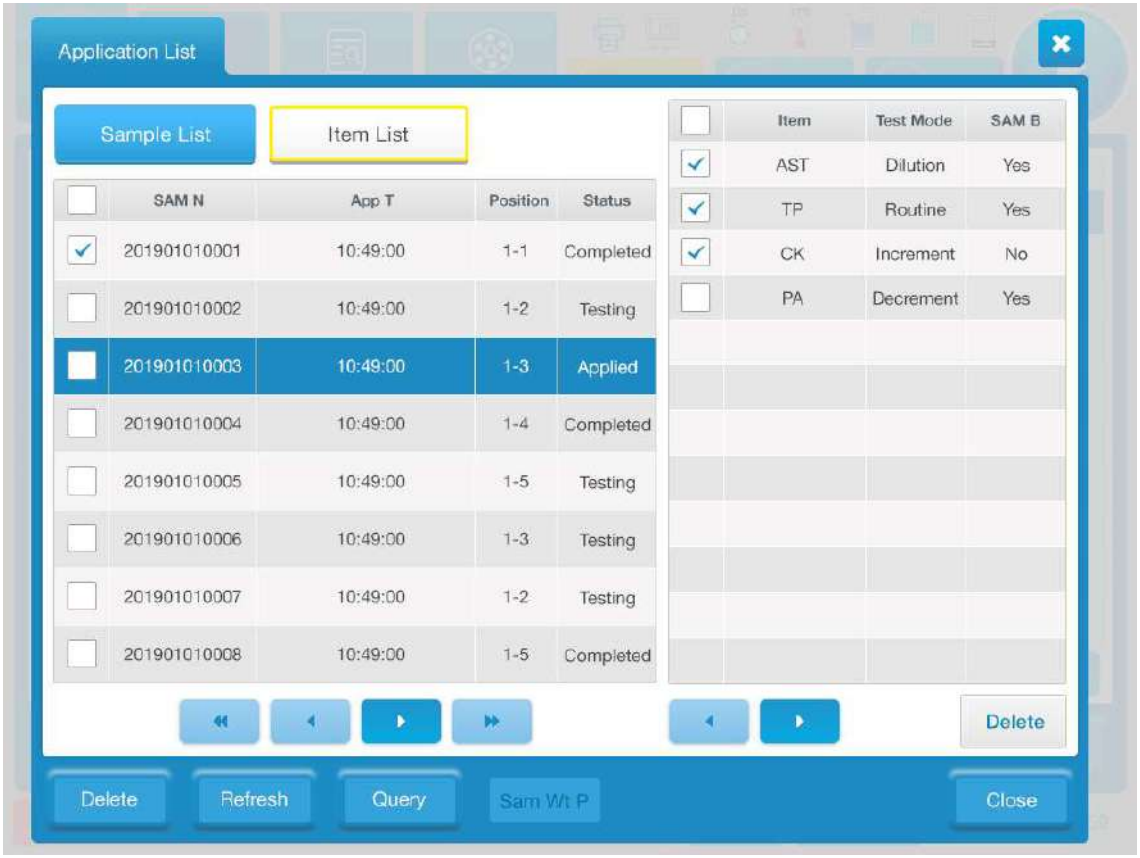


Figure 3-25 Sample Application List

2) Check the sample application to be deleted under "Sample List";

3) After clicking on the **Delete** button, you can select to delete the selected sample, the samples of the designated tray, the designated sample or all samples in the pop-up window, then click the **OK** button;

4) To delete an item, first select a row in the sample list on the left, select the item to be deleted on the right, click **Delete** in the lower right corner, or click **Item List**, select a row, and then click **Delete**.

■ Apply for increase/decrease volume

1) After selecting the applied item, click **Option**;

2) Set the test method in the pop-up "Option" interface;

3) Click the **Save** button.

■ Re-test basic operation sequence

1) Click **Retest** and select the content to be retested in the pop-up window:

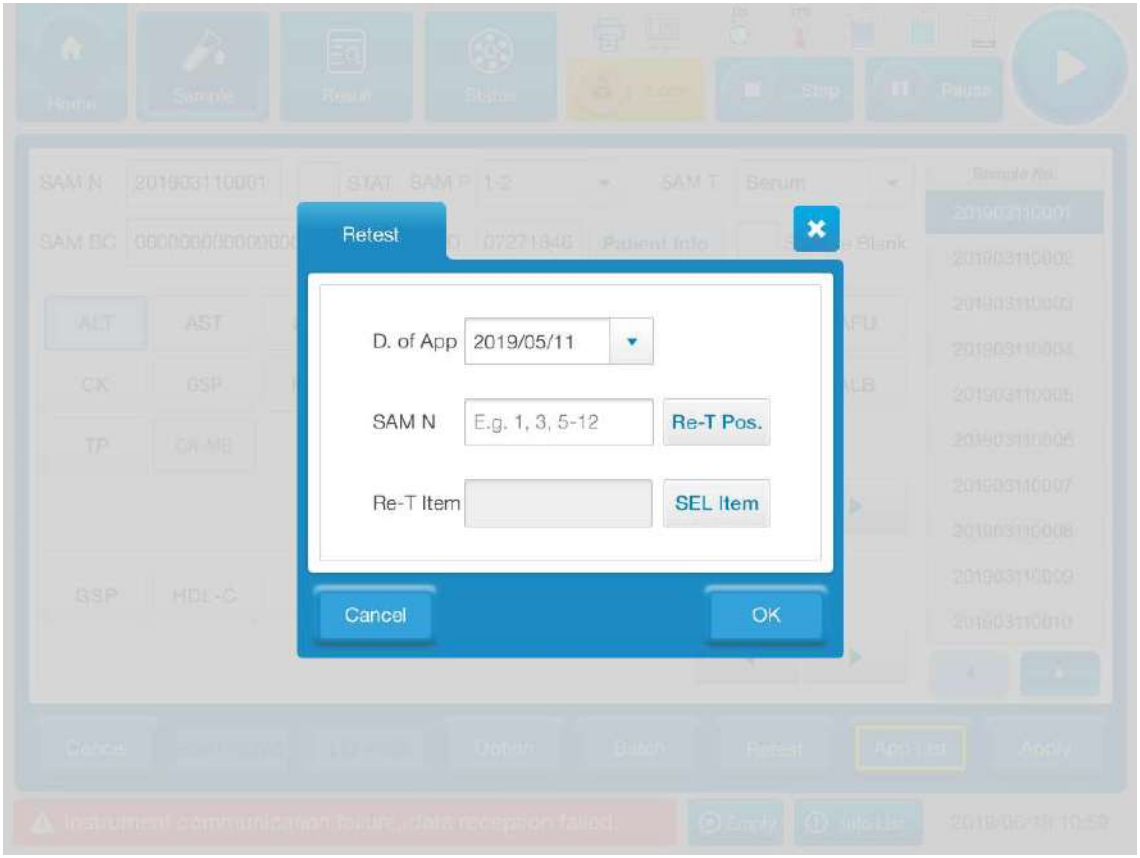


Figure 3-26 Sample Retest

2) Select the date of application, number and item to be retested in the popup window;

3) Click **OK** and the instrument will start retesting.

■ Patient information registration

Patient information interface are as follows:

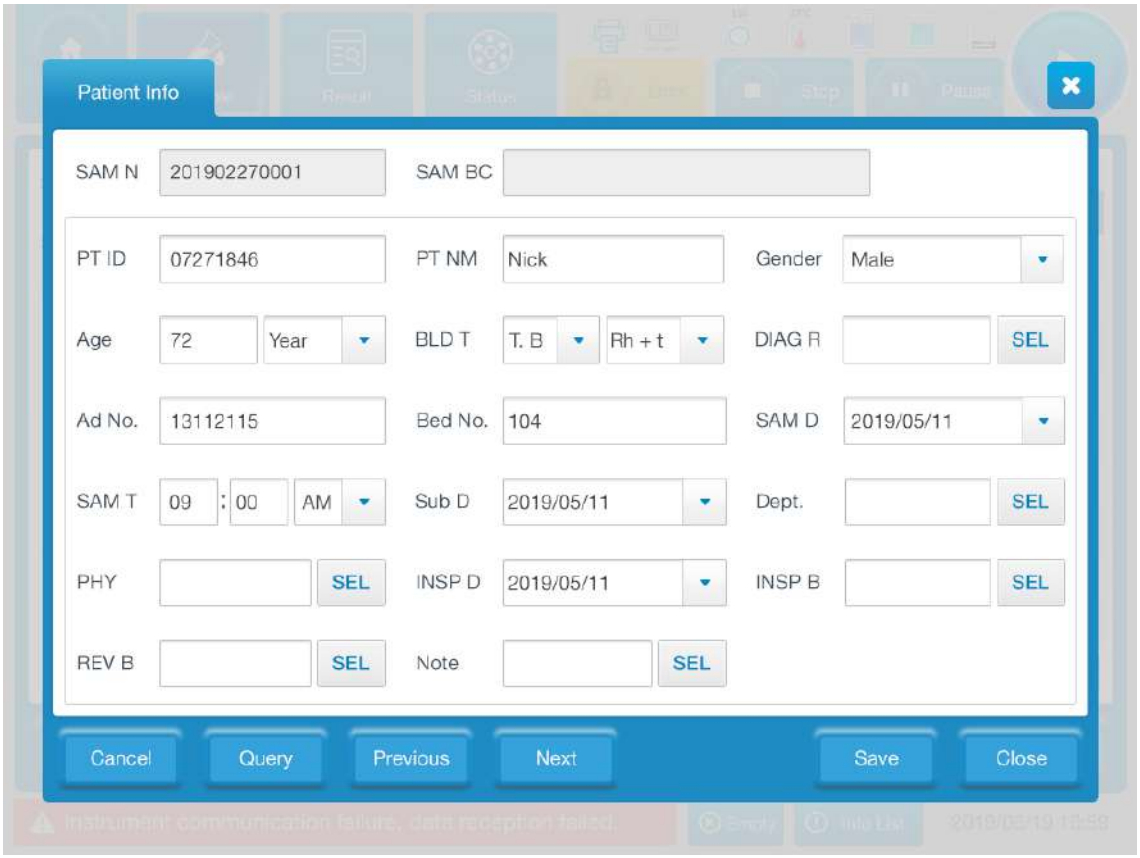


Figure 3-27 Patient Information Registration Form

Basic interpretation of parameters

Parameter	Meaning	Operation
SAM N	Number of samples	No operation required
SAM BC	Barcode of samples	No operation required
PT ID	Patient number	Input directly
PT NM	Name of the current patient	Enter directly in the box
Gender	Gender of the current patient	Select one from the drop-down box
Age	Age of the current patient	The first box is directly entered, and the second box is selected from the drop-down box
BLD T	Blood type of the current patient	Select from the drop-down box
Ad No.	Number of admission	Enter directly in the box
Bed No.	Patient bed number	Enter directly in the box
SAM D	Date of sampling	Direct input or drop-down selection
SAM T	Time of sampling	Direct input or drop-down selection

Parameter	Meaning	Operation
Sub D	Date of sample submission	Direct input or drop-down selection
Dep.	Department where the current patient is located	Enter directly or click to select
Submitter	The physician who issues a test application form to the current patient	Enter directly or click to select
INSP D	Inspection date of sample	Direct input or drop-down selection
DIAG R	Diagnostic reference results of the current patients	Enter directly or click to select
INSP B	The physician who tests a patient sample	Enter directly or click to select
Reviewer	The person who reviews the inspection report	Enter directly or click to select
Note	Indicating the special situation of the current patient or other relevant contents	Enter directly or click to select
Query	Query sample number and barcode	Click directly
Previous	View previous patient information	Click directly
Next	View next patient information	Click directly
Cancel	This entry information is not saved	Click directly
Save	Save this entry information	Click directly
Close	Close the pop up patient information	Click directly

Basic operations

- Enter patient information

  1) Click **Patient Info** to enter the "Patient Information" input interface;

  2) Enter all relevant information and click the **Save** button to save.

3.13. Start

Basic operation

1) Select the type and position of the sample, and click the **Start** button after confirmation;

2) Set the content of test;

3) Click **OK**.

3.14. View testing status and result

- View testing status

  1) Click **Status-Sample Tray**, select the sample position to be viewed on the sample tray status interface, and then view the test status of all items of the specified sample in the test list.

  2) Click **Status-Reagent Tray**, select the reagent position to be viewed on the reagent tray status interface, and then view the reagent information of the reagent of the specified position in the"Reafent Info" area.

  3) Click **Status-Reaction Tray**, you can view the current status of each cuvette on the reaction tray status interface; click **RT Curve** on the reaction tray interface to observe the effective test (sample, calibration, quality control, sample blank, reagent blank).

- View test result

  Click **Result-Current Results** / **Historical Results** on the homepage, and view the current sample test results or previous sample test results on the results interface.

3.15. Pause

- Function description

  1) Suspend the tests that have not been added with R1 in all ongoing tests, and the tests that have been added with R1 will continue to complete the actions of adding S (samples) and R2, and continue the tests;

  2) When sample addition is suspended, the reaction tray will continue to work. After all the application items that have started testing have finished adding samples or R2 reagent (in case of dual reagent items) and the reagent-sample tray and reagent-sample probe stop rotating, the operations of adding samples and adding reagents can be performed.

- Step

  1) Click the **Pause** button at the top right of the interface, and the analyzer will stop sample loading status.

  2) After the suspension of sample addition, click the **Start** button on the right side of the interface to resume the test.

3.16. Stop

Stop all ongoing tests without adding S (single reagent items) or R2 (dual reagent items). This function will only be performed if the user needs to stop the current work for various reasons. Click the button **Stop**, and click **OK** in the pop-up dialog box, then only the single reagent item added with S and the dual reagent item added with R2 will continue, and other

tests will stop immediately.

3.17. Daily maintenance

After the test is finished every day, the instrument shall be maintained according to the maintenance items in the daily maintenance list and the yellow maintenance items displayed. The daily maintenance items include:

- Check external water pipes connection
- Check the remaining amount of concentrated detergent
- Check whether there is leaks or bubbles in the syringe
- Check the probe detergent residual
- Check the balance of acid-base detergent
- Check whether the water outlet of the reagent-sample probe is normal (verify whether the probe inner wall is blocked)
- Check whether the water outlet of the cleaning basin is normal (verify whether the probe outer wall cleaning is normal)

3.18. Shutdown

1) Confirm that the system is in a non-test state;
2) Select **Shutdown-OK** at the bottom right of the homepage interface to wait for the shutdown process to complete;
3) Turn off the power supply of the instrument after the software is turned off.

3.19. Emergency shutdown

This function is only performed when the analyzer fails during operation and cannot exit normally. In case of emergency exit, the analyzer does not execute any shutdown process and exits directly. Click the button **Emergency Shutdown**, and directly click **OK** in the pop-up dialog box to exit the software immediately. If you do not want to shut down the software urgently, click **Cancel**.

3.20. Operation after shutdown

1) Open the reagent-sample tray and take out the calibrator, QC, etc.
2) Check the analyzer table for stains. If so, please wipe the stain clean with a clean soft cloth.
3) Check the high-concentration waste container. If there is any waste liquid, please empty the waste container.
4) Cover the reagent-sample tray and close the upper cover.

4. Software System Operation

This chapter mainly introduces the system status, reagents, results, and setup functions in detail.

4.1. Home page

After normal startup, enter the homepage interface. As shown in the following figure:

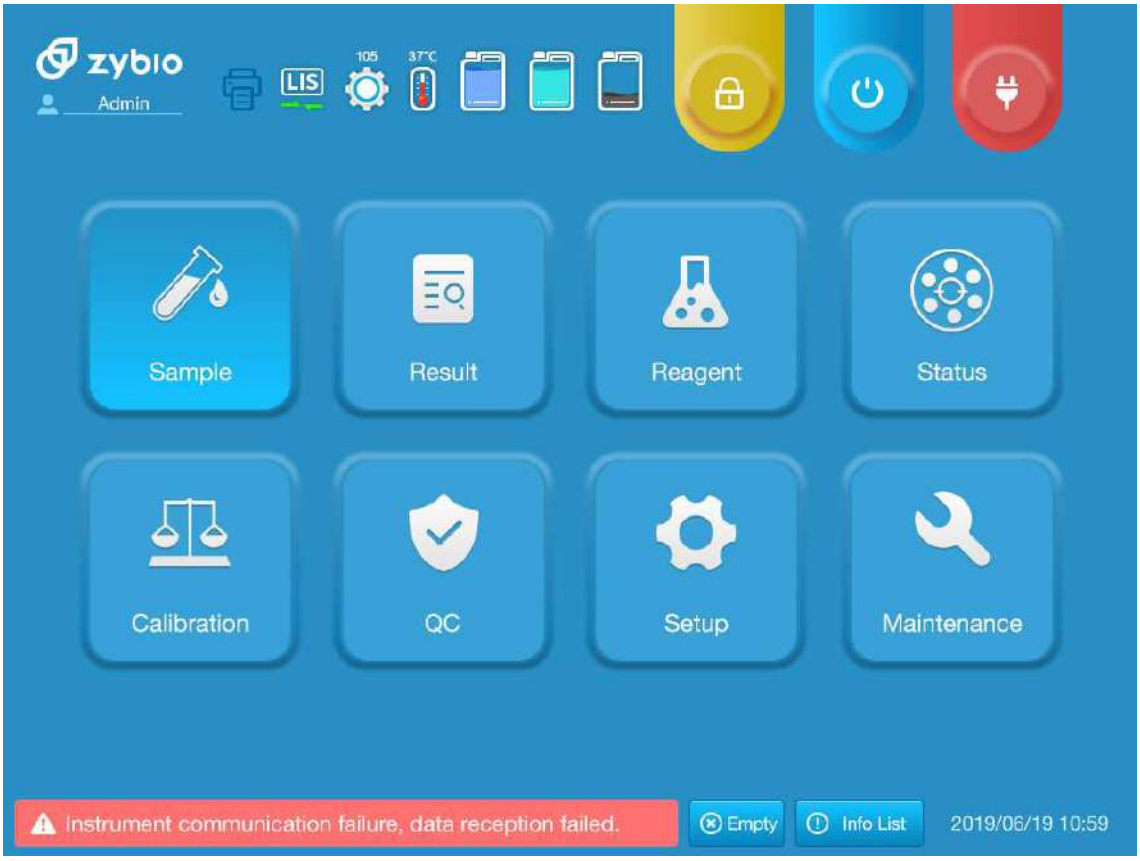


Figure 4-1 Home Page

Description of interface function keys:

Function key	Name	Function
	Sample	Enter the sample application function page to apply for a sample test. Support batch application, patient information entry, sample position setting and other functions.

Function key	Name	Function
	Result	Enter the results review function page to view the test results. It has the functions of retest, recalculation, reaction curve checking, printing, LIS sending, etc.
	Reagent	Enter the reagent management function interface and have the functions of reagent loading, reagent unloading, residual quantity detection, reagent information inquiry, etc.
	Status	Enter the online status viewing function page of the instrument to display relevant information of the sample tray, reagent tray and reaction tray.
	Calibration	Enter the calibration function page to set calibrator information, set reagent position, apply for calibration test and reagent blank test, and query calibration results.
	QC	Enter the quality control function page, you can set up QC information, apply for quality control tests, query quality control results and other operations.
	Setup	Enter the setup function page. It mainly includes test setup, system setup, user setup, items setup and other functions.
	Maintenance	Enter the maintenance function page. It mainly includes daily maintenance and engineering maintenance. Daily maintenance includes periodic maintenance, trouble shooting, data backup, temperature curve, consumable status and unit status. Engineering maintenance includes maintenance and debugging.

Function key	Name	Function
	Lock	Lock the interface and clicking other function keys is invalid.
	Emergency shutdown	Exit the system directly.
	Shutdown	Exit the system normally according to the shutdown process.

4.2. Status

Including the online status of the sample tray, reagent tray and reaction tray, respectively described below.

4.2.1. Sample tray

Check the test status of the applied samples on each sample tray.

Figure 4-2 Sample Tray Status

Basic interpretation of parameters

The meaning of each sample color in the "Sample Tray Status" interface is as follows:

Status	Color	Interpretation
Idle	Blank	Clean cuvette
Occupied	Gray	Sample positions have been occupied by diluent, QC and calibrator, and a routine test cannot be applied
Applied	Blue	Applied test, ready for test
Testing	Green	Sample is under testing
Completed	Yellow	Testing is completed
Resi I	Rosy	Sample is not enough
Not C	Purple	The sample did not complete the test due to abnormalities, failures, etc.
Cl.	Red	Probe collision during the test

The meaning of the shape of each sample position in the “Sample Tray Status” interface is as follows:

Shape	Interpretation
Round	Normal sample
Triangle	STAT
Square	Calibrator
Pentagon	Water
Hexagon	QC

Basic operation

- Sample tray status review

  1) Click trays 1 to 5 to view the test status of the samples on the corresponding sample trays respectively;

  2) In the sample tray on the left, different sample types and test states are represented by different shapes and colors;

  3) After selecting a sample on the sample tray, its information (QC or Calibrator information) is displayed in the "Sample Information" area on the right side of the interface, and the test list area displays the items applied for the sample position.

Attention

When the sample size is not enough, the "Refresh" operation must be performed after the sample is replenished before starting the test.

- Release Immediately

  Select a sample on the sample tray and click **I. R.** to release the current sample position.

- Release

  Click **R. POS.** to release the position where the sample is located. In the pop-up window, you can choose to release the sample status at the specified position or all positions..

- Refresh

  Click **Refresh** to refresh the test status of the sample tray. In the pop-up window, you can choose to refresh the sample status at the specified position or all positions.

- Reaction Curve

  Click **RT Curve** to view the reaction curve of the selected sample that has completed the test.

4.2.2. Reagent tray

The online status interface of reagent tray is shown in the following figure:

Figure 4-3 Reagent Tray Status

■ Reagent tray status review

1) Click on trays 1 to 5 at the left, and then click on the cup position in the tray to view the reagent information on different reagent trays and the items corresponding to the current reagent position.

2) The status of the reagent position on the reagent tray is divided into 6 types: Vacancy, R1, R2, shared reagent position, cleaning solution and diluent, which are respectively marked with different colors. The dilution was fixed as reagent position D and the cleaning solution was fixed as reagent position C.

3) There is a circle in the middle of each reagent position, and different colors show different states of reagents, normal reagent, open-vial shelf life exceeded limit, reagent expired, insufficient reagent, probe collide.

4) In the list of items displayed on the right, gray indicates that reagents have not been associated, and no gray indicates that reagents have been associated. Click on the item and a brown box will appear at the corresponding reagent position in the reagent tray.

5) Click on a reagent position in the reagent tray, and the reagent information will be displayed on the lower right.

■ Residual detection

1) Click the button **Resi D** to open the " Residual Detection" interface:

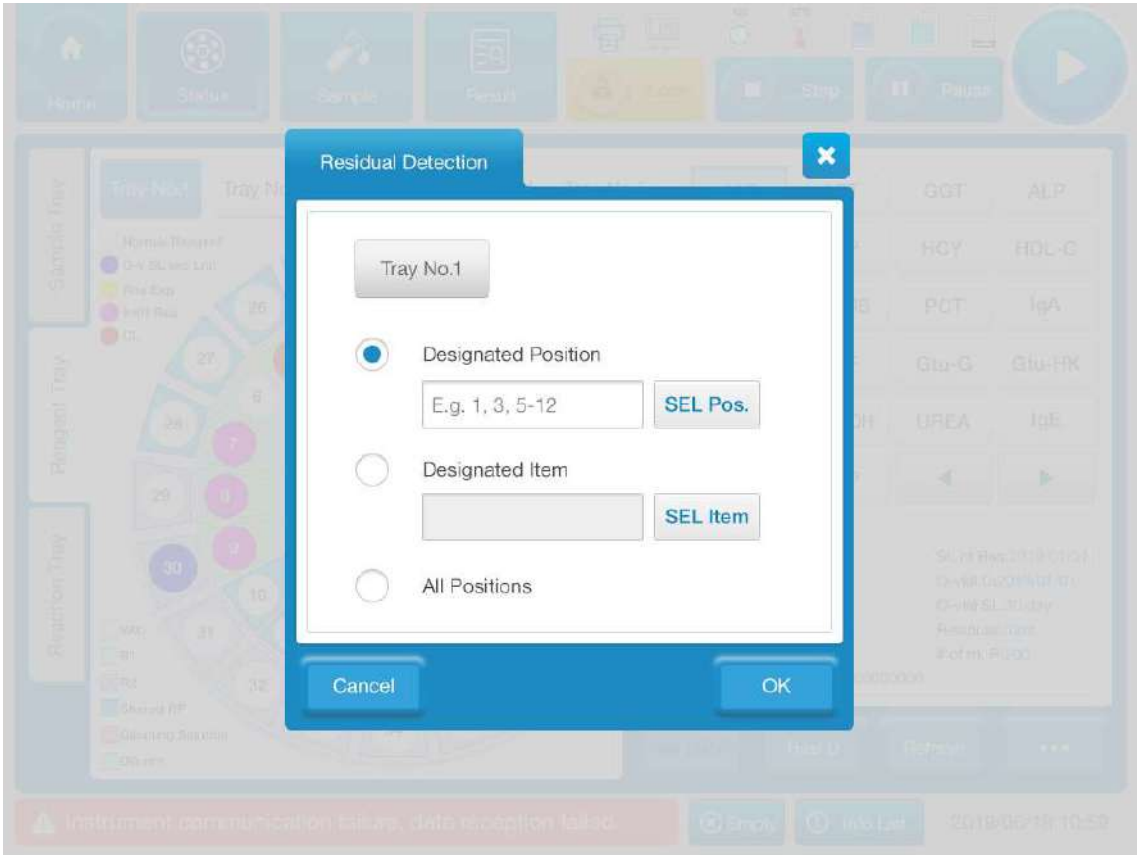


Figure 4-4 Residual Detection

2) Set the content that needs residual detection. You can select the cup position at the specified position, the specified item or all positions for residual detection;

3) To start residual detection, click **OK**, otherwise, click **Cancel**.

Attention

1) R1 and R2 for dual reagent items must be set on the same reagent tray.

2) The remaining amount detection operation can be performed only in the standby mode.

■ Status refresh

1) Click the button **Refresh** to enter the "Status Refresh" interface;

2) Click to select the specified position or all positions to refresh the status.

Attention

When there is a lack of reagent for a certain item, a refresh operation must be performed after the reagent is replenished to start the test of the reagent item, and the state must be refreshed after the striker is restored, as well.

■ Shared reagent position

1) Click **Shared RP** to open the "Shared Reagent Position" interface:

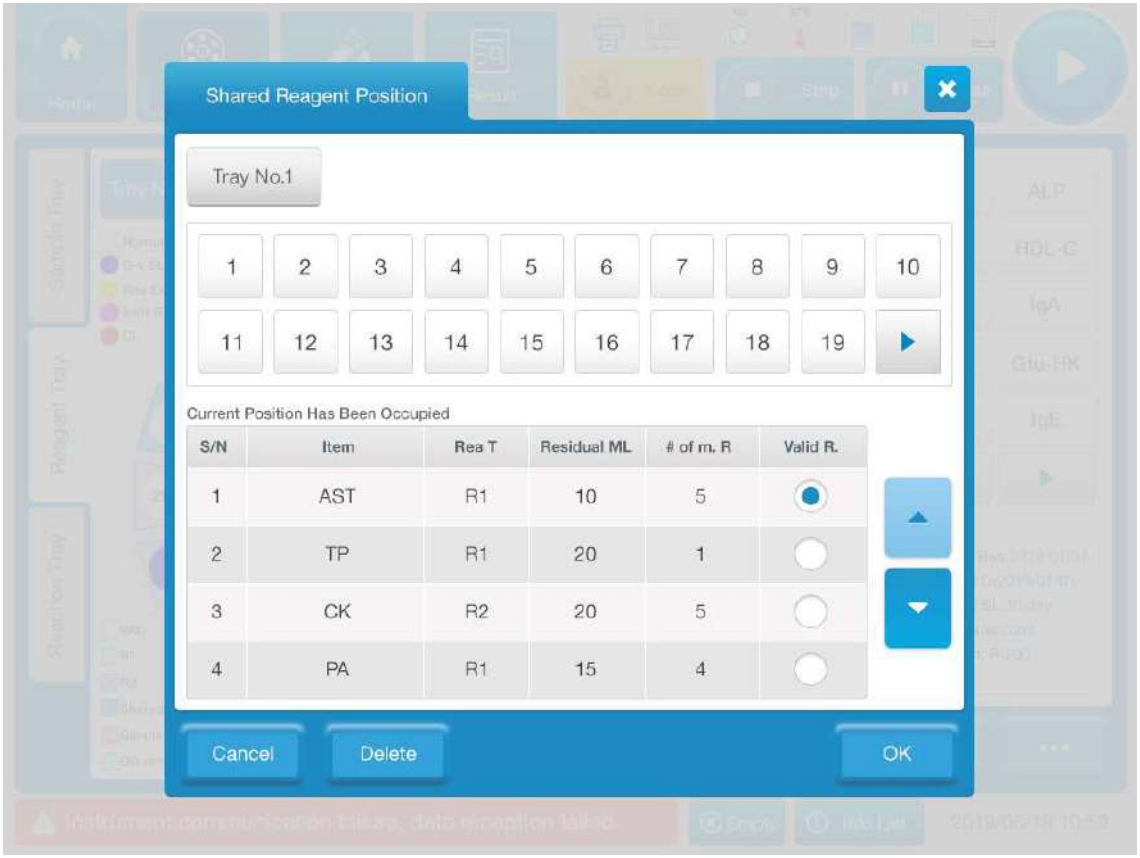


Figure 4-5 Shared Reagent Position

2) Click on the cup number to view the reagent information loaded at the current cup position;

3) Click "Valid R." to switch the reagent currently preferred for this cup.

■ Reagent loading

Click the **Rea LD** button to enter the reagent loading interface, enter the corresponding reagent information and click save.

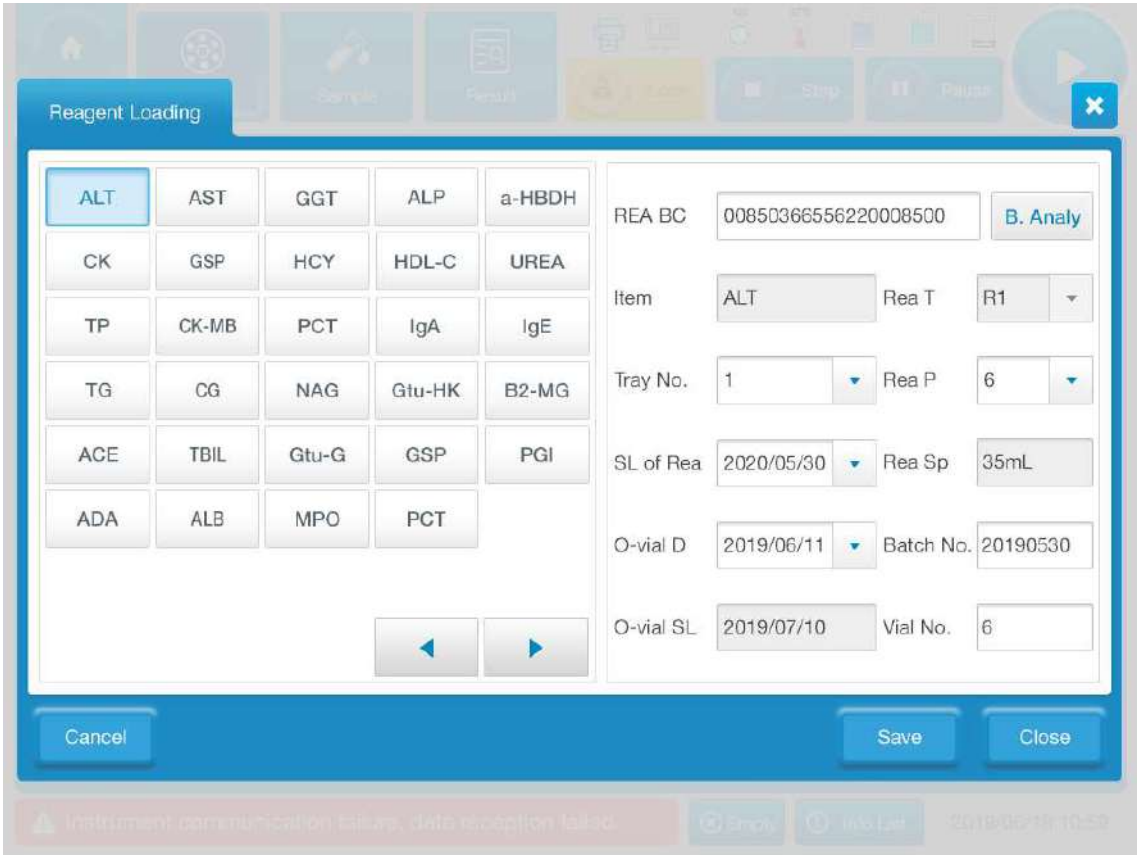


Figure 4-6 Reagent Loading

Basic interpretation of parameters

Parameter	Meaning	Operation
REA BC	Barcode corresponding to reagent	Directly input
B. Analy	Analyzing reagent information corresponding to the bar code	Directly click
Item	Displays the name of the item	No operation required
Rea T	Types of reagents	Drop-down box selection
Tray No.	Set the tray number where reagent locates	Drop-down box selection
Rea P	Set the cup position where the reagent is located	Drop-down box selection
SL of Rea	Effective days after reagent production	Drop-down box selection

Parameter	Meaning	Operation
Rea SP	Reagent bottle specification Inner circle: fixed to 35ml, not optional. Middle circle: fixed to 20ml, not optional.	No operation required
Batch No.	Lot number information of reagent kit	Directly input
O-vial D	The date of reagent bottle opening shall be calculated from the date when the reagent position is set.	Drop-down box selection
Vial No.	Reagent kit bottle number information	Directly input
O-vial SL	The effective time after the reagent is opened is calculated from the days after the reagent position is set.	No operation required

- Reagent unloading

  1) Click on a reagent to be unloaded on the reagent tray, and then click **Rea UNLD**, and click **OK** in the pop-up window.

  2) You can also click **Rea UNLD** directly, click **SEL Pos.** in the pop-up window to select the position, and click **OK** to unload.

  3) Click **SEL Item** in the pop-up window to unload the reagent of the corresponding items; Click **Full Tray Unloaded** to unload all the loaded reagents on the reagent tray.

- Reagent replacement

  1) Click **Rep. Rea.** and enter the corresponding reagent information in the pop-up window;

  2) Click **Save**.

4.2.3. Reaction tray

The online status interface of the reaction tray is shown in the following figure:

Figure 4-7 Status of Reaction Tray

Basic interpretation of parameters

Parameter	Meaning	Operation
Cuv. Pos.	Number of cuvette	Select cuvette position and click **Query** to view the test information of the corresponding cuvette number
Sample No.	Number of the sample	Showed automatically
Type	Testing type	Showed automatically
Item	Testing item	Showed automatically
Result	Test result	Showed automatically
RT Curve	View the real-time absorbance curve of each item in the test	Choose the item and click **RT Curve**

■ Review of reaction tray status

1) Click **Sel. Cuv.**, select the cuvette number and click the **OK** button to return to the reaction tray interfaceand; click **Query** to view the test information of the corresponding cuvette number.

2) The state of the cuvette on the reaction tray is marked with 8 different colors, Idle,

Clean, Dirty, R1, S, R2, END1 and END2, wherein R1, S and R2 respectively indicate that R1, S and R2 are being added, END1 indicates that the test is finished, but no result has been calculated, and END2 indicates that the test is finished and the result has been calculated.

- Day item

  1) Click **Sel. Cuv.**, select the cuvette position and click the **OK** button to return to the reaction tray interface;

  2) Click **Day Item** to view all status of the current cuvette number on the day;

  3) Click **Previous** or **Next** to switch between different status information.

- View reaction curve

  1) During the periodic test, select one of the cuvettes under test on the reaction tray;

  2) Click the **RT Curve** button to pop up the “Reaction Curve” interface, showing the reaction curve.

4.3. Result

Click the button **Result** in the homepage interface to enter the result query interface, as shown in the following figure:

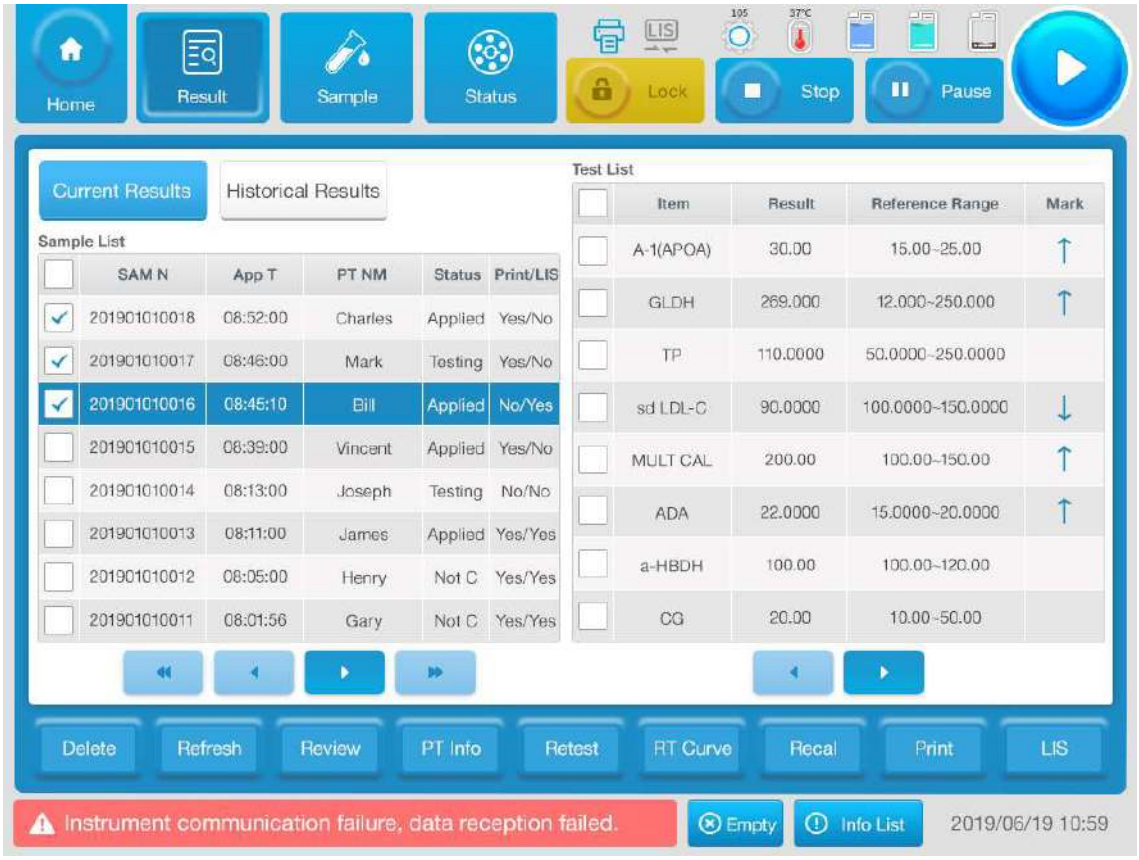


Figure 4-8 Current Results

Including current results and historical results, the basic operations are the same, as follows:

- Refresh

  1) Click the button **Refresh** to refresh the current test results.

- Review

  1) Select a row in the sample list on the left, and the "Test List" on the right will display the test results of all items corresponding to the sample;

  2) Click the button **Review** enter the search criteria in the pop-up dialog box, and click **OK** to display the corresponding results in the sample list.

- Patient information

  1) Select a sample in the sample list and click **PT Info** to open the "Patient Information" interface:

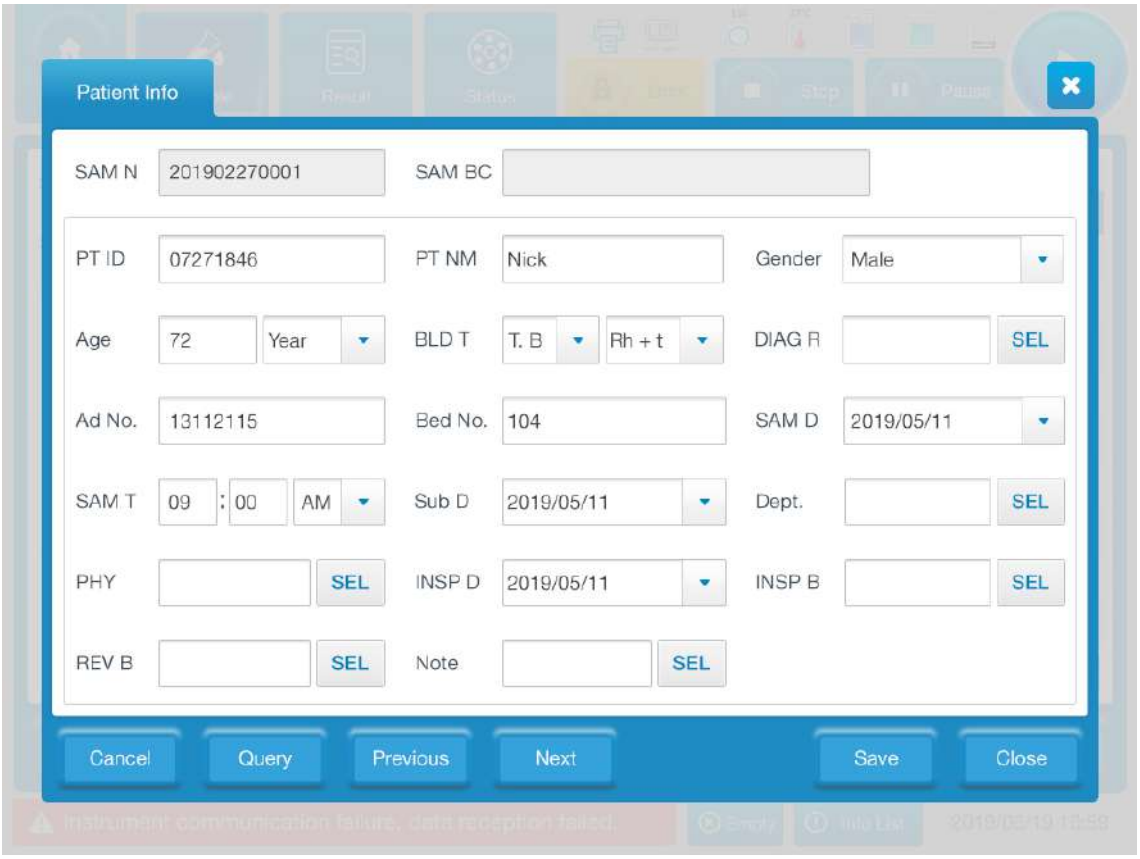


Figure 4-9 Patient Information

  2) Enter the corresponding patient information and click **Save**.

- Retest

  1) After checking the test result, select the items to be retested in the "Test List";

  2) Click the button **Retest** to set the retest mode and retest position (if the retest sample position changed):

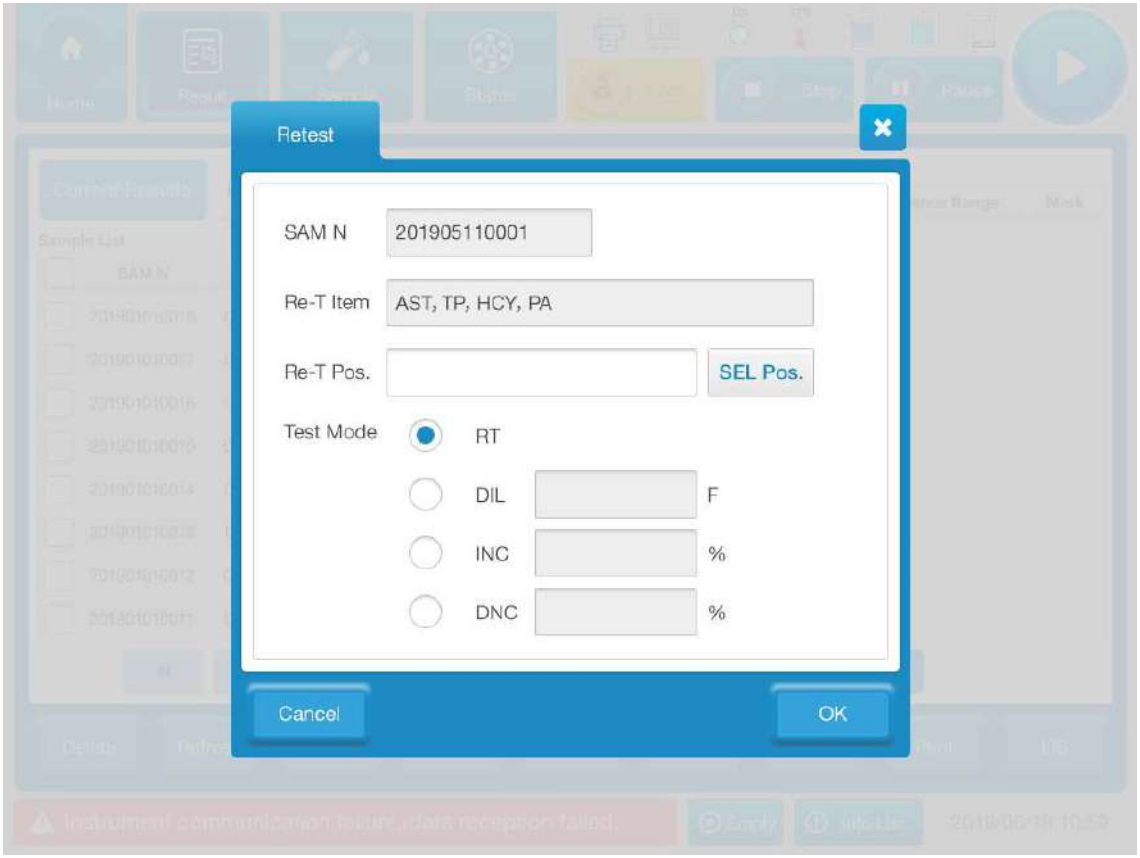


Figure 4-10 Retest

3) Click **OK** to start the retest.

- Reaction curve

1) Check the items in the test list and click the button **RT Curve** to open the "Reaction Curve" interface;

2) You can also click to view the original AD value and the reaction curve of sample blank.

- Recalculation

1) After the results are found, check the items to be recalculated;

2) Click **Recal** to start recalculation.

- Delete result

1) After the result is found, check a sample in the "Sample List", click the button **Delete**, and select **Delete the selected sample** in the pop-up window to delete all tests of the sample;

2) Check the test to be deleted in the "Test List", click the button **Delete**, and click **Delete selected item** in the pop-up window to delete the test;

3) If you need to delete all results, directly click **Delete** and select **Delete all results** in the pop-up window.

- Print

  1) After checking the results, select the sample/item to be printed and click **Print** to display the printing interface.

  2) You can choose to print the currently selected or all the results. You can choose whether to ignore the printed samples or whether to print double rows. You can set the printing sequence, print preview, etc.

  3) After the setting is completed, click **OK** to print the results.

- LIS send

  After checking the results, click **LIS** to jump out of the interface, set the content to be transmitted, and select **OK** to start LIS sending.

4.4. Reagent

"Reagent" interface can view detailed information of all reagents, and can perform basic functions such as reagent loading, reagent unloading, remaining amount detection, etc.

Click **Reagent** in the homepage interface to enter the reagent management interface, as shown in the following figure:

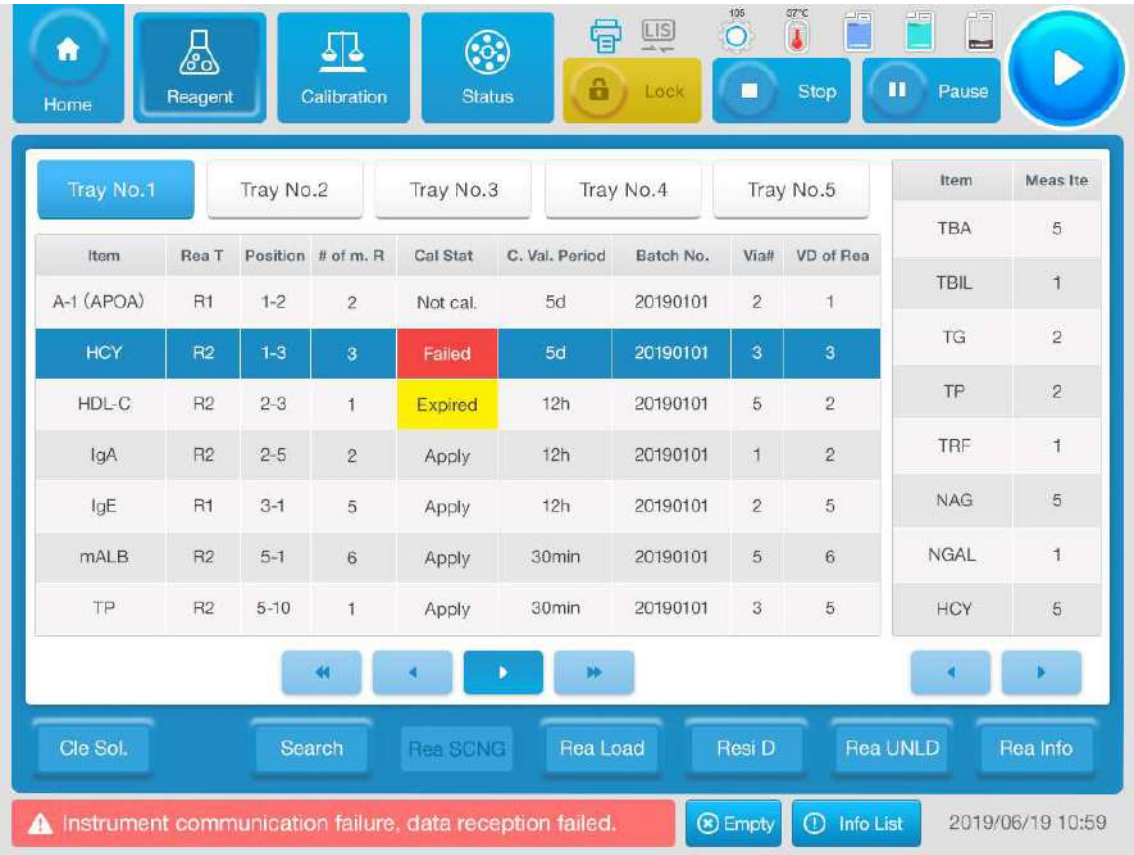


Figure 4-11 Reagent Management

Basic interpretation of parameters

Parameter	Meaning	Operation
Rea T	Types of reagents	No operation required
Position	Tray number and cup position of reagent	No operation required
# of m. R	Number of tests that reagent can perform	No operation required
Cal Stat	If the reagent calibrated	No operation required
C. Val. Period	Validity period of calibration parameters	No operation required
Batch No.	Batch number of the reagent	No operation required

Parameter	Meaning	Operation
Via#	Bottle number of the reagent	No operation required
VD of Rea	Remaining effective days of the reagent	No operation required
Meas Ite	Number of items that reagents can perform	No operation required

Basic operation

- Search
  1) Click the button **Search** to open the "Search" interface;
  2) Select the tray number and item and click **OK** to view the loaded reagent information.
- Reagent loading
  1) Click the button **Rea Load** to open the "Reagent Loading" interface;
  2) Enter the corresponding reagent information and click **Save**.
- Residual detection
  1) Click the button **Resi D** and select the tray number in the pop-up window.
  2) Click **SEL Pos.** at the 'Designated Position' to select a designated reagent position for residual detection;
  3) Click **SEL Item** at "Designated Item" to carry out residual detection on all reagent positions of the specified items;
  4) To carry out residual detection for all positions on the reagent tray, select "All Positions";
  5) To start residual detection, click **OK**; otherwise, click **Cancel**.
- Reagent unloading
  1) Click on the button **Rea UNLD**, in the pop-up window drop-down select tray number;
  2) Similar to the "Residual Detection" function, reagents can be unloaded according to the designated position, designated item or full tray.
- Review reagent information
  1) Click the button **Rea Info** to enter the "Reagent Information" interface to view the detailed information of the reagent;

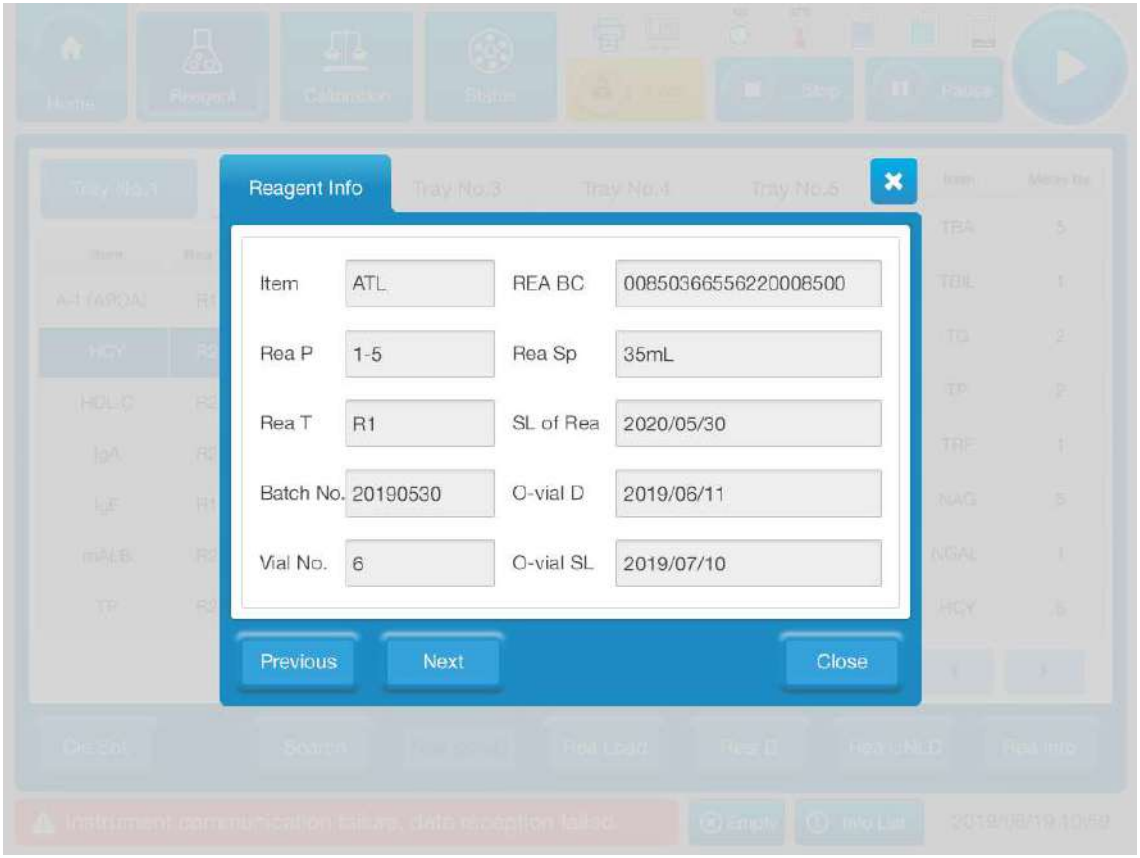


Figure 4-12 Reagent Information

2) Click **Previous** or **Next** to switch to display different reagent information.

4.5. Setup

Including test setup, system setup, user setup, user setup and item setup, which are described separately below.

4.5.1. Test setup

The test setup are divided into upper and lower pages, including basic setup, cleaning setup, result mark, auto retest setup and alarm setup.

As the following figure:

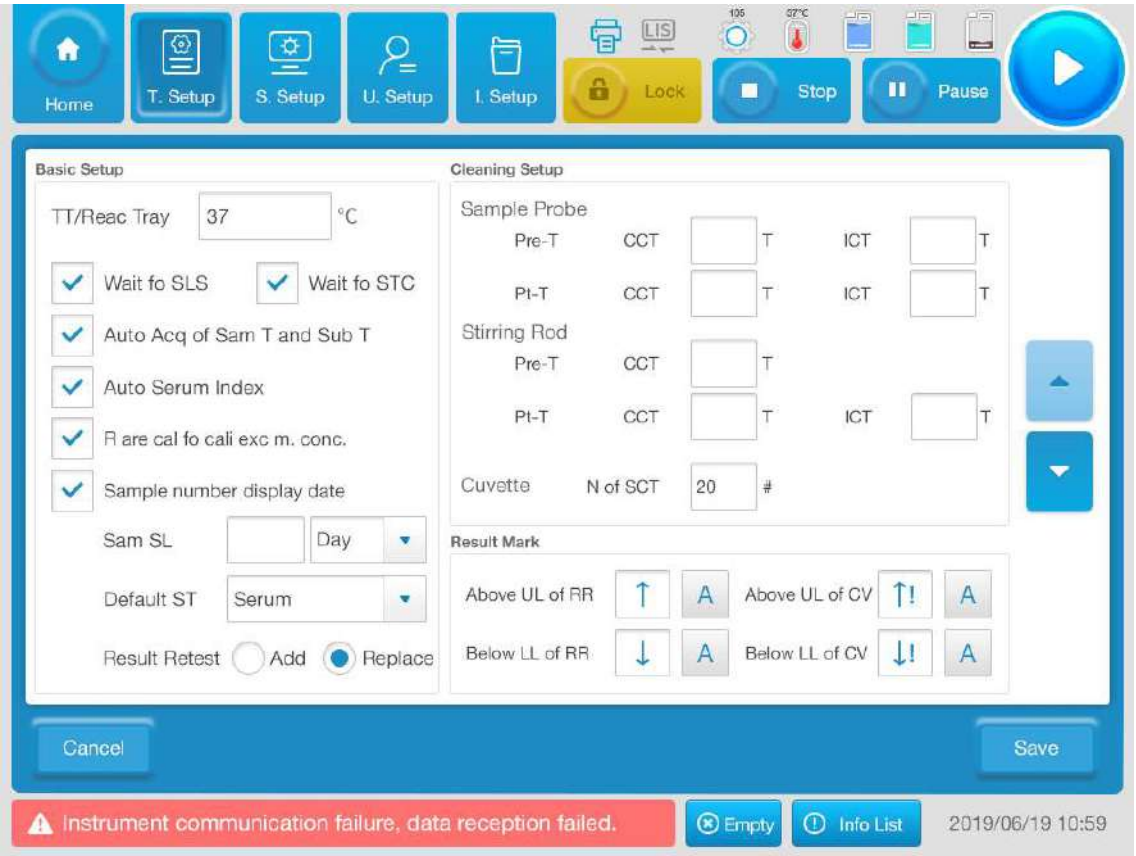


Figure 4-13 Test Setup

4.5.1.1. Basic setup

Basic interpretation of parameters

Parameter	Meaning	Operation
TT/Reac tray	Target temperature during reaction	Enter directly in the box, the default is 37 celsius degrees
Wait fo SLS	Choose whether to wait for the light source to stabilize	Check or uncheck, the default is check

Parameter	Meaning	Operation
Wait to STC	Choose whether to wait for stable temperature control	Check or uncheck, the default is check
Auto Acq of Sam T and Sub T	Automatic acquisition time	Check or uncheck, the default is uncheck
Sam ST	Set the sample shelf life	Enter directly in the box
Default ST	Set the default sample type for the sample application interface	Select directly from the drop-down box
Auto Serum Index	The serum index will be automatically tested when the sample type is serum or plasma	Check or uncheck, the default is uncheck
R are cal fo cali exc m. conc.	Choose if the result needs to be calculated	Check or uncheck, the default is uncheck
Sample number display date	Show the year, month and day before the sample number	Check or uncheck, the default is check
Result Retest	Decide whether the retest result will replace the original result or be added to the result list	Click **Add** or **Replace**

Basic operation

1) Enter the parameters and click **Save**.
2) If you need to modify, directly modify and then click **Save**.

The basic setup, cleaning setup, result marking, automatic retest setup, and alarm setup are the same.

4.5.1.2. Cleaning setup

Parameter	Meaning	Operation
Pre-T CCT	Common cleaning times of reagent-sample probe and stirring rod before testing	Enter directly in the box
Pre-T ICT	Intensified cleaning times of reagent-sample probe and stirring rod before testing	Enter directly in the box
Pt-T CCT	Common cleaning times of reagent-sample probe and stirring rod after testing	Enter directly in the box

Parameter	Meaning	Operation
Pt-T ICT	Intensified cleaning times of reagent- sample probe and stirring rod after testing	Enter directly in the box

4.5.1.3. Result marking

Parameter	Meaning	Operation
Above UL of RR	The test result exceeds the maximum value of the reference range.	Set the color identification of the test results
Above UL of CV	The test result exceeds the maximum value of the critical value range.	Set the color identification of the test results
Below LL of RR	The test result is lower than the minimum value of the reference range.	Set the color identification of the test results
Below LL of CV	The test result is lower than the minimum value of the critical value range	Set the color identification of the test results

4.5.1.4. Automatic retest setup

Parameter	Meaning	Operation
Beyond UL of RR	The test result exceeds the maximum value of the reference range	Check or uncheck, the default is uncheck
Below LL of RR	The test result is lower than the minimum value of the reference range	Check or uncheck, the default is uncheck
Beyond UL of CV	The test result exceeds the maximum value of the critical value range	Check or uncheck, the default is uncheck
Below LL of CV	The test result is lower than the minimum value of the critical value range	Check or uncheck, the default is uncheck
Beyond UL of LR	The test result exceeds the maximum value of the linearity range	Check or uncheck, the default is uncheck
Below LL of LR	The test result is lower than the minimum value of the linearity range	Check or uncheck, the default is uncheck
No Linearity of TR	The test results do not have linearity characteristics	Check or uncheck, the default is uncheck

Parameter	Meaning	Operation
No Calc Int	If the number of photometric points within the delay time and within the substrate depletion limit is less than 2, no calculation interval mark is given.	Check or uncheck, the default is uncheck
Substrate Depl	The substrate was exhausted during the reaction	Check or uncheck, the default is uncheck
Abn Prozone Exam	Abnormal prozone inspection	Check or uncheck, the default is uncheck
Beyond the max. conc calibration react	The test results exceed the calibration reactivity of maximum concentration	Check or uncheck, the default is uncheck

4.5.1.5. Alarm setup

Parameter	Meaning	Operation
Bulb Alarm Limit	The period of the bulb from turn on till alarm	Enter time data directly in the box
Rea Resi Alm LMT	The alarm will start if the reagent residual is less than specified volume	Enter directly in the box
Alm Lmt of ICS Resi	The alarm will start if the probe detergent residual is less than specified volume	Enter directly in the box
Rea SL Alarm	Whether to prompt for alarm when exceeding the validity period of the reagent	Check or uncheck, the default is check
CV Alarm	Alarm or not if the test results exceed the critical value	Check or uncheck, the default is check
AS vol	The volume of the alarm	Enter a volume percentage value in the box
AS	Sounds of alarm	Import from the folder to conduct alarm choice
Display edited result mark	Marking after editing a result	Check or uncheck, the default is check

4.5.2. System setup

System setup includes six parts: Device Setup, Print Setup, LIS Setup, Barcode Setup, Data Dictionary and List setup, which are described below.

4.5.2.1. Device setup

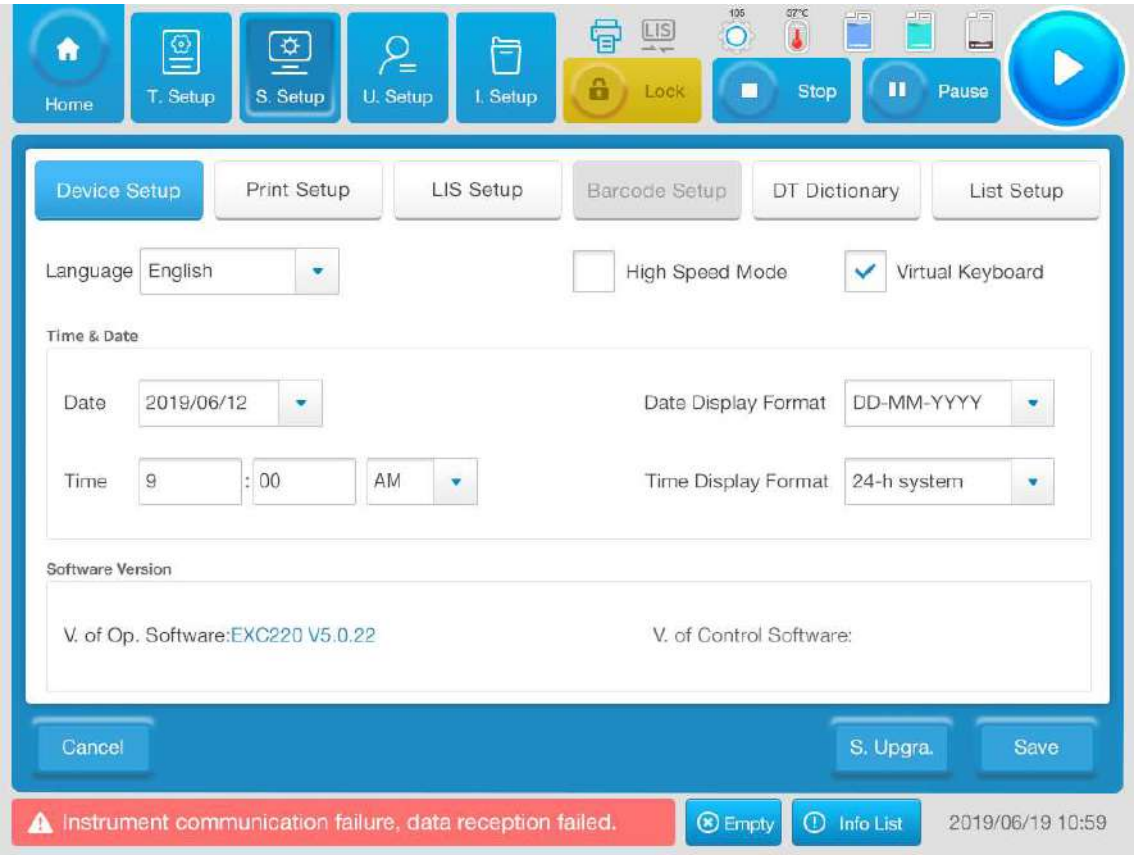


Figure 4-14 Device setup

Basic interpretation of parameters

Parameter	Meaning	Operation
Language	Software interface display language	Drop-down selection
High speed mode	Testing mode is high speed	Check or uncheck, the default is uncheck
Virtual keyboard	Show virtual keyboard at the bottom of the interface	Check or uncheck, the default is check
Date	The date is displayed in the lower right corner of the instrument interface	Select directly from the drop-down box
Date Display Format	Select the date to display the sort of year, month and day	Select directly from the drop-down box

Parameter	Meaning	Operation
Time	Set time	Select directly from the drop-down box
Time Display Format	12 h or 24 h system	Select directly from the drop-down box
V. of Op. Software:	Current operating software version number	No operation required
V. of Control Software:	Current control software version number	No operation required
S. Upgra.	Upgrade current software	Click software upgrade to import the new installation package

Basic operation

1) Directly enter the information and click **Save**.

2) After modifying the data, you can click **Cancel** to restore.

4.5.2.2. Print setup

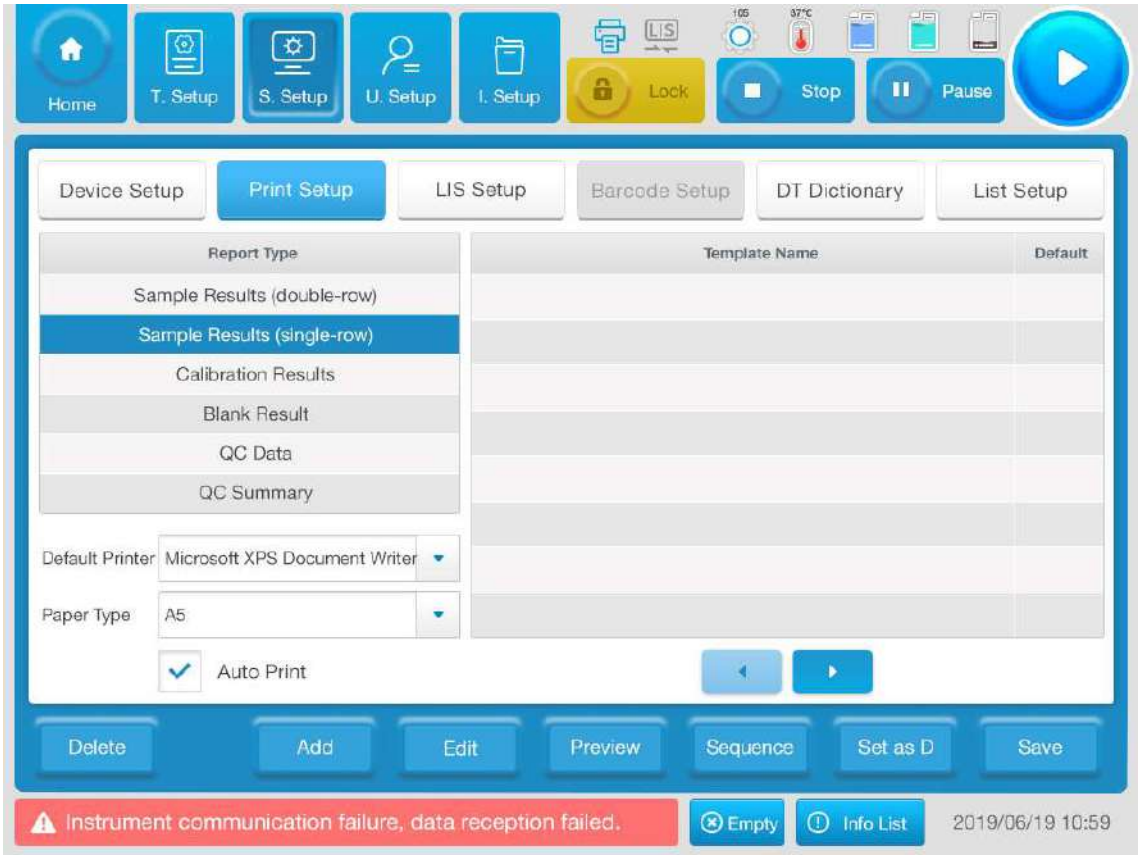


Figure 4-15 Print Setup

Basic operation

■ Print operation

1) The system has 6 report types corresponding to 6 default report templates, which cannot be deleted or edited;

2) Select the report type to add a template, and click **Add** to add a template that is the same as the default template. This template can be edited. After editing, you can click **Preview** to preview. Click **Save** to save; to delete, click **Delete**;

3) You can select the default printer from the drop-down list in the "Default Printer" line; select the printing paper type from the "Paper Type" line; and determine whether automatic printing is required through checking;

4) Click **Sequence** to set the item printing order;

5) Select any template under "Template Name" and click the button **Set as D** to set the template as the default template.

■ Edit template

Select the new template to edit, and click **Edit** to open the following report designer interface, which can be used for simple report design, including font, content, type setting, etc.

Figure 4-16 Report Designer

The report designer shown above includes toolbar, edit bar and save button.

1) "**Settings**" can be used for simple general settings and page and margin settings.

General settings include report name, file code, default font and default font size. Page and margin settings include setting page size, margin and page orientation.

2) Click **Label** to add a label text box in the editing column below and enter a text description in the text box. If the text box needs to import relevant data, it needs to be associated with the name of the relevant data. Select it in the drop-down box, and the data will be imported automatically when printing. If you want to get the ID of the patient in a text box, double-click to the text box and select the ID of the associated patient in the associated drop-down box.

3) Click **Field** to add a field text box in the editing column below. Double-click the text box to enter the field setting dialog box, where you can set the input text type, field type, value, character format, number and date display.

4) Click **Horizontal** or **Vertical** to add horizontal line or vertical line in the editing column below, and you can stretch the length freely.

5) As shown in the figure, the left area of the second line is a tool only applicable to text boxes, which can set font, size, bold, italic, underline and alignment.

6) As shown in the figure, the right area of the second row is a tool only applicable to line segments, and the type and width of line segments can be set.

7) To set the color of the text box and line segments, select the text box, click on the color setting interface to select; select a text box or line segment and click **Delete** to delete. After the operation is completed, click **Save** to save the modified template.

- Printer setup

Select the new template to be set up for printer, and click **Preview** to open the template preview interface as shown in the following figure. Simple printer setup can be made, including page printing setup such as margins.

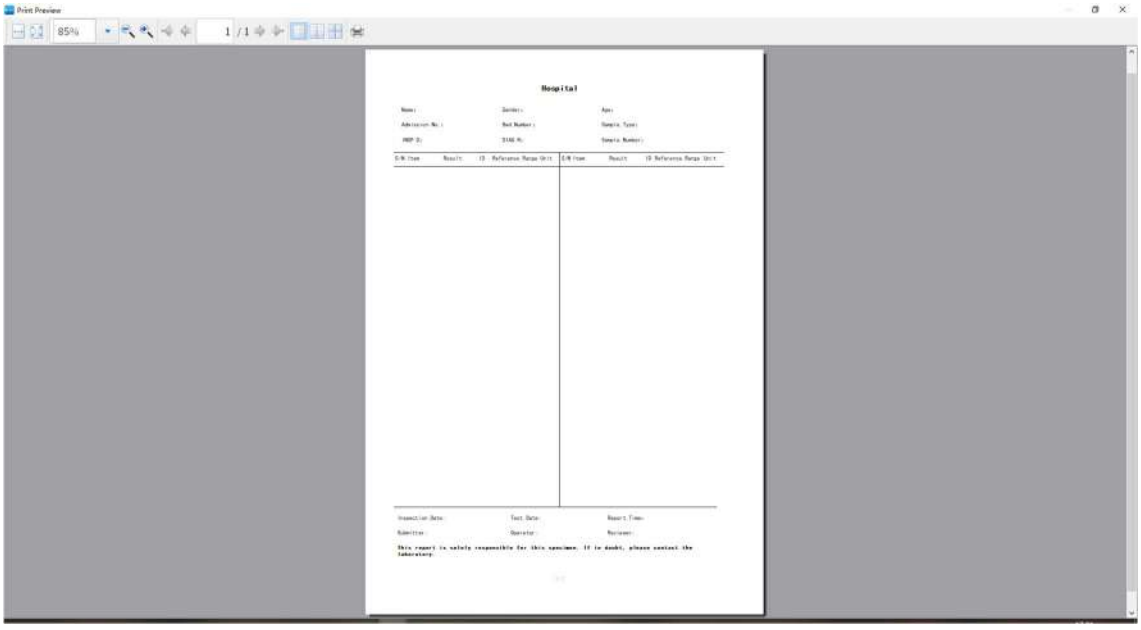


Figure 4-17 Template Preview

4.5.2.3. LIS setup

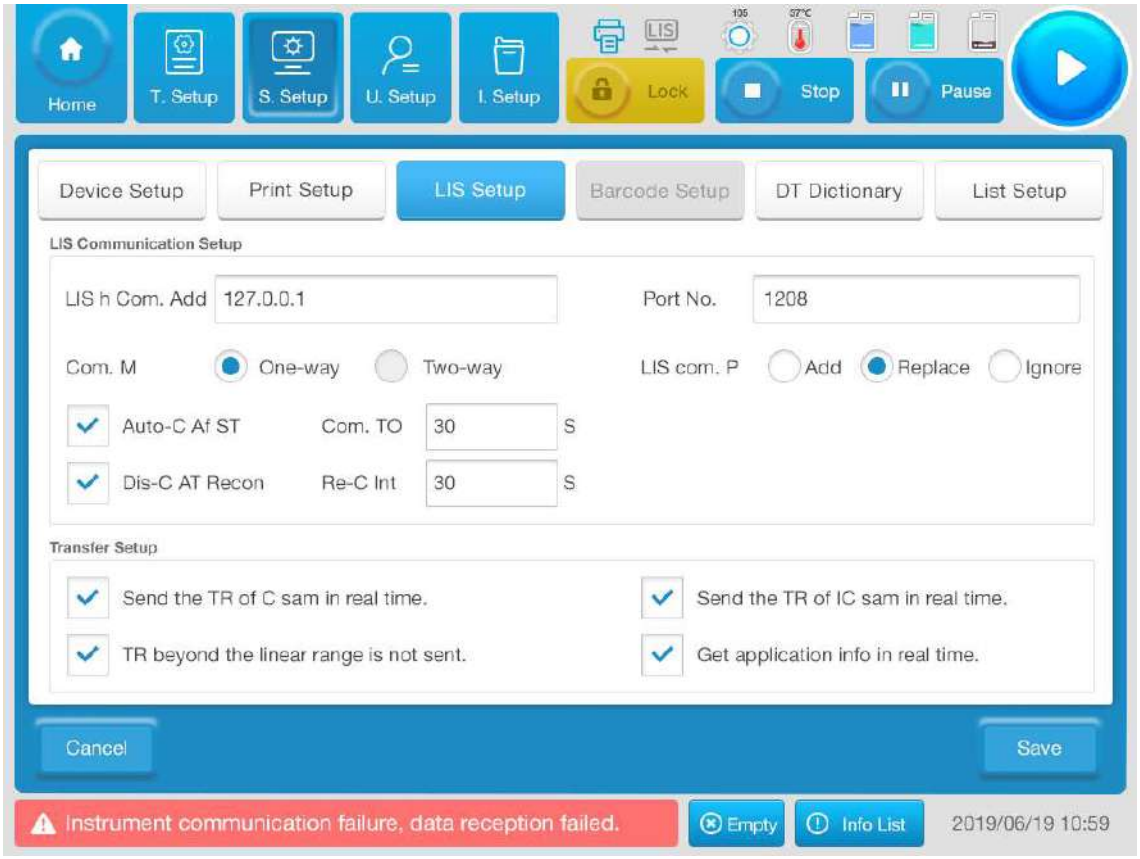


Figure 4-18 LIS Setup

Basic interpretation of parameters

Parameter	Meaning	Operation
LIS h Com. Add	Host communication IP address of LIS	Enter directly in the box
Port No.	Port number of the communication host (the port number entered is the same as that of the communication host)	Enter directly in the box
Com. M	Select a communication mode	Select "One-way" or "Two-way"
LIS communication	Choose to manage LIS communication	Select "Add", "Replace" or "Ignore"
Auto-C Af ST	Choose whether to automatically connect to communication when startup	Check or uncheck, the default is check
Com. TO	Set the time to reconnect automatically after timeout	Enter directly in the box

Parameter	Meaning	Operation
Dis-C AT Recon	Choose to automaticly reconnect or not after disconnection	Check or uncheck, the default is check
Re-C Int	Set the period before connecting automatically	Enter directly in the box
Send the TR of C sam in real time	Select whether to send test results in real time	Check or uncheck, the default is check
Send the TR of IC sam in real time	Select whether to send incomplete sample test results in real time	Check or uncheck, the default is check
TR beyond the linear range is not sent	Select whether to send test results beyond the linearity range	Check or uncheck, the default is check
Get application info in real time	Select whether to send sample application information in real time	Check or uncheck, the default is check

Basic operation

1) Enter the parameters and click **Save**.
2) If you need to modify, directly modify and then click **Save**.

4.5.2.4. Data dictionary

The results unit, sample note, diagnostic reference and patient information can be set.

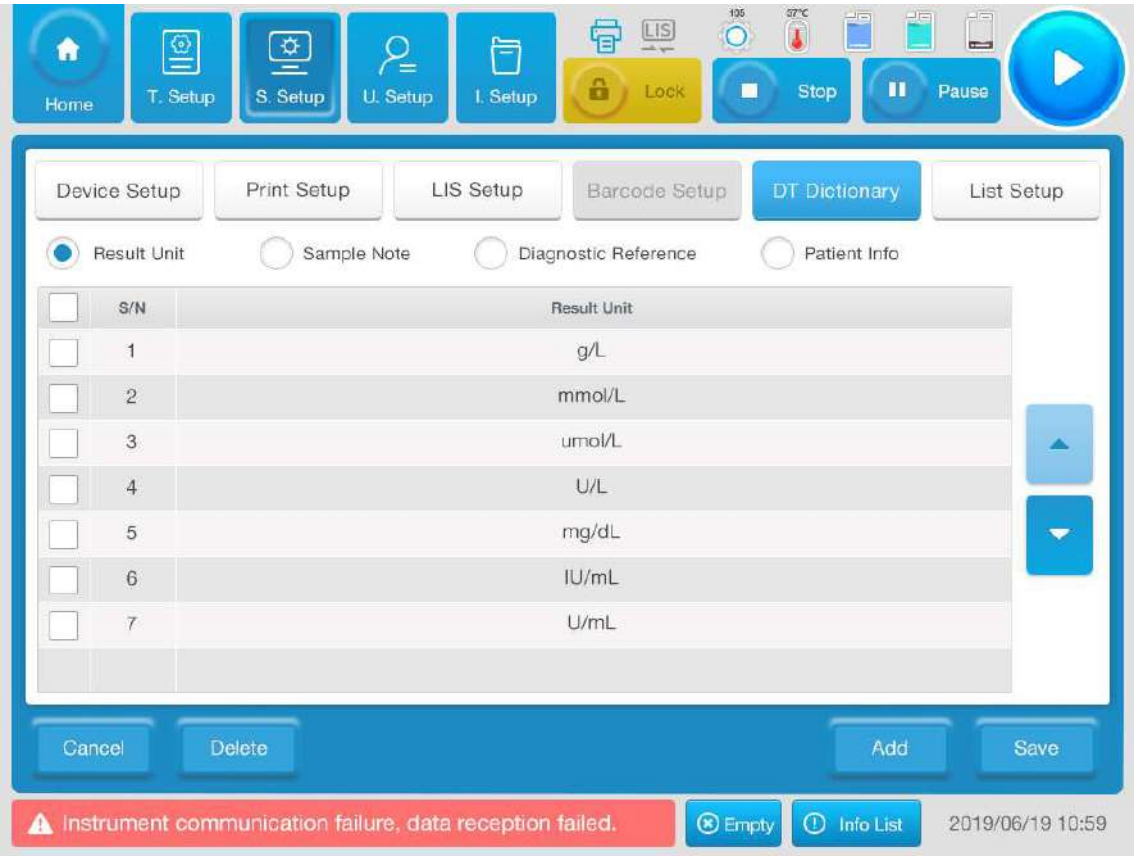


Figure 4-19 Data Dictionary

Basic operation

1) To add a type, select a data dictionary type, click **Add** and enter it in the blank line, and then click **Save**.
2) If you need to delete data under a data dictionary type, select the type and click **Delete**.
3) If you need to modify a type under a data dictionary type, select the type and modify it directly. Click **Save** after completion.
4) If you do not want to save the changes made, click **Cancel**.

4.5.2.5 List setup

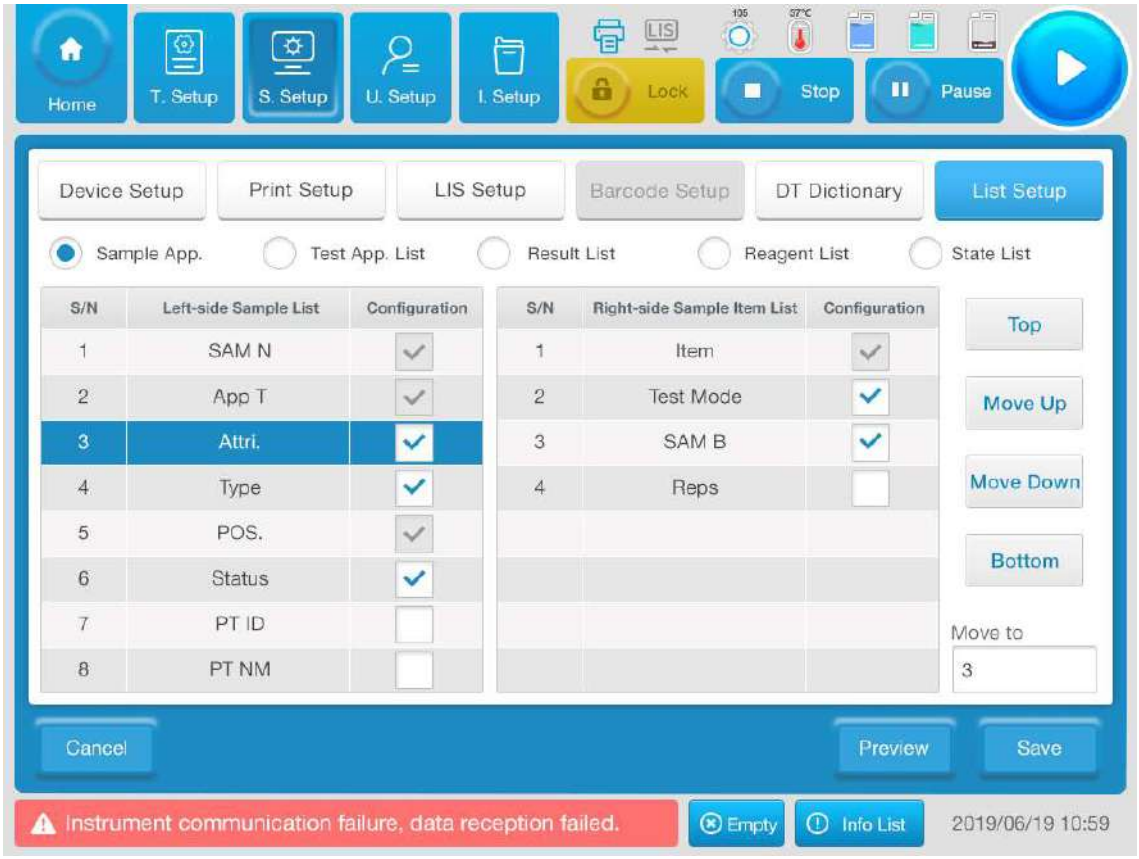


Figure 4-20 List Setup

Basic operation

1) Check or uncheck a configuration to set the display format of the list, and then click the **Preview** button to preview the list format;
2) Click **Save** to save the setting, click **Cancel** to cancel the setting.

4.5.3. User setup

User setup mainly includes user management, hospital setup, department setup and physician setup, which will be described separately below.

4.5.3.1. User management

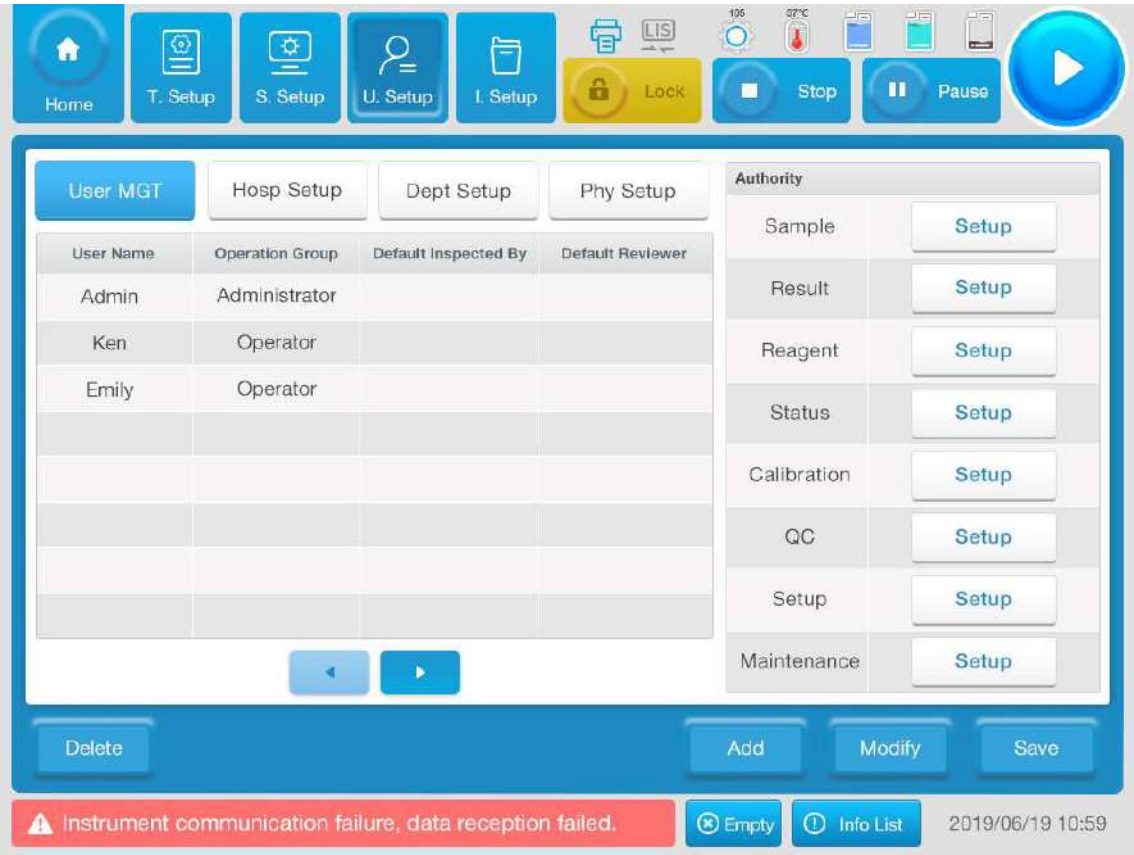


Figure 4-21 User Management

Basic interpretation of parameters

Parameter	Meaning	Operation
Add	Add user account	Click directly
Modify	Modify user information	Click directly
Authority	The interface contents that the corresponding account can view	Click **Setup** to enter the "Authority Setup" interface

Basic operation

1) If you need to add users, click **Add** to open the "Add User" interface, and set the contents of the new account. Set the associated physician, click **A. Phys.** to select the examination physician and reviewer, it can be set as the default. Click **Save** after setting, and click **Save** after all the contents are set;

2) To delete a user name, select the line, click **Delete** to open the interface, and click **OK**-**Save**.

3) To modify, select the line to be modified, click **Modify** to open the modify user interface, enter the modified content, and then click **OK**.

4) If you need to change authority, click **Setup** to open the "Authority Setup" interface, check or uncheck a permission directly, then click **Save**.

4.5.3.2. Hospital setup

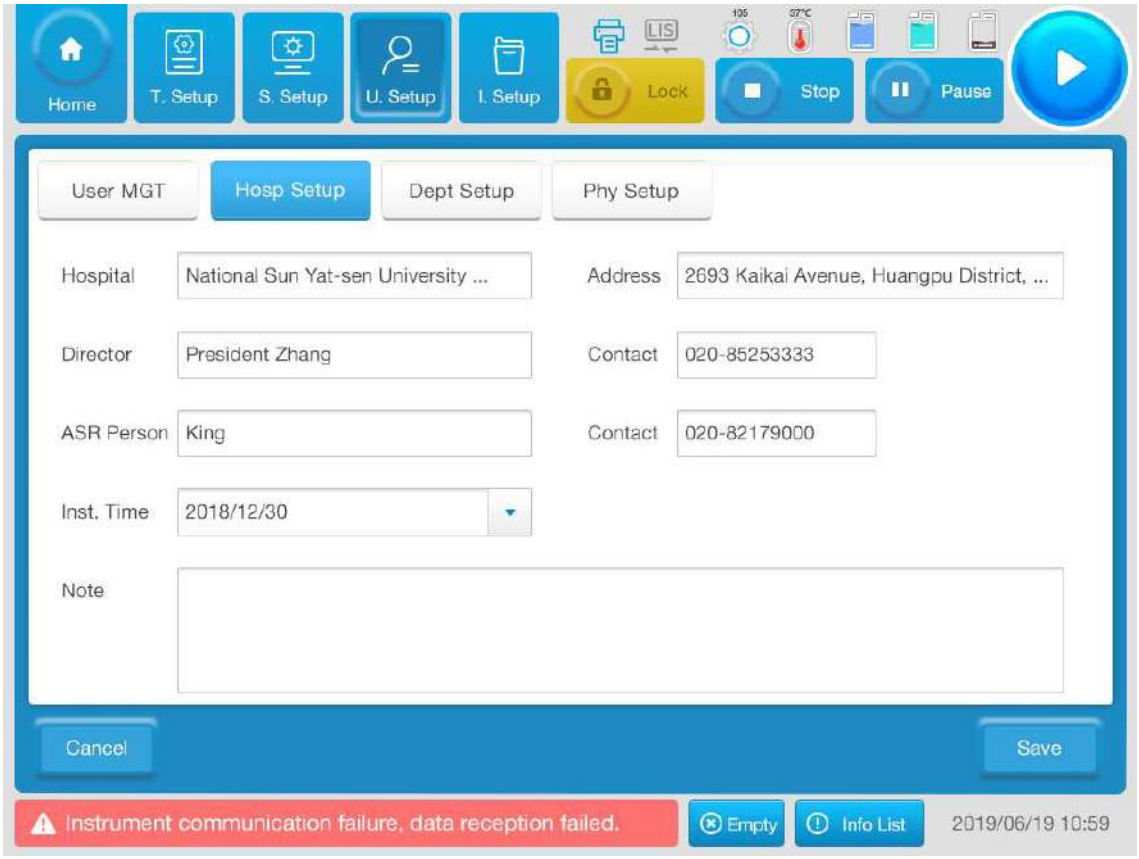


Figure 4-22 Hospital Setup

Basic interpretation of parameters

Parameter	Meaning	Operation
Hospital	Name of hospital	Directly input
Address	Address of the hospital	Directly input
Director	The director of the hospital	Directly input
Contact	The contact number of the person in charge of the hospital or after-sales service	Directly input
ASR Person	Designated person in charge of after-sales of the product	Directly input
Inst. Time	Date when this instrument is installed	Select from the drop-down box
Note	Remarks	Directly input

Basic operation

1) Enter the parameters and click **Save**.

4.5.3.3. Department setup

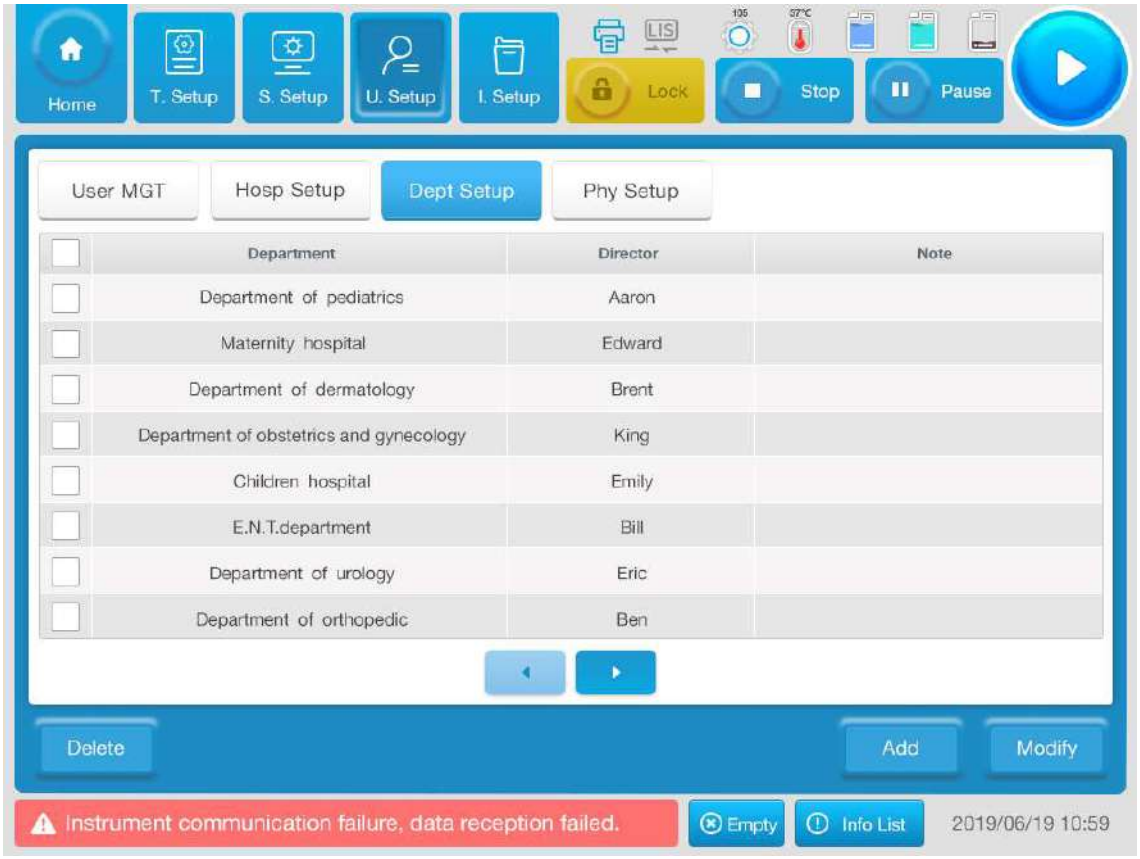


Figure 4-23 Department Setup

Basic interpretation of parameters

Parameter	Meaning	Operation
Department	Displays the name of the department	No operation required
Director	The person who in charges of the department	No operation required
Note	Show comments	No operation required
Add	Add department information	Directly click
Modify	Modify department information	Directly click
Delete	Delete department information	Directly click

Basic operation

1) Add: click **Add** to enter the parameter content in the pop-up window.
2) Modify: check the content to be modified, click **Modify** and enter the parameter content in the pop-up window.
3) Delete: check the content to be deleted and click **Delete**.

4.5.3.4. Physician setup

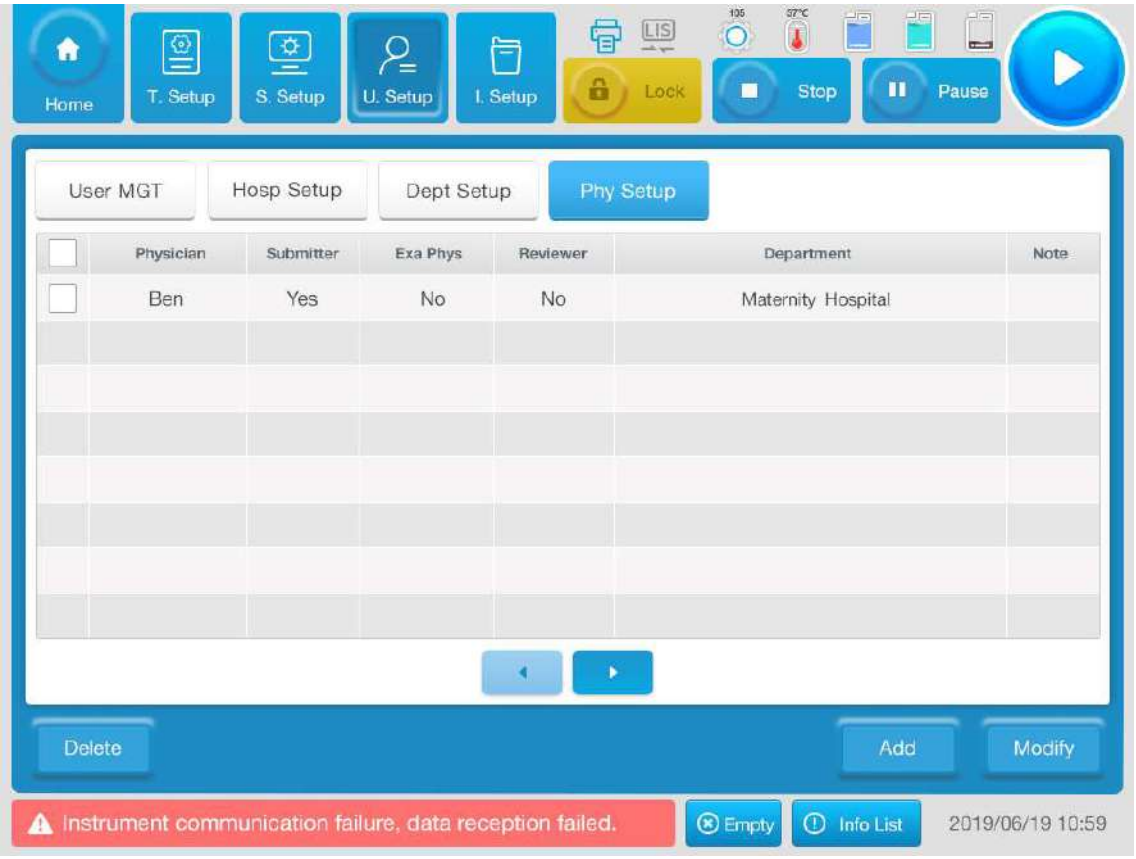


Figure 4-24 Physician Setup

Basic interpretation of parameters

Parameter	Meaning	Operation
Physician	Physician's name	No operation required
Submitter	Submitter or not	No operation required
Exa Phys	Examination physician or not	No operation required
Reviewer	Reviewer or not	No operation required
Department	The department to which the doctor belongs	No operation required
Note	Note	No operation required
Add	Add doctor information	Directly click
Modify	Modify doctor information	Directly click
Delete	Delete doctor information	Directly click

Basic operation

1) Add: click **Add** to enter the parameter content in the pop-up window.

2) Modify: check the content to be modified, click **Modify** and enter the parameter content in the pop-up window.

3) Delete: check the content to be deleted and click **Delete**.

4.5.4. Item setup

It mainly includes routine item, serum index, calculation item, combined item, manual item and cross contamination, which will be described separately below.

4.5.4.1. Regular item

Figure 4-25 Regular Items

Basic operation

■ Add new item

1) Click **Add** to open the "Add Routine Items" interface;

2) Enter the item parameters and click **Save**.

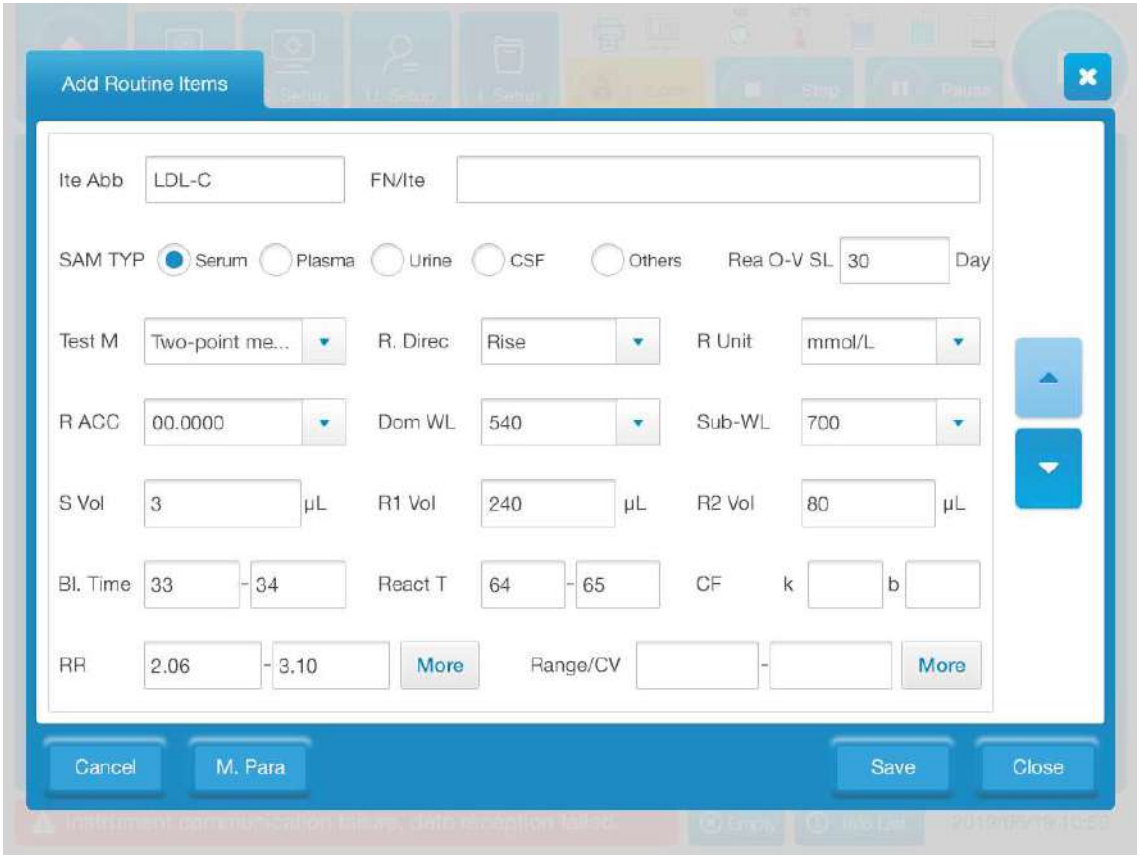


Figure 4-26 Add Routine Items

Basic interpretation of parameters

Parameter	Meaning	Operation
Ite Abb	Short name of the item	Directly input
FN/Ite	Full name of the item	Directly input
SAM TYP	Select the type of the sample	Click the radio box to select
Rea O-V SL	The shelf life after the reagent vial is opened	Directly input
Test M	Set test methods for items include endpoint method, two-point method and kinetic method	Select from the drop-down box
R. Direc	Test reaction direction	Select from the drop-down box
R Unit	Unit of results	Select from the drop-down box
R ACC	Number of decimal places reserved for results	Select from the drop-down box

Parameter	Meaning	Operation
Dom WL	Dominant wavelength to be measured	Select from the drop-down box
Sub-WL	Sub-wavelength to be measured	Select from the drop-down box
S Vol	The sample size added to the test, in microliters	Directly input, range is 2~50 μL
R1 Vol	R1 volume added in the test	Directly input，range is 90~350μL
R2 Vol	R2 volume added in the test	Directly input，range is 10~250μL
Bl. Time	The time before a test initiates a reaction. Single reagent item refers to the time between adding reagent and adding sample, while dual reagent item refers to the time between adding sample and adding R2	Directly input
React T	The period of time used to calculate the starting and ending photometric points	Directly input
CF	Correct the result according to y=kx+b, where x is the measured result, y is the corrected result, k is the slope in the correction formula, and b is the intercept in the correction formula	Enter a specific number in the box, k defaults to 1 and b defaults to 0
RR	Reference range of sample concentration for test results	According to the reference range provided by the kit instructions or professional reference books, enter the specific value in the box
Range/CV	Critical value range of test result	Directly input
More	Set the upper and lower limits of the sample concentration reference range or critical value range for more conditions, including gender, sample type, age, etc.	Click to enter the interface of "setup reference range/critical value range"

Parameter	Meaning	Operation
M. Para	Set monitoring parameters for various conditions, including detection linearity limit, substrate depletion limit, linearity range, reaction degree range, absorbance of working solution, R1 blank absorbance, prozone inspection parameters, etc.	Directly input
Cancel	Do not save the input information	Directly click
Close	Close the interface	Directly click
Save	Save the current parameters	Directly click

- Modify item

  1) Select the item to be modified in the item list, and click **Modify** to enter the "Modify Routine Items" interface;

  2) Enter the modified parameters and click **OK**.

- Delete item

  1) Select the item to be deleted in the item list, and click the button **Delete**.

- Item sequence

  1) Click **Sequence** to open the "Sequence" interface, and select the item/test of which the sequence needs to be changed;

  2) Click **Top** to put the choosen item/test to the first place, and click **Bottom** to put the choosen item/test to the last place.

  3) Click **Move Up** to move up one position of the choosen item/test, and click **Move Down** to move down one position of the choosen item/test.

  4) If you need to move to a specified position, directly enter the specified number in the box on the right of **Move To** and press enter.

  5) To save the settings, click the button **Save**. Click **Close** to return to the main interface of the regular item, otherwise click the **Cancel** button

- Import

  1) Click the button **Import** to open the import item dialog box;

  2) Select the excel file in the local folder to import the item parameters into the item list.

- Export

  1) Select the item to export from the item list;

  2) Click the button **Export** to open the export item dialog box;

3) Select the file path to export the item parameters in the item list to the local folder.

4.5.4.2. Serum index

Serum index refers to the degree of hemolysis, jaundice and lipemia in serum samples.

"Serum index" interface is as follows:

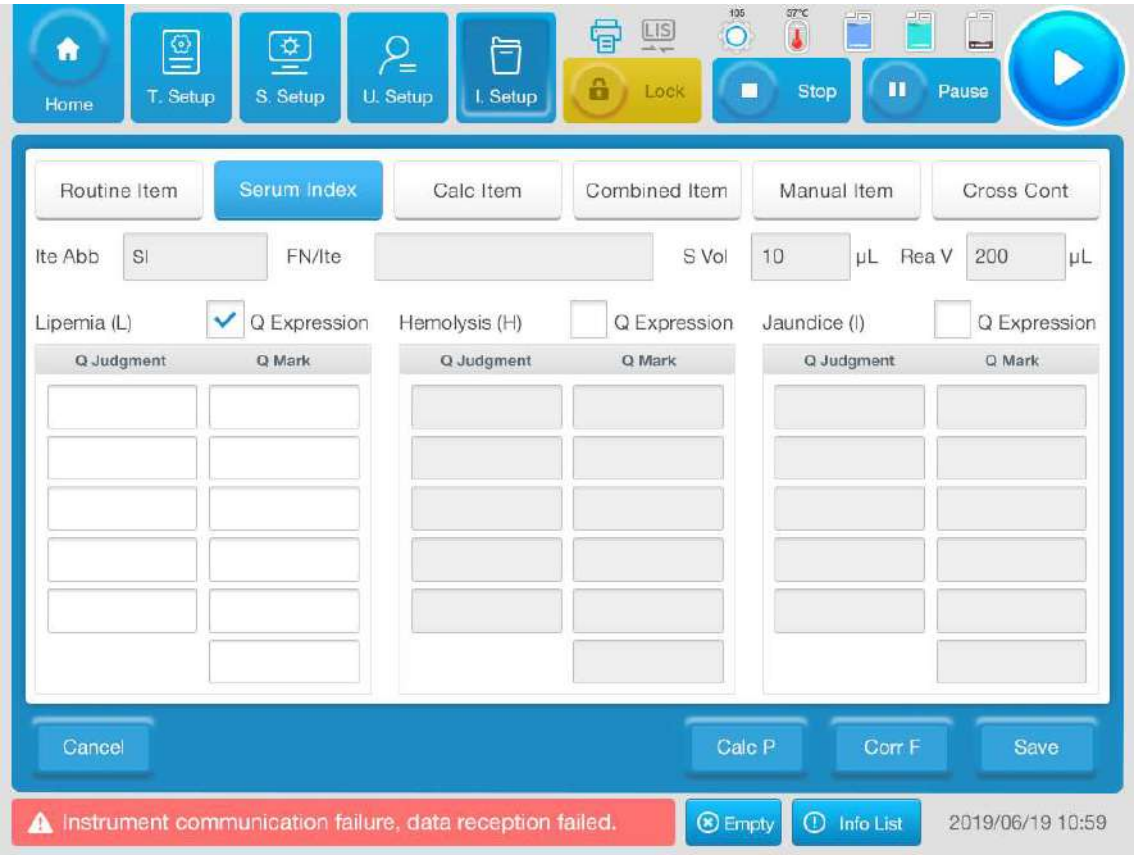


Figure 4-27 Serum Index

Basic interpretation of parameters

Parameter	Meaning	Operation
Ite Abb	Abbreviations for the items	No operation required
FN/Ite	The full name of the items	No operation required
S Vol	The sample is serum, and the sample volume is fixed at 10µL	No operation required
Rea V	The reagent is normal saline and the test volume is fixed at 200 µL	No operation required

Parameter	Meaning	Operation
Q Expression	Whether the test results are expressed according to qualitative marks	Check or uncheck
Q Judgment	The qualitative marker is determined by comparing the test value of hemolysis, icterus or lipemia with the threshold value of qualitative judgment	Enter manually. The qualitative judgment threshold is 5 positive integers or decimals that increase in sequence from top to bottom. Any symbol can be entered in the 6 input boxes of the qualitative mark. Taking lipemia (L) as an example, qualitative judgment inputs L1 to L5 required to be 0<L1<L2<L3<L4<L5. when the result l satisfies L<l1, the corresponding qualitative marker 1; in case of L1<L<L2, it corresponds to qualitative marker 2, and so on
Q Mark	The test results will be displayed as this mark	
Calc P	Six parameters, A, B, C, D, E and F, are set to calculate the serum index results	Enter manually. Among them, B, E and F are not adjustable, being 1.42, 1.31 and 4.55 respectively. A, C and D are adjustable with default values of 2.20, 1.45 and 250 respectively
Corr F	Set the slope and intercept of the correction	Enter manually

Basic operation

1) To qualitatively express the serum index test results, tick the corresponding selection box.
2) Input five ascending positive integer or decimal numbers from top to bottom in that five input boxes for qualitative judgment, and customizing input symbol in the qualitative mark input box;
3) If you want to change the calculation parameters, click **Calc P** and enter the values of A, C and D in the pop-up window.
4) If you want to change the correction factor, click **Corr F** button and enter the slope and intercept values in the pop-up window.
5) After completing the parameter setting, click **Save**.

4.5.4.3. Calculation item

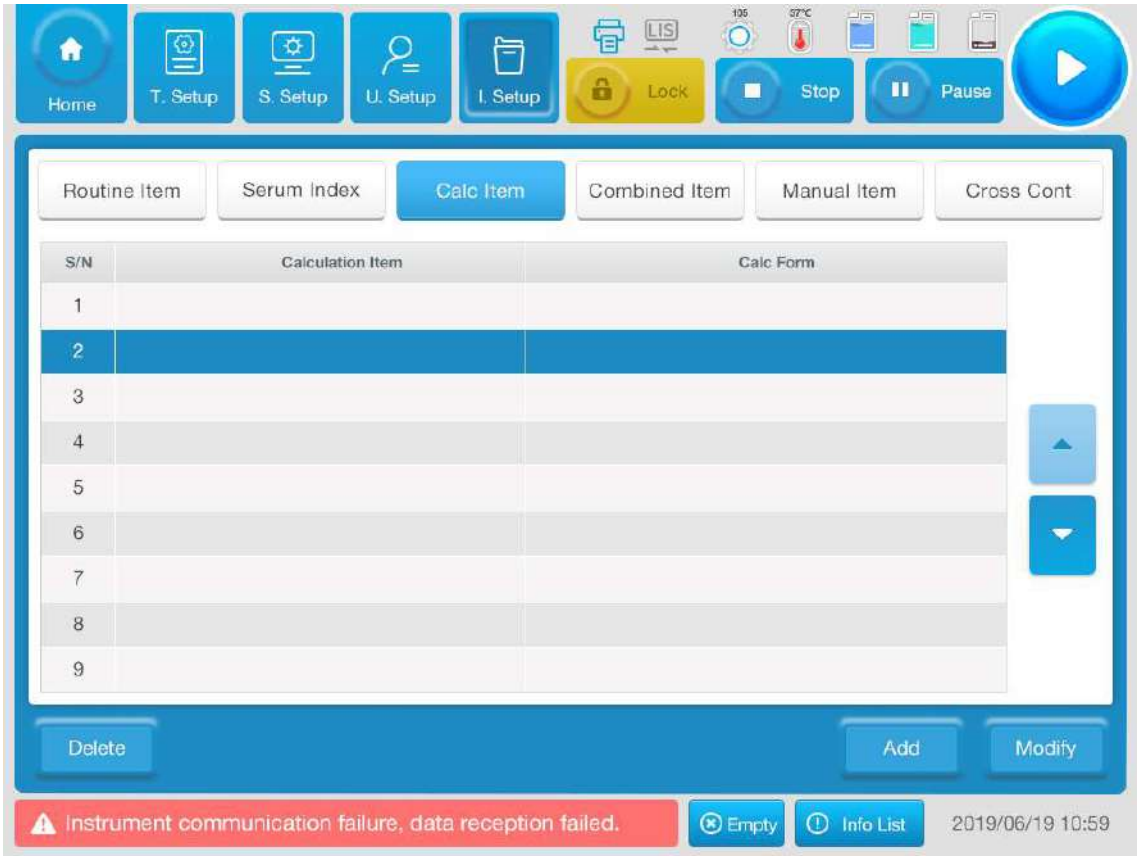


Figure 4-28 Calculation Items

Basic interpretation of parameters

Parameter	Meaning	Operation
S/N	Sequence of the calculation items	No operation required
Calculation Item	Abbreviations of calculation items	No operation required
Calc Form	Formulas for calculation items	No operation required
Add	Add new calculation items	Click directly
Modify	Modify calculation items	Click directly
Delete	Delete calculation items	Select the item first, and then click **Delete**

Basic operation

■ Add calculation items

1) Click **Add** to pop up the "Add Calculation Items" interface;

2) Enter or select the corresponding content in each box;

3) After clicking an item in the item list, click the numeric value and the calculation

symbol in the calculation button selection area to form an expression of the calculation item. The input expression can be seen in the "Calc Form" area.

4) To save added calculation items, click **Save**, otherwise click **Cancel**.

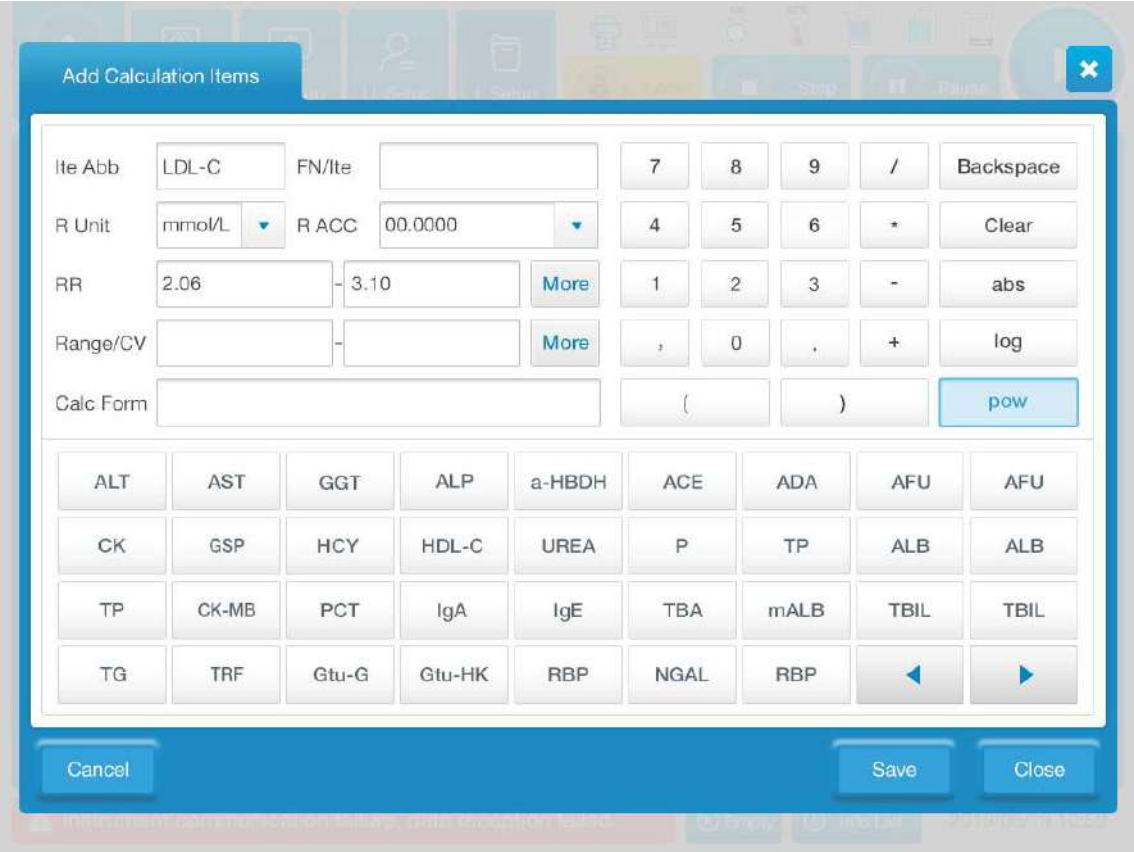


Figure4-29 Add Calculation Items

Basic interpretation of parameters

Parameter	Meaning	Operation
Ite Abb	Abbreviations of calculation items	Enter directly
FN/Ite	Full name of the calculation items	Enter directly
R Unit	Unit of results	Select from the drop-down box
R ACC	Number of decimal places reserved for results	Select from the drop-down box, there are five types: 0,0.0,0.00,0.000,0.0000
RR	Reference range of test results	Enter directly
Range/CV	Critical value range of test result	Enter directly

Parameter	Meaning	Operation
More	Set the upper and lower limits of the sample concentration reference range or critical value range for more conditions, including gender, sample type, age, etc.	Click to enter the interface of "Setup Reference Range/Critical Value Range"
Calc Form	Displays the expression for the calculated item	No operation required

- Modify calculation items

  1) In the calculation item list display area, select the calculation item to be modified, and click **Modify** to enter the "Modify Calculation Items" interface;

  2) Enter or select the corresponding content in each box;

  3) To change the calculation formula, click **Clear** in the calculation area to delete the formula and re-enter the expression;

  4) To save the modified content, click **OK**, otherwise click **Cancel**.

- Delete calculation asssay

  1) Select item;

  2) Click **Delete** and then click **OK** in the pop-up window, otherwise click **Cancel**.

4.5.4.4. Combined item

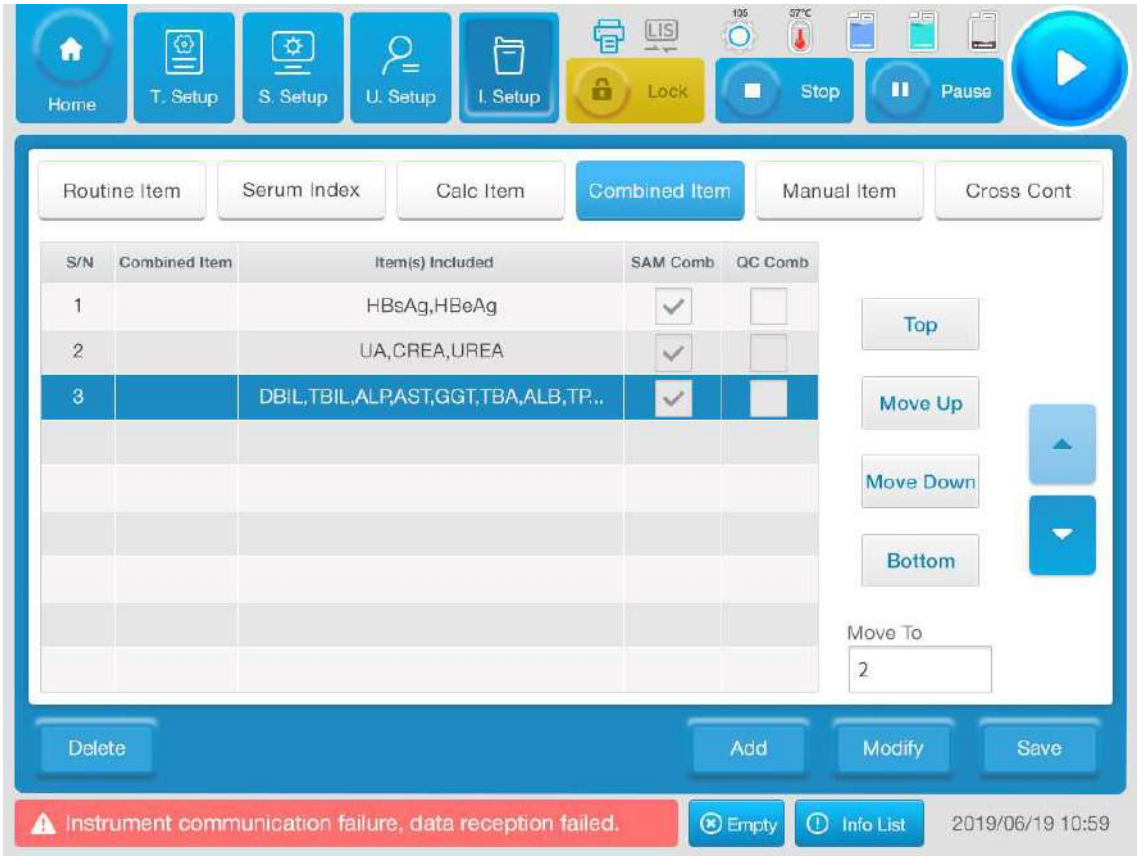


Figure 4-30 Combined Item

Basic interpretation of parameters

Parameter	Meaning	Operation
S/N	Sequence of the combined items	No operation required
Combined Item	Abbreviations for combined items	No operation required
Item(s) Included	Regular items included in this combined items	No operation required
SAM Comb	If the combined items displayed in the sample application list	No operation required
QC Comb	If this combined items displayed in the QC application list	No operation required
Top	The selected calculation items will be displayed at the top	Select the item first, and then click **Top**
Move Up	Move the selected calculation items up one position to display	Select the item first, and then click **Move Up**

Parameter	Meaning	Operation
Move Down	Move the selected calculation items down one position to display	Select the item first, and then click **Move Down**
Bottom	Place the selected calculation items in the last position for display	Select the item first, and then click **Bottom**
Move To	Move the selected calculation items directly to the specified location for display	Select the item first, enter the specified serial number in the box, and then click **Save**

Basic operation

■ Add combined items

1) Click **Add** to pop up the "Add Combined Items" interface:

Figure 4-31 Add Combined Items

2) Enter the abbreviation name and full name of the item;

3) Click on the corresponding item in the regular item list, clicking once indicates selection, and click again to cancel;

4) To display the combined item in the sample application list, check the selection box in the "SAM Comb" column;

5) To display the combined item in the quality control application list, check the selection box in the "QC Comb" column;

6) To save the added combined item, click **Save**.

■ Modify combined items

1) Select the combined item;

2) Click **Modify**;

3) Enter the modified content to delete or add items in the "Item List";

4) To save the modified content, click **Save**.

■ Delete combined item

1) Select the combined items;

2) Click **Delete**.

4.5.4.5. Manual item

Manual items is items where users manually input item parameters and test results. They do not participate in the test but only save, display and print the test results.

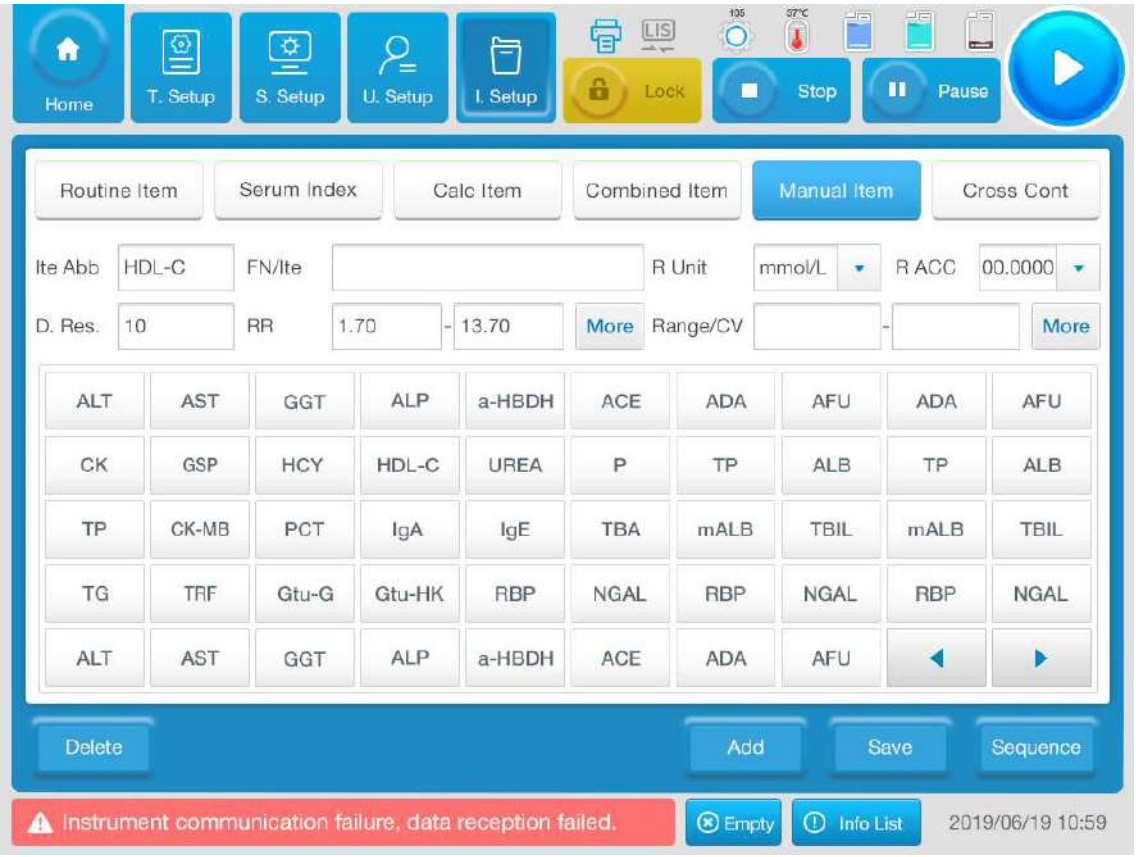


Figure 4-32 Manual Item

Basic operation

- Add manual item
  1) Click **Add**;
  2) Enter or drop down in the box to select the input content, add the entered parameter items to the manual item display area below;
  3) Click **Save**.
- Modify manual item
  1) Select the items to be deleted;
  2) Modify or pull down the content directly in the box;
  3) Click **Save**.
- Delete manual item
  1) Select the items to be deleted;
  2) Click **Delete**;
  3) Click **Save**.
- Manual item sequence
  1) Click **Sequence**;
  2) Sort the items;
  3) Click **Save** to return to the manual item main interface.

4.5.4.6. Cross contamination

Figure 4-33 Cross-Contamination

Basic operation

1) Select a contamination source item in "Cont S Item" area;
2) Select the contaminated item in "Cont Item" and you can select multiple items. For the item, click once is selected and click again is deselected;
3) Check **Rea Cont** or **Cuv Cont** under "Contamination List" on the right;
4) Click **Save**, otherwise, click **Cancel**;
5) Click the **CT Setup** and select the number of times of intensive cleaning and normal cleaning from the pop-up window, and click **OK**.
6) To delete the set cross-contamination items, select them in the "Contamination List" and click **Delete**.

Attention

Please set up the cross-contamination among the analysis items according to the reagent composition provided by the reagent manufacturer, otherwise the analysis results of the items may be affected by cross-contamination.

4.6. Maintenance

4.6.1. Daily maintenance

This function includes periodic maintenance, trouble shooting, data backup, temperature curve, consumable status, and unit status. Daily maintenance is the default maintenance interface. Click the button **Maintenance** in the main menu to display the following page:

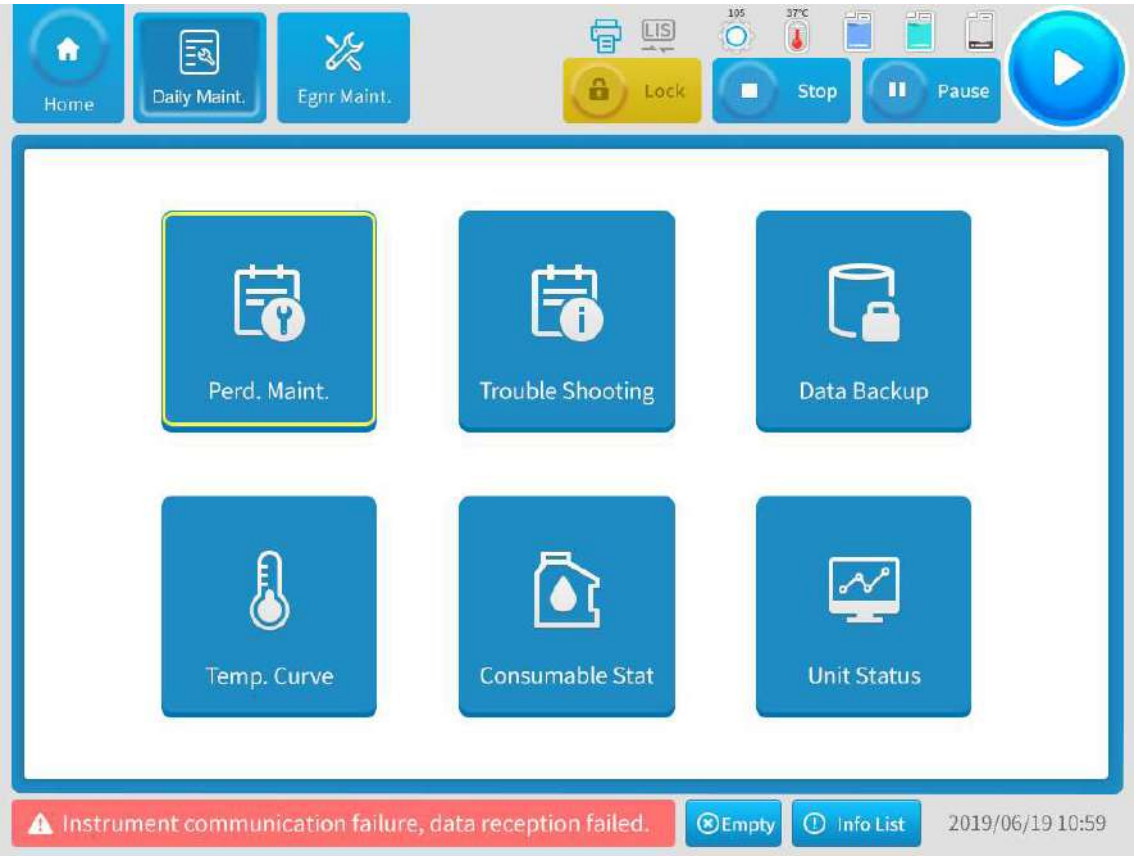


Figure 4-34 Maintenance Interface

4.6.1.1. Periodic maintenance

Periodic maintenance divides the items requiring maintenance by users into daily, weekly, monthly and other (irregular) items according to the maintenance cycle, and also carries out maintenance according to instructions.

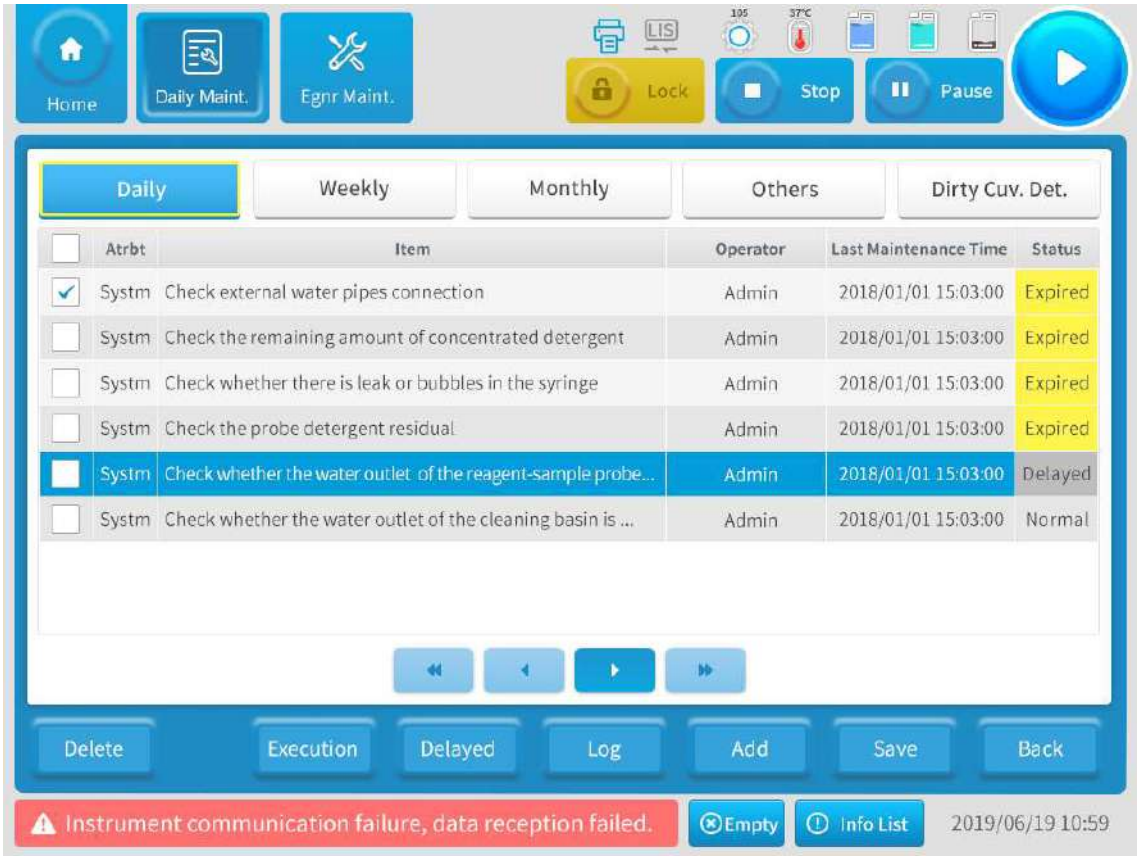


Figure 4-35 Periodic Maintenance

The periodic maintenance list is divided into the following maintenance periodic units:

- Daily-1 day
- Weekly-7 days
- Monthly-30 days
- Others-irregular
- Dirty cuvette detection

4.6.1.2. Trouble shooting

When the instrument fails during operation, the fault code, failure source, fault unit, fault level, fault time, detailed fault description, fault cause and processing method can be viewed on the trouble shooting page. Users can simply handle the instrument fault according to the fault description, which is convenient for users to solve the fault occurred during operation, and at the same time, fault recovery function is available.

Click on the trouble shooting interface as shown in the following figure:

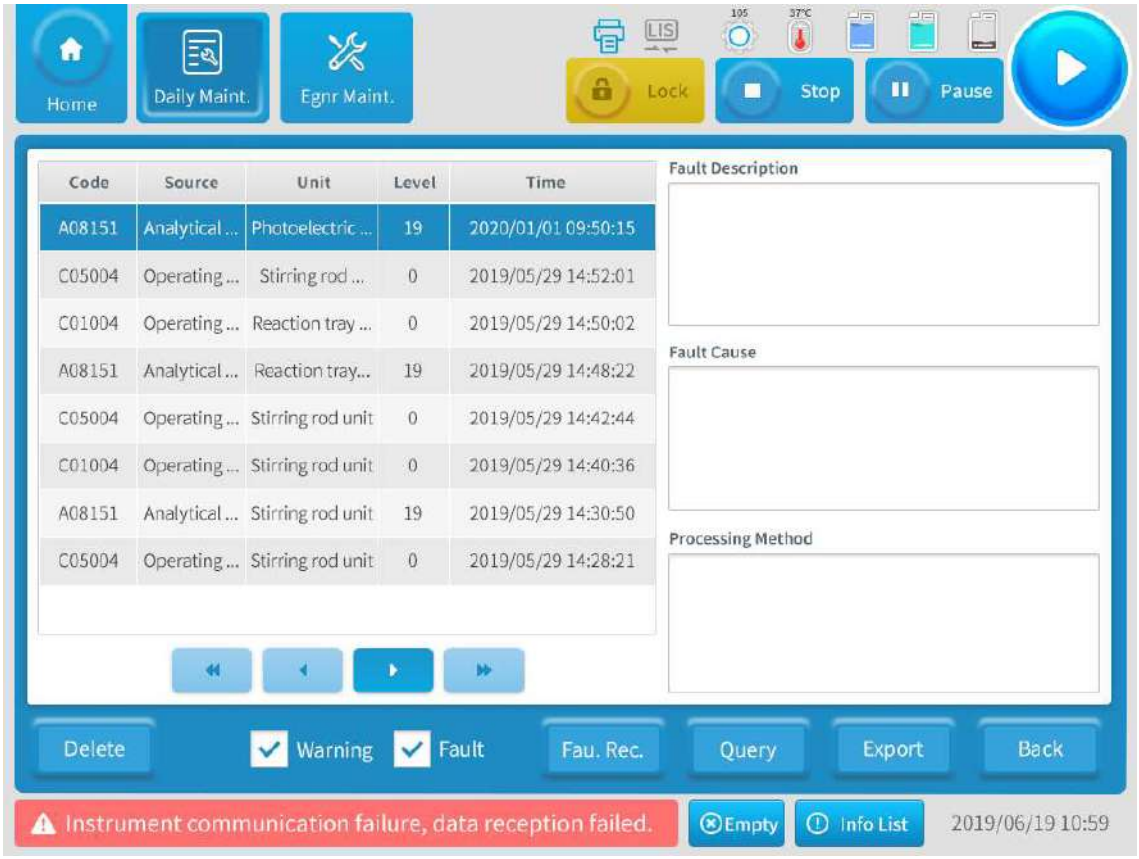


Figure 4-36 Trouble Shooting

Basic interpretation of parameters

Parameter	Meaning	Operation
Code	Failure code	/
Source	Failure source component	/
Unit	Failure source unit	/
Level	Failure level	/
Time	Time of failure occurs	/
Fault Description	Description of fault phenomenon	/
Fault Cause	Preliminary analysis of failure causes	/
Processing Method	Suggestions on trouble shooting	/
Fau. Rec.	Restore the machine from a fault state to a normal state	/
Query	Query failure	Click to open the query interface

Parameter	Meaning	Operation
Warning	Level 0 failure	Mark √ for selection
Fault	Non-level 0 failure	Mark √ for selection
Export Log	Export fault records	Click directly
Delete	Delete the selected fault information	After selecting the information to be deleted, click **Delete**
Back	Close the log query window	Click directly

4.6.1.3. Data backup

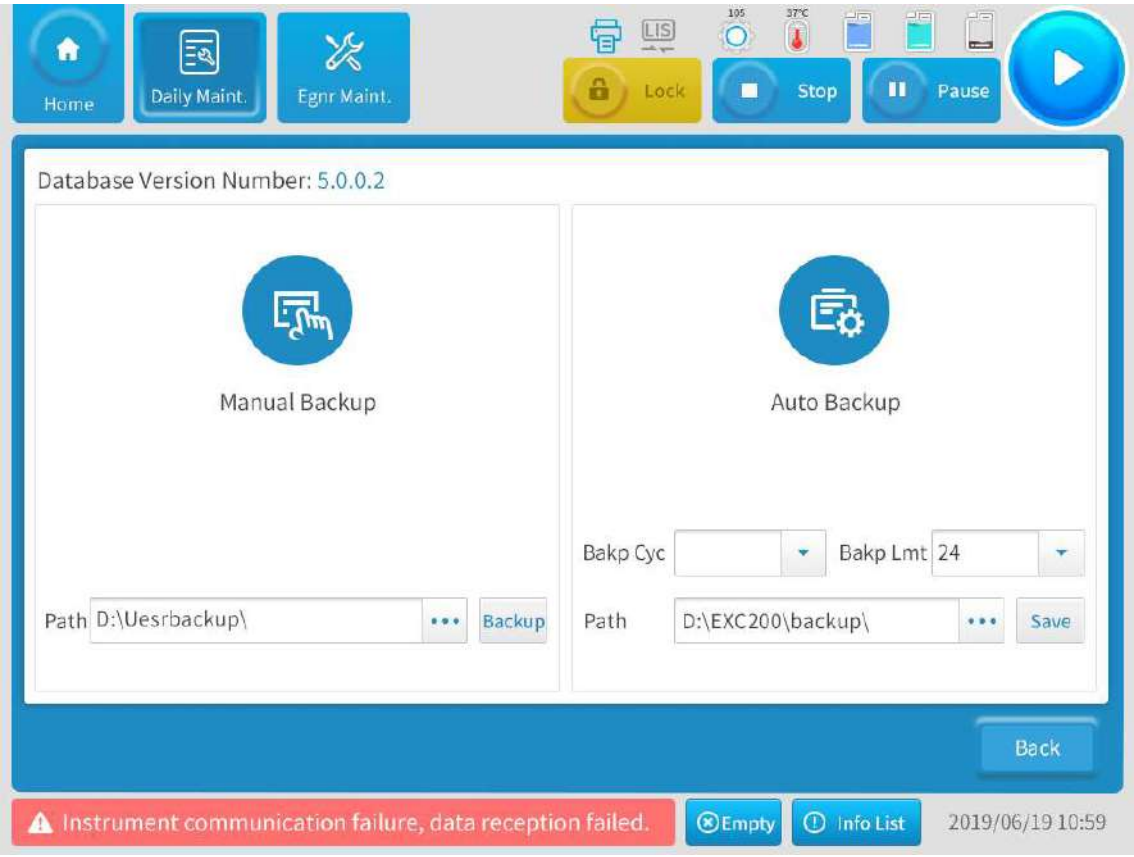


Figure 4-37 Data Backup

Basic operation

- Auto backup

  1) Bakp Cyc: backup interval time;

  2) Bakp Lmt: number of backup package;

  3) Path: enter or select the backup path manually, that is, the storage location;

  4) Set the backup period, backup limit, and path and click **Save**. When the set time is

up, it will remind you to backup all data on the software and power off the analyzer.

- Manual backup

  Enter or select the backup path manually, that is, the storage location, and click **Backup** to start the backup immediately.

4.6.1.4. Temperature curve

The temperature control system includes temperature control (heating) of the reaction tray and reagent refrigeration. The reaction tray carries out temperature sensing and data feedback by a single temperature sensor. The refrigeration module of the reagent-sample tray includes a refrigeration unit composed of two refrigeration plates, which work independently of each other, and one temperature sensor carries out temperature sensing and data feedback respectively.

Click **Temp. Curve** to enter the temperature status interface, where you can view three temperature statuses, including reaction tray temperature, reagent-sample tray temperature 1 and reagent-sample tray temperature 2. Low temperature, normal temperature and high temperature are respectively expressed in blue, green and red. The temperature display includes data and status display.

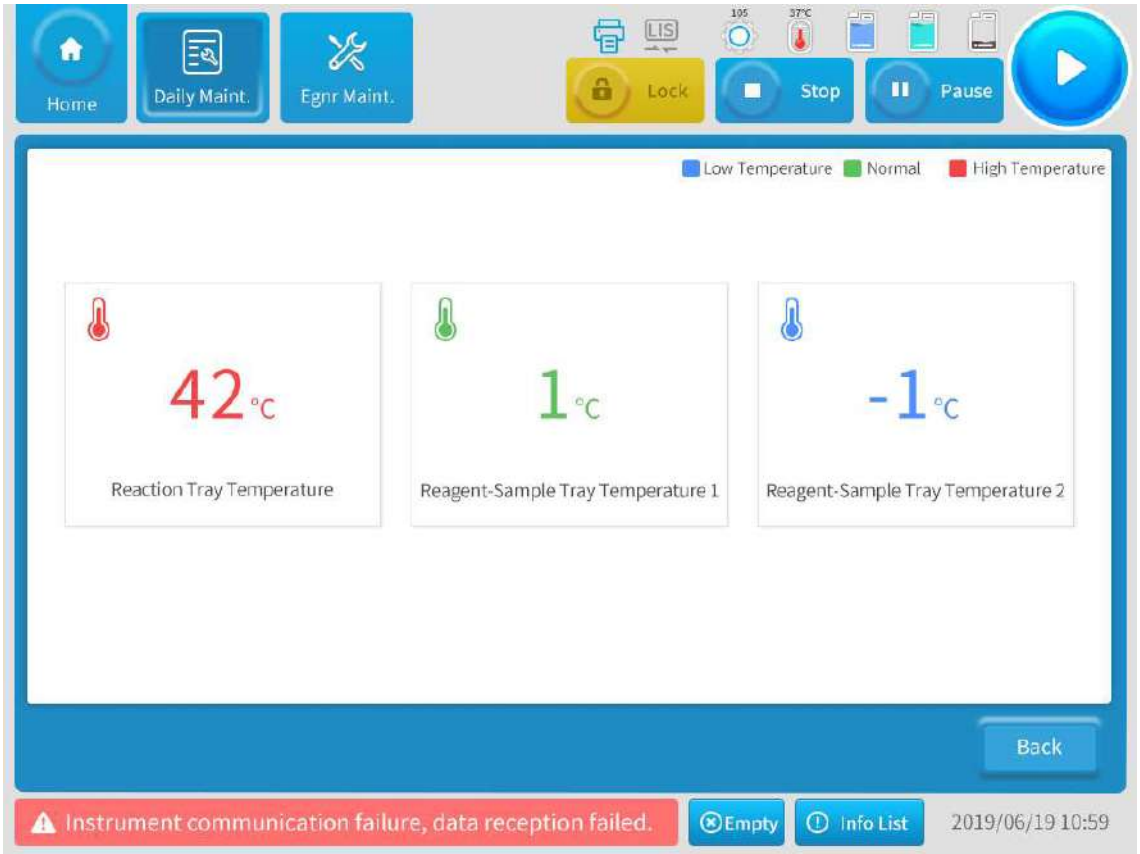


Figure 4-38 Temperature Status

Basic operation

1) Click **Daily Maint.-Temp. Curve** to check the temperature status;

2) Click **Back** to return to the daily maintenance main interface.

4.6.1.5. Consumable status

Use to check the status of concentrated detergent bucket, external purified water tank, waste bucket, probe detergent (#20 reagent position) and diluent (#40 reagent position).

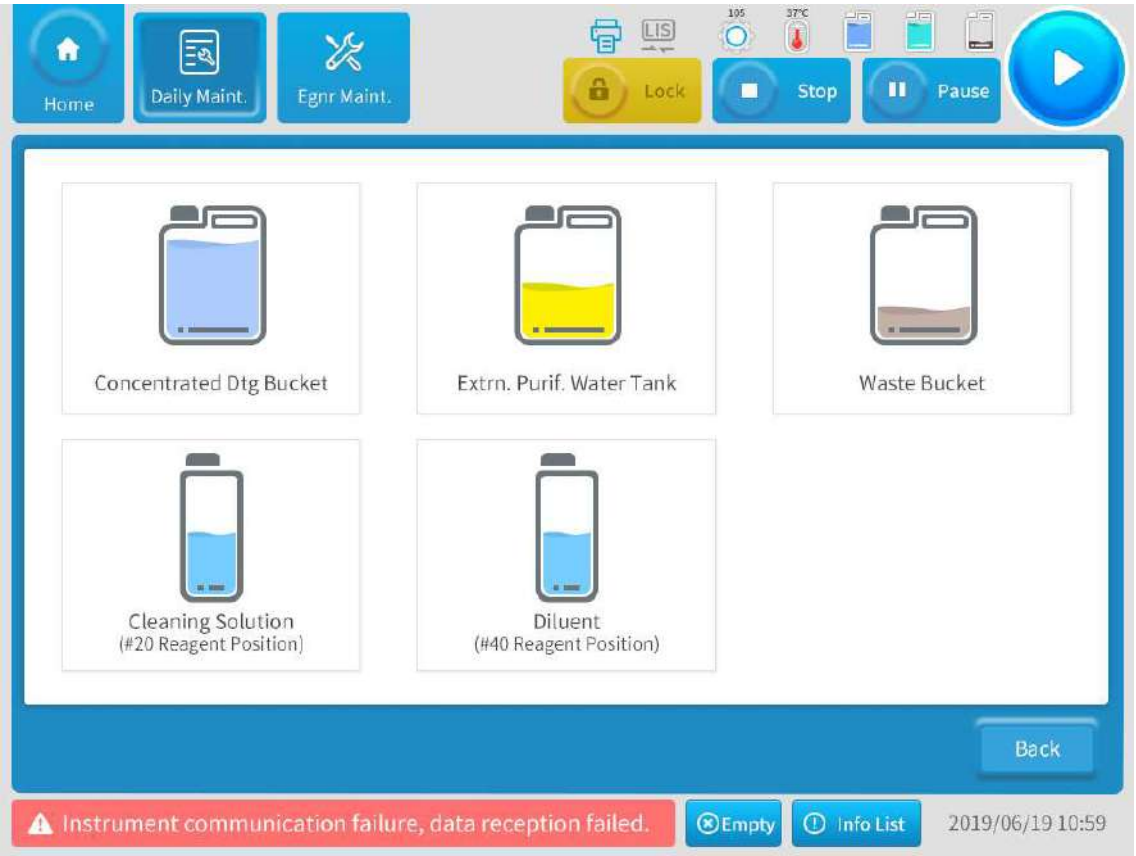


Figure 4-39 Consumables Maintenance

■ Setup

Set the interval inquiry time of liquid level status and whether to inquire regularly, and only refresh the status of 2 water tanks; the remaining amount of probe detergent is indicated during the operation of the instrument.

Basic operation

1) Click **Daily Maint.-Consumable Stat** to judge directly according to the status displayed in the software interface.

2) Each state of the water tank has a corresponding color reminder:

Container	**State**		**Liquid level color display**	
Concentrated detergent bucket	Empty	Not empty	Red	Lavender
Waste bucket	Full	Not full	Red	Sepia

Container	State			Liquid level color display		
External purified water tank	Full	Half full	Not full	Cyan	Yellow	Red
Probe detergent (#20)	Full	Half full	Not full	Wathet	Yellow	Red
Diluent (#40)	Full	Half full	Not full	Wathet	Yellow	Red

3) The color of the container indicates the percentage of the liquid residual. All containers are red alarm for below 10%, concentrated detergent bucket and waste liquid bucket more than 10% are lavender and brown respectively; The remaining three containers are reminded in yellow at 10%~50%, among which the external purified water tank is more than 50% in cyan, and the probe detergent and diluent are more than 50% in normal wathet.

4.6.1.6. Unit status

It is mainly divided into the following units: master control unit, photoelectric unit, temperature control unit, stirring rod unit, reagent-sample probe unit, reaction tray unit, reagent-sample tray unitt, fluidic component unit and barcode unit. The temperature control unit includes temperature control of the reaction tray and refrigeration of the reagent-sample tray.

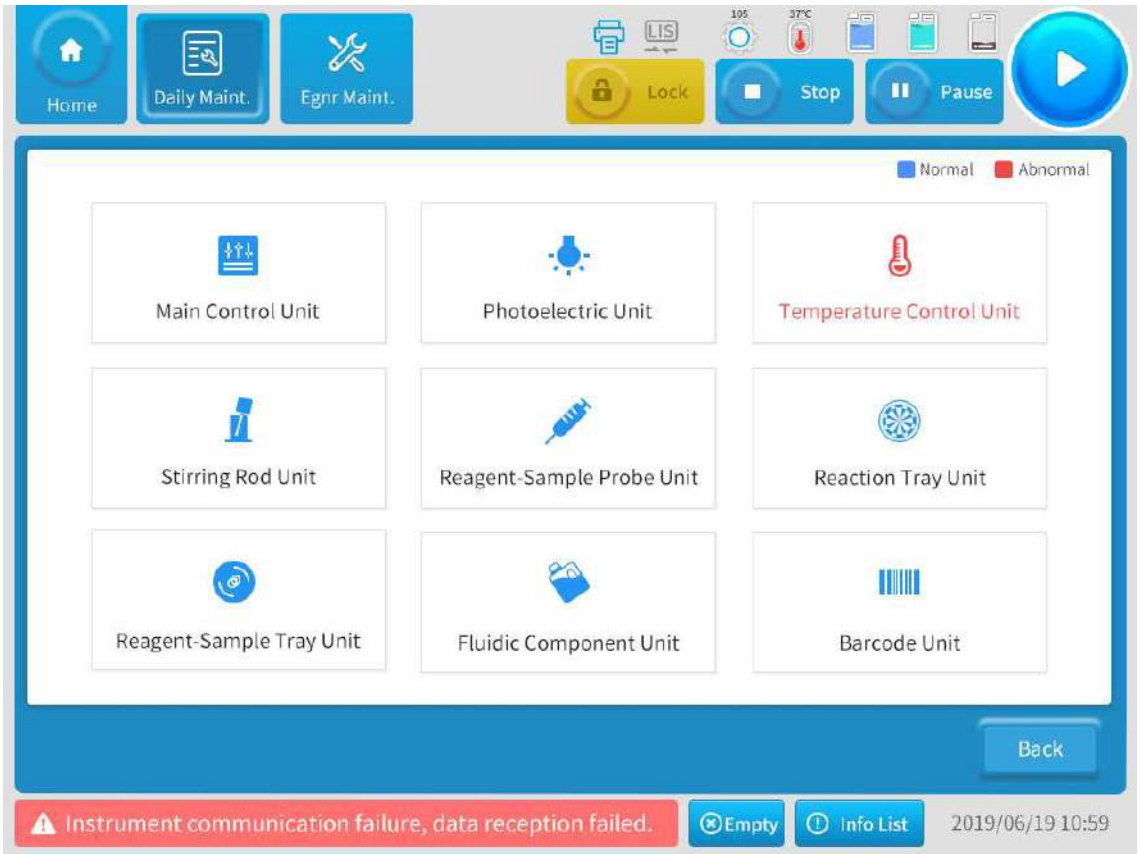


Figure 4-40 Unit Status

Basic operation

Click **Daily Maint.-Unit Status** to judge directly according to the status displayed in the software interface. Blue means normal while red means abnormal.

5. Analysis Principle and Calculation Method

This chapter briefly introduces the measuring principle of the instrument, including:

- Analytical method
- Calibration type and measurement principle
- Prozone inspection

5.1. Analytical method

Using the absorption law of solution to light or the transmission law of suspension to light, the absorbance of each photometric point in the reaction process is monitored, and the concentration or activity of the measured substance is calculated according to the change of absorbance before and after the reaction or the change rate of absorbance in the reaction process, combined with corresponding calibration parameters or calculation factors.

5.2. Analysis process

It includes action process, action position, test process, and photometric points.

5.2.1. Action process

EXC2X series Chemistry Analyzer completes all tests by performing the following actions in a loop:

1) Turn the cuvette under the cleaning head in step 1 for automatic cleaning;
2) After the cleaned cuvettes rotate to the position for first reagent R1 is called the first cycle or the first photometric points, add sample S and the second reagent R2 at the 10th and 23rd cycles, respectively. The absorbance measurement is performed once in each cycle, and the reaction test is completed in the 52nd cycle, that is, the 52nd photometric point, and then automatic cleaning is performed.
3) After cleaning, the cuvette rotates to the bottom of the cleaning head in step 1, and starts the next cycle after cleaning.

5.2.2. Testing process

EXC2X series Chemistry Analyzer performs a fixed test process, with a total of 52 test cycles per reaction.

5.2.3. Photometric points

For the same reaction, metering is performed once per cycle, with a total of 52 photometric points periods. In high-speed mode, the time interval between two adjacent photometric

points is 15 seconds; in normal mode, the time interval between two adjacent photometric points is 22.5 seconds.

*The above time period is for reference only. The specific time period is subject to the software setting after the instrument is installed.

5.3. Analysis method and reactivity calculation

In EXC2X series Chemistry Analyzer, the calculation formula of absorbance is as follows:

Absorbance of solution =Lg (AD water-AD dark)/(AD dissolved-AD dark)

Among them:

1) ‘‘Lg" means carrying out common logarithmic operation with 10 as the base;
2) "AD" means the value of transmitted light intensity after photoelectric conversion and digital-to-analog conversion;
3) "AD dark" means the AD value when the bulb is not turned on, "AD water" means the AD value of purified water in the cuvette, "AD dissolved" means the AD value when the solution to be tested in the cuvette;
4) The absorbance data on the reaction curve of EXC2X series Chemistry Analyzer is a value that is magnified 20,000 times of the absorbance value.

According to the characteristics of reaction speed in the reaction process, EXC2X series Chemistry Analyzers classify all reactions into three categories: endpoint method, two-point method and kinetic method, which are described respectively below.

- Analysis methods: endpoint method, two-point method and kinetic method.
- Reaction time [N] [P]: a period of time from the start of a test to the end of reaction monitoring. For a single reagent item, the reaction time refers to the time after adding S while for dual reagent item, it refers to the time after R2 is added. Such interval includes two input boxes, which respectively input the start time and end time of the reaction monitoring, and are respectively replaced by using N and P.
- Blank time [L] [M]: the time before a test starts a reaction. For a single reagent item, blank time refers to the duration between adding R1 and adding sample S while for dual reagent item, it refers to the duration between adding sample S and R2. The interval also includes two input boxes, which input start time and end time of blank monitoring respectively, and are respectively replaced by using L and M.
- For a dual-wavelength item, A is the difference between the absorbance of dominant wavelength and that of the secondary wavelength; For a single wavelength item, A is the absorbance of the dominant wavelength.

5.3.1. End-point method

After a certain period of time, the reaction reaches the equilibrium point, at which time the absorbance no longer changes, and the increase (or decrease) amplitude of absorbance caused by the reaction is proportional to the concentration of the measured substance. Also

known as the "Balance" method.

5.3.1.1. Single reagent endpoint method

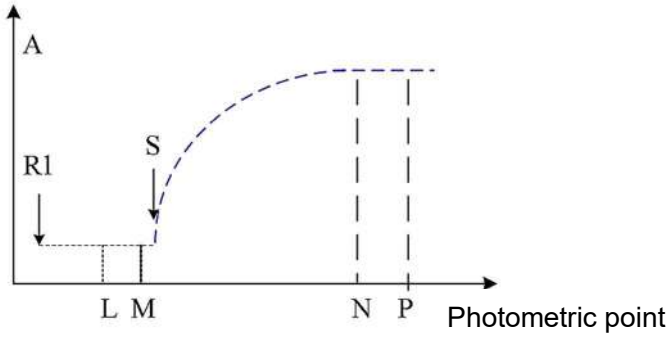


Figure 5-1 Reaction Curve of Single Reagent Endpoint Method

Reaction time [N] [P], 10≤N≤P≤51, where N+4 ≥ P;

Blank time [L] [M], 0≤L≤M≤8, where L+4 ≥ M.

- Calculation of absorbance Ai participating in the calculation of reactivity in the reaction time interval.

  1) If N=P, input [P] [P] and use only one point, then $A_i = A_N$.

  2) If P=N+1, input [N] [N+1], and use two points for $A_i = \frac{A_N + A_{N+1}}{2}$.

  3) If P=N+2, i.e. Input [N] [N+2] and use 3 points, then A_i is the absorbance values after the maximum and minimum values are removed.

  4) If P=N+3, i.e. Input [N] [N+3], and use 4 points,then A_i is the average of the remaining 2 absorbance values after removing the maximum and minimum absorbance values.

  5) If P=N+4, i.e. Input [N] [N+4], and use 5 points,then A_i is the average of the remaining 3 absorbance values after removing the maximum and minimum absorbance values.

- Absorbance participating in the calculation of reactivity in the blank time interval A_b: the calculation method is the same as that of absorbance participating in the calculation of reactivity A_i in the reaction time interval.

- Calculation of reactivity: $R = A_i - KA_b$.

- Where $k = \frac{V_{R1}}{V_{R1} + V_S}$ is the single reagent volume correction factor, V_{R1}, V_S represents the first reagent and sample volume respectively. The second item kA_b in the above R formula represents the reagent blank correction value, and reagent blank can be deducted in real time, but sample blank cannot be deducted. If sample blank

correction is required, a sample blank test must be applied separately. The calculation method of sample blank reactivity R_{Sb} is the same as that of R above, that is $R_{sb} = A_i - kA_b$, so the reactivity after sample blank correction is $R' = R - R_{Sb}$.

5.3.1.2. Dual reagent endpoint method

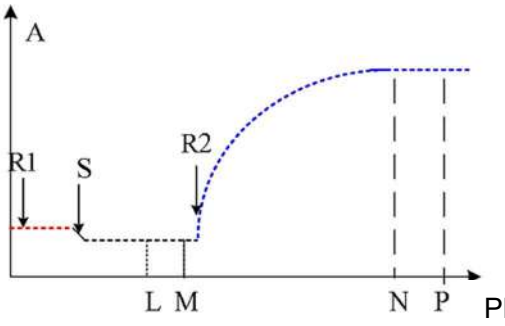


Figure 5-2 Reaction Curve of Dual Reagent Endpoint Method

Reaction time N P, 22≤N≤P≤51, where N+4 ≥ P;

Blank time L M, 10≤L≤M≤21, where L+4 ≥ M.

- Calculation of absorbance *Ai* participating in the calculation of reactivity in the reaction time interval: same as single reagent endpoint method.
- Calculation of absorbance A_b participating in the calculation of reactivity in blank time interval: same as single reagent endpoint method.
- Calculation of reactivity R: $R = A_i - k' A_b$.

1) The second term $k' A_b$ in the formula represents the correction value of the mixed blank of the first reagent and the sample, and $k' = \frac{V_{R1} + V_S}{V_{R1} + V_S + V_{R2}}$ is a dual reagent volume correction factor.

2) The mixed blank of the first reagent and the sample blank can be deducted in real time, but R2 (second reagent) blank cannot be deducted. If R2 correction is required, a reagent blank test must be applied separately. The calculation method of blank reactivity R2 is the same as that of r above, that is R_{R2}, which means $R_{R2} = A_i - k' A_b$, so the reactivity after sample blank correction $R' = R - R_{R2}$.

5.3.2. Two-point method

1) The two-point method is also called the first-order kinetic method, the two-point rate method and the fixed-time method. It means that the reaction rate is proportional to the one-power of the substrate concentration within the specified reaction time, i.e. V=K[S].

Due to the constant consumption of substrate, the whole reaction speed is continuously decreasing, which shows that the increasing (or decreasing) speed of absorbance is smaller and smaller. The increase (or decrease) (△A/min) of absorbance of the reaction solution within the specified reaction time is proportional to the concentration of the measured substance.

2) According to whether the sample blank needs to be deducted, the two-point method is divided into single interval two-point method and dual interval two-point method. The dual interval two-point method can deduct the sample blank in real time, that is, the absorbance change rate between two points in the sample blank period is used as the sample blank deduction.

3) The two-point method can be used to check substrate depletion. If substrate depletion occurs, the corresponding mark will be given on the result.

5.3.2.1. Single reagent two-point method

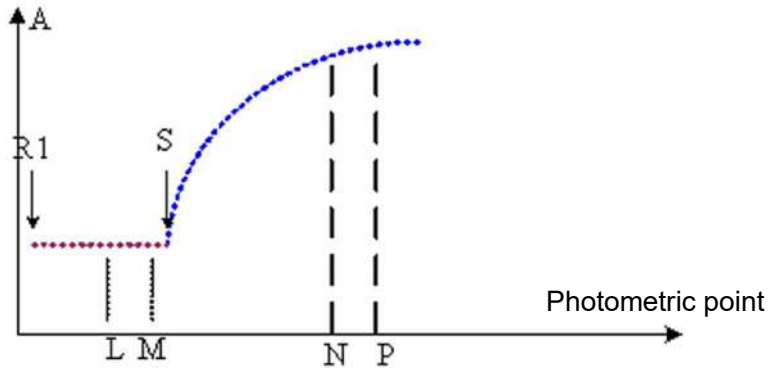


Figure 5-3 Reaction Curve of Single Reagent Two-Point Method

Reaction time [N] [P], 10 ≤ N < P ≤ 51;

Blank time [L] [M], 0≤L<M≤8, L and M are blank by default without performing blank correction.

- Reactivity R calculation: $R = \frac{A_P - A_N}{t_P - t_N}$ (R needs to be converted into R per minute);

- Blank reactivity R_b : the algorithm is the same as the above reactivity R , $R_b = \frac{A_M - A_L}{t_M - t_L}$ (R_b needs to be converted into R_b per minute);

- If blank time is set, blank correction must be carried out. After blank correction, the reactivity $R' = R - KR_b$, where K is the single reagent volume correction factor, $K = \frac{V_{R1}}{V_{R1} + V_S}$.

5.3.2.2. Dual reagent two-point method

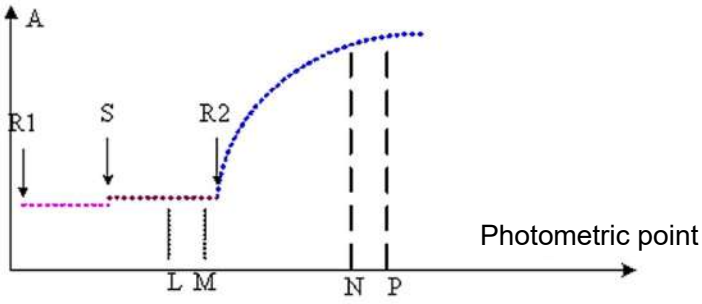


Figure 5-4 Reaction Curve of Dual Reagent Two-Point Method

Reaction time [N] [P], 22 ≤ N < P ≤ 51;

Blank time [L] [M], 10≤L<M≤21, L and M are blank by default without performing blank correction.

- Reactivity R : the algorithm is the same as the single reagent two-point method.
- Reactivity R_b : the algorithm is the same as the single reagent two-point method.
- If blank time is set, blank correction must be carried out. The reactivity after blank correction is $R' = R - K' R_b$ where K' is the dual reagent volume correction factor, $K' = \frac{V_{R1} + V_S}{V_{R1} + V_S + V_{R2}}$. By setting the blank time, the instrument can only automatically deduct the mixed blank of the first reagent and the sample, but cannot deduct the blank of the second reagent. If the blank of the second reagent needs to be deducted, the reagent blank test shall be applied separately. The reactivity algorithm of the second reagent blank R_{R2} is the same as the above-mentioned reactivity R, and the reactivity corrected by the blank of the second reagent $R'' = R - R_{R2}$.

5.3.3. Kinetic method

1) Also called zero-order rate method, rate method and continuous monitoring method, it refers to that the reaction speed is proportional to the zero square of the substrate concentration, i.e. Independent of the substrate concentration. Therefore, during the whole reaction process, the reactant can generate a certain product at a uniform speed, resulting in the absorbance of the measured solution uniformly decreasing or increasing at a certain wavelength. The decreasing or increasing speed (△A/min) is proportional to the activity or concentration of the measured substance (catalyst). It is mainly used for the determination of enzyme activity.
2) In practical application, as the concentration of substrate cannot be infinite, the reaction will no longer be zero-order after the substrate is consumed to a certain

extent as the reaction progresses. Therefore, the zero-order rate method is aimed at a specific time period, and the zero-order reaction time period must be selected for monitoring to ensure the accuracy of the results.

3) According to whether the sample blank needs to be deducted, the kinetic method is divided into single interval two-point method and dual interval two-point method. The dual interval two-point method can deduct the sample blank in real time, that is, the absorbance change rate in the sample blank period is used as the sample blank deduction.

4) Kinetic method can be used to check substrate depletion. If substrate depletion occurs, corresponding prompt marks will be given on the results.

5) The dynamic method can be used to check the linearity limit. If the situation of exceeding the linearity limit occurs, the corresponding prompt mark will be given on the result.

Calculation of reactivity

In the zero-order kinetic reaction interval, the least square method is used to calculate the reactivity, and the least square method calculation formula is as follows:

$$R = \frac{\sum_{i=N}^{P}(t_i - \bar{t}) \cdot (A_i - \overline{A})}{\sum_{i=N}^{P}(t_i - \bar{t})^2}$$

Where N is the starting point of the zero-order kinetic reaction interval and P is the end point of the zero-order kinetic reaction interval, A_i is the absorbance at point i, $\overline{A}$ is the average absorbance from point n to point P, T_i is the time at point i, and $\bar{t}$ is the average time from point L to point M.

5.3.3.1. Single reagent kinetic method

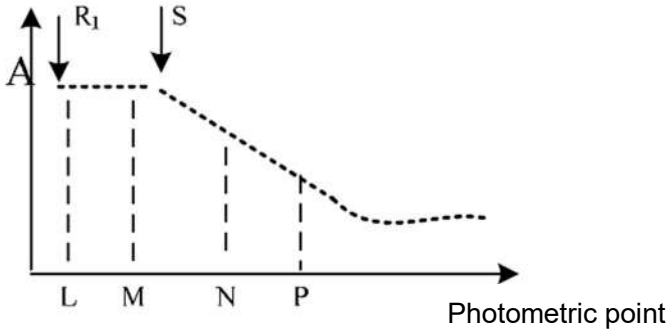


Figure 5-5 Reaction Curve of Single Reagent Rate Method

The reaction time N P, same as that of the single reagent two-point method, but N+2≤P, i.e. At least 3 photometric points are required;

The blank time [L] [M], same as the single reagent two-point method, but L+2≤M, i.e. there must be at least 3 photometric points; the default values of L and M are blank, and no blank correction is performed.

- Reactivity R : $R = \Delta A_{NP}$, Δ means the change rate of absorbance per minute between photometric points (N, P) obtained by least square method.
- Blank reactivity R_b : the algorithm is the same as the above reactivity R , $R = \Delta A_{LM}$.
- If blank time is set, blank correction must be carried out. After blank correction, the reactivity $R' = R - KR_b$, where K is the single reagent volume correction factor, $K = \frac{V_{R1}}{V_{R1} + V_S}$.

5.3.3.2. Dual reagent kinetic method

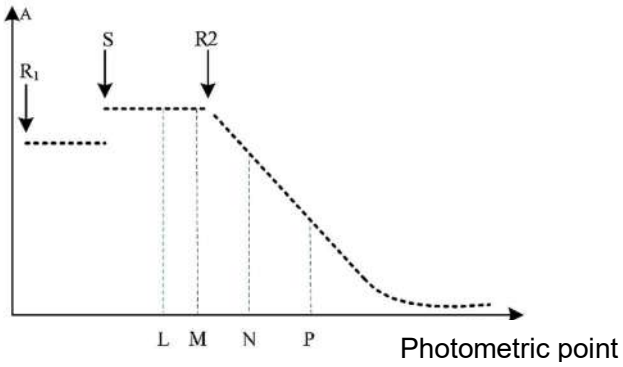


Figure 5-6 Reaction Curve of Dual Reagent Rate Method

The reaction time [N] [P] is the same as that of the dual reagent two-point method, but N+2≤P, i.e. there must be at least 3 photometric points;

The blank time [L] [M] is the same as the dual reagent two-point method, but L+2≤M, i.e. There must be at least 3 photometric points; L=0, M=0 by default without performing blank correction.

- Reactivity R : $R = \Delta A_{NP}$, Δ means the change rate of absorbance per minute between photometric points (N, P) obtained by least square method.
- Reactivity R_b : the algorithm is the same as the single reagent kinetic method.
- If blank time is set, blank correction must be carried out. The reactivity after blank correction is $R' = R - K' \times R_b$ where K' is the dual reagent volume correction factor,

$K'=\frac{V_{R1}+V_S}{V_{R1}+V_S+V_{R2}}$. By setting the blank time, the instrument can only automatically deduct the mixed blank of the first reagent and the sample, but cannot deduct the blank of the second reagent. If the blank of the second reagent needs to be deducted, a reagent blank test shall be applied separately. The reactivity algorithm of the blank of the second reagent R_{R2} is the same as the above-mentioned reactivity R and the reactivity corrected by the blank of the second reagent is $R'' = R - R_{R2}$.

5.4. Calibration

5.4.1. Calibration type

In EXC2X series Chemistry Analyzer, calibration is divided into linear and non-linear calibration. The linear calibration includes single point, two points and multi-point linear calibration, which is mainly applicable to items where the reactant is solution; non-linear calibration mainly includes Logistic-Log4P, Logistic-Log5P, Exponential-5P, Polynomial-5P and Spline. It is mainly applicable to items where the reactant is turbid liquid, such as immunoturbidimetry, etc.

5.4.2. Calibration parameter

The number of calibration parameters and calculation methods are different for different calibration types, which are described respectively below.

1) Single point linear calibration

Formula $C = KR$, where there is one calibration parameter, namely K .

$$K = \frac{C_{\text{Standard}}}{\text{R}_{\text{Standard}}}$$

Where: C is the concentration of the standard value and R is the reaction range of the standard value.

Attention

When performing single-point linear calibration, reagent blank test must be performed at the same time.

2) Two-point linear calibration

Formula $C = K(R - R_0)$, where there are 2 calibration parameters, namely K and R_0.

$$K = \frac{C_2 - \text{C}_1}{\text{R}_2 - \text{R}_1}$$

$$\mathrm{R}_0 = R_1 - \frac{C_1(R_2 - R_1)}{C_2 - C_1}$$

Where,C_1, $C_2$are the concentration of standard 1 and 2 respectively, and R_1 , R_2 are the reaction ranges of standard 1 and 2 respectively.

3) Multipoint linear calibration

Formula $C = K(R - R_0)$, where there are 2 calibration parameters, namely K and R_0.

According to multi-point linear regression, the calibration parameters are calculated.

4) Logistic-Log4P

The calibration formula $\mathrm{R} = R_0 + \mathrm{k}/[1 + e^{-(\mathrm{a}+\mathrm{b}\ln C)}]$ has four parameters, namely, R_0, K, a and b. It is required to provide at least 4 standard values, in which the concentration (activity) of the first standard value is zero, and its corresponding R is equal to R_0, and the rest parameters are determined by iteration method.

5) Logistic-Log5P

The calibration formula $\mathrm{R} = R_0 + \mathrm{k}/[1 + e^{-(\mathrm{a}+\mathrm{b}\ln C+\mathrm{c}*\mathrm{c})}]$ has five parameters, namelyR_0, k, a, b and c. It is required to provide at least 5 standard values, of which the concentration (activity) of the first standard value is zero, and its corresponding R is equal to R_0, and the rest parameters are determined by iteration method.

6) Exponential-5P

The calibration formula $\mathrm{R} = R_0 + Ke^{[\mathrm{a}\ln \mathrm{c}+\mathrm{B}(\ln \mathrm{c})^2+\mathrm{c}(\ln \mathrm{c})^3]}$ has five parameters, namelyR_0, k, a, b and c. It is required to provide at least 5 standard values, of which the concentration (activity) of the first standard value is zero, and its corresponding R is equal to R_0, and the rest parameters are determined by iteration method.

7) Polynomial-5P

The calibration formula $\ln C = a + b(R - R_0) + c(R - R_0)^2 + d(R - R_0)^3$ has five parameters, namely R_0, a, b, c and d. It is required to provide at least 5 standard values, of which the concentration (activity) of the first standard value is zero, and its corresponding R is equal toR_0, and the rest parameters are determined by iteration method.

8) Spline

The calibration formula $\mathrm{C} - \mathrm{C_i} = R_{0i} + a_i(C - C_i) + b_i(C - C_I)^2 + c_i(C - C_i)^3 - \mathrm{R}$ has 4i parameters, namely R_{0i}, a_i ,b_i and c_i. It is required to provide at least 2 standard values and use iterative method to find the parameters of each interval.

5.5. Concentration calculation

1) When the calibration method of the item is K factor method, the calibration is not required, and the theoretical calculation factor K can be directly input. The calculation formula of the concentration is as follows:

$$C = KR/10000$$

Where: K is the input calculation factor and R is the reactivity of the sample to be tested.

2) If the calibration type is linear calibration, Logistic-Log4P or Polynomial-5P, the concentration can be calculated by directly using the calibration parameters and the reactivity amplitude R.

3) If the calibration type is Logistic-Log5P, Exponential-5P or Spline, according to the reaction degree amplitude R and calibration parameters, the positive real root is obtained by dichotomy to calculate the concentration.

5.6. Quality control

5.6.1. Quality control rules

The default quality control rule for EXC2X series Chemistry Analyzer is Westguard multi-rule. Users can select one or more rules to judge the quality control status for different items according to actual needs.

The Westguard multi-rule quality control rule includes 6 sub-rules, and the judgment significance of each sub-rule is as follows:

Representative symbol	Definition	Judgment of quality control
1_{2s}	One point falls outside +2 SD or -2 SD of the mean value	Give a warning
1_{3s}	One point falls outside +3 SD or -3 SD of the mean value	Out of control (random error, systematic error)
2_{2s}	Two consecutive points fall outside +2 SD or -2 SD of the mean value	Out of control (random error)
R_{4s}	The difference between the two values in the same batch exceeds 4 SD	Out of control (random error)
4_{1s}	Four consecutive points fall outside +1 SD or -1 SD of the mean value	Out of control (random error)
10_X	Ten consecutive points fall on the same side of the mean value	Out of control (random error)

The judging flow chart of EXC2X series Chemistry Analyzer for the above sub-rules is as follows:

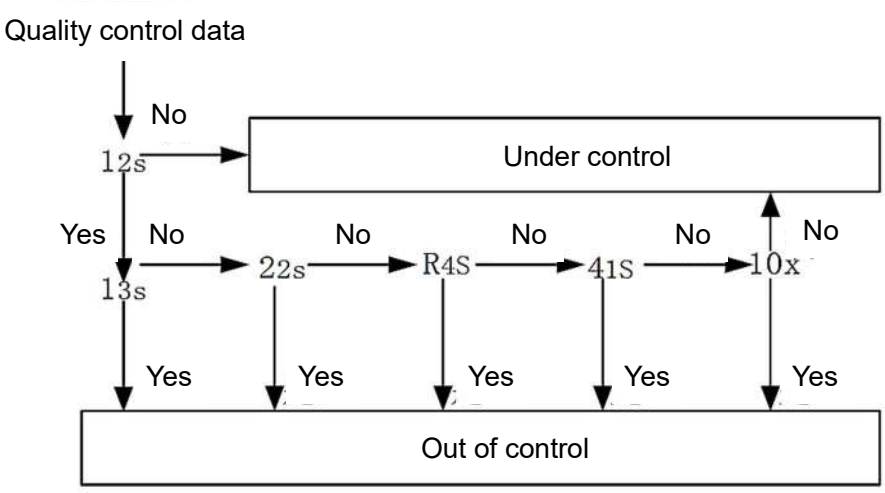


Figure 5-7 Quality Control Rule Judgment Flow Chart

5.6.2. Quality control type

EXC2X series Chemistry Analyzers have three types of quality control, namely real-time quality control, intra-day quality control and inter-day quality control. Quality control status is judged according to the set quality control rules.

- Real-time quality control: to judge the quality control status of 10 consecutive quality control data in one day;
- Intra-day quality control: carry out quality control status judgment on all quality control data in one day;
- Inter-day quality control: to judge the quality control status of all quality control data in different days.

5.6.3. Quality control chart

EXC2X series Chemistry Analyzer has two types of quality control charts, L-J and Twin Plot respectively.

1) L-J quality control chart

   Taking the measured quality control data value as the vertical ordinate, draw a horizontal line from the quality control target value, draw 6 lines parallel to the mean line on the top +1 SD (standard deviation, abbreviated as SD), +2 SD, +3 SD and the bottom －1 SD, －2 SD and －3 SD, and mark the values of the quality QC sample measured each time on the quality control chart, and connect the adjacent points with fine lines.

2) Twin Plot quality control chart

   Twin Plot QC chart can be displayed when one item simultaneously determines two concentrations of QC. According to the target value and standard deviation SD of each QC liquid (input by the user in the quality control setting), the measured value of one

QC liquid is taken as the horizontal coordinate (generally low-concentration QC liquid), the measured value of the other QC liquid is taken as the vertical coordinate (generally high-concentration QC liquid), the average value is taken as the center line, and mark ±1 SD, ±2 SD and ±3 SD lines, and the same measurement results of the two QC liquids form a point on the coordinate, as shown in the following figure:

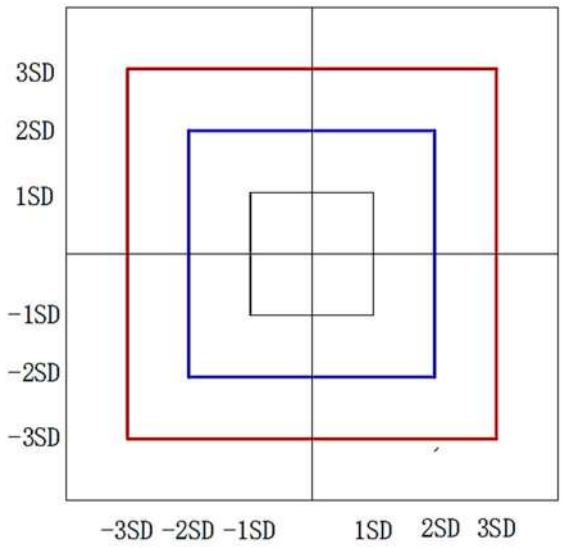


Figure 5-8 Twin Plot Control Chart

The chart can sensitively reflect the system and random errors. The data falling within the blue circle (±2 SD) indicates control. The first or third quadrant between the red circle and the blue circle indicates systematic error. The second or fourth quadrant falling between the red circle and the blue circle indicates random error, while falling outside the red circle indicates random error.

5.7. Other relevant calculations

5.7.1. Relevant calculation of calibration curve

1) Calibration sensitivity

In the specified calibration process, the difference between the reactivity of the maximum concentration calibrator and the minimum concentration calibrator is judged to be unqualified if it is less than the set value.

2) Blank liquid reactivity

Refers to the reactivity of calibrator with zero concentration. If it is higher than the set value, it is judged as unqualified.

3) Calibration repeatability

The difference between the maximum and minimum values of the reactivity measured 3 times for each calibrator is judged to be unqualified if it is higher than the set value.

4) Standard deviation of calibration curve

Only applicable to multi-point linear and non-linear calibration curves. It refers to the square sum of the difference between the reactivity (R) of each calibrator and the reactivity (Ri') calculated according to the calibration curve, divided by the degree of freedom, and then squared. The specific calculation method is as follows:

- Multipoint linear calibration

$$SD = \sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Rij - Ri'\right)^2}{Nn-2}}$$

In the formula: Rij is the reactivity (effective determination times) of a certain determination of the calibrator i, Ri' is the reactivity of the calibrator i calculated according to the calibration curve, N is the number of calibrators, and n is the effective number of repeated determinations.

- Logistic-Log4P

$$SD = \sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Rij - Ri'\right)^2}{Nn-4}}$$

In the formula: Rij is the reactivity (effective determination times) of a certain determination of the calibrator i, Ri' is the reactivity of the calibrator i calculated according to the calibration curve, N is the number of calibrators, and n is the effective number of repeated determinations.

- Logistic-Log5P

$$SD = \sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Rij - Ri'\right)^2}{Nn-5}}$$

In the formula: Rij is the reactivity (effective determination times) of a certain determination of the calibrator i, Ri' is the reactivity of the calibrator i calculated according to the calibration curve, N is the number of calibrators, and n is the effective number of repeated determinations.

- Exponential-5p and polynomial-5p

$$SD = \sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Rij - Ri'\right)^2}{Nn-5}}$$

In the formula: Rij is the reactivity (effective determination times) of a certain determination of the calibrator i, Ri' is the reactivity of the calibrator i calculated according to the calibration curve, N is the number of calibrators, and n is the effective number of repeated

determinations.

- Spline

$$SD = \sqrt{\frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Rij - Ri^{'}\right)^2}{Nn-4}}$$

In the formula: Rij is the reactivity (effective determination times) of a certain determination of the calibrator i, Ri' is the reactivity of the calibrator i calculated according to the calibration curve, N is the number of calibrators, and n is the effective number of repeated determinations.

5) Correlation coefficient of calibration curve

Only applicable to multi-point linear and non-linear calibration curves, and the calculation formula is as follows:

$$R^2 = \frac{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Cij-\overline{C}\right)^2\left(Rij-\overline{R}\right)^2}{\sum_{i=1}^{N}\sum_{j=1}^{n}\left(Cij-\overline{C}\right)^2\sum_{i=1}^{N}\left(Rij-\overline{R}\right)^2}$$

Where: C is the concentration of the calibrator, R is the reactivity, N is the number of calibrators, and n is the effective number of repeated determinations.

5.7.2. Substrate depletion judgment

It is only applicable to kinetic method and two-point method. Some high-concentration (active) samples make the substrate run out quickly, so that the reaction speed is no longer the desired speed (grade 0 or grade 1 reaction). In order to correctly reflect the determination result, the substrate run-out limit judgment is required. The specific judgment method is as follows:

1) Increasing reaction

If the absorbance at any point or points in the period between start and end time is greater than the set value, it is judged as substrate depletion.

2) Descending reaction

If the absorbance at any point or points in the starting and ending time periods is less than the set value, it is judged as substrate depletion.

5.7.3. Linearity check

It is only applicable to the kinetic method, judging whether the straightness of the reaction curve meets the set value within the time period of the reaction between start and end points according to the data of each photometric point. The specific calculation method is as follows:

1) There are more than 9 photometric points in the starting and ending time periods;

Linear limit = (change rate of absorbance at the first 6 points-change rate of absorbance at the last 6 points)/change rate of absorbance at all points

2) 4≤ Photometric points from the start to the end ≤ 8;

Linear limit = (change rate of absorbance at the first 3 points-change rate of absorbance at the last 3 points)/change rate of absorbance at all points

3) Linearity is not calculated in the following cases:

- Photometric points ≤ 3;
- The absorbance change rate is less than 0.006/ min or the difference between absorbance change rates is less than 0.006/ min;
- Reagent blank test, sample blank test and zero concentration calibrator test.

5.7.4. Prozone inspection

In the reaction of antigen and antibody, the insoluble antigen-antibody complex generated is closely related to the proportion of antigen and antibody. When the proportion is appropriate, the insoluble antigen-antibody complex generated is the largest, and the light transmitted at this time is the least, which is equivalent to the maximum absorbance. When the ratio is greater than or less than this ratio, the amount of insoluble antigen-antibody complexes generated will decrease, the transmitted light will increase, and the absorbance will decrease, as shown in the following figure. If two samples with very different concentrations are not examined by the prozone, the amount of insoluble antigen-antibody complexes generated can be equal, and the same determination results will be obtained.

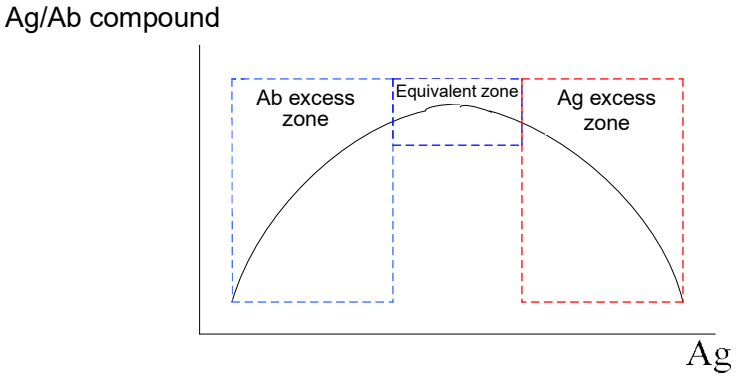


Figure 5-9 Prozone Inspection

In EXC2X series Chemistry Analyzer, perform prozone inspection according to the following methods.

- Dual reagent endpoint method

As shown in the following figure, L is the start point of the reaction, M is the start point of the reaction time interval, N and P are the prozone checkpoints, and L, M, N and P satisfy the following relationship: 22 ≤ L < N < P < M ≤ 51.

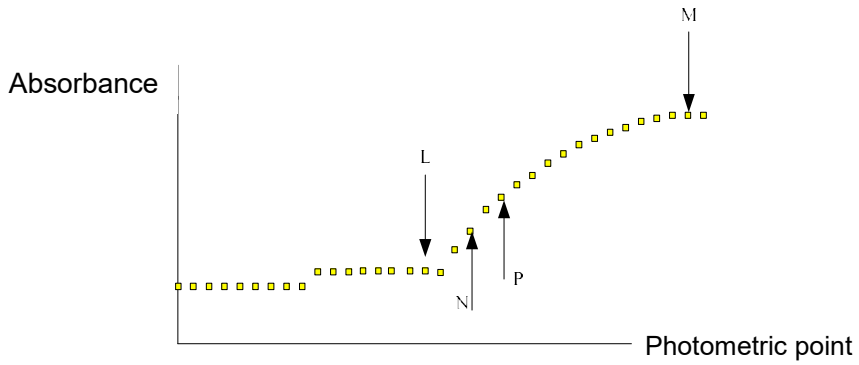


Figure 5-10 Prozone Inspection of Dual Reagent Endpoint Method

The prozone check value (PC) is equal to:

$$PC = \frac{\frac{A_M - A_P}{M - P}}{\frac{A_P - A_N}{P - N}} \times 100\%$$

If PC > set prozone check limit, it is judged that prozone phenomenon exists.

- Single reagent endpoint method

As shown in the following figure, L is the start point of the reaction, M is the start point of the reaction time interval, N and P are the prozone checkpoints, and L, M, N and P satisfy the following relationship: $10 \leq L < N < P < M \leq 51$.

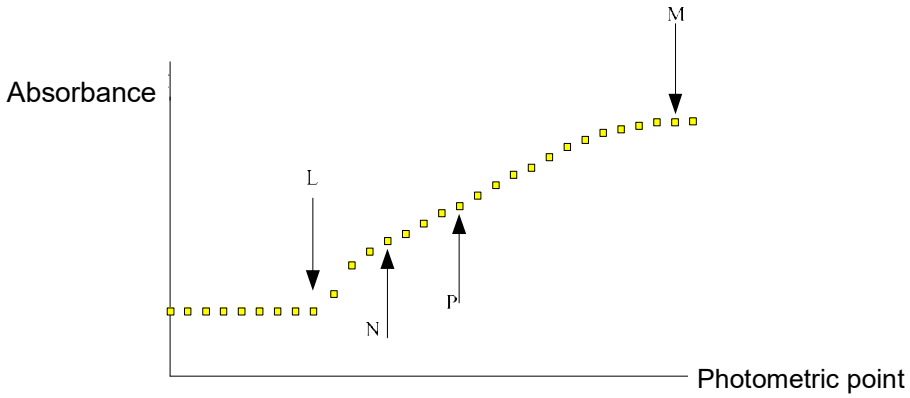


Figure 5-11 Prozone Detection for Single Reagent Endpoint Method

The prozone check value (PC) is equal to:

$$PC = \frac{\frac{A_M - A_P}{M - P}}{\frac{A_P - A_N}{P - N}} \times 100\%$$

If PC > set prozone check limit, it is judged that prozone phenomenon exists.

5.7.5. Reaction equilibrium judgment

It is only applicable to endpoint method. According to the data of each photometric point, it is determined whether the reaction has reached equilibrium at the endpoint time of the reaction. The specific calculation method is as follows:

1) Calculate the difference of absorbance between the endpoint and 3 consecutive photometric points in the future;

2) If all the differences are less than 0.01, it is judged that the balance has been reached, otherwise it has not been reached;

3) If the end point of the reaction is greater than 49, the reaction equilibrium judgment will not be carried out.

5.7.6. Bulb status judgment

After each startup and before starting the test, the reaction tray rotates the cuvette until the light spot stays in the middle of the 63 # to 1 # cuvettes, and then carries out photoelectric collection of all wavelengths, collects data for 10 times at each wavelength, removes the maximum and minimum values, and takes the average value of the number of 8 in the middle as the photoelectric data collected at this time at each wavelength as the basis for judging the luminous intensity of the bulb. When the photoelectric data of any wavelength at all cuvette positions is lower than 18000, the alarm prompts the user to "Please Replace the Bulb Due to Insufficient Luminous Intensity of The Light Source" and allows the user to continue the test. However, a prompt box pops up before each test to prompt the user to "Continue the Test or not because Insufficient Luminous Intensity May Affect the Result". When the photoelectric data of any wavelength in all cuvette positions is lower than 12000, the alarm prompts the user to "Please Replace the Bulb Immediately Due to Seriously Insufficient Luminous Intensity of the Light Source" and the user is prohibited from continuing the test. The user can only continue the test after replacing the bulb and passing the luminous intensity test of the light source as required.

6. Maintenance and Service

This chapter introduces the maintenance methods of the instrument, including common maintenance instructions and regular maintenance. The purpose, use timing, required supplies, instrument status, precautions and operation steps of each maintenance item are introduced in detail.

6.1. Overview

In order to ensure the system reliability and good working condition and service life, please operate and regularly maintain the system in strict accordance with this Operation Manual.

6.1.1. Maintenance tools

- A set of hex wrench
- Cross screwdriver (large, medium and small)
- Stainless steel wire (inner diameter 0.25 mm)
- Plastic syringe (approx. 10 ml, without probe)
- Clean gauze
- Clean cotton swabs
- Brush (for cleaning the barrel)
- Non-ionic surfactant detergent
- Anhydrous ethanol
- 84 disinfectant
- Medical latex gloves

6.2. Regular maintenance items

Regular maintenance items are defined according to the conditions of various parts of the instrument and actual use. Trained personnel are required to strictly implement the items according to the specified cycle to ensure the performance of the instrument and reduce unnecessary service calls. Before performing maintenance, please make sure to read the maintenance procedures in this section thoroughly.

The system provides the add function. You can add the required maintenance items through the customization function except the system-defined maintenance items that are not allowed to be edited. After the maintenance operation is completed, the maintenance log can be filled in according to the maintenance situation to record the abnormalities and other necessary information during maintenance.

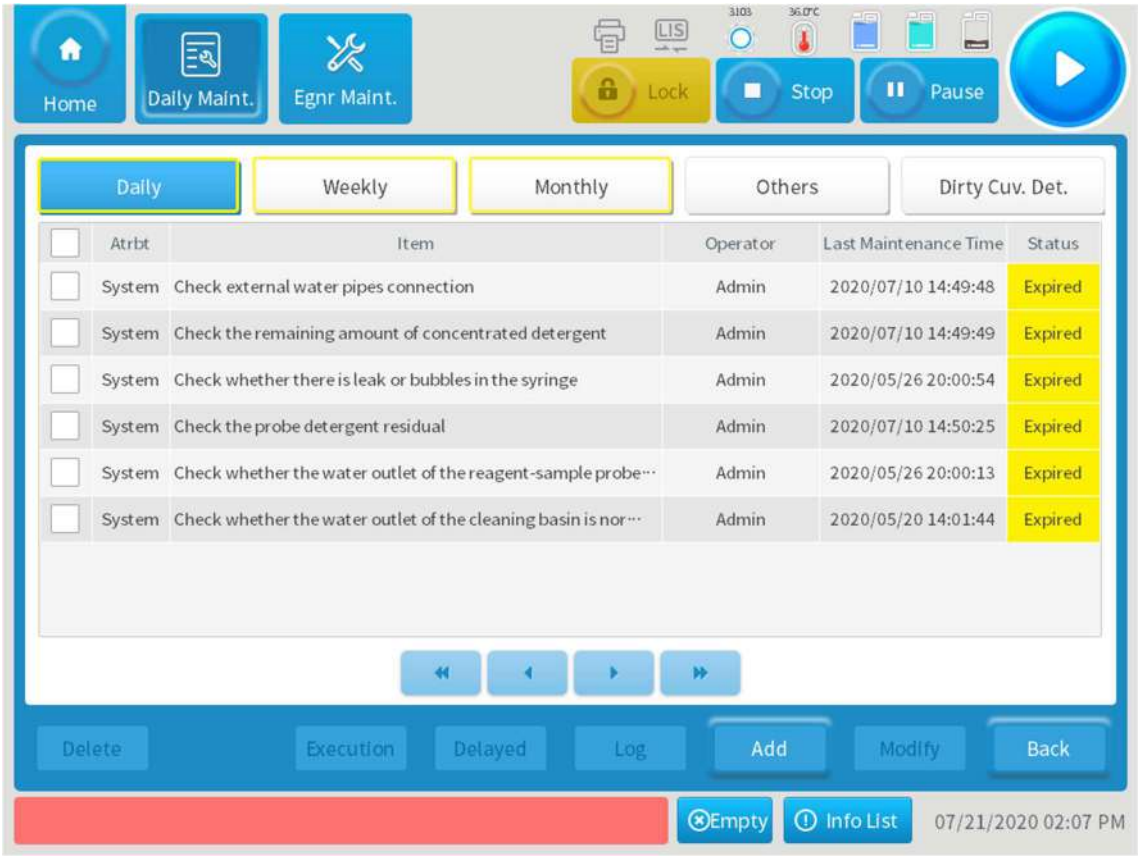


Figure 6-1 Periodic Maintenance

6.2.1. Maintenance cycle

The periodic maintenance list is divided into the following maintenance periodic units:

- Daily-1 day
- Weekly-7 days
- Monthly-30 days

- Others-irregular
- Dirty cuvette detection

The system starts with the current maintenance time of each maintenance item and counts down the maintenance items.

6.2.2. Maintenance content

Maintenance cycle	Maintenance items (Arranged in order)	
Daily	1	Check external water pipes connection
	2	Check the remaining amount of concentrated detergent
	3	Check whether there is leaks or bubbles in the syringe
	4	Check the probe detergent residual
	5	Check whether the water outlet of the reagent-sample probe is normal (verify whether the probe inner wall is blocked)
	6	Check whether the water outlet of the cleaning basin is normal (verify whether the probe outer wall cleaning is normal)
Weekly	1	Check and clean reagent-sample probe and stirring rod (outer wall)
	2	Intensified cleaning for cuvette
	3	Detect for dirty cuvette and lamp
Monthly	1	Clean the cleaning basin for reagent -sample probe and stirring rod
Others	1	System reset
	2	Mechanical reset
	3	Routine cuvette cleaning
	4	Reagent-sample probe intensified cleaning
	5	Stirring rod intensified cleaning

6.2.3. Maintenance interface

- Attribute

Displays the definition properties of the maintenance item. There are two values, "system" and "user". The system indicates that the maintenance item has been set before the

instrument leaves the factory, and the user is the maintenance item which the user adds through the "add" function.

- Item

Displays all system pre-defined items and user-defined maintenance items for the current maintenance cycle.

- Operator

Displays the operator for the current execution of the corresponding maintenance item, i.e. the user ID of the current software login.

- Last maintaince time

Displays the last maintenance time of the item.

- Status

Displays whether the current item has expired or been postponed and the date to be maintained.

- Log

Record exceptions and other necessary information generated during maintenance.

- Add

Addition function is used to add the required maintenance items according to the reagent usage of the instrument. The system also allows modifying and deleting custom maintenance items.

- Modify

If a maintenance item needs to be modified, the system allows it to be modified. Please note that only custom maintenance items are allowed to be modified, and system pre-defined maintenance items are not allowed to be modified.

- Delete

If a maintenance item is not needed, the system allows it to be deleted. Please note that only custom maintenance items are allowed to be deleted, and system pre-defined maintenance items are not allowed to be deleted.

- Delay

The maintenance of the item is delayed by one cycle.

- Execution

After selecting one or more maintenance items, click this button to start the inspection of maintenance items.

6.3. Daily maintenance

The daily maintenance items shall be carried out before the test starts every day, and the reagent-sample probe, cleaning basin, syringe, external water pipes connection and the

remaining amount of concentrated detergent shall be checked.

6.3.1. Connection of external water pipes check

External water pipes connection inspection includes checking for deionized water connection and waste liquid connection.

Abnormal connection of the deionized water will result in the insufficient water supply or water leakage, which may cause the machine works improperly.

Improper connection of waste lines, or full high-concentration waste liquid barrel without emptying in time, will cause waste liquid overflow, environmental pollution, cross-contamination and even damage to instruments. Therefore, it is necessary to check the external water pipes connection of the instrument frequently.

- Purpose

1) Check the connection of deionized water to ensure normal water supply.
2) Check whether the waste liquid pipeline connection and high-concentration waste liquid container are empty to avoid overflow of waste liquid.

- Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

- Instrument status

Before performing maintenance, ensure that the instrument is idle.

Operating steps

1) Check whether the switch of the water purification system or other water storage module is on;
2) Check and confirm that the liquid guide pipe is dredged and free from bending, twisting and leakage of liquid;
3) Check whether the waste liquid discharge system is normal, keep the waste liquid pipeline free from bending, discharge smoothly, and discharge high-concentration waste liquid properly (waste liquid shall be discharged as per local regulations);
4) Empty the waste liquid in the high-concentration waste liquid barrel;
5) Select **Maintenance**-**Perd. Maint.**-**Daily**;
6) Click the check box corresponding to checking external water pipes connection;
7) Click **Execution** to perform maintenance;
8) Click **Log** to record the exceptions or other information to be filed during maintenance;
9) Click **Save** to save the log.

6.3.2. Concentrated detergent volume check

Inadequate balance of concentrated detergent will cause the instrument to fail continuous testing. It is recommended to check the balance of concentrated detergent before starting

the test every day. If it is insufficient, please add it in time.

■ Purpose

Check the remaining amount of the concentrated detergent to avoid the test being unable to continue due to insufficient remaining amount.

■ Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

■ Instrument status

Before performing maintenance, ensure that the instrument is idle.

Operating steps

1) Observe whether the concentrated detergent is sufficient. If it is insufficient, add it in time.
2) Select **Maintenance-Perd. Maint.-Daily**;
3) Click the check box corresponding to checking the balance of concentrated detergent;
4) Click **Execution** to perform maintenance;
5) Click **Log** to record the exceptions or other information to be filed during maintenance;
6) Click **Save** to save the log.

6.3.3. Probe syringe check

Reagent-sample probe syringe is a device for precisely distributing samples and reagents. If the syringe leaks, the dispensing amount will be inaccurate and even damage the syringe. Before starting the analysis every day, be sure to check whether the reagent -sample probe syringe leaks.

■ Purpose

Check the reagent-sample probe syringe for leakage and internal air bubbles.

■ Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

■ Maintenance supplies

Clean gauze.

■ Instrument status

Before performing maintenance, ensure that the instrument is idle.

Operating steps

1) Open the analyzer maintenance window to see the reagent -sample probe syringe;
2) Select **Maintenance-Perd. Maint.-Daily**;
3) Click the check box corresponding to check whether there is leaks or bubbles in the

syringe;

4) Observe whether the syringe leaks liquid, wipe the joints between the syringe and the manually tighted joints with clean gauze, and check whether the gauze is wet to judge whether the liquid leaks:

   - If not, click **No** to proceed to the next step.
   - If there is leakage, tighten the hand-tight joint.
   - Check again. If there is any leakage, please tighten the hand tight joint to confirm whether its gasket is in good condition
   - If the gasket is damaged, please replace it. If the gasket is intact, please replace the syringe, please refer to "6.6.18 Syringe replacement".

5) Check whether there are air bubbles inside the syringe. If there is no bubble, click **Exit** to exit the status; If there are air bubbles, please click **Yes-Continue** perform the maintenance operation of "discharging bubbles from the syringe":

6) Check again whether there are bubbles inside the syringe. If there are still bubbles, click **Continue** to repeat the operation until it is completely discharged;

7) Close the analyzer maintenance window;

8) Click **Log** to record the exceptions or other information to be filed during maintenance;

9) Click **Save** to save the log.

6.3.4. Probe detergent volume check

Insufficient balance of probe detergent will cause the instrument to be unable to continuously test. It is recommended to check the balance of probe detergent before starting the test every day. If it is insufficient, please add it in time.

■ Purpose

Check the remaining content of probe detergent to avoid that the test cannot be preceded due to insufficient of it.

■ Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

■ Instrument status

Before performing maintenance, ensure that the instrument is idle.

Operating steps

1) Select **Maintenance**-**Perd. Maint.**-**Daily**;

2) Select the check box corresponding to checking the balance of probe detergent;

3) Click **Execution**, and then click **Continue** to execute the rotation of reagent-sample probe and drop to the probe intensified cleaning position, record the drop in the liquid level of the current cleaning position, and then mechanically reset.

4) After the maintenance is completed, click **Exit** to exit the maintenance state;

5) Click **Log** to record the exceptions or other information to be filed during maintenance;

6) Click **Save** to save the log.

6.3.5. Probe water discharging check

If there are foreign matters or abnormalities in the reagent-sample probe, the test may be affected, leading to inaccurate results. Therefore, please check whether the water outgoing state of the probe is normal before testing every day.

- Purpose

Check whether the water outgoing state of reagent-sample probe is normal.

- Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

- Instrument status

Before performing maintenance, ensure that the instrument is idle.

Operating steps

1) Open the upper cover of the analyzer;

2) Select **Maintenance-Perd. Maint.-Daily**;

3) Select the check box corresponding to check whether the water outlet of the reagent-sample probe is normal (verify whether the probe inner wall is blocked) ;

4) Click **Execution**, and then click **Continue** to clean the inner wall of reagent-sample probe;

5) Observe the water outgoing condition when cleaning the inner wall of reagent-sample probe (as shown in the following figure). If the cleaning water is sprayed or not vertically discharged from the probe tip, the probe may be blocked. Firstly, carry out "intensified cleaning" maintenance operation; if it is still abnormal, it is necessary to carry out the maintenance operation of "replacing reagent-sample probe" or contact the service engineer.

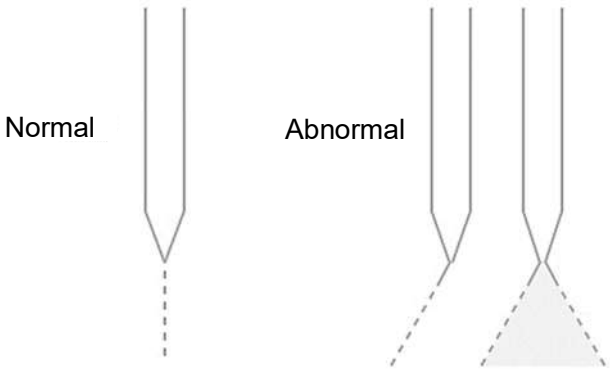


Figure 6-2 Water Outgoing From Probe Inner Wall Cleaning

6) After the maintenance is completed, click **Exit** to exit the maintenance state;

7) Click **Log** to record the exceptions or other information to be filed during maintenance;

8) Click **Save** to save the log.

6.3.6. Cleaning basin check

Foreign matters or abnormalities in the cleaning basin may affect the test and lead to inaccurate results. Therefore, please check whether the outlet state of the cleaning basin is normal before testing every day.

- Purpose

Check whether the water outgoing state of the cleaning basin is normal.

- Maintenance timing

It is recommended to perform this maintenance operation before starting the test every day.

- Instrument status

Before performing maintenance, please ensure that the instrument is powered off or idle.

Operating steps

1) Open the upper cover of the analyzer;

2) Select **Maintenance-Perd. Maint.-Daily**;

3) Select the check box corresponding to check whether the water outlet of the cleaning basin is normal (verify whether the probe outer wall cleaning is normal) .

4) Click **Execution**, and then click **Continue** to clean the outer wall of reagent-sample probe. Refer to the following figure to observe the water output of the cleaning basin.

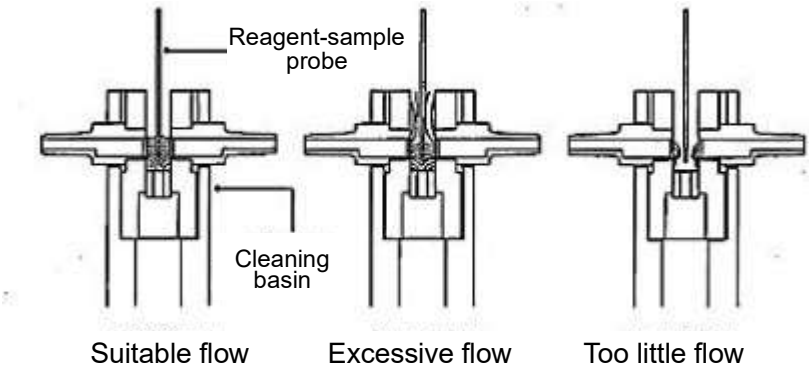


Figure 6-3 Water Outgoing From Probe Outer Wall Cleaning

5) If the flow rate is too small, click **Exit** and clean the cleaning basin before performing the operation of the maintenance item;

6) Click **Log** to record the exceptions or other information to be filed during maintenance;

7) Click **Save** to save the log.

6.4. Weekly maintenance

Mainly for cleaning stirring rod/reagent-sample probe, intensified cleaning (cleaning reagent-sample probe inner wall and reaction ecuvette), cuvette detection and light source lamp detection.

6.4.1. Reagent - sample probe/stirring rod (outer wall) check and cleaning

If the reagent-sample probe and stirring rod are dirty, cross-contamination between samples or reagents may occur and correct analysis results cannot be obtained. To prevent cross contamination, clean reagent-sample probes and stirring rods weekly.

- Purpose

Keep the outer wall of the reagent-sample probe and stirring rod free of contaminants to reduce cross contamination between samples or reagents.

- Maintenance timing

It is recommended to perform this maintenance operation weekly.

- Maintenance supplies

Clean gauze, deionized water, alcohol, tweezers.

- Instrument status

Before performing maintenance, please ensure that the instrument is in shutdown or idle state.

Biological risk

Biological pollution

The table surface should be considered infectious and protective gloves should be worn during operation.

Warning

Please handle with care to avoid cutting your hand on the tip of the probe.

Operating steps

1) Open the upper cover of the analyzer;
2) Click **Maintenance-Perd. Maint.-Weekly**;
3) Select the option to check and clean reagent-sample probe and stirring rod (outer wall).
4) Click **Execution-Continue** to perform reagent-sample probe and strring rod reset operation;
5) Pick up the gauze dipped in alcohol with tweezers and ues it to gently wipe the outer

wall of the reagent-sample probe and stirring rod until clean and smooth;

6) Pick up the gauze dipped in deionized water with tweezers and ues it to gently wipe the alchol;

7) Click **Continue** to clean the outer wall of the probe and stirring rod. Reset the stirring rod vertically after 5 seconds;

8) Click **Log** to record the exceptions or other information to be filed during maintenance;

9) Click **Save** to save the log.

6.4.2. Intensified cleaning for cuvette

Use probe detergent to clean cuvettes.

■ Purpose

Keep the cuvette free of contaminants to reduce cross contamination between samples or reagents.

■ Maintenance timing

It is recommended to perform this maintenance operation weekly.

■ Instrument status

Before performing maintenance, please ensure that the instrument is in shutdown or idle state.

Operating steps

1) Open the upper cover of the analyzer and place sufficient amount of the probe detergent (cleaning dose >26mL) to the C position of the reagent sample tray;

2) Select **Maintenance-Perd. Maint.-Weekly**;

3) Check the option to directly perform dirty cuvette detection after intensified cleaning;

4) Click **Execution**-**Continue**, the system will start to perform intensified cleaning;

5) Click **Exit** to exit the status;

6) Click **Log** to record the exceptions or other information to be filed during maintenance;

7) Click **Save** to save the log.

6.4.3. Detect for dirty cuvette and lamp

■ Purpose

Judging whether the cuvette is dirty or not and whether the light source lamp is too weak by testing the water blank of each cuvette.

■ Maintenance timing

It is recommended to perform this maintenance operation weekly.

■ Instrument status

Before performing maintenance, please ensure that the instrument is powered on for more than 30min and is in the state of shutdown or idle please ensure that the instrument is in idle state.

Operating steps

1) First, make sure that the startup time is more than 30 min so that the light source is stable. Otherwise, please exit the detection process;
2) Select **Maintenance-Perd. Maint.-Weekly**;
3) Select whether to proceed with "detection of dirty cuvette and lamp", if so, click the **Execution** button;
4) Click **Continue** to start the cuvette (dirty) test;
5) Click **Exit** to exit the status;
6) Click **Log** to record the exceptions or other information to be filed during maintenance;
7) Click **Save** to save the log.

For detailed operational procedures and results of dirty cup detection, please refer to "6.6 Dirty Cuvette Detection".

6.5. Monthly maintenance

6.5.1. Clean the cleaning basin

Clean the cleaning basin for reagent-sample probe and stirring rod.

- Purpose

To prevent dust from depositing in the cleaning basin and blocking the cleaning basin after a long time

- Maintenance timing

It is recommended to perform this maintenance operation weekly.

- Maintenance supplies

Cotton swab, sodium hypochlorite (NaClO).

- Instrument status

Before performing maintenance, please ensure that the instrument is in shutdown or idle state.

Biological risk

Biological pollution

All stains should be considered infectious and protective gloves should be worn during operation.

Operating steps for cleaning the cleaning basin

1) Open the upper cover of the analyzer;
2) Select **Maintenance-Perd. Maint.-Monthly**;
3) Select the check box corresponding to clean the cleaning basin for reagent-sample probe and stirring rod;
4) Click **Execution-Continue** to p keep the reagent-sample probe and stirring rod away from the cleaning basin;
5) Use the swab to dip NaClO and wipe each cleaning basin;
6) Click **Continue** to perform the next operation. Please keep away from the moving area of reagent-sample probe and stirring rod pair;
7) Click **Exit** to exit the status;
8) Click **Log** to record the exceptions or other information to be filed during maintenance;
9) Click **Save** to save the log.

6.6. Dirty cuvette detection

- Purpose

Judging whether the cuvette is dirty or not and whether the light source lamp is too weak by testing the water blank of each cuvette.

- Maintenance timing

It is recommended to perform this maintenance operation weekly.

- Instrument status

Before performing maintenance, please ensure that the instrument is powered on for more than 30min and is in the state of shutdown or idle please ensure that the instrument is in idle state.

Operating steps

1) First, make sure that the startup time is more than 30 min so that the light source is stable. Otherwise, please exit the detection process;
2) Select **Maintenance-Perd. Maint.-Dirty Cuv. Det.**;
3) Click **Start** to start the cuvette (dirty) test; If you need to stop the detection process, click the **Stop** button;

   All cuvette positions are displayed on the interface, with dirty cuvette identified by color:

   - Blank: pending test
   - Unmarked: cuvette normal
   - Red: dirty cuvette

4) Click a cuvette position that needs to be viewed, and the "Cuvette Status" interface pops up to display the current and previous detection results of the cuvette：

5) Click **Query Cuv. Det. Result** to view the latest detection results of all the cuvettes;

6) Click **Query Lamp Det. Result** to view the lastest detection result of the lamp;

7) Click **Export** to export the detection data.

6.7. Irregular maintenance items

6.7.1. System reset

■ Purpose

Control the moving parts to perform reset action and cleaning action.

■ Instrument status

When performing this maintenance operation, please ensure that the instrument is in shutdown or idle state.

Operating steps

1) Open the upper cover of the analyzer;

2) Select **Maintenance-Perd. Maint.-Others**;

3) Select the check box corresponding to system reset;

4) Click **Execution** to perform maintenance;

5) Click **Log** to record the exceptions or other information to be filed during maintenance;

6) Click **Save** to save the log.

6.7.2. Mechanical reset

■ Purpose

Control reagent-sample probe, stirring rod and other moving parts to perform mechanical reset.

■ Instrument status

When performing this maintenance operation, please ensure that the instrument is in shutdown or idle state.

Operating steps

1) Open the upper cover of the analyzer;

2) Select **Maintenance-Perd. Maint.-Others**;

3) Select the check box corresponding to mechanical reset;

4) Click **Execution** to perform maintenance;

5) Click **Log** to record the exceptions or other information to be filed during maintenance;

6) Click **Save** to save the log.

6.7.3. Routine cuvette cleaning

■ Purpose

Keep the cuvette free of contaminants to reduce cross contamination between samples or reagents.

■ Instrument status

When performing this maintenance operation, please ensure that the instrument is in shutdown or idle state.

Operating steps

1) Open the upper cover of the analyzer and prepare sufficient amount of concentrated detergent;
2) Select **Maintenance-Perd. Maint.-Others**;
3) Select the check box corresponding to routine cuvette cleaning;
4) Click **Execution** to perform maintenance;
5) Click **Log** to record the exceptions or other information to be filed during maintenance;
6) Click **Save** to save the log.

6.7.4. Reagent-sample probe intensified cleaning

■ Purpose

Reduce cross-contamination between reagents or samples, and avoid sludge of waste liquid in waste liquid pipeline.

■ Instrument status

When performing this maintenance operation, please ensure that the instrument is in shutdown or idle state.

Operating steps

1) Open the upper cover of the analyzer;
2) Place sufficient concentrated detergent at position C of reagent-sample tray;
3) Select **Maintenance-Perd. Maint.-Others**;
4) Select the check box corresponding to reagent-sample probe intensified cleaning;
5) Click **Execution** to perform maintenance;
6) Click **Log** to record the exceptions or other information to be filed during maintenance;
7) Click **Save** to save the log.

6.7.5. Stirring rod intensified cleaning

■ Purpose

Reduce cross-contamination between reagents or samples, and avoid sludge of waste

liquid in waste liquid pipeline.

- Instrument status

When performing this maintenance operation, please ensure that the instrument is in shutdown or idle state.

Operating steps

1) Open the upper cover of the analyzer;
2) Place sufficient concentrated detergent at position C of reagent-sample tray;
3) Select **Maintenance-Perd. Maint.-Others**;
4) Select the check box corresponding to stirring rod intensified cleaning;
5) Click **Execution** to perform maintenance;
6) Click **Log** to record the exceptions or other information to be filed during maintenance;
7) Click **Save** to save the log.

6.7.6. Analyzer table cleaning

Reagents, reaction solutions and serum are easy to drip on the analyzer table, which should be removed in time. In order to ensure a clean working environment and reduce biological risks, exposed parts such as analyzer table and tray cover should be cleaned in time.

- Purpose

Clean the analyzer table and tray cover and keep the working environment and table clean and tidy, so as to reduce the risk of cross contamination.

- Maintenance supplies

Clean gauze, deionized water, cotton swab.

- Instrument status

When performing this maintenance operation, please ensure that the instrument is in shutdown or idle state.

Biological risk

Biological pollution

The table surface should be considered infectious and protective gloves should be worn during operation.

Operating steps

1) Please confirm that the instrument is in shutdown or idle state before opening the upper cover of the analyzer.
2) Wipe the analyzer table and tray cover with gauze dipped in a small amount of deionized water.
3) Cover the upper cover of the analyzer.

6.7.7. Reagent-sample tray cleaning

When the reagent is accidentally spilled in the reagent-sample tray, or dust is accumulated on the inner wall through visual inspection, it should be cleaned in time to reduce the risk of cross contamination.

- Purpose

Clean the reagent-sample storehouse assembly, keep the working environment and table clean and tidy, so as to reduce the risk of cross contamination.

- Maintenance timing

It is recommended to perform this maintenance operation weekly.

- Maintenance supplies

Clean gauze, deionized water, alcohol, cotton swab.

- Instrument status

When performing this maintenance operation, please ensure that the instrument is in shutdown or idle state.

Biological risk

Biological pollution

The table surface should be considered infectious and protective gloves should be worn during operation.

Operating steps

1) Please confirm that the instrument is in shutdown or idle state;
2) Uncover the reagent-sample storehouse, remove the reagent-sample tray and place it in a safe and reliable place;
3) Wipe the inner tray with gauze dipped in a small amount of deionized water or alcohol. When necessary, a small amount of neutral detergent can be dipped into gauze to wipe it;
4) Wipe the tray body with gauze dipped in a small amount of deionized water or alcohol. For the dirt on the sample position, use cotton swab to dip in a small amount of alcohol to wipe;
5) Put the reagent-sample tray back into the storehouse and cover the tray.

6.7.8. Overheating protection device

In order to ensure the effective operation of the equipment, the safety inspection of the overheating protection device should be performed once a year. Methods as below:

Put the plastic sealing part of the temperature protection switch in 90 ~ 100 ℃ water (or boiled water) for 5 minutes. If the heating wire which measured by a multimeter breaks, the overheat protection device is normal, otherwise it will fail.

Repeated tests in this section may damage equipment and reduce protection against danger.

Caution

6.7.9. Reaction groove cleaning

1) Turn off the analysis switch;
2) Remove the cleaning head and remove the reaction tray cover.
3) Loosen the reaction tray fixing screw;
4) Hold the two sides of the reaction tray with both hands respectively, and evenly exert upward force to remove the reaction tray;
5) Dip clean gauze or cotton swab into the supernatant lotion, clean all parts of the inner wall of the reaction tank until there is no obvious stain, and then dry with clean gauze;
6) Install the reaction tray and fix the fastening screws;
7) Cover the reaction tray, and then install the cleaning head.

Biological pollution

All stains should be considered infectious and protective gloves should be worn during operation.

Biological risk

6.7.10. Drive rod wipe

Wipe the drive rod of reagent-sample probe and stirring rod respectively.

1) Turn off the switch of the analysis unit;
2) Move the stirring rod so that its driving rod rotates to an angle suitable for wiping;
3) Wipe the drive rod up and down lightly with clean gauze until there are no obvious dust or stains, then apply lubricating oil, and pull the drive rod up and down to evenly distribute the lubricating oil on the drive rod;
4) Wipe the driving rod of the reagent-sample probe by same method ;
5) Move the reagent-sample probe and stirring rod above the corresponding cleaning basin.

6.7.11. Check pure water bucket

On the left side of the analyzer, a pure water bucket will be placed.

Check the pure water bucket: check whether the bottom of the pure water bucket is clean. If it is dirty, clean the pure water bucket thoroughly before use.

6.7.12. Clean probe tube/suction nozzle of cuvette

If the probe tube of the cuvette cleaning mechanism is not clean, there will be adhesion of reaction liquid, moisture and the like, which should be checked in time after daily shutdown. In case of the above situation, please refer to the following steps for cleaning:

1) Dip a clean cotton swab with absolute ethyl alcohol and gently wipe the drainage probe tube and probe tip until there is no obvious adherent
2) Dip a clean cotton swab with absolute ethyl alcohol, and gently wipe the suction probe tube and probe tip until there is no obvious adherent.
3) Clean cotton swabs with purified water and gently wipe the four sides and upper and lower parts of the suction nozzle until there is no obvious adherent.
4) Dip a clean cotton swab with absolute ethyl alcohol and gently wipe the four sides and upper and lower parts of the suction nozzle until there is no obvious adherent.

Attention

When cleaning, attention should be paid to the possibility that cotton fibers on cotton swabs may be clamped between the drainage probe tube and the suction probe tube, and the cotton fibers should be removed in time if necessary.

Biological risk

Biological pollution

All parts shall be considered infectious and protective gloves shall be worn during operation.

6.7.13. Waste bucket cleaning

This step can be omitted if the waste liquid is directly discharged into the sewer; otherwise, it will be carried out according to the following step:

1) Unscrew the waste liquid bucket cover and take out the waste liquid sensor and waste liquid pipe;
2) Take out the waste liquid bucket, wash it thoroughly with a brush and then put it in.

Biological risk

Biological pollution

All waste liquid shall be considered infectious and protective gloves shall be worn during operation.

6.7.14. Probe dredge

When the probe is blocked, it needs to be dredged immediately.

1) Turn off the analysis switch;;
2) Turn the reagent-sample probe to the appropriate position and open the upper cover of the reagent-sample probe rocker arm;

3) Pull off the connection line with the liquid level detection plate;

4) Loosen the teflon tube connecting the reagent-sample probe;

5) Loosen the compression spring piece;

6) Take out reagent-sample probe upwards;

7) Use stainless steel wire with an inner diameter of 0.25 mm to dredge the reagent-sample probe upwards from the probe tip, and dredge repeatedly back and forth for many times;

8) Connect a disposable syringe with a reagent-sample probe through a matching hose, draw water into the probe tube through the syringe, and make sure that water is ejected from the probe tip in a straight line, which indicates that the probe tube has been dredged;

9) Install the reagent-sample probe and close the cover of the rocker arm in the reverse sequence of the above operation;

10) Move the reagent-sample probe above the cleaning basin.

Biological risk

Biological pollution

Reagent-sample probes should be considered infectious and protective gloves should be worn during operation.

6.7.15. Probe replacement

When the probe is broken, bent or cannot be dredged after being blocked, it needs to be replaced immediately. Refer to "Sample Probe Dredge" in the previous section for the operation process.

1) Turn off the analysis switch;

2) Move the reagent-sample probe to a suitable position, open the upper cover of the reagent-sample probe rocker arm, loosen the teflon tube, and pull off the lead of the liquid level detection sensor;

3) Loosen the compression spring piece and take out the reagent-sample probe;

4) Install the new probe on the rocker arm, press on the spring leaf, connect the teflon tube, insert the lead of the liquid level detection sensor, and close the upper cover of the rocker arm;

5) Move the reagent-sample probe above the cleaning basin.

Biological risk

Biological pollution

Reagent-sample probe should be considered infectious and protective gloves should be worn during operation.

6.7.16. Stirring rod replacement

When the stirring rod is broken, bent or frequently hung, it needs to be replaced immediately.

1) Turn off the analysis switch;
2) Move the stirring rod to a suitable position;
3) Loosen the two top screws fixed on the rotating shaft of the stirring motor;
4) Take off the stirring rod;
5) Install the new stirring rod upward into the rotating shaft of the motor until it touches.
6) Fix the stirring rod on the rotating shaft of the stirring motor by using two jacking screws.

Biological risk

Biological pollution

Mixing rod shall be considered infectious and protective gloves shall be worn during operation.

6.7.17. Bulb replacement

When the bulb is used for more than half a year, or when the analyzer prompts that the bulb needs to be replaced, it needs to be replaced immediately.

Note: before replacing the bulb, make sure that the power supply of the analysis unit is turned off; otherwise the light beam emitted by the light bulb will cause damage to eyes.

Caution

Screw falls off

When loosening or fixing the bulb screws, be careful not to fall off the screws.

1) Turn off the switch of the analysis unit and carry out the following steps after half an hour;
2) Take off the automatic cleaning head, and then remove the reaction tray cover;
3) After removing the reaction tray, loosen the fixing screws on the bulb base with M3 hexagonal screwdriver;
4) After the light source lamp is removed, loosen the power cord of the light source lamp on the binding post;
5) Take out the old bulb;
6) Install the new bulb, screw in the fixing screw, and plug in the power cord of the new bulb;
7) Install the reaction tray and screw on the fixing screw;
8) Close the cover of the reaction tray and install the cleaning head.

High temperature

High temperature, scald

Before replacing the bulb, please turn off the power switch and wait at least 30 minutes until the lamp has cooled down.

Strong light

Before replacing the bulb, make sure that the power of the analysis unit is turned off, otherwise the light beam from the lamp will cause eye damage.

6.7.18. Syringe replacement

This maintenance is performed when the syringe leak or other malfunction occurs.

1) Open the maintenance window on the left rear of the analyzer to see the reagent-sample probe syringe;
2) Firstly, loosen up the fixing screws at the piston end of the syringe, and then loosen up the two fixing screws of the tee joint;
3) Take out the syringe and tee joint, pinch the metal part on the upper part of the syringe, rotate counterclockwise to separate the syringe from the tee joint, and take off the syringe;
4) Push the metal thread on the upper part of the new syringe into the thread opening of the tee joint and rotate clockwise to fix it;

Caution

Sealing washer

There is a sealing gasket in the threaded opening of the tee joint, be careful not to lose it when disassembling.

5) Place the syringe in the installation position, and sleeve the piston end of the syringe into the drive screw; screw on the tee joint and the fixing screw of the syringe piston end.

6.7.19. Peristaltic pump head replacement

1) Turn off the switch of the analysis unit and open the maintenance window at the left rear of the analyzer to see the peristaltic pump;
2) Pull out the peristaltic pump head which is connected with rubber tube from the pipe. Then press the snap on both ends of peristaltic pump head and pull out the pump head. Replace a new pump head;
3) Replace the new peristaltic pump head， connect the pipeline and install the maintenance window.

6.7.20. Cleaning and replacing liquid tubes

The liquid tubes need irregularly maintenance every six months or one year by engineers. The instrument casing needs to be disassembled to check whether the pipeline is dirty or blocked. If there is, remove it and wash it with 84 disinfectant and water or replace it directly.

6.8. Replacement parts list

6.8.1. Components for users replacement

- Reagent-sample probe, stirring rod
- Bulb
- Peristaltic pump tube

6.8.2. Components for engineers replacement

- Main power switch
- Power switch of analysis unit
- Overheating protection device
- Other devices

6.9. Maintenance log

The following table lists the components to be maintained and gives the recommended maintenance schedule. Please copy these tables monthly and make records in the column corresponding to the maintenance date after the maintenance is completed.

Table 6-1 Daily Maintenance Items

_ _ _ _yy_ _ _ _ mm

	Maintenance items (daily)	Maintenance records																													
		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
1	Check external water pipes connection																															
2	Check the remaining amount of concentrated detergent																															
3	Check whether there is leaks or bubbles in the syringe																															
4	Check the probe detergent residual																															
5	Check whether the probe outlet water is normal																															
6	Check whether the cleaning basin outlet water is normal																															

Table 6-2 Weekly Maintenance Items

_ _ _ _yy_ _ _ _ mm

	Maintenance items (weekly)	Maintenance records																													
		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
1	Check and clean reagent-sample probe and stirring rod ((outer wall)																															
2	Intensified cleaning for cuvette																															
3	Detect for dirty cuvette and lamp																															

Table 6-3 Monthly Maintenance Items

_ _ _ _yy_ _ _ _ mm

	Maintenance items (monthly)	Maintenance records																												
		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
1	Clean cleaning basin of reagent -sample probe and stirring rod																															

Table 6-4 Other Maintenance Items

_ _ _ _ yy_ _ _ _mm _ _ _ _ dd

	Maintenance items (other)	Maintenance records																												
		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
1	System reset																															
2	Mechanical reset																															
3	Routine cuvette cleaning																															
4	Reagent-sample probe intensified cleaning																															
5	Cleaning basin intensified cleaning																															

7. Alarm and Management

7.1. Data alarm interface

Data alarm is a kind of mark for abnormal test results, and the corresponding mark is displayed on the software interface to prompt.

1. The "Mark" column of the interface **Status-Sample Tray** displays all the marks indicating that the test result of the current sample/ calibrator /QC is abnormal in the current item. If it is blank, the test result is normal. The display marks and corresponding reasons are as follows:

Serial number	Marker	Reason	Calibrator	QC	Sample
1	ADE	Adi≤Adid ADi≤ADid	Applicable	Applicable	Applicable
2	RBK	R1 blank absorbance exceeds the limit	Applicable	Applicable	Applicable
3	ABS	Absorbance of working fluid exceeds the limit	Applicable	Applicable	Applicable
4	RCE	Incorrect calculation of reactivity	Applicable	Applicable	Applicable
5	RCT	Reactivity of working fluid exceeds the limit	Applicable	Applicable	Applicable
6	PRO	Abnormal examination of prozone	Applicable	Applicable	Applicable
7	PROE	Error in prozone inspection calculation	Applicable	Applicable	Applicable
8	BOE	Substrate depletion	Applicable	Applicable	Applicable
9	NLN	Non-linearity interval	Applicable	Applicable	Applicable
10	ENC	No calculation interval	Applicable	Applicable	Applicable
11	EXP	Enzyme linearity expansion calculated result reactivity	Applicable	Applicable	Applicable
12	LIN	Linearity is less than the limit	Applicable	Applicable	Applicable
13	MBK	Mixed blank absorbance exceeds limit	Applicable	/	/
14	BLK	Blank reactivity exceeds limit	Applicable	/	/

15	RRN	Check if the sample reactivity exceeds that of maximum concentration calibrator	/	Applicable	Applicable
16	RRNE	The concentration calculation failed after exceeding the reactivity of the maximum concentration calibrator	/	Applicable	Applicable
17	LOW	The sample reactivity is lower than the minimum concentration standard reactivity check	/	Applicable	Applicable
18	LRG	Sample concentration exceeds the upper limit of linearity range	/	Applicable	Applicable
19	LRL	Sample concentration exceeds the lower limit of linearity range	/	Applicable	Applicable
20	↑!	Sample concentration exceeds the upper limit of critical value range	/	/	Applicable
21	↓!	Sample concentration exceeds the lower limit of critical value range	/	/	Applicable
22	↑	Sample concentration exceeds the upper limit of normal reference range	/	/	Applicable
23	↓	Sample concentration exceeds the lower limit of normal reference range	/	/	Applicable

2. The "Mark" and "Note" in the result query interface indicates that the sample test result is abnormal. The result is normal in case of blank display. The display marks and corresponding reasons are as follows:

Serial number	Marker	Reason	Mark	Note
1	ADE	ADi≤ADid		Applicable
2	RBK	R1 blank absorbance exceeds the limit		Applicable
3	ABS	Absorbance of working fluid exceeds the limit		Applicable
4	RCE	Incorrect calculation of reactivity		Applicable
5	RCT	Reactivity of working fluid exceeds the		Applicable

		limit		
6	PRO	Abnormal examination of prozone		Applicable
7	PROE	Error in prozone inspection calculation		Applicable
8	BOE	Substrate depletion		Applicable
9	NLN	Non-linearity interval		Applicable
10	ENC	No calculation interval		Applicable
11	EXP	Reactivity of enzyme linearity expansion calculation results		Applicable
12	LIN	Linearity is less than the limit		Applicable
13	RRN	Sample reactivity exceeds maximum concentration standard reactivity examination		Applicable
14	RRNE	The concentration calculation failed after exceeding the maximum concentration standard reaction degree		Applicable
15	LOW	The sample reactivity is lower than the minimum concentration standard reactivity check		Applicable
16	LRG	Sample concentration exceeds the upper limit of linearity range		Applicable
17	LRL	Sample concentration exceeds the lower limit of linearity range		Applicable
18	↑!	Sample concentration exceeds the upper limit of critical value range	Applicable	
19	↓!	Sample concentration exceeds the lower limit of critical value range	Applicable	
20	↑	Sample concentration exceeds the upper limit of normal reference range	Applicable	
21	↓	Sample concentration exceeds the lower limit of normal reference range	Applicable	
22	ER	Use expired reagent		Applicable
23	DCP	Use deferred calibration parameters		Applicable

3. The "Mark" in **Calibration-Cal R** indicates that the calibration test result is abnormal. The result is normal in case of blank display. The display marks and corresponding reasons are as follows:

Serial number	Marker	Reason	Mark
1	DMON	Non-linear calibration data is not monotonous	Applicable

2	CDE	Concentration divided by 0 (reactivity 0)	Applicable
3	COV	Nonlinear calibration iteration does not converge	Applicable
4	CMON	The nonlinear calibration curve is not monotonous	Applicable
5	ER	Use expired reagent	Applicable

4. The "Prompt" in the interface of **QC-QC Data** indicates that the quality control test result is abnormal. The result is normal in case of blank display. The display marks and corresponding reasons are as follows:

Serial number	Marker	Reason	Prompt
1	ADE	ADi≤ADid	Applicable
2	RBK	R1 blank absorbance exceeds the limit	Applicable
3	ABS	Absorbance of working fluid exceeds the limit	Applicable
4	RCE	Incorrect calculation of reactivity	Applicable
5	RCT	Reactivity of working fluid exceeds the limit	Applicable
6	PRO	Abnormal examination of prozone	Applicable
7	PROE	Error in prozone inspection calculation	Applicable
8	BOE	Substrate depletion	Applicable
9	NLN	Non-linearity interval	Applicable
10	ENC	No calculation interval	Applicable
11	EXP	Reactivity of enzyme linearity expansion calculation results	Applicable
12	LIN	Linearity is less than the limit	Applicable
13	RRN	Check whether the reactivity of QC exceeds the maximum concentration of standard value	Applicable
14	RRNE	The concentration calculation failed because of exceeding the reactivity of maximum concentration calibrator	Applicable
15	LOW	The reactivity of the QC sample is lower than that of the minimum concentration standard value	Applicable
16	LRG	The concentration of the QC sample exceeds the upper limit of the linearity range	Applicable
17	LRL	The concentration of the QC sample exceeds the lower limit of the linearity range	Applicable
18	ER	Use expired reagent	Applicable
19	DCP	Use deferred calibration parameters	Applicable

7.2. Instrument alarm and management

7.2.1. Overview

When the analyzer gives an alarm, according to the alarm level, the system will automatically process it in the following 7 ways, and display it with a high-brightness red bar at the bottom of the operation software interface. After clicking **Info List** button on the right side of the red bar, detailed fault information, possible causes and solutions will pop up.

1) Prohibit testing

   Only diagnosis and maintenance are allowed, and no tests are allowed to start.

2) Shutdown

   Stop all current tests; the analyzer is in standby state, waiting for wake up.

3) Stop the new test

   Stop all tests that have not yet started, and continue the tests that have been added.

4) Stop testing related samples

   Stop testing some samples and continue other tests.

5) Stop testing related reagents

   Stop testing some reagents and continue other tests.

6) Warning

   Only the warning message pops up, and the analyzer does not make any processing.

7) Prompt

   Only the prompt message pops up, and the analyzer does not make any processing.

This chapter lists all the fault alarm information of the system and their corresponding treatment measures. Please deal with the system in a timely manner according to the treatment measures provided. If the alarm state cannot be released after the measures are taken, please contact Zybio.

7.2.2. Alarm information inquiry

EXC2X series chemistry analyzer instrument operation error query, click **Maintenance-Trouble Shooting** to enter the following figure:

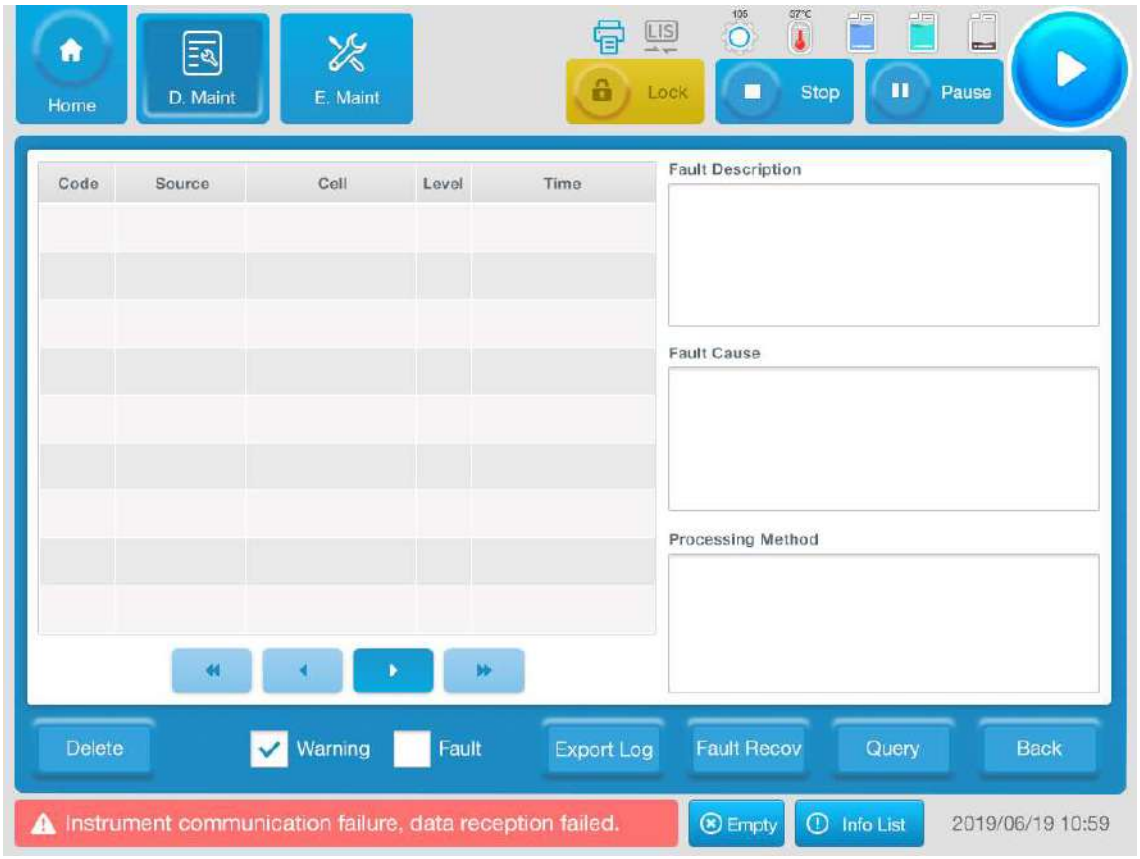


Figure 7-1 Trouble Shooting

7.2.3. Instrument operation error table

Malfunction code	Error Description	Error Explanation	Troubleshooting
F00001	A unit malfunctioned during periodic test	A unit malfunctioned during execution	Execute the periodic recovery command
F00002	A unit malfunctioned during the recovery period, recovery failed, but the photoelectric data collection can continue.	A unit malfunctioned during execution	Log out and reboot the host computer, start Power On Self Test
F00003	A unit malfunctioned during period recovery, recovery failed, and the host computer is interrupted	A unit malfunctioned during execution	Log out and reboot the host computer, start Power On Self Test
F00004	A unit malfunctioned during periodic test	A unit malfunctioned during execution	Execute the periodic recovery command
F00005	A unit malfunctioned during periodic test	A unit malfunctioned during execution	Execute the periodic recovery command
F00006	A unit malfunctioned during periodic test	A unit malfunctioned during execution	Execute the periodic recovery command
F00007	A unit malfunctioned during periodic test	Error in execution of a unit	Execute the periodic recovery command

F00008	The sampling probe is not in the vertical start position and cannot be rotated	1. The sampling probe is not in the vertical start position; 2. Malfunction of the vertical start position sensor of the sampling probe or wire malfunction	Check the wires and connectors, execute the vertical reset command of the sampling probe first, and then execute the corresponding rotation command. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00009	During the lowering of the sampling probe, the surface of the probe detergent can be detected, but the probe detergent is insufficient (the sampling probe will touch the bottom of the reagent cup in the following 5 steps or less)	1. Insufficient probe detergent;	1. Replenish the probe detergent. If the problem persists, please contact the Technical Support Department of Zybio Inc..
F00010	During the lowering of the sampling probe, the surface of the probe detergent cannot be detected, indicating malfunction of the liquid surface sensor of the sampling probe or no probe detergent in the cleaning container.	1. No probe detergent; 2. Malfunction of the liquid surface sensor.	1. Replenish reagents, 2. Check wires and sensors. If the problem persists, please contact the Technical Support Department of Zybio Inc..

F00011	During the vertical movement of the sampling probe to the start position，no signal for the start position sensor was detected till it completes its maximum number of steps.	1. Strong light or strong electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. The stepper motor is broken; 4. The start position sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00012	Collision occurred during the vertical downward movement of the sampling probe.	1. The reagent bottle cap is not open; 2. The sample tube cover is not open; 3. Reagent/Sample tray cover or reaction tray cover is not positioned correctly; 4. Strong electromagnetic interference; 5. The collision sensor is broken or poor wire connection.	1. Check whether the reagent bottle cap is open and whether the reagent is misplaced; 2. Check whether the sample tube cover is open and whether the sample is misplaced; 3. Place the reagent/sample tray cover and the reaction tray cover in the correct positions; 4. Eliminate possible electromagnetic interference. If the problem persists, please contact the Technical Support Department of Zybio Inc..

F00013	During the vertical downward movement of the sampling probe from the start position, the sampling probe did not leave the start position before the specified number of steps is completed, indicating malfunction of the start position sensor of the sampling probe or lost steps.	1. Strong light or strong electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. The stepper motor is broken; 4. The start position sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00014	The liquid surface is detected before the sampling probe reaches the mouth of the reagent bottle during its lowering process,, indicating malfunction of the liquid surface sensor of the sampling probe or water droplets on the sampling probe tip.	1. The dirty tip of the sampling probe leads to water droplets hanging on the tip; 2. Insufficient cleaning solution in the container leads to water hanging on the sampling probe tip; 3. The sensitivity of the liquid surface sensor increases; 4. Strong electromagnetic interference.	1. Check the surface level of the cleaning container. If the cleaning solution is insufficient, replenish it immediately. 2. Check the sampling probe tip. If it is dirty, wipe it lightly with absorbent cotton swab dipped in absolute ethanol. 3. Eliminate possible electromagnetic interference. If the problem persists, please contact the Technical Support Department of Zybio Inc..
F00015	During the lowering of the sampling probe, the liquid surface of the reagent can be detected, but the amount of reagent is insufficient, the sampling probe will touch the bottom of the reagent cup in the following 5 steps or less.	1. Insufficient reagent	1. Add reagents. If the problem persists, please contact the Technical Support Department of Zybio Inc..

F00016	During the lowering of the sampling probe, the surface of the reagent cannot be detected, indicating malfunction of the liquid surface sensor of the sampling probe or no reagent in the reagent bottle.	1. No reagent; 2. Reagent misplaced; 3. malfunction of the liquid surface sensor.	1. Check the position of the reagent; 2. Add reagent; 3. Check wires and sensors. If the problem persists, please contact the Technical Support Department of Zybio Inc..
F00017	The sampling probe is not in the vertical start position and cannot reach the specified position. If operate by force, the sampling probe will be damaged, so the operation cannot be carried out.	The sampling probe is not in the vertical start position	1. Execute the vertical reset command of the sampling probe, and then execute the related lowering command. If the problem persists, please contact the Technical Support Department of Zybio Inc..
F00018	Although there was no intake of the sample in the current period, when moving down to the reaction cup, it was detected that the sampling probe was not in the vertical start position.	1. Strong light or strong electromagnetic interference; 2. The start position sensor is broken or poor wire connection; 3 The vertical reset command of the sampling probe was not executed first.	First, execute the vertical reset command, eliminate the strong light or strong electromagnetic interference, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00019	There was intake of the sample in the current period, but when moving down to the reaction cup, it was detected that the sampling probe was not in the vertical start position.?	1. Strong light or strong electromagnetic interference; 2. The start position sensor is broken or poor wire connection 3 The vertical reset command of the sampling probe was not executed first.	First, execute the vertical reset command, eliminate the strong light or strong electromagnetic interference, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..

F00020	Although there was intake of the sample before, when cleaning the sampling probe, it was found that the sampling probe was not in the start position and could not be lowered to complete the cleaning.	1. Strong light or strong electromagnetic interference; 2. The start position sensor is broken or poor wire connection 3 The vertical reset command of the sampling probe was not executed first.	First, execute the vertical reset command, eliminate the strong light or strong electromagnetic interference, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00021	Although there was no intake of the sample before, when cleaning the sampling probe, it was found that the sampling probe was not in the start position and could not be lowered to complete the cleaning.	1. Strong light or strong electromagnetic interference; 2. The start position sensor is broken or poor wire connection 3 The vertical reset command of the sampling probe was not executed first.	First, execute the vertical reset command, eliminate the strong light or strong electromagnetic interference, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00022	The sampling probe is not in the start position and cannot be lowered to the specified position to complete the enhanced cleaning	1. Strong light or strong electromagnetic interference; 2. The start position sensor is broken or poor wire connection; 3 The vertical reset command of the sampling probe was not executed first.	First, execute the vertical reset command, eliminate the strong light or strong electromagnetic interference, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..

F00023	There was intake of the sample, but the sampling probe was not in the start position, and the sampling probe could not be lowered to the cleaning container to release the cleaning solution and complete cleaning	1. Strong light or strong electromagnetic interference; 2. The start position sensor is broken or poor wire connection; 3 The vertical reset command of the sampling probe was not executed first.	First, execute the vertical reset command, eliminate the strong light or strong electromagnetic interference, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00024	Although there was no intake of the sample, the sampling probe was not in the start position and sampling probe could not be lowered to the cleaning container and complete cleaning process.	1. Strong light or strong electromagnetic interference; 2. The start position sensor is broken or poor wire connection 3 The vertical reset command of the sampling probe was not executed first.	First, execute the vertical reset command, eliminate the strong light or strong electromagnetic interference, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00025	During the horizontal rotation of the sampling probe to the start position, the start position sensor did not be detected by the sampling probe before the maximum number of steps is completed, the start position sensor may be broken or there is step loss.	1. Strong light or strong electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. The stepper motor is broken; 4. The start position sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..

F00026	The sampling probe was originally at the start position. To rotate horizontally to the start position, it must rotate counterclockwise for a certain number of steps before rotating clockwise to the start position. The sampling probe did not leave the start position after a specified number of steps had been completed. The start position sensor may be broken or there is step loss.	1. Strong light or strong electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. The stepper motor is broken; 4. The start position sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00027	During the horizontal rotation of the sampling probe to the cleaning position, the cleaning position was not found before the specified number of steps were completed. The encoding disk sensor may be broken or there is step loss of the motor.	1. Strong light or strong electromagnetic interference; 2. Poor contact of the stepper motor wires leads to step loss; 3. The stepper motor is broken; 4. The horizontal encoding disk sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00028	The sampling probe could not rotate to the position of the specified reagent cup, and the horizontal encoding disk sensor of the sampling probe may be broken or there was step loss.	1. Strong light or strong electromagnetic interference; 2. Poor contact of the stepper motor wires leads to step loss; 3. The stepper motor is broken; 4. The horizontal encoding disk sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..

F00029	The sampling probe could not rotate to the specified sample cup, the horizontal encoding disk sensor may be broken or there was step loss.	1. Strong light or strong electromagnetic interference; 2. Poor contact of the stepper motor wires leads to step loss; 3. The stepper motor is broken; 4. The horizontal encoding disk sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00030	Unable to find the position of the sampling probe before rotation. The problem may be that the horizontal rotation reset of the sampling probe was not performed prior to the rotation, or there was an error during the rotation reset. Please complete the horizontal rotation reset of the sampling probe first.	1. No rotation reset command is executed	1. Execute the rotation reset command of the sampling probe, and then execute the rotation command. If the problem persists, please contact the Technical Support Department of Zybio Inc..
F00031	During the horizontal rotation of the sampling probe to the position of the reaction tray, the position of the reaction tray was not found before the specified number of steps was completed	1. Strong light or strong electromagnetic interference; 2. Poor contact of the stepper motor wires leads to step loss; 3. The stepper motor is broken; 4. The horizontal encoding disk sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..

F00032	The liquid surface is detected before the sampling probe reaches the mouth of the sample cup during its lowering process, indicating malfunction of the liquid surface sensor of the sampling probe or water droplets on the sampling probe tip.	1. The dirty tip of the sampling probe leads to water droplets hanging on the tip; 2. Insufficient cleaning solution in the container leads to water hanging on the sampling probe tip; 3. The sensitivity of the liquid surface sensor increases; 4. Strong electromagnetic interference.	1. Check the surface level of the cleaning container. If the cleaning solution is insufficient, replenish it immediately. 2. Check the sampling probe tip. If it is dirty, wipe it lightly with absorbent cotton swab dipped in absolute ethanol. 3. Eliminate possible electromagnetic interference. If the problem persists, please contact the Technical Support Department of Zybio Inc..
F00033	When cleaning the inner wall of the sampling probe, the electromagnetic valve cannot be opened correctly to complete cleaning	1. Strong electromagnetic interference; 2. The cleaning solution valve is broken or poor wire connection 3. The valve driver board is broken.	After eliminating the strong electromagnetic interference, check the wires and pump valve and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00034	When the liquid pump is working in a long time or cleaning the outer wall of the sampling probe, the liquid pump cannot be opened.	1. Strong electromagnetic interference; 2. The cleaning fluid pump is broken or poor wire connection; 3. The pump driver board is broken	After eliminating the strong electromagnetic interference, check the wires and pump valve and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..

F00035	When cleaning the inner and outer walls of the sampling probe, the electromagnetic valve was first opened, but the liquid pump could not be normally turned on after 0.8 seconds. Therefore, the electromagnetic valve needs to be closed, but the electromagnetic valve could not be normally closed.	1. Strong electromagnetic interference; 2. The inner wall cleaning fluid valve is broken or poor wire connection; 3. The cleaning pump is broken or poor wire connection 4. The pump valve driver board is broken.	After eliminating the strong electromagnetic interference, check the wires and pump valve and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00036	After cleaning the sampling probe, neither the liquid pump nor the electromagnetic valve can be turned off or closed correctly.	1. Strong electromagnetic interference; 2. The inner wall cleaning fluid valve is broken or poor wire connection; 3. The cleaning pump is broken or poor wire connection 4. The pump valve driver board is broken.	After eliminating the strong electromagnetic interference, check the wires and pump valve and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00037	The electromagnetic valve cannot be normally closed after cleaning the sampling probe.	1. Strong electromagnetic interference; 2. The inner wall cleaning fluid valve is broken or poor wire connection; 3. The valve driver board is broken.	After eliminating the strong electromagnetic interference, check the wires and pump valve and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..

F00038	After cleaning the sampling probe, the liquid pump cannot be normally turned off.	1. Strong electromagnetic interference; 2. The cleaning pump is broken or poor wire connection. 3. The pump driver board is broken	After eliminating the strong electromagnetic interference, check the wires and pump valve and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00039	When cleaning the inner and outer walls of the sampling probe, the cleaning valve on the inner and outer walls of the sampling probe cannot be normally opened.	1. Strong electromagnetic interference; 2. The inner wall cleaning fluid valve is broken or poor wire connection; 3. The valve driver board is broken	After eliminating the strong electromagnetic interference, check the wires and pump valve and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00040	The sampling syringe could not reach the start position before the maximum number of steps is completed. The start position sensor of the sampling syringe may be broken or there is step loss.	1. Strong light or strong electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. The stepper motor is broken; 4. The start position sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00041	A unit malfunctioned during periodic test	A unit malfunctioned during execution	Execute the periodic recovery command

F00042	Checksum error in the command frame received by the sampling probe unit.	1. Strong electromagnetic interference; 2. Loose serial line; 3. Poor serial line connection.	1. Check and fix the serial line after shutdown the machine; 2. After eliminating strong electromagnetic interference . Restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00043	During the lowering of the sampling probe, the liquid surface of the sample can be detected, but the amount of sample is insufficient (the sampling probe will touch the bottom of the sample cup in the following 5 steps or less).	1. Insufficient sample ;	1. Add sample. If the problem persists, please contact the Technical Support Department of Zybio Inc..
F00044	During the lowering of the sampling probe, the liquid surface of the sample can not be detected, indicating the liquid surface sensor of the sampling probe may be broken or there is no sample in the sample bottle.	1. No samples; 2. Misposition of the sample; 3. Malfunction of the liquid level sensor.	1. Check the position of the sample; 2. Add samples and; 3. Check wires and sensors. If the problem persists, please contact the Technical Support Department of Zybio Inc..

F00045	Before rotating the sampling probe to the specified reagent cup position, it was found that the reagent cup position code transmitted in the command was not a number between 1 to 60(for 100 series it should be 1 to 40), and could not rotate in the specified reagent cup position.	The issued command contains illegal cup position number	The command issued by the user must contain legal cup position number.
F00046	When the sampling probe moves to the vertical start position, it reaches the vertical start position too early.	The possible reasons are that the vertical start position sensor of the sampling probe is broken or there is external light interference.	Check whether there is light interference, if the problem persists, contact the manufacturer.
F00047	When the sampling syringe moves to the vertical start position, it reaches the vertical start position too early	The possible reasons are that the vertical start position sensor of the sampling syringe is broken or there is external light interference.	Check whether there is light interference first, if the problem persists, contact the manufacturer.
F00048	During the vertical reset of the sampling syringe, it cannot leave the vertical start position.	1. Strong light or strong electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. The stepper motor is broken; 4. The start position sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..

F00049	Before rotating the sampling probe to the specified sample cup position, it was found that the sample cup position transmitted in the command was not a number between 1 to 60(for 100 series it should be 1 to 40), cup and the sampling probe could not be rotated to the specified position.	The issued command contains illegal cup position number	The command issued by the user must contain legal cup position number.
F00050	A unit malfunctioned during periodic test	A unit malfunctioned during execution	Execute the periodic recovery command
F00051	Invalid unit command for the sampling probe	The command issued by the host computer is an illegal unit command for the sampling probe	Check whether the issued command are correct
F00052	This indicates that the horizontal encoding disk of the sampling probe is broken or lost step.	1. Strong light or strong electromagnetic interference; 2. Poor contact of the stepper motor wires leads to step loss; 3. The stepper motor is broken; 4. The horizontal encoding disk sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..

F00053	This indicates that the horizontal encoding disk of the sampling probe is broken or lost step.	1. Strong light or strong electromagnetic interference; 2. Poor contact of the stepper motor wires leads to step loss; 3. The stepper motor is broken; 4. The horizontal encoding disk sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00054	This indicates that the horizontal encoding disk of the sampling probe is broken or lost step.	1. Strong light or strong electromagnetic interference; 2. Poor contact of the stepper motor wires leads to step loss; 3. The stepper motor is broken; 4. The horizontal encoding disk sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00055	During online dilution, the liquid surface of the sample can be detected during the lowering process of the sampling probe, but the amount of sample is insufficient (the sampling probe will touch the bottom of the sample cup in the following 5 steps or less).	1. Insufficient sample ;	1. Add sample. If the problem persists, please contact the Technical Support Department of Zybio Inc..

F00056	During online dilution, the liquid surface of the sample cannot be detected during the lowering process of the sampling probe, indicating that the liquid surface sensor of the sampling probe is broken or there is no sample in the sample bottle.	1. Insufficient sample; 2. Misposition of the sample; 3. The liquid surface sensor is broken.	1. Check the position of the sample; 2. Add samples and; 3. Check wires and sensors. If the problem persists, please contact the Technical Support Department of Zybio Inc..
F00057	The start position sensor for of the sampling probe for horizontal rotation is broken or lost steps	1. Strong light or strong electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. The stepper motor is broken; 4. The start position sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00058	Insufficient sample in the reaction cup, and there is a risk of damaging the sampling probe when it moves downward?	1. The amount set by the software is greater than the maximum amount allowed in the reaction cup.	Please contact the Technical Support Department of Zybio Inc..

F00066	During the rotation of reagent or sample tray, the encoding disk malfunctioned or lost step.	1. Strong light or strong electromagnetic interference; 2. Poor contact of the step motor wires leads to step loss; 3. The step motor is broken; 4. The encoding disk is broken or poor wire connection 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00067	Indicates malfunction of the start position sensor or lost step	1. Strong light or strong electromagnetic interference; 2. Poor connection of the step motor wires leads to step loss; 3. The step motor is broken; 4. The start position sensor is broken or poor wire connection. 5, motor driver board problem; 6, sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00068	Indicates malfunction of the encoding disk of the reagent tray or lost step	1. Strong light or strong electromagnetic interference; 2. Poor contact of the step motor wires leads to step loss; 3. The step motor is broken; 4. The encoding disk is broken or poor wire connection 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..

F00069	Indicates malfunction of the encoding disk of the reagent tray or lost step	1. Strong light or strong electromagnetic interference; 2. Poor contact of the step motor wires leads to step loss; 3. The step motor is broken; 4. The encoding disk is broken or poor wire connection 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00070	The stirring rod did not stop moving until the maximum number of steps was completed, indicating malfunction of the start position sensor of the stirring rod or lost step	1. Strong light or strong electromagnetic interference; 2. Poor connection of the step motor wires leads to step loss; 3. The step motor is broken; 4. The start position sensor is broken or poor wire connection. 5, motor driver board problem; 6, sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00071	The stirring rod did not leave the start position until the specified number of steps in the vertically downward direction is completed	1. Strong light or strong electromagnetic interference; 2. Poor connection of the step motor wires leads to step loss; 3. The step motor is broken; 4. The start position sensor is broken or poor wire connection. 5, motor driver board problem; 6, sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..

F00072	The stirring rod is not in the start position, and cannot correctly be lowered to the specified position, and lowering by force may damage the stirring rod, so the operation cannot be carried out.	1. The stirring rod is not in the vertical start position; 2. The stirring rod vertical start position sensor malfunction or wire defect;	Check the wire or plug and execute the vertical reset command to the stirring rod. If the problem persists, please contact the Technical Support Department of Zybio Inc..
F00073	The stirring motor cannot be turned on correctly.	1. Strong electromagnetic interference; 2. Poor wire connection; 3. The driver board is broken.	After eliminating the strong electromagnetic interference , check the wires and boards and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00074	The stirring motor cannot be correctly turned off.	1. Strong electromagnetic interference; 2. Poor wire connection; 3. The driver board is broken.	After eliminating the strong electromagnetic interference , check the wires and boards and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00079	During the horizontal rotation of the stirring rod to the start position, the start position was not found before the maximum number of searching steps was completed.	1. Strong light or strong electromagnetic interference; 2. Poor connection of the step motor wires leads to step loss; 3. The step motor is broken; 4. The start position sensor is broken or poor wire connection. 5, motor driver board problem; 6, sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..

F00080	The stirring rod was already in the start position. To rotate horizontally to the start position, it must first leave the start position and then rotate to the start position again. After the specified number of steps, the stirring rod never left the start position . The start position sensor may be broken or lost step.	1. Strong light or strong electromagnetic interference; 2. Poor connection of the step motor wires leads to step loss; 3. The step motor is broken; 4. The start position sensor is broken or poor wire connection. 5, motor driver board problem; 6, sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00081	During the horizontal rotation of the stirring rod to the cleaning position, no cleaning position was found before the maximum number of searching steps was completed. the encoding disk may be broken, or lost step, or encoding disk signal error happened.?	1. Strong light or strong electromagnetic interference; 2. Poor contact of the stepper motor wires leads to step loss; 3. The stepper motor is broken; 4. The horizontal encoding disk sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00082	During the horizontal rotation of the stirring rod to the cleaning position, the cleaning position was not found before the maximum number of searching steps was completed in the deceleration system. The encoding disk may be broken, or lost step?	1. Strong light or strong electromagnetic interference; 2. Poor contact of the stepper motor wires leads to step loss; 3. The stepper motor is broken; 4. The horizontal encoding disk sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..

F00083	During the horizontal rotation of the stirring rod to the position of the reaction tray, the reaction tray was not found before the maximum number of searching steps was completed, and the encoding disk may be broken or lost step.	1. Strong light or strong electromagnetic interference; 2. Poor contact of the stepper motor wires leads to step loss; 3. The stepper motor is broken; 4. The horizontal encoding disk sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00084	During the horizontal rotation of the stirring rod to the position of the reaction tray, the reaction tray was not found before the maximum number of searching steps was completed during deceleration. And the encoding disk may be broken, or lost step.	1. Strong light or strong electromagnetic interference; 2. Poor contact of the stepper motor wires leads to step loss; 3. The stepper motor is broken; 4. The horizontal encoding disk sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00085	The horizontal position of the stirring rod is unknown before the rotation.	It may be that the horizontal rotation reset for the stirring rod was not done before the rotation or an error occurred during the rotation.	To complete the operation correctly, please complete the horizontal rotation reset of the stirring rod first.
F00086	When the stirring rod moves to the vertical start position, it reaches the vertical start position too early	.It maybe that the vertical start position sensor of the stirring rod is broken or there is external light interference.	Check whether there is light interference, if the problem persists, contact the manufacturer.

F00087	The stirring rod is not in the vertical start position and cannot rotate.	1. The stirring rod is not in the vertical start position; 2. Malfunction of the vertical start position sensor of the stirring rod or wire malfunction	Do the vertical reset command of the stirring rod first, check the wires and connectors, and then execute the rotation command. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00088	Checksum error in the command frame received by the stirring rod unit	1. Strong electromagnetic interference; 2. Loose serial line; 3. Poor serial line connection.	1. Check and fix the serial line after shutdown the machine; 2. After eliminating strong electromagnetic interference . Restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00089	The cleaning head is not in the vertical start position and the reaction tray cannot be rotated	1. The cleaning head is not in the vertical start position; 2. Cleaning head vertical start position sensor malfunction or wire malfunction	Execute the vertical reset command of the cleaning head first, check the wires and connectors, and then execute the corresponding command. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00090	Error in validating the unit command received by the reaction disk Checksum filed of the command frame is different from the calculated checksum, and the returned command has responded to the incorrect frame. Or invalid command	1. Strong electromagnetic interference; 2. Loose serial line; 3. Poor serial line connection.	1. Check and fix the serial line after shutdown the machine; 2. After eliminating strong electromagnetic interference . Restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..

F00091	No signal from the encoding disk is detected before the maximum number of steps to a cup position(the cup before the one that has been stopped) in the reaction tray was completed.	1. Strong light or strong electromagnetic interference; 2. Poor contact of the step motor wires leads to step loss; 3. The step motor is broken; 4. The encoding disk is broken or poor wire connection 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00092	The start position of the reaction tray is not found after the reaction tray is rotated one round during the process when it rotates to the specified cup position by reaction try start position rotate, indicating the start position sensor of the reaction tray malfunctioned or lost step.?	1. Strong light or strong electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. The stepper motor is broken; 4. The start position sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00093	While rotating to the static sampling position, no signal was detected by the encoding disk before the maximum number of steps to the position of the stop cup on the reaction tray was completed. Indicates the encoding disk of the reaction tray malfunctioned or lost step.?	1. Strong light or strong electromagnetic interference; 2. Poor contact of the step motor wires leads to step loss; 3. The step motor is broken; 4. The encoding disk is broken or poor wire connection 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..

F00094	The stopping position of the stopped cup on the reaction tray cannot be found before the rotation, and the rotation cannot be completed.	The possible reason is that the rotation reset operation of the reaction tray has not been performed before, or the operation of directly rotating the reaction tray motor has been performed after rotation reset of the reaction tray, which makes it impossible to know the current cup position stopped on the reaction tray.	First, perform the rotation reset operation of the reaction disk, then perform other operations. If the problem persists, please contact the Technical Support Department of Zybio Inc..
F00102	.Malfunction of the start position sensor or lost step	1. Strong light or strong electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. The stepper motor is broken; 4. The start position sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating strong light or strong electromagnetic interference , check whether the sensor plug is loose, or whether the sensor wire is broken, and restart the machine. If the error still recurs, please contact the Technical Support Department of Zybio Inc..
F00103	Malfunction of the start position sensor	1. Strong light or strong electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. The stepper motor is broken; 4. The start position sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating strong light or strong electromagnetic interference , check whether the sensor plug is loose, or whether the sensor wire is broken, and restart the machine. If the error still recurs, please contact the Technical Support Department of Zybio Inc..

F00104	The cleaning head did not leave the start position until the specified lowering steps is completed	1. Strong light or strong electromagnetic interference; 2. Poor wire connection of stepper motor leads to step loss; 3. The stepper motor is broken; 4. The start position sensor is broken or poor wire connection. 5. Motor driver board problem; 6. Sensor wire or plug problems.	After eliminating the strong light or strong electromagnetic interference, check the sensor plug and wire, and restart the machine. If the error persists, please contact the Technical Support Department of Zybio Inc..
F00105	The cleaning head is not in the start position before moving to the cleaning position	Vertical reset of cleaning head is not performed	Perform the vertical reset of the cleaning head before other operations. If the problem persists, please contact the Technical Support Department of Zybio Inc..
F00106	The cleaning head reaches the start position before completing the 185 steps of moving upwards, and cannot continue	The cleaning head was not in the correct position to perform the operation, or the start position sensor of the cleaning head malfunctioned	First, reset the cleaning head vertically, then lower the cleaning head to the cleaning position, and then perform the operation. If the error still recurs, please contact the Technical Support Department of Zybio Inc..
F00107	The waiting time plus the running time of the peristaltic pump exceeds the allowable range.	Illegal waiting time setting for the peristaltic pump	Reset the waiting time of the peristaltic pump

F00108	When the cleaning head is vertically reset, it goes to the vertical start position too early	The problem may be that the start position sensor of the cleaning head malfunctioned or the signal of the start position sensor of the cleaning head is interfered by external light.	Check the sensor, plug and wires of the cleaning head, and then perform this operation. If the problem persists, please contact the Technical Support Department of Zybio Inc..
F00111	The current temperature of the reaction tray exceeds the specified temperature value by 10 degrees.	1. Strong electromagnetic interference; 2. The temperature sensor wire is loose or falls off; 3. Abnormal temperature control.	Remove strong electromagnetic interference and check the wires. If the problem persists, please contact the Technical Support Department of Zybio Inc..
F00112	The reaction tray is not in the normal temperature range (target temperature ±2) for the first time after the time for establishing the specified temperature has passed (about 14 minutes).	1. Strong electromagnetic interference; 2. The temperature sensor wire is loose or falls off; 3. Abnormal temperature control.	Remove strong electromagnetic interference and check the wires. If the problem persists, please contact the Technical Support Department of Zybio Inc..
F00113	When the temperature is normally controlled, the current temperature value deviates from the normal range (target temperature ±2) after the time for establishing the specified temperature has passed (about 14 minutes) .	1. Strong electromagnetic interference; 2. The temperature sensor wire is loose or falls off; 3. Abnormal temperature control.	Remove strong electromagnetic interference and check the wires. If the problem persists, please contact the Technical Support Department of Zybio Inc..

F00114	When the temperature is normally controlled, the temperature exceeds the specified temperature by at least 10 degrees during 10 consecutive temperature detection.	1. Strong electromagnetic interference; 2. The temperature sensor wire is loose or falls off; 3. Abnormal temperature control.	Remove strong electromagnetic interference and check the wires. If the problem persists, please contact the Technical Support Department of Zybio Inc..
F00115	The system is currently in a state where parameters cannot be changed.	The analyzer is running	Stop the analyzer and put it in standby.
F00116	When setting the target temperature,it's value is higher than 95 degrees.	The target temperature value has been set incorrectly.	Reset the target temperature value.
F00119	The temperature maintains at least 10 degrees higher than the target temperature, and the temperature control automatically shut down. The AD value of the static temperature of 0 may be FF, resulting in a negative value in the result calculation, which may be due to the malfunction of the 0 degree reference resistor.	1. The AD value of static temperature 0 may be FF, resulting in a negative value in the result calculation thus resulting in incorrect temperature value, which may be caused by the failure of the 0 degree reference resistor; 2. Temperature AD jumps caused by grid interference.	Contact the Technical Support Department of Zybio Inc. in a timely manner.
F00127	The command received by the master control unit is illegal.	The command received by the master control unit is illegal.	Check whether the command is correct.

8. Transportation and Storage

8.1. Shipping instructions

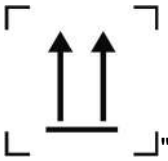
The analyzer shall be transported in the packaged state according to the requirements of the order contract, and shall be protected from severe impact, vibration, rain and snow splash and exposure during transportation.

8.2. Storage condition

The packaged analyzer shall be stored in a clean room with ambient temperature of -20℃ ~ +55℃, relative humidity of 10% ~ 90%, atmospheric pressure of 50.0 kPa ~ 106.0 kPa, no corrosive gas and good ventilation.

8.3. Package symbol explanation

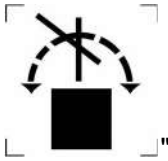
"Fragile ": Handle the transport package with care.



"Upward": The transport package shall be vertically upward during transportation.

"Keep Dry ": This transport package cannot be wetted by rain.

"No Stacking": This transport package can only be placed in two layers.



"No Rolling": This transport package cannot be rolled.

"Storage Temperature".

Note: The diagram is for reference only, and the picture of the outer packing box of the product shall prevail.

Appendix A

A.1. Product classification

According to the Classification Catalogue of Medical Devices (2017 Edition), the Chemistry Analyzer belongs to the chemistry analysis equipment in the subdirectory of clinical examination equipment. The management category is class II and the classification code is 22-02.

A.2. Commonly used terminology

A.2.1. AD value

The photocurrent generated by the light reaching the detector flows through the fixed resistor and is amplified and converted into an optical voltage (analog signal), and the voltage is converted into a value with a corresponding size (the size is related to the number of AD positions selected) through AD conversion (digital-to-analog conversion), and the value is the AD value.

A.2.2 Dark current

The value output by the circuit when the light source is not turned on (i.e. when there is no signal light) is expressed in AD value. Dark current is equivalent to circuit background and must be deducted when calculating absorbance.

A.2.3 Water blank

Absorbance value when the cuvette is filled with purified water. Because absorbance values are relative, i.e. based on a certain absorbance value, the absorbance of water blank is defined as 0 in EXC2X series Chemistry Analyzer, i.e. the absorbance value of reaction water blank should be subtracted from any other absorbance.

A.2.4 Photometric points

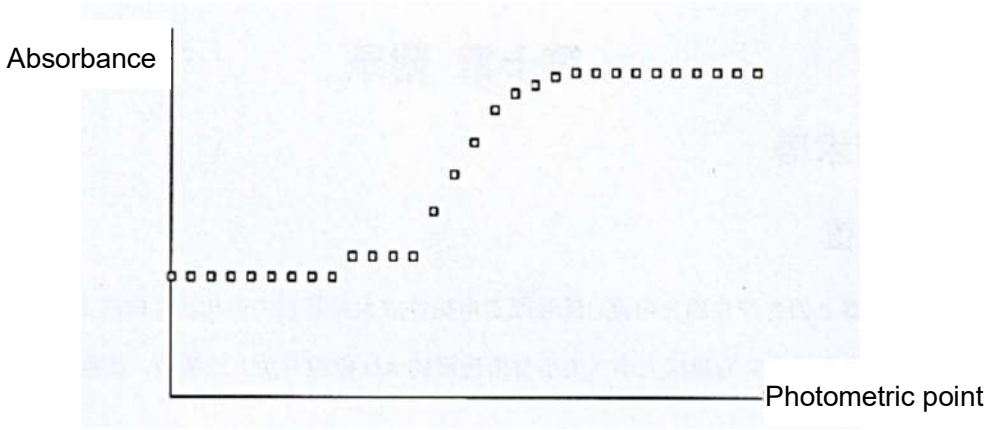
The specific time for photoelectric color comparison is generally expressed in specific numerical values, and there is a strict and fixed time relationship between each photometric point.

A.2.5 Absorbance

The negative common logarithm of the transmitted light intensity divided by the incident light intensity. In EXC2X series Chemistry Analyzer, the incident light intensity is AD value when the cuvette is filled with deionized water, and the absorbance value displayed is calculated absorbance value ×10000.

A.2.6 Reaction curve

A series of points consisting of photometric points as horizontal coordinate and absorbance as vertical coordinate. The typical reaction curve of EXC2X series Chemistry Analyzer is as follow:



A.2.7 Reaction range

Changes or rates of absorbance before and after the reaction or during the reaction.

A.2.8 Calibration

Also known as calibration.One or more samples with known concentration (or activity) (also known as calibrators) are measured for their reactivity. According to the calibration method (linear or non-linear) selected by the user, an optimal curve is used to fit the data set (concentration, reactivity) and the mathematical expression of this curve is calculated. Using this curve, the reactivity of the sample with unknown concentration (or activity) can be measured, that is, the concentration (or activity) of the sample can be calculated.

A.2.9 Calibration curve

For a series of points consisting of concentration (or activity) as horizontal coordinate and reactivity as vertical ordinate, the curve is fitted with the best mathematical equation.

A.2.10 Calibration parameters

Specify other items in the standard curve expression except concentration and reactivity.

A.3. Consumables list

Serial number	Name of consumables	Specifications/units
1	Detergent	5 L/ barrel
2	Detergent	35 mL/ bottle
3	Detergent	20 mL/ bottle

A.4. Packing list

Serial number	Name	Quantity
1	Host	1
2	Manual	1
3	Warranty card	1
4	Packing list	1
5	Easy operation guide	1
6	User acceptance form	1
7	Waste liquid drain assembly 1	1
8	Waste liquid drain assembly 2	1
9	Purified water inlet pipe assembly	1
10	Cleaning solution inlet pipe assembly	1
11	Pure water float sensor assembly	1
12	Cleaning solution float sensor assembly	1
13	Waste liquid container level sensor assembly	1
14	Power cord	1

A.5. Basic parameters

Model	EXC200	EXC220
Instrument type	Discrete	
Light source	Halogen lamp 12 V, 20 W	
Analytical method	End point method, two-point method, kinetic method, supporting single/dual reagent, single/dual wavelength	
Reaction tray	63 cuvettes with optical diameter of 5mm	
Reagent capability	40	
Sample capability	40	
Sample volume	(2 ~ 50) μL, step by 0.5 μL	
Reagent volume	(10 ~ 400) μL, step by 0.5 μL	
Wavelength	(340～800) nm	
Light splitting method	Post-splitting 12 wavelength	
Power	Not more than 500VA	
Minimum reaction volume (μL)	90	100
Water consumption	≤5 L/H	
Test speed	Constant speed 160 T/H	
Reagent-sample probe	It has the functions of liquid level detection, volume tracking and vertical collision avoidance	
Dimensions (width × depth × height)	710 mm×705 mm×635 mm	

Printing function		Supports HP, EPSON and other printers	
Software component	Name	Software of Chemistry Analyzer	
	Model	EXC200	EXC220
	Release Version	V5	

A.6. Performance parameters

Parameter name	Parameter content			
Stray light	Absorbance shall not be less than 4.5 A			
Temperature accuracy and fluctuation	The temperature value is within ±0.2℃ of the set value, and the fluctuation degree is less than ±0.1℃			
Carryover	≤0.005%			
Linearity range of absorbance	The maximum absorbance of relative bias within ±5% should not be less than 4.0			
Absorbance accuracy	Absorbance value A		Allowable error △A	
	0.5		±0.02	
	1.0		±0.04	
Accuracy and repeatability of sample addition	Category	Adding volume (μL)	Accuracy error	Coefficient variation
	Sample	2	±4%	≤2%
		5	±4%	≤2%
		50	±4%	≤1%
	Reagent	10	±3%	≤2%
		400	±3%	≤1%
Clinical intra-item precision	Item name	Concentration range		Coefficient variation
	ALT (alanine aminotransferase)	30 U/L～50 U/L		≤4%
	UREA (urea)	7.0 mmol/L~11.0 mmol/L		≤2.5%
	TP (total protein)	50.0 g/L～70.0 g/L		≤2%

A.7. Input and output equipment

Warning

External equipment such as printers must pass CCC (S&E) mandatory authentication. Using unqualified external equipment may cause abnormal system operation and personal injury.

- External barcode scanner (Optional)
- Printer (Optional)
- Power supply

Voltage	100-240 V~，50/60 Hz
Input power	≤500 VA

A.8. Electromagnetic compatibility

- The radio frequency emission of this equipment is very low and the possibility of interference to nearby electronic equipment is very small.
- Portable and mobile radio frequency communication equipment may affect this equipment, and other equipment used in the vicinity of this equipment at the same time shall meet the relevant requirements of electromagnetic compatibility.
- It is suitable for use in non-domestic and all facilities that are not directly connected to the public low-voltage power supply network of domestic houses.
- The power socket shall have reliable protective grounding measures and shall use the matched power cord, components and accessories that come with it.
- The floor shall be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic materials, the relative humidity shall be at least 30%.
- Network power supply shall have the quality used in typical commercial or hospital environment.
- If the user needs to keep the equipment running continuously during power interruption, it is recommended that the user use uninterruptible power supply.
- The power frequency magnetic field in the expected installation site shall be measured to ensure it is low enough. This equipment should be far away from power frequency magnetic field source. Under special circumstances, magnetic shielding materials should be installed to ensure the normal operation of the equipment.
- This IVD equipment meets the emission and anti-interference requirements specified in GB/T 18268.

Warning

In addition to accessories and cables sold by the manufacturer of this equipment as spare parts for internal components, the use of accessories and cables other than those specified may lead to an increase in equipment emission or a decrease in anti-interference.

Warning

This equipment should not be used close to or stacked on top of other equipment. If it has to be used close to or stacked on top of other equipment, it should be observed and verified that it can operate normally under its own configuration.

Warning

Do not use this equipment near strong radiation sources (e.g. Unshielded RF sources), otherwise it may interfere with the normal operation of the equipment.

Warning

This equipment is designed and inspected as per the Glass 1 Category A in GB4824. In the family environment, this equipment may cause radio interference, which requires protective measures.

Warning

It is recommended that the electromagnetic environment be evaluated before the equipment is used, and the user is responsible for ensuring the electromagnetic compatibility environment of the equipment to enable normal operation.

A.9. Contamination levels

Rated pollution level: level 2

A.10. Working environment

Working environment	Ambient temperature: 10℃ ~ 30℃ Environmental relative humidity: 30% ~ 85% Atmospheric pressure: 70.0 kPa ~ 106.0 kPa Altitude: Below 3000m

Attention

Please be sure to store and use the analyzer under the specified environmental conditions.

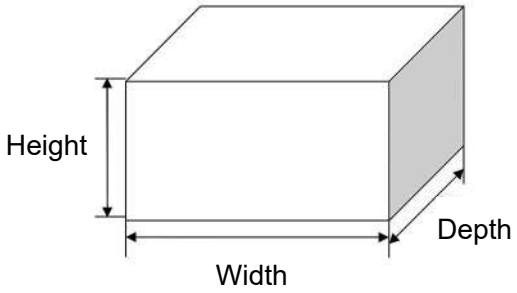
A.11. Storage environment

Storage environment	Ambient temperature: -20℃ ~ 55℃ Relative humidity: 10% ~ 90% Atmospheric pressure: 50 kPa ~106 kPa

A.12. Transport environment

Transportation environment	Ambient temperature: -20℃ ~ 55℃ Relative humidity: 10% ~ 90% Atmospheric pressure: 50 kPa ~106 kPa

A.13. Overall dimensions and weight



Analyzer	Overall dimensions and weight
Dimensions (Width × Depth × Height)	710 mm×705 mm×635 mm
Weight (Gross Weight)	80 kg

A.14. Communication interface

Test port	RS-232 communication serial port (only for engineers for commissioning)
Computer and network interface	Net port

A.15. Training

In order to use this product correctly and give full play to its performance, Zybio will send its internal after sales service engineers or agents designated by Zybio to train users.

A.16. Contraindications

None

A.17. Names and contents of toxic and harmful substances or elements

Part name	Toxic and harmful substances or elements					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent chromium (Cr(V)	Polybrominated biphenyl (PBB)	Polybrominated diphenyl ether (PBDE)
Reaction tray assembly	○	○	○	○	○	○
Reagent-sample tray assembly	○	○	○	○	○	○
Reagent-sample probe+stirring rod assembly	○	○	○	○	○	○
Syringe assembly	○	○	○	○	○	○
Rack	○	○	○	×	○	○
Metal casing	○	○	○	×	○	○
Plastic casing	○	○	○	○	○	○
Pumps, valves	○	○	○	○	○	○
Liquid pipeline and joint	○	○	○	○	○	○
Liquid bottle	○	○	○	○	○	○
Heater	○	○	○	○	○	○
Refrigeration module	○	○	○	○	○	○
Fan	○	○	○	○	○	○
Circuit board	○	○	○	○	○	○
Switch	○	○	○	○	○	○
Motor	○	○	○	○	○	○
Wire rod	○	○	○	○	○	○
Optical system	○	○	○	○	×	×
Packaging materials	○	○	○	○	○	○

○: Indicates that the content of the toxic and harmful substances in all homogeneous materials of the component is below the limit specified in SJ/T 11363-2006.

×: Indicates that the content of the toxic and harmful substances in at least one homogeneous material of the component exceeds the limit requirements specified in SJ/T 11363-2006.

Hexavalent chromium is used in the surface coating of metal stamping parts during processing.

zybio

Chemistry Analyzer EXC 200

A cost-effective choice dedicated for small healthcare institutions

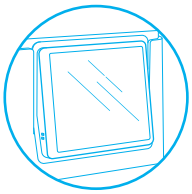
Chemistry

www.zybio.com

Chemistry Analyzer EXC 200

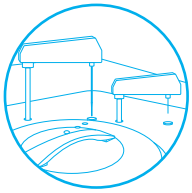
(An automated desktop chemistry analyzer dedicated for small healthcare institution)
EXC 200 is an optimal compact desktop clinical chemistry solution which offers a maximum throughput of 240T/H. With a comprehensive test menu and easy integration of STAT samples, EXC 200 is an ideal clinical solution for small healthcare institution. What's more, the HD screen guarantees your easy and intuitive operation. High quality components from top manufacturer as well as low cross contamination rate ensure the stability of the system, meanwhile low water consumption offers cost-effective value.

Function



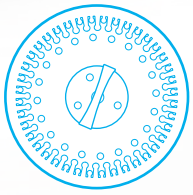
User Friendly

- Integrated design combines operation system with the analyzer
- Colorful touch screen and intuitive user-friendly navigation menu
- Waste with high concentration and low concentration are discharged separately, more environmentally friendly
- Support various sample tube types
- Various sample types are available
- Matched with around 100 testing items



Economic Usage

- Lower reaction volume: 90 μL
- Less water consumption: ≤ 5 L/H
- Precise reagent absorption with step by 0.5 μL
- Reusable plastic cuvettes



Excellent Performance

- 24-hour non-stop cooling to keep reagent in good condition
- High pressure wash probe both inside and outside to keep low carry-over : ≤0.005%
- Probe designed with liquid detection, auto-depth adjustment and collision protection
- Key parts imported from top suppliers
- Advanced absorbance reading with the linearity is 0-4.0 Abs
- Post spectrophotometry optical system to make a more reliable result

Assay Menu

Zybio offers over 100 kinds of chemistry parameters, covering hepatic, renal, cardiac&cardiovascular, diabetes, coagulation, inflammation, pancreatitis, etc. Besides reagents for our own chemistry analyzer, we also provide customized reagents matching other brands. Flexible package can be customized according to client requirements.

- Ready to use
- Stable liquid
- Comprehensive menu
- Bulk package available upon request

Hepatic Panel
ALB, TP, DBIL, TBIL, AST, ALT, ALP, GGT, TBA, ADA, ChE, 5'-NT
Renal Panel
UREA, UA, CREA, Cys C, α1-MG, UTRF, β2-MG, NGAL, mALB
Lipids Panel
CHOL, Apo A1, Apo B, TG, LDL-C, HDL-C, Lp(a)
Cardiac & Cardiovascular Panel
hs-CRP, HCY, Lp-PLA2, LDH, CK, CK-MB, α-HBDH, MYO, H-FABP
Diabetes Panel
GLU, HbA1c, GA, GSP, LAC
Coagulation Panel
D-D
Specific Proteins Panel
IgG, IgA, IgM, C3, C4, IgE, Fer, CSF/UTP, TRF
Rheumatic & Rheumatoid Panel
ASO, RF
Electrolytes Panel
Fe, Zn, CO2 , Ca, P, Mg
Inflammation Panel
CRP
Pancreatitis Panel
α-AMY, LPS

Specification

General Feature	
Throughput	Up to 240 T/H
Methodology	End point, Fixed-time (two point), Kinetic
Principle	Absorbance photometry, Turbidimetry
Programming	Open/close system(optional)
Optical System	
Light source	Halogen-tungsten lamp
Wavelength	(340-800) nm, in total 12 wavelengths
Absorption range	0-4.0 Abs
Resolution	0.0001 Abs
Sample System	
Sample capacity	40 positions
Sample volume	2-50 μL, step by 0.5 μL
Sample probe	Liquid level detection, auto-depth adjustment, and collision protection
Sample type	Serum, plasma, urine, and CSF
Reagent System	
Reagent capacity	40 positions
Reagent volume	10-400 μL, step by 0.5 μL
Reaction System	
Cuvette	63 cuvettes with 5mm optical path diameter
Reaction volume	90-450 μL
Reaction temperature	37± 0.2 °C
Cuvette Washing	
6-step washing station	
Control	
Control type	Real-time, within-day, between-day control and etc
Control rule	Westgard
Calibration	
Calibration mode	One-point, two-point, multi-point, Logistic-Log4/5P, Exponential-5P, Polynomial-5P and Spline
Operation System	
Operation system	Windows 10, support LIS
Host interface	RS232, TCP/IP
Others	
Power supply	100-240 V, 50/60 Hz
Cooling way	Constant air cooling
Water consumption	≤ 5 L/H
Dimension(mm)	710(W)×705(D) ×635(H)
Weight	90 kg

Zybio Inc.
Address: No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District,
400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA
Tel: +86-23 6865 5509 Fax: +86-23 6869 9779
Email: info@zybio.com Website: www.zybio.com

EN-C-SH-EXC200-20250226H

Chemistry

zybio

Qualified

TRAINING CERTIFICATE

CERTIFICATION

To

Vitalie Goreacii

From

Sanmedico

Accomplish the training on

Fully automatic desktop biochemical analyzer EXC200 & Fully-automatic Urinalysis U3600

During

January 19th, 2024.

Training contents:

- **Basic knowledge**
- **Basic principle**
- **Reagent kits**
- **Operation**
- **Installation**
- **Maintenance**
- **Mechanical structure**

The trainee is authorized to do installation, maintenance and repair on above machine.

Trainer: Perry Jiang

Date: 2024.01.20

Cert. Code: 20240120PJP01

Validity date (2 Years)

Zybio Inc.

CE IVD

zybio

Instructions for Use of Clinical Chemistry Multi-Analyte Calibrator

Package Specification

REF	Specification
01.09.0D.00.CA.02	1 Level × 5 mL × 10
012212047	1 Level × 5 mL × 6
01.09.0D.00.CA.04	1 Level × 5 mL × 1

Intended Use

This product is matched for the calibration of 31 biochemical items of Zybio Inc. (albumin, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, calcium, cholinesterase, total cholesterol, creatine kinase, carbon dioxide, creatinine, direct bilirubin, ferrum, γ-glutamyl transferase, glutamate dehydrogenase, glucose, lactate, leucine amino peptidase, lactate dehydrogenase, lipase, magnesium, inorganic phosphorus, total bile acid, total bilirubin, triglyceride, total protein, uric acid, urea, zinc, α-amylase, α-hydroxybutyrate dehydrogenase and β-hydroxybutyrate).

Principle

A detection system is calibrated through the measurement on the calibrators with known concentration, so as to establish the metrological traceability of the measurement results for our system.

Reagents Components and Concentration

Human serum matrix.

It contains 31 biochemical items: Albumin (ALB), alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), calcium (Ca), cholinesterase (ChE), total cholesterol (CHOL), creatine kinase (CK), carbon dioxide (CO_2), creatinine (CREA), direct bilirubin (DBIL), ferrum/iron (Fe), γ-glutamyl transferase (GGT), glutamate dehydrogenase (GLDH), glucose (GLU), lactate (LAC), leucine amino peptidase (LAP), lactate dehydrogenase (LDH), lipase (LPS), magnesium (Mg), inorganic phosphorus (P), total bile acid (TBA), total bilirubin (TBIL), triglyceride (TG), total protein (TP), uric acid (UA), urea (UREA), zinc (Zn), α-amylase (α-AMY), α-hydroxybutyrate dehydrogenase (α-HBDH) and β-hydroxybutyrate (β-HB).

Note: The traceability information is shown in the attached form, and the labeled value is shown in the target value list.

Storage and Validity

1. The product should be stored at 2 - 8 °C and kept away from direct light. The unopened product is valid for 24 months.
2. The re-dissolved components are stable for 2 days at 2 - 8 °C and 28 days at (-15) - (- 25) °C. (Freeze/thaw only once).
3. Alkaline phosphatase levels will increase during the stabilization time. It is recommended to stabilize at 15 - 25 °C for 1 hour after re-dissolution before detection. It is necessary to timely screw the bottle cap for preservation when CO_2 is not used after re-dissolution. And also it is necessary to kept away from direct light when direct bilirubin and total bilirubin are re-dissolved and subsequent preservation.
4. The production date and expiration date are available on package label.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Warnings and Precautions

1. For calibration during in vitro diagnostic clinical chemistry analysis. Do not be used for other purposes.
2. If the results are inconsistent with the specified values, the experiment should be stopped, and retested after the possible causes were analyzed.
3. This product can only be frozen and thawed once after re-constitution, avoiding repeatedly frozen and thawed.
4. Please use this product according to the specified method. The use of non-specified method and purpose cannot ensure the accuracy of the results.
5. If the product is contaminated with bacteria, the stability of many components will be reduced. If there are obvious signs that the product has been contaminated with microorganism, do not use it.
6. It is necessary to follow the routine precautions for the laboratory operation when using this product.
7. If the product accidentally enters the eyes, mouth or sticks to the skin, immediately wash thoroughly with water and go to the hospital if necessary.
8. The opened product shall be stored sealed according to the specified method. Do not use after the expiration date.
9. This product shall be stored according to the specified method and kept away from direct light.
10. Warning: This product contains human-derived or animal-derived ingredients. At present, there is no way to completely ensure that it is free of infectious substances, and there is also the possibility of contamination during use; this product and samples should be regarded as potential sources of infection, operators should take protective measures and follow the laboratory safe operation regulations; all wastes should be disposed of in accordance with local regulatory requirements.

Test Process

1. Take out the calibrator, carefully open the cap to avoid loss of contents, and accurately reconstitute with purified water marked on the label.
2. Carefully tighten the cap and place it at room temperature, out of direct light for 30 minutes. During reconstitution, gently rotate the vial several times to ensure complete dissolution of the contents. Do not shake the vial vigorously to avoid foam.
3. After the completion of reconstitution, please immediately operate according to the instructions for use (ALP should be stable for 1 hour before detection), add the calibrator according to the instructions for use of reagent, and calibrate in the linear calibration mode.
4. If it cannot be used immediately or after use, please timely put it back to the specified storage conditions.

Performance Characteristics

1. Appearance: yellowish lyophilized powder, and yellowish or yellow liquid after re-dissolution.
2. Moisture content: ≤ 5%.
3. Trueness: the trueness of the measurement value shall meet | En | ≤ 1.
4. Homogeneity:

4.1 within-vial homogeneity: within-vial $CV \leq 10\%$.

4.2 Between-vial homogeneity: between-vial $CV \leq 15\%$.

Materials Required (but not provided)

Chemistry analyzer, reagents, control, general lab equipment and consumable.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community
	Biological Risks		

Zybio Inc.
Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.
Web: www.zybio.com
E-mail: info@zybio.com
Tel: +86 (0)23 6895 9999
Fax: +86 (0)23 6869 9779

EC REP
Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Current Version: 02 Date of Issue: May, 2022

CE IVD

zybio

Instructions Attached Form

Serial Number	Substance Detected	Project Name	Traceability Information
1	ALB	Albumin (ALB) Kit (Bromocresol Green Method)	ERM-DA470k/IFCC
2	ALP	Alkaline Phosphatase (ALP) Kit (Enzymatic Method)	IFCC reference measurement procedure (37℃) for ALP
3	ALT	Alanine Aminotransferase (ALT) Kit (Enzymatic Method)	IFCC reference measurement procedure (37℃) for ALT
4	AST	Aspartate Aminotransferase (AST) Kit (Enzymatic Method)	IFCC reference measurement procedure (37℃) for AST
5	Ca	Calcium (Ca) Kit (Arsenazo III Method)	SRM 909c NIST
6	CHE	Choline Esterase (ChE) Kit (Butyryl Thiocholine Method)	manufacturer's working calibrator
7	CHOL	Total Cholesterol (CHOL) Kit (Enzymatic Method)	SRM 909c NIST
8	CHOL	Total Cholesterol (CHOL) Kit (Single) (Enzymatic Method)	SRM 909c NIST
9	CK	Creatine Kinase (CK) Kit (Rate Method)	IFCC reference measurement procedure (37℃) for CK
10	CO_2	Carbon Dioxide (CO2) Kit (Enzymatic Method)	manufacturer's working calibrator
11	CREA	Creatinine (CREA) Kit (Enzymatic Method)	SRM 909c NIST
12	DBIL	Direct Bilirubin (DBIL) Kit (Vanadate Oxidation Method)	manufacturer's working calibrator
13	Fe	Ferrum (Fe) Kit (5-Br-PADAP Chromogenic Method)	SRM 909c NIST
14	Fe	Iron (Fe) Kit (Ferrozine Method)	SRM 909c NIST
15	GGT	Gamma-Glutamyl Transferase (GGT) Kit (Enzymatic Method)	IFCC reference measurement procedure (37℃) for GGT
16	GLDH	Glutamate Dehydrogenase (GLDH) Kit (Rate Method)	manufacturer's working calibrator
17	GLU	Glucose (GLU) Kit (Hexokinase Method)	GBW(E)091043
18	LAC	Lactate (LAC) Kit (Lactate Oxidase Method)	manufacturer's working calibrator
19	LAP	Leucine Amino Peptidase (LAP) Kit (Rate Method)	manufacturer's working calibrator
20	LDH	Lactate Dehydrogenase (LDH) Kit (Rate Method)	IFCC reference measurement procedure (37℃) for LDH
21	LPS	Lipase (LPS) Kit (Colorimetric Method)	manufacturer's working calibrator
22	Mg	Magnesium (Mg) Kit (Xylidyl Blue Method)	SRM 909c NIST
23	P	Inorganic Phosphorus (P) Kit (Direct UV Method)	manufacturer's working calibrator
24	TBA	Total Bile Acids (TBA) Kit (Enzymatic Cycling Method)	manufacturer's working calibrator
25	TBIL	Total Bilirubin (TBIL) Kit (Vanadate Oxidation Method)	manufacturer's working calibrator
26	TG	Triglyceride (TG) Kit (Enzymatic Method)	SRM 909c NIST
27	TG	Triglyceride (TG) Kit (Single) (Enzymatic Method)	SRM 909c NIST
28	TP	Total Protein (TP) Kit (Biuret Method)	SRM 909c NIST
29	UA	Uric Acid (UA) Kit (Uricase Method)	SRM 909c NIST
30	UREA	Urea (UREA) Kit (Urease-GLDH Method)	SRM 909c NIST
31	Zn	Zinc (Zn) Kit (Colorimetric Method)	manufacturer's working calibrator
32	α-AMY	α-Amylase (α-AMY) Kit (E-pNP-G7 Method)	IFCC reference measurement procedure (37℃) for AMY
33	α-HBDH	α-Hydroxybutyric Acid Dehydrogenase (α-HBDH) Kit (Rate Method)	manufacturer's working calibrator
34	β-HB	β-Hydroxybutyrate (β-HB) Kit (Enzymatic Method)	manufacturer's working calibrator

Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.
Tel: +86 (0)23 6895 9999 Fax: +86 (0)23 6869 9779 E-mail: info@zybio.com Web: www.zybio.com

Concentrated Detergent

Product Name

Concentrated Detergent

Package Specification

REF	Specification
042304002	5 L/bottle×1
042304003	5 L/bottle×4

Intended Purpose

This product is used for cleaning of chemistry analyzer.

Product principle

This product is a detergent for the chemistry analyzer cleaning. The Potassium hydroxide is a strong oxidant with the ability to clean, disinfect and remove dirts. The surfactant in the detergent can effectively reduce the surface tension of the residue in the analyzer, so that the residue can be easily cleaned out.

Main Components

Potassium hydroxide (28 g/L)

Storage and Stability

1. The products should be stored at 2 - 35 ℃ and kept away from freezing. The unopened products are valid for 24 months.
2. Once opened, the products are stable for 60 days at 15 - 30 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on the package lable.

Applicable Instrument

Zybio EXC200 series, Zybio EXC400 series, Zybio EXC800 series, Zybio EXC2000 series Chemistry Analyzer. Other models can be used after verification.

Usage

The detergent is a necessary reagent for cleaning the reaction system of the chemistry analyzer. As different instruments apply to different methods, please refer to the manual of instruments while using.

Warnings and Precautions

1. The product contains potassium hydroxide which is an alkaline.
2. The product contains severe eye irritant, mild skin irritant. Please wear eye protection and latex gloves when handling. If the detergent gets into your mouth or contacts with your eyes or skin, rinse with plenty of water immediately or consult a doctor if necessary.
3. Avoid freezing during transportation and storage; prevent dust from entering the reagents and use up within 60 days after opening.
4. Do not use product past the expiration date.
5. This product is for in vitro diagnostic use only. Please properly dispose of waste liquid and package in accordance with local regulations.
6. 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.

Symbol Interpretation

Symbol	Title and Description	Symbol	Title and Description
IVD	*In vitro* diagnostic medical device	LOT	Batch code
	Consult instructions for use		Use-by date
CE	CE marking of conformity		Manufacturer
EC REP	Authorized Representative in the European Community		Temperature limit
REF	Catalogue number	UDI	Unique device identifier
	Date of manufacture		Warning

Zybio Inc.
No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.
Web: www.zybio.com
E-mail: info@zybio.com
Tel: +86 (0)23 6895 9999
Fax: +86 (0)23 6869 9779

EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Current Version: 02 Date of Issue: November, 2024

Tel: +86(0)23 6865 5509

Fax: +86(0)23 6869 9779

Probe Detergent

Product Name
Probe Detergent

Package Specification

REF	Specification
042304004	30 mL/bottle×8
042304005	60 mL/bottle×8

Intended Purpose
This product is used for cleaning of chemistry analyzer.

Product principle
This product is a detergent for the chemistry analyzer cleaning. The Potassium hydroxide is a strong oxidant with the ability to clean, disinfect and remove dirts. The surfactant in the detergent can effectively reduce the surface tension of the residue in the analyzer, so that the residue can be easily cleaned out.

Main Components
Potassium hydroxide (2.8 g/L)

Storage and Stability
1. The products should be stored at 2 - 35 °C and kept away from freezing. The unopened products are valid for 24 months.
2. Once opened, the products are stable for 60 days at 2 - 8 °C. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on the package label.

Applicable Instrument
Zybio EXC200 series, Zybio EXC400 series, Zybio EXC800 series, Zybio EXC2000 series Chemistry Analyzer. Other models can be used after verification.

Usage
The detergent is a necessary reagent for cleaning the reaction system of the chemistry analyzer. As different instruments apply to different methods, please refer to the manual of instruments while using.

Warnings and Precautions
1. The product contains potassium hydroxide which is an alkaline.
2. The product contains severe eye irritant, mild skin irritant. Please wear eye protection and latex gloves when handling. If the detergent gets into your mouth or contacts with your eyes or skin, rinse with plenty of water immediately or consult a doctor if necessary.
3. Avoid freezing during transportation and storage; prevent dust from entering the reagents and use up within 60 days after opening.
4. Do not use product past the expiration date.
5. This product is for in vitro diagnostic use only. Please properly dispose of waste liquid and package in accordance with local regulations.
6. 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.

Symbol Interpretation

Symbol	Title and Description	Symbol	Title and Description
IVD	*In vitro* diagnostic medical device	LOT	Batch code
	Consult instructions for use		Use-by date
CE	CE marking of conformity		Manufacturer
EC REP	Authorized Representative in the European Community		Temperature limit
REF	Catalogue number	UDI	Unique device identifier
	Date of manufacture		

Zybio Inc.
No. 45, Shilin Avenue, Tiaodeng Town, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.
Web: www.zybio.com
E-mail: info@zybio.com
Tel: +86 (0)23 6895 9999
Fax: +86 (0)23 6869 9779

EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Current Version: 02 Date of Issue: November, 2024

PRODUCT INFORMATION

HE1532

1328UE

Please note that for Human Assayed Multi-Sera Level 3 lot 1328UE,
AST (GOT) is stable for **4 days** at +2°C to +8°C.
AST (GOT) is also stable for 8 hours at +15°C to +25°C,
and 28 days when frozen once at –18°C to –24°C.

Please note that for Human Assayed Multi-Sera Level 3 lot 1328UE, the following values are currently unavailable and will be updated in due course:

METHOD (Elec.)
Albumin (electrophoresis)
alpha-1-globulin
alpha-1-globulin
beta-globulin
gamma-globulin

CCS INC235 / CCS INC120

FORM NO. 8373-GP
REVISION (2)
2 Aug 2019

HUMAN ASSAYED MULTI-SERA - LEVEL 3 (HUM ASY CONTROL 3)

CAT. NO.	HE1532	**GTIN:**	05055273203608	**SIZE:**	20 x 5ml
CAT. NO.	HS2611	**GTIN:**	05055273203813	**SIZE:**	5 x 5ml
LOT NO.	1328UE	**EXPIRY:**	2027-03-28		

INTENDED USE
This product is intended for *in vitro* diagnostic use, in the quality control of diagnostic assays. The Human Assayed Multi-sera is for the control of accuracy.

DEVICE DESCRIPTION
The Human Assayed Multi-sera is supplied at 2 levels, level 2 and 3. Target values and ranges are supplied for the analytes listed in the values section at both levels.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.
However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY
OPENED: Store refrigerated (+2°C to +8°C). Reconstituted serum is stable for 8 hours at +15°C to +25°C or 7 days at +2°C to +8°C, and 28 days when frozen once at –18°C to –24°C. (See Limitations)

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

LIMITATIONS
For Total & Prostatic Acid Phosphatase, the material should be stabilised by adding 1 drop (25µl - 30µl) of 0.7M Acetic acid solution to 1ml of the serum exactly 30 minutes after reconstitution. After stabilisation Total and Prostatic Acid Phosphatase is stable for 2 hours at +15°C to +25°C, 2 days at +2°C to +8°C, and 28 days when frozen once at –18°C to –24°C.
Alkaline Phosphatase levels in the reconstituted serum will rise over the stability period. It is recommended that the reconstituted serum is allowed to stand for 1 hour at +15°C to +25°C before measurement.
Bilirubin in the serum is light sensitive and it is recommended that the serum is stored in the dark. Stored in the dark, it is stable for 4 days at +2°C to +8°C. Do not store at +15°C to +25°C. Do not freeze.
GLDH is stable for 2 days at 2 - 8°C.
NEFA is stable for 1 day at +2°C to +8°C.
Total PSA is stable for 4 days at +2°C to +8°C, or 28 days in aliquots frozen at –18°C to –24°C.
AST (GOT) is stable for 4 days at +2°C to +8°C, 8 hours at +15°C to +25°C and 28 days when frozen once at -18°C to -24°C.
Bacterial contamination of the reconstituted serum will cause reductions in the stability of many components.
Different lot numbers of this control should not be interchanged, as the values assigned to the controls vary from lot to lot.
The control should not be used as a calibration material.

Due to the zinc content in some batches of rubber stoppers, the QC and calibrator material should be aliquoted into polypropylene tubes and stored at +2°C to +8°C to ensure stable zinc levels throughout the stability period.

PREPARATION FOR USE
The Human Assayed Multi-sera is supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised serum with exactly 5ml of distilled water at +15°C to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.

2. Refer to the Control section of the individual analyser application.

3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED
Human Assayed Multi-sera - Level 3 20 x 5ml / 5 x 5ml

MATERIALS REQUIRED BUT NOT PROVIDED
Volumetric pipette

ASSIGNED VALUES
Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

Each batch of assayed human serum is submitted to reference laboratories for assignment against international Reference Standards. Where international Reference Standards are unavailable, Reference Methods are used. Values are also collected from approx. 3000 laboratories worldwide and using a unique statistical analysis, a value is assigned.

With each batch, a control range is provided for individual parameters and each parameter method. The control range is equivalent to the assigned mean ±2S.D.

If an instrument specific value is not available, refer to the Method section. If necessary, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

NOTES
® All trademarks recognised.

(1) Applies only in Germany. Ranges established according to the Guidelines of the Federal Chamber of Physicians in Germany.
(2) Values established by reference laboratories officially recognised by the Federal Chamber of Physicians in Germany.
(3) DGKC: German Society for Clinical Chemistry.
(4) IFCC: International Federation of Clinical Chemistry.
(5) SCE: Scandinavian Committee on Enzymes.

EC REP Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

11 Sep '23 me

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	30.4	25.9	34.9	2.25	4.50	Bromocresol Green
	g/dl	3.04	2.59	3.49	0.23	0.45	
	g/l	28.7	24.4	33.0	2.15	4.30	Bromocresol Purple
	g/dl	2.87	2.44	3.30	0.22	0.43	
	g/l	29.5	25.1	33.9	2.20	4.40	Ortho Vitros Microslide Systems
	g/dl	2.95	2.51	3.39	0.22	0.44	
	g/l	30.3	25.8	34.8	2.25	4.50	Turbidimetric Assays
	g/dl	3.03	2.58	3.48	0.23	0.45	
Alkaline Phosphatase	U/l	304	259	349	22.50	45.00	Ortho Vitros Microslide Systems 37°C
	U/l	362	308	416	27.00	54.00	AMP optimised to IFCC 37°C
	U/l	282	240	324	21.00	42.00	AMP optimised to IFCC 30°C
	U/l	231	197	265	17.00	34.00	AMP optimised to IFCC 25°C
	U/l	361	307	415	27.00	54.00	AMP non-optimised 37°C
	U/l	281	239	323	21.00	42.00	AMP non-optimised 30°C
	U/l	231	196	266	17.50	35.00	AMP non-optimised 25°C
	U/l	346	295	397	25.50	51.00	Colorimetric 37°C
	U/l	270	230	310	20.00	40.00	Colorimetric 30°C
	U/l	221	189	253	16.00	32.00	Colorimetric 25°C
ALT (GPT)	U/l	142	113	171	14.50	29.00	Colorimetric 37°C
	U/l	105	84	126	10.50	21.00	Colorimetric 30°C
	U/l	80	64	96	8.00	16.00	Colorimetric 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
ALT (GPT)	U/l	152	122	182	15.00	30.00	Ortho Vitros Microslide Systems 37°C
	U/l	146	117	175	14.50	29.00	Tris buffer with P5P 37°C
	U/l	108	87	129	10.50	21.00	Tris buffer with P5P 30°C
	U/l	82	66	98	8.00	16.00	Tris buffer with P5P 25°C
	U/l	139	111	167	14.00	28.00	Tris buffer without P5P 37°C
	U/l	103	82	124	10.50	21.00	Tris buffer without P5P 30°C
	U/l	78	62	94	8.00	16.00	Tris buffer without P5P 25°C
	U/l	144	115	173	14.50	29.00	Phosphate buffer DGKC 37°C
	U/l	107	85	129	11.00	22.00	Phosphate buffer DGKC 30°C
	U/l	81	65	97	8.00	16.00	Phosphate buffer DGKC 25°C
	U/l	140	112	168	14.00	28.00	Tris buffer with P5P NVKC 37°C
	U/l	104	83	125	10.50	21.00	Tris buffer with P5P NVKC 30°C
	U/l	79	63	95	8.00	16.00	Tris buffer with P5P NVKC 25°C
	U/l	152	121	183	15.50	31.00	Ortho Vitros MicroSlide visible 37°C
	U/l	134	107	161	13.50	27.00	Tris buffer SCE 37°C
	U/l	99	79	119	10.00	20.00	Tris buffer SCE 30°C
	U/l	75	60	90	7.50	15.00	Tris buffer SCE 25°C
Amylase Pancreatic	U/l	257	218	296	19.50	39.00	Immunoinhibition EPS substrate 37°C
	U/l	249	211	287	19.00	38.00	Roche EPS Liquid 37°C
	U/l	288	245	331	21.50	43.00	Randox Liquid Ethylidene pNPG7 37°C
Amylase Total	U/l	299	254	344	22.50	45.00	pNP Maltotrioside substrates 37°C
	U/l	310	263	357	23.50	47.00	Siemens - blocked pNPG7 37°C
	U/l	295	251	339	22.00	44.00	Randox Lyo. Ethylidene pNPG7 37°C
	U/l	310	264	356	23.00	46.00	Randox Liquid Ethylidene pNPG7 37°C
	U/l	333	283	383	25.00	50.00	Siemens - maltopenta/hexaoside 37°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
Amylase Total	U/l	277	236	318	20.50	41.00	Roche Integra 2-chloro-pNPG7 37°C
	U/l	176	149	203	13.50	27.00	Ortho Vitros Microslide Systems 37°C
	U/l	275	234	316	20.50	41.00	Other Roche 2-chloro-pNPG7 37°C
	U/l	273	232	314	20.50	41.00	Roche liquid stable pNPG7 37°C
	U/l	329	280	378	24.50	49.00	Siemens 2-chloro-pNPG3 37°C
	U/l	295	251	339	22.00	44.00	bioMerieux 2-chloro-pNPG3 37°C
	U/l	289	246	332	21.50	43.00	Beckman Coulter - blocked pNPG7 37°C
	U/l	292	248	336	22.00	44.00	Beckman Synchron AMY7 37°C
	U/l	299	254	344	22.50	45.00	I.L. 2-chloro-pNPG3 37°C
	U/l	315	268	362	23.50	47.00	Abbott Architect / Alinity cal factor 3806 37°C
	U/l	307	261	353	23.00	46.00	Abbott Architect / Alinity cal factor 3431 37°C
	U/l	291	247	335	22.00	44.00	Beckman CNPG3 (Extinction Coeff) 37°C
	U/l	275	233	317	21.00	42.00	BM/Roche Colorimetric pNPG7 37°C
	U/l	301	256	346	22.50	45.00	Abbott - blocked pNPG7 37°C
	U/l	304	258	350	23.00	46.00	Abbott Alinity Amylase 2 37°C
	U/l	304	259	349	22.50	45.00	Abbott Architect 37°C
Apolipoprotein A-1	g/l	1.14	0.94	1.35	0.10	0.21	Immunoturbidimetric
	mg/dl	114	93.5	135	10.25	20.50	
Apolipoprotein B	g/l	0.70	0.58	0.83	0.06	0.13	Immunoturbidimetric
	mg/dl	70.3	57.6	83.0	6.35	12.70	
AST (GOT)	U/l	136	109	163	13.50	27.00	Colorimetric 37°C
	U/l	92	74	110	9.00	18.00	Colorimetric 30°C
	U/l	65	52	78	6.50	13.00	Colorimetric 25°C
	U/l	172	138	206	17.00	34.00	Ortho Vitros Microslide visible slide 37°C
	U/l	155	124	186	15.50	31.00	Tris buffer with P5P 37°C
	U/l	105	84	126	10.50	21.00	Tris buffer with P5P 30°C
	U/l	74	59	89	7.50	15.00	Tris buffer with P5P 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
AST (GOT)	U/l	132	105	159	13.50	27.00	Tris buffer without P5P 37°C
	U/l	89	71	107	9.00	18.00	Tris buffer without P5P 30°C
	U/l	63	50	76	6.50	13.00	Tris buffer without P5P 25°C
	U/l	137	109	165	14.00	28.00	Phosphate buffer DGKC 37°C
	U/l	93	74	112	9.50	19.00	Phosphate buffer DGKC 30°C
	U/l	65	52	78	6.50	13.00	Phosphate buffer DGKC 25°C
	U/l	131	105	157	13.00	26.00	Tris buffer SCE 37°C
	U/l	89	71	107	9.00	18.00	Tris buffer SCE 30°C
	U/l	62	50	74	6.00	12.00	Tris buffer SCE 25°C
Bile Acids	µmol/l	40.2	32.2	48.2	4.00	8.00	4th Generation Colorimetric
	µmol/l	41.8	33.4	50.2	4.20	8.40	5th Generation Colorimetric
Bicarbonate	mmol/l	18.5	14.7	22.3	1.90	3.80	Colorimetric
	mmol/l	21.1	16.7	25.5	2.20	4.40	Ortho Vitros Microslide Systems
	mmol/l	19.2	15.3	23.1	1.95	3.90	Enzymatic
Bilirubin Direct	µmol/l	27.2	21.5	32.9	2.85	5.70	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.59	1.26	1.92	0.17	0.33	
	µmol/l	28.8	22.8	34.8	3.00	6.00	Diazo with Sulphanilic Acid
	mg/dl	1.68	1.33	2.03	0.18	0.35	
	µmol/l	29.4	23.2	35.6	3.10	6.20	Diazo with Dichloroaniline (DCA)
	mg/dl	1.72	1.36	2.08	0.18	0.36	
	µmol/l	30.1	23.8	36.4	3.15	6.30	Oxidation to Biliverdin/Vanadate
	mg/dl	1.76	1.39	2.13	0.19	0.37	
	µmol/l	33.2	26.2	40.2	3.50	7.00	Modified Jendrassik
	mg/dl	1.94	1.53	2.35	0.21	0.41	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Bilirubin Total	µmol/l	74.3	58.7	89.9	7.80	15.60	Vitros 250/500/700/950 Total Bilirubin
	mg/dl	4.35	3.43	5.27	0.46	0.92	
	µmol/l	83.0	65.5	101	8.75	17.50	Diazo with Dichloroaniline (DCA)
	mg/dl	4.86	3.83	5.89	0.52	1.03	
	µmol/l	80.8	63.8	97.8	8.50	17.00	Diazo with Sulphanilic Acid
	mg/dl	4.73	3.73	5.73	0.50	1.00	
	µmol/l	77.2	61.0	93.4	8.10	16.20	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.52	3.57	5.47	0.48	0.95	
	µmol/l	77.9	61.5	94.3	8.20	16.40	Nitrobenzenediazonium salt
	mg/dl	4.56	3.60	5.52	0.48	0.96	
	µmol/l	76.2	60.2	92.2	8.00	16.00	Diazonium ion
	mg/dl	4.46	3.52	5.40	0.47	0.94	
	µmol/l	89.3	70.6	108	9.35	18.70	Oxidation to Biliverdin/Vanadate
	mg/dl	5.22	4.13	6.31	0.55	1.09	
	µmol/l	91.1	72.0	110	9.55	19.10	Modified Jendrassik
	mg/dl	5.33	4.21	6.45	0.56	1.12	
Calcium	mmol/l	3.77	3.39	4.15	0.19	0.38	Cresolphthalein complexone
	mg/dl	15.1	13.6	16.6	0.75	1.50	
	mmol/l	3.66	3.29	4.03	0.19	0.37	Ortho Vitros Microslide Systems
	mg/dl	14.7	13.2	16.2	0.75	1.50	
	mmol/l	3.73	3.36	4.10	0.19	0.37	Methylthymol blue
	mg/dl	14.9	13.5	16.3	0.70	1.40	
	mmol/l	3.82	3.44	4.20	0.19	0.38	Arsenazo III
	mg/dl	15.3	13.8	16.8	0.75	1.50	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Calcium	mmol/l	3.78	3.40	4.16	0.19	0.38	Phosphonazo
	mg/dl	15.2	13.6	16.8	0.80	1.60	
	mmol/l	3.90	3.51	4.29	0.20	0.39	NM-BAPTA
	mg/dl	15.6	14.1	17.1	0.75	1.50	
Cholesterol	mmol/l	6.99	6.08	7.90	0.46	0.91	Ortho Vitros Microslide Systems
	mg/dl	270	235	305	17.50	35.00	
	mmol/l	7.36	6.40	8.32	0.48	0.96	Cholesterol Oxidase - Abell Kendall
	mg/dl	284	247	321	18.50	37.00	
	mmol/l	7.40	6.43	8.37	0.49	0.97	Cholesterol Oxidase - IDMS
	mg/dl	286	248	324	19.00	38.00	
	mmol/l	7.37	6.41	8.33	0.48	0.96	Cholesterol Dehydrogenase
	mg/dl	284	247	321	18.50	37.00	
Chloride	mmol/l	111	106	116	2.50	5.00	Colorimetric
	mmol/l	115	109	121	3.00	6.00	Ortho Vitros Microslide Systems
	mmol/l	113	107	119	3.00	6.00	ISE indirect
	mmol/l	114	108	120	3.00	6.00	ISE direct
Cholinesterase	U/l	5437	4349	6525	544.00	1088.00	Colorimetric Butyrylthiocholine 37°C
	U/l	5218	4174	6262	522.00	1044.00	Ortho Vitros Microslide Systems 37°C
	U/l	9332	7465	11198	933.50	1867.00	Colorimetric - Butyrythiochol. Dimension 37°C
CK Total	U/l	390	320	460	35.00	70.00	Ortho Vitros Microslide Systems 37°C
	U/l	514	421	607	46.50	93.00	CK-NAC serum start (DGKC) 37°C
	U/l	322	264	380	29.00	58.00	CK-NAC serum start (DGKC) 30°C
	U/l	218	179	257	19.50	39.00	CK-NAC serum start (DGKC) 25°C
	U/l	511	419	603	46.00	92.00	CK-NAC substrate start (DGKC) 37°C
	U/l	320	262	378	29.00	58.00	CK-NAC substrate start (DGKC) 30°C
	U/l	217	178	256	19.50	39.00	CK-NAC substrate start (DGKC) 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
CK Total	U/l	510	418	602	46.00	92.00	CK-NAC (IFCC) 37°C
	U/l	319	262	376	28.50	57.00	CK-NAC (IFCC) 30°C
	U/l	217	178	256	19.50	39.00	CK-NAC (IFCC) 25°C
	U/l	558	458	658	50.00	100.00	Monothioglycerol 37°C
	U/l	349	287	411	31.00	62.00	Monothioglycerol 30°C
	U/l	237	195	279	21.00	42.00	Monothioglycerol 25°C
Copper	µmol/l	24.7	19.7	29.7	2.50	5.00	Atomic absorption
	µg/dl	157	125	189	16.00	32.00	
	µmol/l	24.0	19.2	28.8	2.40	4.80	Colorimetric
	µg/dl	153	122	184	15.50	31.00	
Cortisol	nmol/l	985	739	1231	123.00	246.00	Roche Cobas e402/e801
	µg/dl	35.5	26.6	44.4	4.45	8.90	
Creatinine	µmol/l	356	284	428	36.00	72.00	Alkaline picrate with deproteinization
	mg/dl	4.02	3.21	4.83	0.41	0.81	
	µmol/l	357	286	428	35.50	71.00	Alkaline picrate no deproteinization
	mg/dl	4.03	3.23	4.83	0.40	0.80	
	µmol/l	374	299	449	37.50	75.00	Enzymatic UV method
	mg/dl	4.23	3.38	5.08	0.43	0.85	
	µmol/l	372	298	446	37.00	74.00	Creatinine PAP method
	mg/dl	4.20	3.37	5.03	0.42	0.83	
	µmol/l	346	277	415	34.50	69.00	Jaffe rate blanked
	mg/dl	3.91	3.13	4.69	0.39	0.78	
	µmol/l	366	293	439	36.50	73.00	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	4.14	3.31	4.97	0.42	0.83	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Creatinine	µmol/l	374	299	449	37.50	75.00	Vitros DT60/DT60 II/DTSC II
	mg/dl	4.23	3.38	5.08	0.43	0.85	
	µmol/l	355	284	426	35.50	71.00	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	4.01	3.21	4.81	0.40	0.80	
	µmol/l	370	296	444	37.00	74.00	Vitros IDMS Traceable
	mg/dl	4.18	3.34	5.02	0.42	0.84	
D-3-Hydroxybutyrate	mmol/l	1.14	0.97	1.31	0.09	0.17	Tris buffer 100mmol pH 8.5
Digoxin	nmol/l	2.99	2.39	3.59	0.30	0.60	Immunoturbidimetric
	ng/ml	2.34	1.87	2.81	0.24	0.47	
Folate	nmol/l	5.49	4.17	6.81	0.66	1.32	Roche Cobas e402/e801
	ng/ml	2.42	1.84	3.00	0.29	0.58	
Free T4	pmol/l	49.0	36.7	61.3	6.15	12.30	Abbott Architect
	ng/dl	3.82	2.86	4.78	0.48	0.96	
	pg/ml	38.2	28.6	47.8	4.80	9.60	Abbott Architect
	pmol/l	66.6	49.9	83.3	8.35	16.70	Siemens Centaur XP/XPT/Classic
	ng/dl	5.19	3.89	6.49	0.65	1.30	
	pg/ml	51.9	38.9	64.9	6.50	13.00	Siemens Centaur XP/XPT/Classic
	pmol/l	72.4	54.3	90.5	9.05	18.10	Siemens Immulite 2000/2500
	ng/dl	5.65	4.24	7.06	0.71	1.41	
	pg/ml	56.5	42.4	70.6	7.05	14.10	Siemens Immulite 2000/2500
	pmol/l	75.5	56.6	94.4	9.45	18.90	Siemens Immulite 1000
	ng/dl	5.89	4.41	7.37	0.74	1.48	
	pg/ml	58.9	44.1	73.7	7.40	14.80	Siemens Immulite 1000
	pmol/l	65.7	49.3	82.1	8.20	16.40	Beckman DxI800
	ng/dl	5.12	3.85	6.39	0.64	1.27	
	pg/ml	51.2	38.5	63.9	6.35	12.70	Beckman DxI800

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
Free T4	pmol/l	62.1	46.6	77.6	7.75	15.50	Beckman Access
	ng/dl	4.84	3.63	6.05	0.61	1.21	
	pg/ml	48.4	36.3	60.5	6.05	12.10	Beckman Access
	pmol/l	80.6	60.5	101	10.05	20.10	Tosoh Series
	ng/dl	6.29	4.72	7.86	0.79	1.57	
	pg/ml	62.9	47.2	78.6	7.85	15.70	Tosoh Series
	pmol/l	92.8	69.6	116	11.60	23.20	Vitros ECi
	ng/dl	7.24	5.43	9.05	0.91	1.81	
	pg/ml	72.4	54.3	90.5	9.05	18.10	Vitros ECi
	pmol/l	77.2	57.9	96.5	9.65	19.30	Roche Cobas 4000/E411
	ng/dl	6.02	4.52	7.52	0.75	1.50	
	pg/ml	60.2	45.2	75.2	7.50	15.00	Roche Cobas 4000/E411
	pmol/l	76.8	57.6	96.0	9.60	19.20	Roche Cobas e601/602
	ng/dl	5.99	4.49	7.49	0.75	1.50	
	pg/ml	59.9	44.9	74.9	7.50	15.00	Roche Cobas e601/602
	pmol/l	76.7	57.6	95.8	9.55	19.10	Biomerieux Vidas FT4N Kit
	ng/dl	5.98	4.49	7.47	0.75	1.49	
	pg/ml	59.8	44.9	74.7	7.45	14.90	Biomerieux Vidas FT4N Kit
	pmol/l	81.0	60.8	101	10.10	20.20	Siemens Dimension Exl LOCI
	ng/dl	6.32	4.74	7.90	0.79	1.58	
	pg/ml	63.2	47.4	79.0	7.90	15.80	Siemens Dimension Exl LOCI
	pmol/l	69.6	52.2	87.0	8.70	17.40	Siemens Centaur CP
	ng/dl	5.43	4.07	6.79	0.68	1.36	
	pg/ml	54.3	40.7	67.9	6.80	13.60	Siemens Centaur CP

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
Free T4	pmol/l	55.6	41.7	69.5	6.95	13.90	Mindray CL 8000i/6000i/2000i/1200i/1000i
	ng/dl	4.34	3.25	5.43	0.55	1.09	
	pg/ml	43.4	32.5	54.3	5.45	10.90	Mindray CL 8000i/6000i/2000i/1200i/1000i
	pmol/l	79.0	59.2	98.8	9.90	19.80	Roche Cobas e402/e801
	ng/dl	6.16	4.62	7.70	0.77	1.54	
	pg/ml	61.6	46.2	77.0	7.70	15.40	Roche Cobas e402/e801
Gentamicin	µmol/l	19.0	15.2	22.8	1.90	3.80	Gravimetric
	µg/ml	9.08	7.27	10.9	0.91	1.81	
gamma-GT	U/l	172	146	198	13.00	26.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	136	115	157	10.50	21.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	106	90	122	8.00	16.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
	U/l	201	171	231	15.00	30.00	Ortho Vitros Microslide Systems 37°C
	U/l	173	147	199	13.00	26.00	Gamma glutamyl-4-nitroanilide 37°C
	U/l	136	116	156	10.00	20.00	Gamma glutamyl-4-nitroanilide 30°C
	U/l	107	91	123	8.00	16.00	Gamma glutamyl-4-nitroanilide 25°C
	U/l	179	152	206	13.50	27.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	141	120	162	10.50	21.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	110	94	126	8.00	16.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
	U/l	187	159	215	14.00	28.00	Randox Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	147	125	169	11.00	22.00	Randox Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	115	98	132	8.50	17.00	Randox Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
GLDH	U/l	34	26	41	3.75	7.50	Triethanolamine buffer 50 mmol 37°C
	U/l	26	20	32	3.00	6.00	Triethanolamine buffer 50 mmol 30°C
	U/l	21	16	26	2.50	5.00	Triethanolamine buffer 50 mmol 25°C
Glucose	mmol/l	15.1	12.8	17.4	1.15	2.30	Ortho Vitros Microslide Systems
	mg/dl	272	231	313	20.50	41.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Glucose	mmol/l	16.0	13.6	18.4	1.20	2.40	Glucose dehydrogenase
	mg/dl	288	245	331	21.50	43.00	
	mmol/l	15.9	13.6	18.2	1.15	2.30	Hexokinase
	mg/dl	287	245	329	21.00	42.00	
	mmol/l	15.7	13.4	18.0	1.15	2.30	Oxygen electrode
	mg/dl	283	241	325	21.00	42.00	
	mmol/l	15.9	13.5	18.3	1.20	2.40	Glucose oxidase
	mg/dl	287	243	331	22.00	44.00	
alpha-HBDH	U/l	387	306	468	40.50	81.00	Oxobutyrate < 10 mmol/l 37°C
	U/l	292	231	353	30.50	61.00	Oxobutyrate < 10 mmol/l 30°C
	U/l	219	173	265	23.00	46.00	Oxobutyrate < 10 mmol/l 25°C
HDL - Cholesterol	mmol/l	2.67	2.27	3.07	0.20	0.40	Direct HDL PPD
	mg/dl	103	87.6	118	7.70	15.40	
	mmol/l	2.49	2.12	2.86	0.19	0.37	Direct HDL Immunoseparation
	mg/dl	96.1	81.8	110	7.15	14.30	
	mmol/l	2.51	2.14	2.88	0.19	0.37	Vitros Magnetic HDL
	mg/dl	96.9	82.6	111	7.15	14.30	
	mmol/l	2.43	2.07	2.79	0.18	0.36	Direct Clearance Method
	mg/dl	93.8	79.9	108	6.95	13.90	
	mmol/l	2.51	2.13	2.89	0.19	0.38	Vitros dHDL PTA/MgCl2 direct precipitation
	mg/dl	96.9	82.2	112	7.35	14.70	
	mmol/l	2.66	2.27	3.05	0.20	0.39	HDL - Ultra
	mg/dl	103	87.6	118	7.70	15.40	
	mmol/l	2.99	2.54	3.44	0.23	0.45	Direct HDL Roche 4th Generation
	mg/dl	115	98.0	132	8.50	17.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Immunoglobulin A	g/l	1.94	1.46	2.42	0.24	0.48	Immunoturbidimetric
	mg/dl	194	146	242	24.00	48.00	
Immunoglobulin G	g/l	6.14	5.03	7.25	0.56	1.11	Immunoturbidimetric
	mg/dl	614	503	725	55.50	111.00	
Immunoglobulin M	g/l	0.65	0.52	0.78	0.07	0.13	Immunoturbidimetric
	mg/dl	65.1	52.1	78.1	6.50	13.00	
Iron	µmol/l	38.7	31.8	45.6	3.45	6.90	Colorimetric with ppt.
	µg/dl	216	178	254	19.00	38.00	
	µmol/l	39.2	32.1	46.3	3.55	7.10	Colorimetric without ppt.
	µg/dl	219	179	259	20.00	40.00	
	µmol/l	36.2	29.7	42.7	3.25	6.50	Ortho Vitros Microslide Systems
	µg/dl	202	166	238	18.00	36.00	
Lactate	mmol/l	5.98	4.90	7.06	0.54	1.08	Colorimetric Lactate Oxidase
	mg/dl	53.9	44.1	63.7	4.90	9.80	
	mmol/l	5.50	4.51	6.49	0.50	0.99	Ortho Vitros Microslide Systems
	mg/dl	49.6	40.6	58.6	4.50	9.00	
	mmol/l	6.05	4.96	7.14	0.55	1.09	Ion selective electrode
	mg/dl	54.5	44.7	64.3	4.90	9.80	
	mmol/l	5.60	4.59	6.61	0.51	1.01	UV LDH
	mg/dl	50.5	41.4	59.6	4.55	9.10	
LD (LDH)	U/l	363	308	418	27.50	55.00	L->P 37°C
	U/l	262	222	302	20.00	40.00	L->P 30°C
	U/l	184	156	212	14.00	28.00	L->P 25°C
	U/l	737	627	847	55.00	110.00	P->L Scandinavian & Dutch 37°C
	U/l	532	453	611	39.50	79.00	P->L Scandinavian & Dutch 30°C
	U/l	374	318	430	28.00	56.00	P->L Scandinavian & Dutch 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
LD (LDH)	U/l	713	606	820	53.50	107.00	P->L German methods 37°C
	U/l	515	438	592	38.50	77.00	P->L German methods 30°C
	U/l	361	307	415	27.00	54.00	P->L German methods 25°C
	U/l	718	610	826	54.00	108.00	P->L SFBC 37°C
	U/l	518	440	596	39.00	78.00	P->L SFBC 30°C
	U/l	364	309	419	27.50	55.00	P->L SFBC 25°C
	U/l	364	310	418	27.00	54.00	L->P IFCC 37°C
	U/l	263	224	302	19.50	39.00	L->P IFCC 30°C
	U/l	185	157	213	14.00	28.00	L->P IFCC 25°C
	U/l	403	343	463	30.00	60.00	Ortho Vitros IFCC Traceable 37°C
Lipase	U/l	72	58	86	7.00	14.00	Other Colorimetric 37°C
	U/l	827	663	991	82.00	164.00	Ortho Vitros Microslide Systems 37°C
	U/l	77	61	93	8.00	16.00	Roche Colorimetric 37°C
	U/l	102	82	122	10.00	20.00	Randox Colorimetric 37°C
Lithium	mmol/l	2.41	2.12	2.70	0.15	0.29	Ortho Vitros Microslide Systems
	mg/dl	1.67	1.47	1.87	0.10	0.20	
	mmol/l	1.95	1.72	2.18	0.12	0.23	Flame photometry
	mg/dl	1.35	1.19	1.51	0.08	0.16	
	mmol/l	2.04	1.79	2.29	0.13	0.25	Ion selective electrode
	mg/dl	1.42	1.24	1.60	0.09	0.18	
	mmol/l	2.01	1.77	2.25	0.12	0.24	Spectrophotometric
	mg/dl	1.40	1.23	1.57	0.09	0.17	
Magnesium	mmol/l	2.00	1.76	2.24	0.12	0.24	Arsenazo III
	mg/dl	4.86	4.28	5.44	0.29	0.58	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Magnesium	mmol/l	2.03	1.79	2.27	0.12	0.24	Ortho Vitros Microslide Systems
	mg/dl	4.93	4.35	5.51	0.29	0.58	
	mmol/l	2.03	1.78	2.28	0.13	0.25	Atomic absorption
	mg/dl	4.93	4.33	5.53	0.30	0.60	
	mmol/l	1.88	1.65	2.11	0.12	0.23	Calmagite
	mg/dl	4.57	4.01	5.13	0.28	0.56	
	mmol/l	2.00	1.76	2.24	0.12	0.24	Xylidyl Blue
	mg/dl	4.86	4.28	5.44	0.29	0.58	
	mmol/l	2.03	1.78	2.28	0.13	0.25	Methylthymol blue
	mg/dl	4.93	4.33	5.53	0.30	0.60	
	mmol/l	2.02	1.78	2.26	0.12	0.24	Chlorphosphonazo III
	mg/dl	4.91	4.33	5.49	0.29	0.58	
	mmol/l	2.03	1.79	2.27	0.12	0.24	Enzymatic
	mg/dl	4.93	4.35	5.51	0.29	0.58	
NEFA	mmol/l	0.47	0.38	0.56	0.05	0.09	Colorimetric
Osmolality	mOsm/kg	346	277	415	34.50	69.00	Calculated
	mOsm/kg	373	299	447	37.00	74.00	Freezing point depression
Paracetamol	mmol/l	0.59	0.48	0.71	0.06	0.12	Gravimetric
	mg/l	90.0	72.0	108	9.00	18.00	
Phosphate Inorganic	mmol/l	2.16	1.84	2.48	0.16	0.32	Ortho Vitros Microslide Systems
	mg/dl	6.70	5.70	7.70	0.50	1.00	
	mmol/l	2.23	1.89	2.57	0.17	0.34	Phosphomolybdate enzymatic
	mg/dl	6.91	5.86	7.96	0.53	1.05	
	mmol/l	2.25	1.91	2.59	0.17	0.34	Phosphomolybdate UV
	mg/dl	6.98	5.92	8.04	0.53	1.06	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Potassium	mmol/l	5.92	5.62	6.22	0.15	0.30	Ortho Vitros Microslide Systems
	mmol/l	6.18	5.87	6.49	0.16	0.31	Enzymatic
	mmol/l	5.63	5.35	5.91	0.14	0.28	Flame photometry
	mmol/l	5.90	5.61	6.19	0.15	0.29	ISE method - direct
	mmol/l	6.03	5.73	6.33	0.15	0.30	ISE method - indirect
	mmol/l	5.62	5.34	5.90	0.14	0.28	Colorimetric
Protein Total	g/l	47.8	38.3	57.3	4.75	9.50	Ortho Vitros Microslide Systems
	g/dl	4.78	3.83	5.73	0.48	0.95	
	g/l	46.8	37.4	56.2	4.70	9.40	Biuret reaction end point
	g/dl	4.68	3.74	5.62	0.47	0.94	
	g/l	45.6	36.5	54.7	4.55	9.10	Biuret reaction kinetic
	g/dl	4.56	3.65	5.47	0.46	0.91	
PSA Total	ng/ml =	15.3	11.5	19.1	1.90	3.80	Tosoh Series
	ng/ml =	23.8	17.8	29.8	3.00	6.00	Beckman Access standardised to Hybritech
	ng/ml =	20.2	15.2	25.2	2.50	5.00	bioMerieux VIDAS TPSA
	ng/ml =	16.1	12.1	20.1	2.00	4.00	Abbott Architect
	ng/ml =	20.1	15.1	25.1	2.50	5.00	Ortho Vitros ECi
	ng/ml =	19.9	14.9	24.9	2.50	5.00	Siemens Dimension
	ng/ml =	21.2	15.9	26.5	2.65	5.30	Cobas E411
	ng/ml =	20.9	15.7	26.1	2.60	5.20	Roche Cobas 6000/8000
Salicylate	mmol/l	0.87	0.70	1.04	0.09	0.17	Gravimetric
	mg/dl	12.0	9.60	14.4	1.20	2.40	
Sodium	mmol/l	154	146	162	4.00	8.00	Ortho Vitros Microslide Systems
	mmol/l	157	149	165	4.00	8.00	Enzymatic

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28 Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Sodium	mmol/l	156	148	164	4.00	8.00	Flame photometry
	mmol/l	155	147	163	4.00	8.00	ISE method - direct
	mmol/l	158	150	166	4.00	8.00	ISE method - indirect
	mmol/l	151	143	159	4.00	8.00	Colorimetric
Theophylline	µmol/l	139	111	167	14.00	28.00	Gravimetric
	µg/ml	25.0	20.0	30.0	2.50	5.00	
Thyroid Stimulating Hormone	µU/ml =	1.05	0.84	1.26	0.10	0.21	Abbott Architect
	µU/ml =	1.45	1.16	1.74	0.15	0.29	bioMerieux VIDAS TSH
	µU/ml =	1.41	1.12	1.70	0.15	0.29	Siemens Immulite 1000
	µU/ml =	1.47	1.18	1.76	0.15	0.29	Roche Elecsys
	µU/ml =	1.29	1.03	1.55	0.13	0.26	Beckman Access Fast TSH
	µU/ml =	1.27	1.01	1.53	0.13	0.26	Beckman Access hyperTSH 3rd Generation
	µU/ml =	1.31	1.04	1.58	0.14	0.27	Tosoh Series
	µU/ml =	1.30	1.04	1.56	0.13	0.26	Vitros ECi
	µU/ml =	1.52	1.22	1.82	0.15	0.30	Roche Cobas 4000/E411
	µU/ml =	1.48	1.18	1.78	0.15	0.30	Roche Cobas e601/602
	µU/ml =	1.31	1.04	1.58	0.14	0.27	Monobind Inc. ELISA / CLIA
	µU/ml =	1.18	0.95	1.41	0.12	0.23	Siemens Dimension Exl LOCI
	µU/ml =	1.27	1.01	1.53	0.13	0.26	Beckman DxI 600/800 Access (3rd IS)
	µU/ml =	1.46	1.17	1.75	0.15	0.29	Roche Cobas e402/e801
	µU/ml =	1.23	0.98	1.48	0.12	0.25	Siemens Atellica IM
TIBC	µmol/l	35.9	28.4	43.4	3.75	7.50	Ortho Vitros Microslide Systems
	µg/dl	201	159	243	21.00	42.00	
	µmol/l	37.8	29.8	45.8	4.00	8.00	Removal of excess free iron
	µg/dl	211	167	255	22.00	44.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
TIBC	µmol/l	41.6	32.8	50.4	4.40	8.80	FE+UIBC(saturation with iron)
	µg/dl	233	183	283	25.00	50.00	
	µmol/l	39.0	30.8	47.2	4.10	8.20	Calculated from Transferrin
	µg/dl	218	172	264	23.00	46.00	
Tobramycin	µmol/l	15.6	12.5	18.7	1.55	3.10	Gravimetric
	µg/ml	7.30	5.85	8.75	0.73	1.45	
Total T3	nmol/l	2.51	1.88	3.14	0.32	0.63	Abbott Architect
	ng/ml	1.63	1.22	2.04	0.21	0.41	
	ng/dl	163	122	204	20.50	41.00	Abbott Architect
	nmol/l	3.08	2.31	3.85	0.39	0.77	BioMerieux Vidas
	ng/ml	2.01	1.50	2.52	0.26	0.51	
	ng/dl	201	150	252	25.50	51.00	BioMerieux Vidas
	nmol/l	3.59	2.69	4.49	0.45	0.90	Siemens Centaur XP/XPT/Classic
	ng/ml	2.34	1.75	2.93	0.30	0.59	
	ng/dl	234	175	293	29.50	59.00	Siemens Centaur XP/XPT/Classic
	nmol/l	2.91	2.18	3.64	0.37	0.73	Beckman DxI800
	ng/ml	1.89	1.42	2.36	0.24	0.47	
	ng/dl	189	142	236	23.50	47.00	Beckman DxI800
	nmol/l	3.65	2.74	4.56	0.46	0.91	Roche Elecsys
	ng/ml	2.38	1.78	2.98	0.30	0.60	
	ng/dl	238	178	298	30.00	60.00	Roche Elecsys
	nmol/l	3.12	2.34	3.90	0.39	0.78	Beckman Access
	ng/ml	2.03	1.52	2.54	0.26	0.51	
	ng/dl	203	152	254	25.50	51.00	Beckman Access
	nmol/l	2.67	2.00	3.34	0.34	0.67	Tosoh Series
	ng/ml	1.74	1.30	2.18	0.22	0.44	
	ng/dl	174	130	218	22.00	44.00	Tosoh Series

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
Total T3	nmol/l	4.28	3.21	5.35	0.54	1.07	Vitros ECi
	ng/ml	2.79	2.09	3.49	0.35	0.70	
	ng/dl	279	209	349	35.00	70.00	Vitros ECi
	nmol/l	3.55	2.66	4.44	0.45	0.89	Roche Cobas 4000/E411
	ng/ml	2.31	1.73	2.89	0.29	0.58	
	ng/dl	231	173	289	29.00	58.00	Roche Cobas 4000/E411
	nmol/l	3.51	2.63	4.39	0.44	0.88	Roche Cobas e601/602
	ng/ml	2.29	1.71	2.87	0.29	0.58	
	ng/dl	229	171	287	29.00	58.00	Roche Cobas e601/602
	nmol/l	3.67	2.75	4.59	0.46	0.92	Siemens Centaur CP
	ng/ml	2.39	1.79	2.99	0.30	0.60	
	ng/dl	239	179	299	30.00	60.00	Siemens Centaur CP
	nmol/l	3.68	2.76	4.60	0.46	0.92	Roche Cobas e402/e801
	ng/ml	2.40	1.80	3.00	0.30	0.60	
	ng/dl	240	180	300	30.00	60.00	Roche Cobas e402/e801
Total T4	nmol/l	234	176	292	29.00	58.00	Abbott Architect
	µg/dl	18.3	13.7	22.9	2.30	4.60	
	ng/ml	183	137	229	23.00	46.00	Abbott Architect
	nmol/l	216	162	270	27.00	54.00	BioMerieux Vidas
	µg/dl	16.8	12.6	21.0	2.10	4.20	
	ng/ml	168	126	210	21.00	42.00	BioMerieux Vidas
	nmol/l	254	190	318	32.00	64.00	Siemens Centaur XP/XPT/Classic
	µg/dl	19.8	14.8	24.8	2.50	5.00	
	ng/ml	198	148	248	25.00	50.00	Siemens Centaur XP/XPT/Classic

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28 Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Total T4	nmol/l	278	209	347	34.50	69.00	Beckman Access
	µg/dl	21.7	16.3	27.1	2.70	5.40	
	ng/ml	217	163	271	27.00	54.00	Beckman Access
	nmol/l	222	166	278	28.00	56.00	Tosoh Series
	µg/dl	17.3	12.9	21.7	2.20	4.40	
	ng/ml	173	129	217	22.00	44.00	Tosoh Series
	nmol/l	240	180	300	30.00	60.00	Vitros ECi
	µg/dl	18.7	14.0	23.4	2.35	4.70	
	ng/ml	187	140	234	23.50	47.00	Vitros ECi
	nmol/l	223	167	279	28.00	56.00	Roche Cobas 4000/E411
	µg/dl	17.4	13.0	21.8	2.20	4.40	
	ng/ml	174	130	218	22.00	44.00	Roche Cobas 4000/E411
	nmol/l	216	162	270	27.00	54.00	Roche Cobas e601/602
	µg/dl	16.8	12.6	21.0	2.10	4.20	
	ng/ml	168	126	210	21.00	42.00	Roche Cobas e601/602
	nmol/l	260	195	325	32.50	65.00	Siemens Centaur CP
	µg/dl	20.3	15.2	25.4	2.55	5.10	
	ng/ml	203	152	254	25.50	51.00	Siemens Centaur CP
	nmol/l	208	156	260	26.00	52.00	Roche Cobas e402/e801
	µg/dl	16.2	12.2	20.2	2.00	4.00	
	ng/ml	162	122	202	20.00	40.00	Roche Cobas e402/e801
Transferrin	g/l	1.79	1.43	2.15	0.18	0.36	Immunoturbidimetric
	mg/dl	179	143	215	18.00	36.00	
Triglycerides	mmol/l	2.95	2.48	3.42	0.24	0.47	Lipase/GPO-PAP no correction
	mg/dl	261	219	303	21.00	42.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Triglycerides	mmol/l	2.94	2.47	3.41	0.24	0.47	Lipase/GPO-PAP 0.11mmol/l correction
	mg/dl	260	219	301	20.50	41.00	
	mmol/l	2.97	2.50	3.44	0.24	0.47	L/G Kinase EP. no correction
	mg/dl	263	221	305	21.00	42.00	
	mmol/l	2.97	2.49	3.45	0.24	0.48	L/G kinase EP. 0.11 mmol/l correction
	mg/dl	263	220	306	21.50	43.00	
	mmol/l	2.97	2.50	3.44	0.24	0.47	Lipase/Glycerol Dehydrogenase
	mg/dl	263	221	305	21.00	42.00	
	mmol/l	3.49	2.93	4.05	0.28	0.56	Ortho Vitros Microslide Systems
	mg/dl	309	259	359	25.00	50.00	
Uric Acid (Urate)	mmol/l	0.52	0.45	0.58	0.03	0.07	Ortho Vitros Microslide Systems
	mg/dl	8.67	7.54	9.80	0.57	1.13	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase catalase 340nm
	mg/dl	9.11	7.93	10.3	0.59	1.18	
	mmol/l	0.56	0.49	0.63	0.04	0.07	Reduction methods
	mg/dl	9.37	8.15	10.6	0.61	1.22	
	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.19	8.00	10.4	0.60	1.19	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.11	7.93	10.3	0.59	1.18	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Spectrophotometric at 280-290
	mg/dl	9.07	7.90	10.2	0.59	1.17	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.04	7.86	10.2	0.59	1.18	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Urea	mmol/l	18.7	15.9	21.5	1.40	2.80	Ortho Vitros Microslide Systems
	mg/dl	112	95.6	128	8.20	16.40	
	mmol/l	19.2	16.3	22.1	1.45	2.90	Urease end point
	mg/dl	115	98.0	132	8.50	17.00	
	mmol/l	19.3	16.4	22.2	1.45	2.90	Urease kinetic
	mg/dl	116	98.6	133	8.70	17.40	
	mmol/l	18.7	15.9	21.5	1.40	2.80	Urease hypochlorite
	mg/dl	112	95.6	128	8.20	16.40	
	mmol/l	19.3	16.4	22.2	1.45	2.90	BUN
	mg/dl	54.2	46.1	62.3	4.05	8.10	
Vitamin B12	pmol/l	296	237	355	29.50	59.00	Roche Cobas e402/e801
	pg/ml	401	321	481	40.00	80.00	
Zinc	µmol/l	32.0	25.6	38.4	3.20	6.40	Atomic absorption
	µg/dl	209	167	251	21.00	42.00	
	µmol/l	32.0	25.6	38.4	3.20	6.40	Colorimetric with deproteinisation
	µg/dl	209	167	251	21.00	42.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Abbott Alinity/ Architect c/ci Systems®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	29.5	25.1	33.9	2.20	4.40	Bromocresol Green
	g/dl	2.95	2.51	3.39	0.22	0.44	
	g/l	28.6	24.3	32.9	2.15	4.30	Bromocresol Purple
	g/dl	2.86	2.43	3.29	0.22	0.43	
Alkaline Phosphatase	U/l	353	300	406	26.50	53.00	AMP optimised to IFCC 37°C
	U/l	352	299	405	26.50	53.00	AMP non-optimised 37°C
	U/l	345	293	397	26.00	52.00	Colorimetric 37°C
ALT (GPT)	U/l	137	110	164	13.50	27.00	Tris buffer without P5P 37°C
Amylase Pancreatic	U/l	251	214	288	18.50	37.00	Immunoinhibition EPS substrate 37°C
Amylase Total	U/l	314	267	361	23.50	47.00	Abbott Architect / Alinity cal factor 3806 37°C
	U/l	308	262	354	23.00	46.00	Abbott Architect / Alinity cal factor 3431 37°C
	U/l	312	265	359	23.50	47.00	Abbott - blocked pNPG7 37°C
AST (GOT)	U/l	125	100	150	12.50	25.00	Tris buffer without P5P 37°C
Bile Acids	µmol/l	44.2	35.4	53.0	4.40	8.80	Enzymatic Colorimetric
Bicarbonate	mmol/l	16.8	13.3	20.3	1.75	3.50	Enzymatic
Bilirubin Direct	µmol/l	30.4	24.0	36.8	3.20	6.40	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.78	1.40	2.16	0.19	0.38	
	µmol/l	31.0	24.5	37.5	3.25	6.50	Diazo with Sulphanilic Acid
	mg/dl	1.81	1.43	2.19	0.19	0.38	
	µmol/l	31.4	24.8	38.0	3.30	6.60	Diazo with Dichloroaniline (DCA)
	mg/dl	1.84	1.45	2.23	0.20	0.39	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Abbott Alinity/ Architect c/ci Systems®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Bilirubin Total	µmol/l	85.2	67.3	103	8.95	17.90	Diazo with Dichloroaniline (DCA)
	mg/dl	4.98	3.94	6.02	0.52	1.04	
	µmol/l	86.4	68.2	105	9.10	18.20	Diazo with Sulphanilic Acid
	mg/dl	5.05	3.99	6.11	0.53	1.06	
Calcium	mmol/l	3.80	3.42	4.18	0.19	0.38	Cresolphthalein complexone
	mg/dl	15.2	13.7	16.7	0.75	1.50	
	mmol/l	3.83	3.45	4.21	0.19	0.38	Arsenazo III
	mg/dl	15.4	13.8	17.0	0.80	1.60	
Cholesterol	mmol/l	7.26	6.32	8.20	0.47	0.94	Cholesterol Oxidase - Abell Kendall
	mg/dl	280	244	316	18.00	36.00	
	mmol/l	7.36	6.40	8.32	0.48	0.96	Cholesterol Oxidase - IDMS
	mg/dl	284	247	321	18.50	37.00	
	mmol/l	7.41	6.45	8.37	0.48	0.96	Cholesterol Dehydrogenase
	mg/dl	286	249	323	18.50	37.00	
Chloride	mmol/l	114	108	120	3.00	6.00	ISE indirect
Cholinesterase	U/l	6165	4932	7398	616.50	1233.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	517	424	610	46.50	93.00	CK-NAC serum start (DGKC) 37°C
	U/l	522	428	616	47.00	94.00	CK-NAC substrate start (DGKC) 37°C
	U/l	520	427	613	46.50	93.00	CK-NAC (IFCC) 37°C
	U/l	525	431	619	47.00	94.00	Abbott CK-NAC (IFCC) 37°C
Creatinine	µmol/l	369	296	442	36.50	73.00	Alkaline picrate with deproteinization
	mg/dl	4.17	3.34	5.00	0.42	0.83	
	µmol/l	380	304	456	38.00	76.00	Alkaline picrate no deproteinization
	mg/dl	4.29	3.44	5.14	0.43	0.85	
	µmol/l	376	301	451	37.50	75.00	Enzymatic UV method
	mg/dl	4.25	3.40	5.10	0.43	0.85	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Abbott Alinity/ Architect c/ci Systems®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Creatinine	µmol/l	393	315	471	39.00	78.00	IDMS traceable
	mg/dl	4.44	3.56	5.32	0.44	0.88	
gamma-GT	U/l	176	150	202	13.00	26.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	177	150	204	13.50	27.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	174	148	200	13.00	26.00	DCL gamma glutamyl-3-carboxy-4-nitroanilide 37°C
Glucose	mmol/l	16.0	13.6	18.4	1.20	2.40	Hexokinase
	mg/dl	288	245	331	21.50	43.00	
	mmol/l	16.1	13.6	18.6	1.25	2.50	Glucose oxidase
	mg/dl	290	245	335	22.50	45.00	
HDL - Cholesterol	mmol/l	2.71	2.30	3.12	0.21	0.41	Direct HDL PPD
	mg/dl	105	88.8	121	8.10	16.20	
	mmol/l	2.48	2.11	2.85	0.19	0.37	Direct HDL Immunoseparation
	mg/dl	95.7	81.4	110	7.15	14.30	
	mmol/l	2.71	2.30	3.12	0.21	0.41	Direct Clearance Method
	mg/dl	105	88.8	121	8.10	16.20	
	mmol/l	2.67	2.27	3.07	0.20	0.40	HDL - Ultra
	mg/dl	103	87.6	118	7.70	15.40	
Iron	µmol/l	41.7	34.2	49.2	3.75	7.50	Colorimetric with ppt.
	µg/dl	233	191	275	21.00	42.00	
	µmol/l	41.6	34.1	49.1	3.75	7.50	Colorimetric without ppt.
	µg/dl	233	191	275	21.00	42.00	
Lactate	mmol/l	6.32	5.18	7.46	0.57	1.14	Colorimetric Lactate Oxidase
	mg/dl	56.9	46.7	67.1	5.10	10.20	
LD (LDH)	U/l	358	304	412	27.00	54.00	L->P 37°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Abbott Alinity/ Architect c/ci Systems®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
LD (LDH)	U/l	354	301	407	26.50	53.00	L->P IFCC 37°C
Lipase	U/l	68	54	82	7.00	14.00	Other Colorimetric 37°C
Lithium	mmol/l	1.98	1.75	2.21	0.12	0.23	Spectrophotometric
	mg/dl	1.37	1.22	1.52	0.08	0.15	
Magnesium	mmol/l	2.02	1.78	2.26	0.12	0.24	Arsenazo III
	mg/dl	4.91	4.33	5.49	0.29	0.58	
	mmol/l	1.97	1.73	2.21	0.12	0.24	Xylidyl Blue
	mg/dl	4.79	4.20	5.38	0.30	0.59	
	mmol/l	2.02	1.78	2.26	0.12	0.24	Enzymatic
	mg/dl	4.91	4.33	5.49	0.29	0.58	
Osmolality	mOsm/kg	349	279	419	35.00	70.00	Calculated
Phosphate Inorganic	mmol/l	2.22	1.88	2.56	0.17	0.34	Phosphomolybdate enzymatic
	mg/dl	6.88	5.83	7.93	0.53	1.05	
	mmol/l	2.21	1.88	2.54	0.17	0.33	Phosphomolybdate UV
	mg/dl	6.85	5.83	7.87	0.51	1.02	
Potassium	mmol/l	6.01	5.71	6.31	0.15	0.30	ISE method - indirect
Protein Total	g/l	47.4	38.0	56.8	4.70	9.40	Biuret reaction end point
	g/dl	4.74	3.80	5.68	0.47	0.94	
	g/l	47.2	37.8	56.6	4.70	9.40	Biuret reaction kinetic
	g/dl	4.72	3.78	5.66	0.47	0.94	
PSA Total	ng/ml =	15.7	11.8	19.6	1.95	3.90	Abbott Architect
Sodium	mmol/l	158	150	166	4.00	8.00	ISE method - indirect
Thyroid Stimulating Hormone	µU/ml =	1.05	0.84	1.26	0.10	0.21	Abbott Architect
TIBC	µmol/l	45.4	35.9	54.9	4.75	9.50	FE+UIBC(saturation with iron)
	µg/dl	254	201	307	26.50	53.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Abbott Alinity/ Architect c/ci Systems®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Triglycerides	mmol/l	2.94	2.47	3.41	0.24	0.47	Lipase/GPO-PAP no correction
	mg/dl	260	219	301	20.50	41.00	
	mmol/l	2.93	2.46	3.40	0.24	0.47	Lipase/GPO-PAP 0.11mmol/l correction
	mg/dl	259	218	300	20.50	41.00	
	mmol/l	2.89	2.43	3.35	0.23	0.46	L/G Kinase EP. no correction
	mg/dl	256	215	297	20.50	41.00	
	mmol/l	2.95	2.48	3.42	0.24	0.47	Lipase/Glycerol Dehydrogenase
	mg/dl	261	219	303	21.00	42.00	
	mmol/l	2.95	2.48	3.42	0.24	0.47	Abbott Architect 2000i
	mg/dl	261	219	303	21.00	42.00	
Uric Acid (Urate)	mmol/l	0.54	0.47	0.62	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.14	7.95	10.3	0.60	1.19	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.14	7.96	10.3	0.59	1.18	
	mmol/l	0.53	0.46	0.60	0.03	0.07	Spectrophotometric at 280-290
	mg/dl	8.90	7.74	10.1	0.58	1.16	
	mmol/l	0.54	0.47	0.61	0.03	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.02	7.86	10.2	0.58	1.16	
Urea	mmol/l	19.9	16.9	22.9	1.50	3.00	Urease end point
	mg/dl	120	102	138	9.00	18.00	
	mmol/l	19.8	16.8	22.8	1.50	3.00	Urease kinetic
	mg/dl	119	101	137	9.00	18.00	
	mmol/l	19.8	16.8	22.8	1.50	3.00	BUN
	mg/dl	55.6	47.3	63.9	4.15	8.30	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

ABX Pentra 400®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	29.8	25.3	34.3	2.25	4.50	Bromocresol Green
	g/dl	2.98	2.53	3.43	0.23	0.45	
ALT (GPT)	U/l	149	119	179	15.00	30.00	Tris buffer without P5P 37°C
AST (GOT)	U/l	149	120	178	14.50	29.00	Tris buffer without P5P 37°C
Bilirubin Direct	µmol/l	28.9	22.9	34.9	3.00	6.00	Diazo with Sulphanilic Acid
	mg/dl	1.69	1.34	2.04	0.18	0.35	
	µmol/l	28.9	22.8	35.0	3.05	6.10	Diazo with Dichloroaniline (DCA)
	mg/dl	1.69	1.33	2.05	0.18	0.36	
Bilirubin Total	µmol/l	90.3	71.4	109	9.45	18.90	Diazo with Dichloroaniline (DCA)
	mg/dl	5.28	4.18	6.38	0.55	1.10	
	µmol/l	90.4	71.4	109	9.50	19.00	Diazo with Sulphanilic Acid
	mg/dl	5.29	4.18	6.40	0.56	1.11	
Calcium	mmol/l	4.05	3.64	4.46	0.21	0.41	Arsenazo III
	mg/dl	16.2	14.6	17.8	0.80	1.60	
Cholesterol	mmol/l	7.60	6.62	8.58	0.49	0.98	Cholesterol Oxidase - Abell Kendall
	mg/dl	293	256	330	18.50	37.00	
Chloride	mmol/l	113	107	119	3.00	6.00	ISE direct
CK Total	U/l	510	418	602	46.00	92.00	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	345	276	414	34.50	69.00	Alkaline picrate no deproteinization
	mg/dl	3.90	3.12	4.68	0.39	0.78	
	µmol/l	342	274	410	34.00	68.00	Jaffe rate blanked
	mg/dl	3.86	3.10	4.62	0.38	0.76	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

ABX Pentra 400®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
gamma-GT	U/l	175	148	202	13.50	27.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	178	151	205	13.50	27.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
Glucose	mmol/l	16.2	13.8	18.6	1.20	2.40	Hexokinase
	mg/dl	292	249	335	21.50	43.00	
	mmol/l	16.6	14.1	19.1	1.25	2.50	Glucose oxidase
	mg/dl	299	254	344	22.50	45.00	
HDL - Cholesterol	mmol/l	2.76	2.35	3.17	0.21	0.41	Direct HDL PPD
	mg/dl	107	90.7	123	8.15	16.30	
	mmol/l	2.81	2.39	3.23	0.21	0.42	Direct HDL PEGME
	mg/dl	108	92.3	124	7.85	15.70	
	mmol/l	2.66	2.26	3.06	0.20	0.40	HDL - Ultra
	mg/dl	103	87.2	119	7.90	15.80	
Iron	µmol/l	38.8	31.8	45.8	3.50	7.00	Colorimetric with ppt.
	µg/dl	217	178	256	19.50	39.00	
	µmol/l	40.1	32.9	47.3	3.60	7.20	Colorimetric without ppt.
	µg/dl	224	184	264	20.00	40.00	
LD (LDH)	U/l	386	328	444	29.00	58.00	L->P IFCC 37°C
Lipase	U/l	68	55	81	6.50	13.00	Other Colorimetric 37°C
Magnesium	mmol/l	1.92	1.69	2.15	0.12	0.23	Xylidyl Blue
	mg/dl	4.67	4.11	5.23	0.28	0.56	
Phosphate Inorganic	mmol/l	2.61	2.22	3.00	0.20	0.39	Phosphomolybdate UV
	mg/dl	8.09	6.88	9.30	0.61	1.21	
Potassium	mmol/l	5.75	5.47	6.03	0.14	0.28	ISE method - direct
Protein Total	g/l	50.0	40.0	60.0	5.00	10.00	Biuret reaction end point
	g/dl	5.00	4.00	6.00	0.50	1.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

ABX Pentra 400®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
Sodium	mmol/l	154	146	162	4.00	8.00	ISE method - direct
Triglycerides	mmol/l	3.08	2.59	3.57	0.25	0.49	Lipase/GPO-PAP no correction
	mg/dl	273	229	317	22.00	44.00	
Uric Acid (Urate)	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.06	7.88	10.2	0.59	1.18	
	mmol/l	0.54	0.47	0.62	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.14	7.95	10.3	0.60	1.19	
	mmol/l	0.52	0.45	0.59	0.03	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	8.75	7.61	9.89	0.57	1.14	
Urea	mmol/l	18.1	15.4	20.8	1.35	2.70	Urease kinetic
	mg/dl	109	92.6	125	8.20	16.40	
	mmol/l	18.1	15.4	20.8	1.35	2.70	BUN
	mg/dl	50.8	43.2	58.4	3.80	7.60	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman Coulter AU Series®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
Albumin	g/l	29.2	24.9	33.5	2.15	4.30	Bromocresol Green
	g/dl	2.92	2.49	3.35	0.22	0.43	
	g/l	29.2	24.8	33.6	2.20	4.40	Bromocresol Purple
	g/dl	2.92	2.48	3.36	0.22	0.44	
Alkaline Phosphatase	U/l	398	339	457	29.50	59.00	AMP optimised to IFCC 37°C
	U/l	395	335	455	30.00	60.00	AMP non-optimised 37°C
ALT (GPT)	U/l	146	117	175	14.50	29.00	Colorimetric 37°C
	U/l	147	117	177	15.00	30.00	Tris buffer without P5P 37°C
	U/l	144	115	173	14.50	29.00	Beckman Mod. IFCC Ref. without P5P 37°C
	U/l	147	118	176	14.50	29.00	Beckman (Extinction Coefficient) 37°C
Amylase Pancreatic	U/l	249	212	286	18.50	37.00	Immunoinhibition EPS substrate 37°C
Amylase Total	U/l	285	242	328	21.50	43.00	pNP Maltotrioside substrates 37°C
	U/l	293	249	337	22.00	44.00	Beckman Synchron CX4/CX5/CX7 37°C
	U/l	291	247	335	22.00	44.00	Beckman AS - dyed amylopectin 37°C
	U/l	289	246	332	21.50	43.00	Beckman Coulter - blocked pNPG7 37°C
	U/l	291	247	335	22.00	44.00	Beckman Synchron AMY7 37°C
	U/l	291	248	334	21.50	43.00	Beckman CNPG3 (Extinction Coeff) 37°C
AST (GOT)	U/l	137	109	165	14.00	28.00	Colorimetric 37°C
	U/l	138	110	166	14.00	28.00	Tris buffer without P5P 37°C
	U/l	134	107	161	13.50	27.00	Tris buffer SCE 37°C
Bicarbonate	mmol/l	20.1	15.9	24.3	2.10	4.20	Enzymatic

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman Coulter AU Series®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Bilirubin Direct	µmol/l	23.4	18.5	28.3	2.45	4.90	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.37	1.08	1.66	0.15	0.29	
	µmol/l	30.6	24.2	37.0	3.20	6.40	Oxidation to Biliverdin/Vanadate
	mg/dl	1.79	1.42	2.16	0.19	0.37	
	µmol/l	23.5	18.6	28.4	2.45	4.90	Diazo/ Sulphanilic Beckman DxC
	mg/dl	1.37	1.09	1.65	0.14	0.28	
Bilirubin Total	µmol/l	82.8	65.4	100	8.70	17.40	Diazo with Dichloroaniline (DCA)
	mg/dl	4.84	3.83	5.85	0.51	1.01	
	µmol/l	85.1	67.2	103	8.95	17.90	Diazo with Sulphanilic Acid
	mg/dl	4.98	3.93	6.03	0.53	1.05	
	µmol/l	83.9	66.3	102	8.80	17.60	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.91	3.88	5.94	0.52	1.03	
	µmol/l	84.8	67.0	103	8.90	17.80	Diazonium ion
	mg/dl	4.96	3.92	6.00	0.52	1.04	
	µmol/l	89.6	70.8	108	9.40	18.80	Oxidation to Biliverdin/Vanadate
	mg/dl	5.24	4.14	6.34	0.55	1.10	
	µmol/l	83.2	65.7	101	8.75	17.50	DPD (Beckman AU)
	mg/dl	4.87	3.84	5.90	0.52	1.03	
Calcium	mmol/l	3.82	3.44	4.20	0.19	0.38	Cresolphthalein complexone
	mg/dl	15.3	13.8	16.8	0.75	1.50	
	mmol/l	3.88	3.49	4.27	0.20	0.39	Ion selective electrode
	mg/dl	15.6	14.0	17.2	0.80	1.60	
	mmol/l	3.87	3.49	4.25	0.19	0.38	Arsenazo III
	mg/dl	15.5	14.0	17.0	0.75	1.50	
	mmol/l	3.86	3.47	4.25	0.20	0.39	NM-BAPTA
	mg/dl	15.5	13.9	17.1	0.80	1.60	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman Coulter AU Series®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Cholesterol	mmol/l	7.43	6.46	8.40	0.49	0.97	Cholesterol Oxidase - Abell Kendall
	mg/dl	287	249	325	19.00	38.00	
	mmol/l	7.52	6.54	8.50	0.49	0.98	Cholesterol Oxidase - IDMS
	mg/dl	290	252	328	19.00	38.00	
	mmol/l	7.55	6.56	8.54	0.50	0.99	Cholesterol Dehydrogenase
	mg/dl	291	253	329	19.00	38.00	
Chloride	mmol/l	113	107	119	3.00	6.00	ISE indirect
Cholinesterase	U/l	5018	4015	6021	501.50	1003.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	552	452	652	50.00	100.00	CK-NAC (IFCC) 37°C
	U/l	561	460	662	50.50	101.00	Monothioglycerol 37°C
	U/l	543	445	641	49.00	98.00	Beckman CK-NAC (Extinction Coeff) 37°C
Copper	µmol/l	25.3	20.2	30.4	2.55	5.10	Colorimetric
	µg/dl	161	128	194	16.50	33.00	
Creatinine	µmol/l	354	283	425	35.50	71.00	Alkaline picrate with deproteinization
	mg/dl	4.00	3.20	4.80	0.40	0.80	
	µmol/l	352	281	423	35.50	71.00	Alkaline picrate no deproteinization
	mg/dl	3.98	3.18	4.78	0.40	0.80	
	µmol/l	367	294	440	36.50	73.00	Enzymatic UV method
	mg/dl	4.15	3.32	4.98	0.42	0.83	
	µmol/l	380	304	456	38.00	76.00	Creatinine PAP method
	mg/dl	4.29	3.44	5.14	0.43	0.85	
	µmol/l	347	277	417	35.00	70.00	Jaffe rate blanked
	mg/dl	3.92	3.13	4.71	0.40	0.79	
	µmol/l	358	287	429	35.50	71.00	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	4.05	3.24	4.86	0.41	0.81	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman Coulter AU Series®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
Creatinine	µmol/l	352	282	422	35.00	70.00	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	3.98	3.19	4.77	0.40	0.79	
	µmol/l	361	289	433	36.00	72.00	IDMS traceable
	mg/dl	4.08	3.27	4.89	0.41	0.81	
D-3-Hydroxybutyrate	mmol/l	1.17	1.00	1.34	0.09	0.17	Tris buffer 100mmol pH 8.5
gamma-GT	U/l	175	149	201	13.00	26.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	181	154	208	13.50	27.00	Gamma glutamyl-4-nitroanilide 37°C
	U/l	181	153	209	14.00	28.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	179	152	206	13.50	27.00	DCL gamma glutamyl-3-carboxy-4-nitroanilide 37°C
	U/l	178	152	204	13.00	26.00	Beckman Szasz (Extinction Coeff) 37°C
Glucose	mmol/l	16.1	13.6	18.6	1.25	2.50	GOD/02-Beckman method
	mg/dl	290	245	335	22.50	45.00	
	mmol/l	15.8	13.4	18.2	1.20	2.40	Glucose dehydrogenase
	mg/dl	285	241	329	22.00	44.00	
	mmol/l	15.9	13.5	18.3	1.20	2.40	Hexokinase
	mg/dl	287	243	331	22.00	44.00	
	mmol/l	16.1	13.7	18.5	1.20	2.40	Glucose oxidase
	mg/dl	290	247	333	21.50	43.00	
HDL - Cholesterol	mmol/l	2.53	2.15	2.91	0.19	0.38	Direct HDL PPD
	mg/dl	97.7	83.0	112	7.35	14.70	
	mmol/l	2.51	2.13	2.89	0.19	0.38	Direct HDL Immunoseparation
	mg/dl	96.9	82.2	112	7.35	14.70	
	mmol/l	2.37	2.01	2.73	0.18	0.36	Direct HDL PEGME
	mg/dl	91.5	77.6	105	6.95	13.90	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman Coulter AU Series®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
HDL - Cholesterol	mmol/l	2.46	2.09	2.83	0.19	0.37	Direct Clearance Method
	mg/dl	95.0	80.7	109	7.15	14.30	
	mmol/l	2.56	2.18	2.94	0.19	0.38	HDL - Ultra
	mg/dl	98.8	84.1	114	7.35	14.70	
	mmol/l	2.73	2.32	3.14	0.21	0.41	Direct HDL Roche 4th Generation
	mg/dl	105	89.6	120	7.70	15.40	
Iron	µmol/l	39.6	32.5	46.7	3.55	7.10	Colorimetric with ppt.
	µg/dl	221	182	260	19.50	39.00	
	µmol/l	39.4	32.3	46.5	3.55	7.10	Colorimetric without ppt.
	µg/dl	220	181	259	19.50	39.00	
Lactate	mmol/l	5.88	4.82	6.94	0.53	1.06	Colorimetric Lactate Oxidase
	mg/dl	53.0	43.4	62.6	4.80	9.60	
LD (LDH)	U/l	369	314	424	27.50	55.00	L->P 37°C
	U/l	780	663	897	58.50	117.00	P->L Scandinavian & Dutch 37°C
	U/l	740	629	851	55.50	111.00	P->L German methods 37°C
	U/l	362	308	416	27.00	54.00	L->P IFCC 37°C
	U/l	370	314	426	28.00	56.00	L to P Beckman (Extinction Coeff) 37°C
Lipase	U/l	71	57	85	7.00	14.00	Other Colorimetric 37°C
Lithium	mmol/l	2.03	1.79	2.27	0.12	0.24	Spectrophotometric
	mg/dl	1.41	1.24	1.58	0.09	0.17	
Magnesium	mmol/l	1.95	1.72	2.18	0.12	0.23	Arsenazo III
	mg/dl	4.74	4.18	5.30	0.28	0.56	
	mmol/l	2.01	1.77	2.25	0.12	0.24	Calmagite
	mg/dl	4.88	4.30	5.46	0.29	0.58	
	mmol/l	2.01	1.77	2.25	0.12	0.24	Xylidyl Blue
	mg/dl	4.88	4.30	5.46	0.29	0.58	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman Coulter AU Series®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Magnesium	mmol/l	2.11	1.86	2.36	0.13	0.25	Methylthymol blue
	mg/dl	5.13	4.52	5.74	0.31	0.61	
Osmolality	mOsm/kg	356	285	427	35.50	71.00	Calculated
Phosphate Inorganic	mmol/l	2.22	1.89	2.55	0.17	0.33	Phosphomolybdate enzymatic
	mg/dl	6.88	5.86	7.90	0.51	1.02	
	mmol/l	2.25	1.91	2.59	0.17	0.34	Phosphomolybdate UV
	mg/dl	6.98	5.92	8.04	0.53	1.06	
	mmol/l	2.26	1.92	2.60	0.17	0.34	Beckman PHOSm (365nm)
	mg/dl	7.01	5.95	8.07	0.53	1.06	
Potassium	mmol/l	6.00	5.70	6.30	0.15	0.30	ISE method - indirect
Protein Total	g/l	45.3	36.2	54.4	4.55	9.10	Biuret reaction CX4/5/7
	g/dl	4.53	3.62	5.44	0.46	0.91	
	g/l	45.8	36.6	55.0	4.60	9.20	Biuret reaction end point
	g/dl	4.58	3.66	5.50	0.46	0.92	
	g/l	45.5	36.4	54.6	4.55	9.10	Biuret reaction kinetic
	g/dl	4.55	3.64	5.46	0.46	0.91	
Sodium	mmol/l	158	150	166	4.00	8.00	ISE method - indirect
TIBC	µmol/l	42.6	33.7	51.5	4.45	8.90	FE+UIBC(saturation with iron)
	µg/dl	238	188	288	25.00	50.00	
	µmol/l	43.1	34.0	52.2	4.55	9.10	Direct Colorimetric
	µg/dl	241	190	292	25.50	51.00	
	µmol/l	36.9	29.1	44.7	3.90	7.80	Calculated from Transferrin
	µg/dl	206	163	249	21.50	43.00	
Triglycerides	mmol/l	2.95	2.48	3.42	0.24	0.47	Lipase/GPO-PAP no correction
	mg/dl	261	219	303	21.00	42.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman Coulter AU Series®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Triglycerides	mmol/l	2.91	2.44	3.38	0.24	0.47	Lipase/GPO-PAP 0.11mmol/l correction
	mg/dl	258	216	300	21.00	42.00	
	mmol/l	2.97	2.50	3.44	0.24	0.47	L/G Kinase EP. no correction
	mg/dl	263	221	305	21.00	42.00	
	mmol/l	2.91	2.45	3.37	0.23	0.46	L/G kinase EP. 0.11 mmol/l correction
	mg/dl	258	217	299	20.50	41.00	
	mmol/l	2.96	2.49	3.43	0.24	0.47	Lipase/Glycerol Dehydrogenase
	mg/dl	262	220	304	21.00	42.00	
Uric Acid (Urate)	mmol/l	0.56	0.49	0.64	0.04	0.07	Reduction methods
	mg/dl	9.44	8.22	10.7	0.61	1.22	
	mmol/l	0.56	0.48	0.63	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.32	8.11	10.5	0.61	1.21	
	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.27	8.08	10.5	0.60	1.19	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Spectrophotometric at 280-290
	mg/dl	9.09	7.91	10.3	0.59	1.18	
	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.21	8.01	10.4	0.60	1.20	
Urea	mmol/l	19.5	16.6	22.4	1.45	2.90	Beckman-Conductivity
	mg/dl	117	99.8	134	8.60	17.20	
	mmol/l	19.3	16.4	22.2	1.45	2.90	Urease end point
	mg/dl	116	98.6	133	8.70	17.40	
	mmol/l	19.4	16.5	22.3	1.45	2.90	Urease kinetic
	mg/dl	117	99.2	135	8.90	17.80	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman Coulter AU Series®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
Urea	mmol/l	19.4	16.5	22.3	1.45	2.90	Urease hypochlorite
	mg/dl	117	99.2	135	8.90	17.80	
	mmol/l	19.4	16.5	22.3	1.45	2.90	BUN
	mg/dl	54.4	46.2	62.6	4.10	8.20	
Zinc	µmol/l	30.9	24.7	37.1	3.10	6.20	Colorimetric with deproteinisation
	µg/dl	202	161	243	20.50	41.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman DxC600/800®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	29.6	25.2	34.0	2.20	4.40	Bromocresol Purple
	g/dl	2.96	2.52	3.40	0.22	0.44	
Alkaline Phosphatase	U/l	366	311	421	27.50	55.00	AMP optimised to IFCC 37°C
	U/l	369	314	424	27.50	55.00	AMP non-optimised 37°C
ALT (GPT)	U/l	136	109	163	13.50	27.00	Beckman Mod. IFCC Ref. without P5P 37°C
Amylase Total	U/l	294	250	338	22.00	44.00	Beckman Synchron AMY7 37°C
AST (GOT)	U/l	128	103	153	12.50	25.00	Beckman Mod. IFCC Ref. without P5P 37°C
Bilirubin Total	µmol/l	82.3	65.0	99.6	8.65	17.30	Diazo with Sulphanilic Acid
	mg/dl	4.81	3.80	5.82	0.51	1.01	
Calcium	mmol/l	3.83	3.45	4.21	0.19	0.38	Ion selective electrode
	mg/dl	15.4	13.8	17.0	0.80	1.60	
Cholesterol	mmol/l	7.38	6.42	8.34	0.48	0.96	Cholesterol Oxidase - Abell Kendall
	mg/dl	285	248	322	18.50	37.00	
Chloride	mmol/l	114	108	120	3.00	6.00	ISE indirect
Cholinesterase	U/l	5382	4306	6458	538.00	1076.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	554	454	654	50.00	100.00	Monothioglycerol 37°C
Creatinine	µmol/l	357	286	428	35.50	71.00	Alkaline picrate no deproteinization
	mg/dl	4.03	3.23	4.83	0.40	0.80	
	µmol/l	375	300	450	37.50	75.00	Jaffe rate blanked
	mg/dl	4.24	3.39	5.09	0.43	0.85	
	µmol/l	371	297	445	37.00	74.00	IDMS traceable
	mg/dl	4.19	3.36	5.02	0.42	0.83	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman DxC600/800®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Glucose	mmol/l	15.7	13.3	18.1	1.20	2.40	Hexokinase
	mg/dl	283	240	326	21.50	43.00	
HDL - Cholesterol	mmol/l	2.56	2.17	2.95	0.20	0.39	Direct HDL PPD
	mg/dl	98.8	83.8	114	7.50	15.00	
Iron	µmol/l	39.3	32.2	46.4	3.55	7.10	Colorimetric without ppt.
	µg/dl	220	180	260	20.00	40.00	
Lactate	mmol/l	5.72	4.69	6.75	0.52	1.03	Colorimetric Lactate Oxidase
	mg/dl	51.5	42.3	60.7	4.60	9.20	
LD (LDH)	U/l	308	261	355	23.50	47.00	L->P 37°C
Lipase	U/l	79	63	95	8.00	16.00	Other Colorimetric 37°C
Magnesium	mmol/l	1.96	1.73	2.19	0.12	0.23	Calmagite
	mg/dl	4.76	4.20	5.32	0.28	0.56	
Phosphate Inorganic	mmol/l	2.29	1.95	2.63	0.17	0.34	Phosphomolybdate UV
	mg/dl	7.10	6.05	8.15	0.53	1.05	
Potassium	mmol/l	6.03	5.73	6.33	0.15	0.30	ISE method - indirect
Protein Total	g/l	46.2	37.0	55.4	4.60	9.20	Biuret reaction end point
	g/dl	4.62	3.70	5.54	0.46	0.92	
Sodium	mmol/l	157	149	165	4.00	8.00	ISE method - indirect
Triglycerides	mmol/l	3.09	2.59	3.59	0.25	0.50	Lipase/GPO-PAP no correction
	mg/dl	273	229	317	22.00	44.00	
	mmol/l	2.88	2.42	3.34	0.23	0.46	L/G Kinase EP. no correction
	mg/dl	255	214	296	20.50	41.00	
Uric Acid (Urate)	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.07	7.88	10.3	0.60	1.19	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman DxC600/800®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Urea	mmol/l	19.3	16.4	22.2	1.45	2.90	Beckman-Conductivity
	mg/dl	116	98.6	133	8.70	17.40	
	mmol/l	19.5	16.5	22.5	1.50	3.00	Urease kinetic
	mg/dl	117	99.2	135	8.90	17.80	
	mmol/l	19.5	16.6	22.4	1.45	2.90	BUN
	mg/dl	54.7	46.5	62.9	4.10	8.20	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

BIOSYSTEMS A15

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	31.7	26.9	36.5	2.40	4.80	Bromocresol Green
	g/dl	3.17	2.69	3.65	0.24	0.48	
Alkaline Phosphatase	U/l	362	308	416	27.00	54.00	AMP optimised to IFCC 37°C
	U/l	282	240	324	21.00	42.00	AMP optimised to IFCC 30°C
	U/l	231	197	265	17.00	34.00	AMP optimised to IFCC 25°C
ALT (GPT)	U/l	145	116	174	14.50	29.00	Tris buffer without P5P 37°C
	U/l	107	86	128	10.50	21.00	Tris buffer without P5P 30°C
	U/l	82	65	99	8.50	17.00	Tris buffer without P5P 25°C
AST (GOT)	U/l	140	112	168	14.00	28.00	Tris buffer without P5P 37°C
	U/l	95	76	114	9.50	19.00	Tris buffer without P5P 30°C
	U/l	67	53	81	7.00	14.00	Tris buffer without P5P 25°C
Bilirubin Total	µmol/l	83.1	65.7	101	8.70	17.40	Diazo with Sulphanilic Acid
	mg/dl	4.86	3.84	5.88	0.51	1.02	
	µmol/l	81.5	64.4	98.6	8.55	17.10	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.77	3.77	5.77	0.50	1.00	
Calcium	mmol/l	3.50	3.15	3.85	0.18	0.35	Arsenazo III
	mg/dl	14.0	12.6	15.4	0.70	1.40	
Cholesterol	mmol/l	7.47	6.50	8.44	0.49	0.97	Cholesterol Oxidase - Abell Kendall
	mg/dl	288	251	325	18.50	37.00	
	mmol/l	7.37	6.41	8.33	0.48	0.96	Cholesterol Oxidase - IDMS
	mg/dl	284	247	321	18.50	37.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

BIOSYSTEMS A15

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Creatinine	µmol/l	345	276	414	34.50	69.00	Alkaline picrate no deproteinization
	mg/dl	3.90	3.12	4.68	0.39	0.78	
	µmol/l	357	286	428	35.50	71.00	Jaffe rate blanked
	mg/dl	4.03	3.23	4.83	0.40	0.80	
gamma-GT	U/l	174	148	200	13.00	26.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	137	117	157	10.00	20.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	107	91	123	8.00	16.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
Glucose	mmol/l	15.8	13.4	18.2	1.20	2.40	Glucose oxidase
	mg/dl	285	241	329	22.00	44.00	
Phosphate Inorganic	mmol/l	2.31	1.97	2.65	0.17	0.34	Phosphomolybdate UV
	mg/dl	7.16	6.11	8.21	0.53	1.05	
Protein Total	g/l	49.2	39.4	59.0	4.90	9.80	Biuret reaction end point
	g/dl	4.92	3.94	5.90	0.49	0.98	
Triglycerides	mmol/l	2.92	2.45	3.39	0.24	0.47	Lipase/GPO-PAP no correction
	mg/dl	258	217	299	20.50	41.00	
Uric Acid (Urate)	mmol/l	0.57	0.49	0.64	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.51	8.28	10.7	0.62	1.23	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.11	7.91	10.3	0.60	1.20	
	mmol/l	0.55	0.48	0.63	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.29	8.08	10.5	0.61	1.21	
Urea	mmol/l	17.0	14.4	19.6	1.30	2.60	Urease end point
	mg/dl	102	86.5	118	7.75	15.50	
	mmol/l	19.0	16.2	21.8	1.40	2.80	Urease kinetic
	mg/dl	114	97.4	131	8.30	16.60	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

BIOSYSTEMS A15

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Urea	mmol/l	19.0	16.2	21.8	1.40	2.80	BUN
	mg/dl	53.3	45.3	61.3	4.00	8.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

BIOSYSTEMS A25

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	31.7	26.9	36.5	2.40	4.80	Bromocresol Green
	g/dl	3.17	2.69	3.65	0.24	0.48	
ALT (GPT)	U/l	151	121	181	15.00	30.00	Tris buffer without P5P 37°C
	U/l	112	90	134	11.00	22.00	Tris buffer without P5P 30°C
	U/l	85	68	102	8.50	17.00	Tris buffer without P5P 25°C
AST (GOT)	U/l	143	114	172	14.50	29.00	Tris buffer without P5P 37°C
	U/l	97	77	117	10.00	20.00	Tris buffer without P5P 30°C
	U/l	68	54	82	7.00	14.00	Tris buffer without P5P 25°C
Bilirubin Total	µmol/l	81.4	64.3	98.5	8.55	17.10	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.76	3.76	5.76	0.50	1.00	
Cholesterol	mmol/l	7.47	6.50	8.44	0.49	0.97	Cholesterol Oxidase - Abell Kendall
	mg/dl	288	251	325	18.50	37.00	
	mmol/l	7.19	6.25	8.13	0.47	0.94	Cholesterol Oxidase - IDMS
	mg/dl	278	241	315	18.50	37.00	
Creatinine	µmol/l	361	289	433	36.00	72.00	Alkaline picrate no deproteinization
	mg/dl	4.08	3.27	4.89	0.41	0.81	
	µmol/l	347	278	416	34.50	69.00	Jaffe rate blanked
	mg/dl	3.92	3.14	4.70	0.39	0.78	
gamma-GT	U/l	180	153	207	13.50	27.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	142	121	163	10.50	21.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	111	94	128	8.50	17.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

BIOSYSTEMS A25

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Glucose	mmol/l	15.8	13.4	18.2	1.20	2.40	Glucose oxidase
	mg/dl	285	241	329	22.00	44.00	
HDL - Cholesterol	mmol/l	2.42	2.06	2.78	0.18	0.36	Direct Clearance Method
	mg/dl	93.4	79.5	107	6.95	13.90	
Phosphate Inorganic	mmol/l	2.40	2.04	2.76	0.18	0.36	Phosphomolybdate UV
	mg/dl	7.44	6.32	8.56	0.56	1.12	
Protein Total	g/l	49.2	39.3	59.1	4.95	9.90	Biuret reaction end point
	g/dl	4.92	3.93	5.91	0.50	0.99	
Triglycerides	mmol/l	2.81	2.36	3.26	0.23	0.45	Lipase/GPO-PAP no correction
	mg/dl	249	209	289	20.00	40.00	
	mmol/l	2.96	2.49	3.43	0.24	0.47	L/G Kinase EP. no correction
	mg/dl	262	220	304	21.00	42.00	
	mmol/l	2.86	2.40	3.32	0.23	0.46	Lipase/Glycerol Dehydrogenase
	mg/dl	253	212	294	20.50	41.00	
Uric Acid (Urate)	mmol/l	0.56	0.49	0.64	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.46	8.23	10.7	0.62	1.23	
	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.26	8.06	10.5	0.60	1.20	
Urea	mmol/l	17.9	15.2	20.6	1.35	2.70	Urease kinetic
	mg/dl	108	91.4	125	8.30	16.60	
	mmol/l	17.9	15.2	20.6	1.35	2.70	BUN
	mg/dl	50.2	42.7	57.7	3.75	7.50	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Biotecnica/Wiener BT and CB Series

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	30.7	26.1	35.3	2.30	4.60	Bromocresol Green
	g/dl	3.07	2.61	3.53	0.23	0.46	
Alkaline Phosphatase	U/l	365	310	420	27.50	55.00	AMP optimised to IFCC 37°C
	U/l	284	241	327	21.50	43.00	AMP optimised to IFCC 30°C
	U/l	233	198	268	17.50	35.00	AMP optimised to IFCC 25°C
ALT (GPT)	U/l	140	112	168	14.00	28.00	Tris buffer without P5P 37°C
	U/l	104	83	125	10.50	21.00	Tris buffer without P5P 30°C
	U/l	79	63	95	8.00	16.00	Tris buffer without P5P 25°C
AST (GOT)	U/l	134	107	161	13.50	27.00	Tris buffer without P5P 37°C
	U/l	91	72	110	9.50	19.00	Tris buffer without P5P 30°C
	U/l	64	51	77	6.50	13.00	Tris buffer without P5P 25°C
Bilirubin Direct	µmol/l	31.0	24.5	37.5	3.25	6.50	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.81	1.43	2.19	0.19	0.38	
	µmol/l	27.4	21.6	33.2	2.90	5.80	Diazo with Sulphanilic Acid
	mg/dl	1.60	1.26	1.94	0.17	0.34	
	µmol/l	25.4	20.1	30.7	2.65	5.30	Diazo with Dichloroaniline (DCA)
	mg/dl	1.49	1.18	1.80	0.16	0.31	
Bilirubin Total	µmol/l	83.2	65.7	101	8.75	17.50	Diazo with Dichloroaniline (DCA)
	mg/dl	4.87	3.84	5.90	0.52	1.03	
	µmol/l	75.3	59.5	91.1	7.90	15.80	Diazo with Sulphanilic Acid
	mg/dl	4.41	3.48	5.34	0.47	0.93	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Biotecnica/Wiener BT and CB Series

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Bilirubin Total	µmol/l	76.5	60.4	92.6	8.05	16.10	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.48	3.53	5.43	0.48	0.95	
Calcium	mmol/l	3.82	3.44	4.20	0.19	0.38	Cresolphthalein complexone
	mg/dl	15.3	13.8	16.8	0.75	1.50	
	mmol/l	3.63	3.27	3.99	0.18	0.36	Arsenazo III
	mg/dl	14.5	13.1	15.9	0.70	1.40	
Cholesterol	mmol/l	7.35	6.39	8.31	0.48	0.96	Cholesterol Oxidase - Abell Kendall
	mg/dl	284	247	321	18.50	37.00	
	mmol/l	7.43	6.47	8.39	0.48	0.96	Cholesterol Oxidase - IDMS
	mg/dl	287	250	324	18.50	37.00	
Chloride	mmol/l	110	105	115	2.50	5.00	Colorimetric
Cholinesterase	U/l	5198	4158	6238	520.00	1040.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	518	425	611	46.50	93.00	CK-NAC (IFCC) 37°C
	U/l	324	266	382	29.00	58.00	CK-NAC (IFCC) 30°C
	U/l	220	181	259	19.50	39.00	CK-NAC (IFCC) 25°C
Creatinine	µmol/l	349	280	418	34.50	69.00	Alkaline picrate no deproteinization
	mg/dl	3.94	3.16	4.72	0.39	0.78	
	µmol/l	398	319	477	39.50	79.00	Creatinine PAP method
	mg/dl	4.50	3.60	5.40	0.45	0.90	
	µmol/l	341	273	409	34.00	68.00	Jaffe rate blanked
	mg/dl	3.85	3.08	4.62	0.39	0.77	
gamma-GT	U/l	173	147	199	13.00	26.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	136	116	156	10.00	20.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	107	91	123	8.00	16.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
	U/l	170	144	196	13.00	26.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	134	113	155	10.50	21.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	105	89	121	8.00	16.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Biotecnica/Wiener BT and CB Series

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Glucose	mmol/l	15.8	13.5	18.1	1.15	2.30	Glucose oxidase
	mg/dl	285	243	327	21.00	42.00	
HDL - Cholesterol	mmol/l	2.55	2.16	2.94	0.20	0.39	Direct HDL PPD
	mg/dl	98.4	83.4	113	7.50	15.00	
	mmol/l	2.56	2.18	2.94	0.19	0.38	Direct Clearance Method
	mg/dl	98.8	84.1	114	7.35	14.70	
Iron	µmol/l	35.9	29.5	42.3	3.20	6.40	Colorimetric with ppt.
	µg/dl	201	165	237	18.00	36.00	
LD (LDH)	U/l	631	536	726	47.50	95.00	P->L German methods 37°C
	U/l	456	387	525	34.50	69.00	P->L German methods 30°C
	U/l	320	272	368	24.00	48.00	P->L German methods 25°C
Phosphate Inorganic	mmol/l	2.39	2.04	2.74	0.18	0.35	Phosphomolybdate UV
	mg/dl	7.41	6.32	8.50	0.55	1.09	
Potassium	mmol/l	6.09	5.78	6.40	0.16	0.31	ISE method - direct
Protein Total	g/l	50.9	40.7	61.1	5.10	10.20	Biuret reaction end point
	g/dl	5.09	4.07	6.11	0.51	1.02	
Sodium	mmol/l	157	150	164	3.50	7.00	ISE method - direct
Triglycerides	mmol/l	2.91	2.45	3.37	0.23	0.46	Lipase/GPO-PAP no correction
	mg/dl	258	217	299	20.50	41.00	
Uric Acid (Urate)	mmol/l	0.55	0.47	0.62	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.16	7.96	10.4	0.60	1.20	
	mmol/l	0.53	0.46	0.60	0.03	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	8.95	7.80	10.1	0.58	1.15	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Biotecnica/Wiener BT and CB Series

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Uric Acid (Urate)	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.11	7.93	10.3	0.59	1.18	
Urea	mmol/l	18.9	16.1	21.7	1.40	2.80	Urease kinetic
	mg/dl	114	96.8	131	8.60	17.20	
	mmol/l	18.9	16.1	21.7	1.40	2.80	BUN
	mg/dl	53.0	45.1	60.9	3.95	7.90	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

COBAS INTEGRA®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	30.1	25.6	34.6	2.25	4.50	Bromocresol Purple
	g/dl	3.01	2.56	3.46	0.23	0.45	
	g/l	31.6	26.9	36.3	2.35	4.70	Turbidimetric Assays
	g/dl	3.16	2.69	3.63	0.24	0.47	
Alkaline Phosphatase	U/l	347	295	399	26.00	52.00	Roche Integra AMP buffer 37°C
	U/l	270	230	310	20.00	40.00	Roche Integra AMP buffer 30°C
	U/l	222	189	255	16.50	33.00	Roche Integra AMP buffer 25°C
	U/l	345	293	397	26.00	52.00	AMP optimised to IFCC 37°C
	U/l	269	228	310	20.50	41.00	AMP optimised to IFCC 30°C
	U/l	220	187	253	16.50	33.00	AMP optimised to IFCC 25°C
	U/l	343	291	395	26.00	52.00	Colorimetric 37°C
	U/l	267	227	307	20.00	40.00	Colorimetric 30°C
	U/l	219	186	252	16.50	33.00	Colorimetric 25°C
ALT (GPT)	U/l	132	106	158	13.00	26.00	Tris buffer without P5P 37°C
	U/l	98	78	118	10.00	20.00	Tris buffer without P5P 30°C
	U/l	74	60	88	7.00	14.00	Tris buffer without P5P 25°C
Amylase Total	U/l	281	239	323	21.00	42.00	Roche Integra 2-chloro-pNPG7 37°C
	U/l	281	239	323	21.00	42.00	Roche liquid stable pNPG7 37°C
AST (GOT)	U/l	126	101	151	12.50	25.00	Tris buffer without P5P 37°C
	U/l	85	68	102	8.50	17.00	Tris buffer without P5P 30°C
	U/l	60	48	72	6.00	12.00	Tris buffer without P5P 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

COBAS INTEGRA®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Bicarbonate	mmol/l	18.8	14.9	22.7	1.95	3.90	Enzymatic
	mmol/l	17.7	14.1	21.3	1.80	3.60	
Bilirubin Direct	µmol/l	31.7	25.0	38.4	3.35	6.70	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.85	1.46	2.24	0.20	0.39	
	µmol/l	31.9	25.2	38.6	3.35	6.70	Diazo with Sulphanilic Acid
	mg/dl	1.87	1.47	2.27	0.20	0.40	
	µmol/l	32.0	25.3	38.7	3.35	6.70	Roche DPD JG standardised
	mg/dl	1.87	1.48	2.26	0.20	0.39	
	µmol/l	31.0	24.5	37.5	3.25	6.50	Diazo with Dichloroaniline (DCA)
	mg/dl	1.81	1.43	2.19	0.19	0.38	
	µmol/l	32.0	25.3	38.7	3.35	6.70	Roche DPD Doumas standardised
	mg/dl	1.87	1.48	2.26	0.20	0.39	
Bilirubin Total	µmol/l	75.3	59.5	91.1	7.90	15.80	Diazo with Dichloroaniline (DCA)
	mg/dl	4.41	3.48	5.34	0.47	0.93	
	µmol/l	76.2	60.2	92.2	8.00	16.00	Diazo with Sulphanilic Acid
	mg/dl	4.46	3.52	5.40	0.47	0.94	
	µmol/l	76.3	60.3	92.3	8.00	16.00	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.46	3.53	5.39	0.47	0.93	
	µmol/l	76.4	60.3	92.5	8.05	16.10	Diazonium ion
	mg/dl	4.47	3.53	5.41	0.47	0.94	
Calcium	mmol/l	3.89	3.50	4.28	0.20	0.39	Cresolphthalein complexone
	mg/dl	15.6	14.0	17.2	0.80	1.60	
	mmol/l	3.87	3.49	4.25	0.19	0.38	Arsenazo III
	mg/dl	15.5	14.0	17.0	0.75	1.50	
	mmol/l	3.92	3.53	4.31	0.20	0.39	NM-BAPTA
	mg/dl	15.7	14.1	17.3	0.80	1.60	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

COBAS INTEGRA®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Cholesterol	mmol/l	7.30	6.35	8.25	0.48	0.95	Cholesterol Oxidase - Abell Kendall
	mg/dl	282	245	319	18.50	37.00	
	mmol/l	7.27	6.32	8.22	0.48	0.95	Cholesterol Oxidase - IDMS
	mg/dl	281	244	318	18.50	37.00	
Chloride	mmol/l	114	109	119	2.50	5.00	ISE indirect
CK Total	U/l	508	416	600	46.00	92.00	CK-NAC serum start (DGKC) 37°C
	U/l	318	260	376	29.00	58.00	CK-NAC serum start (DGKC) 30°C
	U/l	216	177	255	19.50	39.00	CK-NAC serum start (DGKC) 25°C
	U/l	505	414	596	45.50	91.00	CK-NAC substrate start (DGKC) 37°C
	U/l	316	259	373	28.50	57.00	CK-NAC substrate start (DGKC) 30°C
	U/l	215	176	254	19.50	39.00	CK-NAC substrate start (DGKC) 25°C
	U/l	508	416	600	46.00	92.00	CK-NAC (IFCC) 37°C
	U/l	318	260	376	29.00	58.00	CK-NAC (IFCC) 30°C
	U/l	216	177	255	19.50	39.00	CK-NAC (IFCC) 25°C
Creatinine	µmol/l	351	281	421	35.00	70.00	Alkaline picrate with deproteinization
	mg/dl	3.97	3.18	4.76	0.40	0.79	
	µmol/l	365	292	438	36.50	73.00	Alkaline picrate no deproteinization
	mg/dl	4.12	3.30	4.94	0.41	0.82	
	µmol/l	377	302	452	37.50	75.00	Roche Creatinine Plus
	mg/dl	4.26	3.41	5.11	0.43	0.85	
	µmol/l	334	268	400	33.00	66.00	Jaffe rate blanked
	mg/dl	3.77	3.03	4.51	0.37	0.74	
	µmol/l	354	283	425	35.50	71.00	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	4.00	3.20	4.80	0.40	0.80	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

COBAS INTEGRA®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Creatinine	µmol/l	353	283	423	35.00	70.00	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	3.99	3.20	4.78	0.40	0.79	
	µmol/l	366	293	439	36.50	73.00	IDMS traceable
	mg/dl	4.14	3.31	4.97	0.42	0.83	
gamma-GT	U/l	176	149	203	13.50	27.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	139	117	161	11.00	22.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	109	92	126	8.50	17.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
	U/l	183	155	211	14.00	28.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	144	122	166	11.00	22.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	113	96	130	8.50	17.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
Glucose	mmol/l	16.3	13.8	18.8	1.25	2.50	Hexokinase
	mg/dl	294	249	339	22.50	45.00	
	mmol/l	16.2	13.7	18.7	1.25	2.50	Glucose oxidase
	mg/dl	292	247	337	22.50	45.00	
Iron	µmol/l	39.0	32.0	46.0	3.50	7.00	Colorimetric with ppt.
	µg/dl	218	179	257	19.50	39.00	
	µmol/l	39.6	32.5	46.7	3.55	7.10	Colorimetric without ppt.
	µg/dl	221	182	260	19.50	39.00	
LD (LDH)	U/l	374	318	430	28.00	56.00	L->P 37°C
	U/l	270	230	310	20.00	40.00	L->P 30°C
	U/l	190	161	219	14.50	29.00	L->P 25°C
	U/l	373	317	429	28.00	56.00	L->P IFCC 37°C
	U/l	269	229	309	20.00	40.00	L->P IFCC 30°C
	U/l	189	161	217	14.00	28.00	L->P IFCC 25°C
Lipase	U/l	72	58	86	7.00	14.00	Roche Colorimetric 37°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

COBAS INTEGRA®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Lithium	mmol/l	2.13	1.88	2.38	0.13	0.25	Ion selective electrode
	mg/dl	1.48	1.31	1.65	0.09	0.17	
Magnesium	mmol/l	1.96	1.73	2.19	0.12	0.23	Xylidyl Blue
	mg/dl	4.76	4.20	5.32	0.28	0.56	
	mmol/l	1.96	1.73	2.19	0.12	0.23	Chlorphosphonazo III
	mg/dl	4.76	4.20	5.32	0.28	0.56	
Phosphate Inorganic	mmol/l	2.27	1.93	2.61	0.17	0.34	Phosphomolybdate enzymatic
	mg/dl	7.04	5.98	8.10	0.53	1.06	
	mmol/l	2.29	1.94	2.64	0.18	0.35	Phosphomolybdate UV
	mg/dl	7.10	6.01	8.19	0.55	1.09	
Potassium	mmol/l	6.04	5.74	6.34	0.15	0.30	ISE method - indirect
Protein Total	g/l	44.2	35.4	53.0	4.40	8.80	Biuret reaction end point
	g/dl	4.42	3.54	5.30	0.44	0.88	
	g/l	45.0	36.0	54.0	4.50	9.00	Biuret reaction kinetic
	g/dl	4.50	3.60	5.40	0.45	0.90	
Sodium	mmol/l	157	149	165	4.00	8.00	ISE method - indirect
TIBC	µmol/l	40.7	32.1	49.3	4.30	8.60	FE+UIBC(saturation with iron)
	µg/dl	228	179	277	24.50	49.00	
Triglycerides	mmol/l	3.03	2.55	3.51	0.24	0.48	Lipase/GPO-PAP no correction
	mg/dl	268	226	310	21.00	42.00	
	mmol/l	2.95	2.48	3.42	0.24	0.47	Lipase/GPO-PAP 0.11mmol/l correction
	mg/dl	261	219	303	21.00	42.00	
	mmol/l	2.96	2.48	3.44	0.24	0.48	L/G Kinase EP. no correction
	mg/dl	262	219	305	21.50	43.00	
	mmol/l	3.04	2.56	3.52	0.24	0.48	L/G kinase EP. 0.11 mmol/l correction
	mg/dl	269	227	311	21.00	42.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

COBAS INTEGRA®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Triglycerides	mmol/l	3.03	2.55	3.51	0.24	0.48	Lipase/Glycerol Dehydrogenase
	mg/dl	268	226	310	21.00	42.00	
Uric Acid (Urate)	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.22	8.01	10.4	0.61	1.21	
	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.22	8.03	10.4	0.60	1.19	
	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.24	8.03	10.5	0.61	1.21	
Urea	mmol/l	18.6	15.8	21.4	1.40	2.80	Urease end point
	mg/dl	112	95.0	129	8.50	17.00	
	mmol/l	18.8	16.0	21.6	1.40	2.80	Urease kinetic
	mg/dl	113	96.2	130	8.40	16.80	
	mmol/l	18.8	16.0	21.6	1.40	2.80	BUN
	mg/dl	52.8	44.9	60.7	3.95	7.90	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Elitech/Vitalab Selectra Series

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	31.2	26.5	35.9	2.35	4.70	Bromocresol Green
	g/dl	3.12	2.65	3.59	0.24	0.47	
ALT (GPT)	U/l	142	113	171	14.50	29.00	Tris buffer without P5P 37°C
AST (GOT)	U/l	135	108	162	13.50	27.00	Tris buffer without P5P 37°C
Bilirubin Total	µmol/l	75.0	59.2	90.8	7.90	15.80	Diazo with Sulphanilic Acid
	mg/dl	4.39	3.46	5.32	0.47	0.93	
Calcium	mmol/l	3.79	3.41	4.17	0.19	0.38	Arsenazo III
	mg/dl	15.2	13.7	16.7	0.75	1.50	
Cholesterol	mmol/l	7.34	6.38	8.30	0.48	0.96	Cholesterol Oxidase - Abell Kendall
	mg/dl	283	246	320	18.50	37.00	
	mmol/l	7.45	6.48	8.42	0.49	0.97	Cholesterol Oxidase - IDMS
	mg/dl	288	250	326	19.00	38.00	
CK Total	U/l	534	437	631	48.50	97.00	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	357	286	428	35.50	71.00	Alkaline picrate no deproteinization
	mg/dl	4.03	3.23	4.83	0.40	0.80	
	µmol/l	368	295	441	36.50	73.00	Creatinine PAP method
	mg/dl	4.16	3.33	4.99	0.42	0.83	
	µmol/l	363	291	435	36.00	72.00	Jaffe rate blanked
	mg/dl	4.10	3.29	4.91	0.41	0.81	
gamma-GT	U/l	178	151	205	13.50	27.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
Glucose	mmol/l	15.5	13.2	17.8	1.15	2.30	Hexokinase
	mg/dl	279	238	320	20.50	41.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Elitech/Vitalab Selectra Series

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Glucose	mmol/l	16.0	13.6	18.4	1.20	2.40	Glucose oxidase
	mg/dl	288	245	331	21.50	43.00	
Iron	µmol/l	35.5	29.1	41.9	3.20	6.40	Colorimetric without ppt.
	µg/dl	198	163	233	17.50	35.00	
LD (LDH)	U/l	377	320	434	28.50	57.00	L->P IFCC 37°C
Phosphate Inorganic	mmol/l	2.33	1.98	2.68	0.18	0.35	Phosphomolybdate UV
	mg/dl	7.22	6.14	8.30	0.54	1.08	
Protein Total	g/l	50.6	40.5	60.7	5.05	10.10	Biuret reaction end point
	g/dl	5.06	4.05	6.07	0.51	1.01	
Triglycerides	mmol/l	2.97	2.49	3.45	0.24	0.48	Lipase/GPO-PAP no correction
	mg/dl	263	220	306	21.50	43.00	
Uric Acid (Urate)	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.26	8.06	10.5	0.60	1.20	
	mmol/l	0.57	0.50	0.65	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.64	8.40	10.9	0.62	1.24	
Urea	mmol/l	18.9	16.1	21.7	1.40	2.80	Urease kinetic
	mg/dl	114	96.8	131	8.60	17.20	
	mmol/l	18.9	16.1	21.7	1.40	2.80	BUN
	mg/dl	53.0	45.1	60.9	3.95	7.90	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

HITACHI SERIES®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	30.2	25.7	34.7	2.25	4.50	Bromocresol Green
	g/dl	3.02	2.57	3.47	0.23	0.45	
ALT (GPT)	U/l	144	115	173	14.50	29.00	Tris buffer without P5P 37°C
	U/l	107	85	129	11.00	22.00	Tris buffer without P5P 30°C
	U/l	81	65	97	8.00	16.00	Tris buffer without P5P 25°C
AST (GOT)	U/l	137	109	165	14.00	28.00	Tris buffer without P5P 37°C
	U/l	93	74	112	9.50	19.00	Tris buffer without P5P 30°C
	U/l	65	52	78	6.50	13.00	Tris buffer without P5P 25°C
Bilirubin Direct	µmol/l	27.4	21.6	33.2	2.90	5.80	Diazo with Sulphanilic Acid
	mg/dl	1.60	1.26	1.94	0.17	0.34	
	µmol/l	27.3	21.6	33.0	2.85	5.70	Diazo with Dichloroaniline (DCA)
	mg/dl	1.60	1.26	1.94	0.17	0.34	
Bilirubin Total	µmol/l	83.6	66.1	101	8.75	17.50	Diazo with Dichloroaniline (DCA)
	mg/dl	4.89	3.87	5.91	0.51	1.02	
	µmol/l	84.3	66.6	102	8.85	17.70	Diazo with Sulphanilic Acid
	mg/dl	4.93	3.90	5.96	0.52	1.03	
Calcium	mmol/l	3.97	3.57	4.37	0.20	0.40	Cresolphthalein complexone
	mg/dl	15.9	14.3	17.5	0.80	1.60	
	mmol/l	3.79	3.41	4.17	0.19	0.38	Arsenazo III
	mg/dl	15.2	13.7	16.7	0.75	1.50	
Cholesterol	mmol/l	7.38	6.42	8.34	0.48	0.96	Cholesterol Oxidase - Abell Kendall
	mg/dl	285	248	322	18.50	37.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

HITACHI SERIES®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Cholesterol	mmol/l	7.37	6.41	8.33	0.48	0.96	Cholesterol Oxidase - IDMS
	mg/dl	284	247	321	18.50	37.00	
	mmol/l	7.49	6.52	8.46	0.49	0.97	Cholesterol Dehydrogenase
	mg/dl	289	252	326	18.50	37.00	
Chloride	mmol/l	114	108	120	3.00	6.00	Colorimetric
	mmol/l	112	106	118	3.00	6.00	ISE indirect
CK Total	U/l	525	431	619	47.00	94.00	CK-NAC (IFCC) 37°C
	U/l	329	270	388	29.50	59.00	CK-NAC (IFCC) 30°C
	U/l	223	183	263	20.00	40.00	CK-NAC (IFCC) 25°C
Creatinine	µmol/l	345	276	414	34.50	69.00	Alkaline picrate with deproteinization
	mg/dl	3.90	3.12	4.68	0.39	0.78	
	µmol/l	349	279	419	35.00	70.00	Alkaline picrate no deproteinization
	mg/dl	3.94	3.15	4.73	0.40	0.79	
	µmol/l	343	275	411	34.00	68.00	Jaffe rate blanked
	mg/dl	3.88	3.11	4.65	0.39	0.77	
gamma-GT	U/l	169	144	194	12.50	25.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	133	113	153	10.00	20.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	104	89	119	7.50	15.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
	U/l	172	146	198	13.00	26.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	136	115	157	10.50	21.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	106	90	122	8.00	16.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
Glucose	mmol/l	16.0	13.6	18.4	1.20	2.40	Glucose oxidase
	mg/dl	288	245	331	21.50	43.00	
Iron	µmol/l	38.6	31.7	45.5	3.45	6.90	Colorimetric without ppt.
	µg/dl	216	177	255	19.50	39.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

HITACHI SERIES®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Lactate	mmol/l	5.67	4.65	6.69	0.51	1.02	Colorimetric Lactate Oxidase
	mg/dl	51.1	41.9	60.3	4.60	9.20	
LD (LDH)	U/l	727	618	836	54.50	109.00	P->L German methods 37°C
	U/l	525	446	604	39.50	79.00	P->L German methods 30°C
	U/l	369	313	425	28.00	56.00	P->L German methods 25°C
Phosphate Inorganic	mmol/l	2.38	2.02	2.74	0.18	0.36	Phosphomolybdate UV
	mg/dl	7.38	6.26	8.50	0.56	1.12	
Potassium	mmol/l	6.08	5.78	6.38	0.15	0.30	ISE method - indirect
Protein Total	g/l	46.8	37.4	56.2	4.70	9.40	Biuret reaction end point
	g/dl	4.68	3.74	5.62	0.47	0.94	
Sodium	mmol/l	158	150	166	4.00	8.00	ISE method - indirect
Triglycerides	mmol/l	2.93	2.46	3.40	0.24	0.47	Lipase/GPO-PAP no correction
	mg/dl	259	218	300	20.50	41.00	
	mmol/l	2.94	2.47	3.41	0.24	0.47	Lipase/Glycerol Dehydrogenase
	mg/dl	260	219	301	20.50	41.00	
Uric Acid (Urate)	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.14	7.96	10.3	0.59	1.18	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.02	7.85	10.2	0.59	1.17	
	mmol/l	0.54	0.47	0.60	0.03	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	8.99	7.83	10.2	0.58	1.16	
Urea	mmol/l	18.9	16.1	21.7	1.40	2.80	Urease end point
	mg/dl	114	96.8	131	8.60	17.20	
	mmol/l	19.8	16.8	22.8	1.50	3.00	Urease kinetic
	mg/dl	119	101	137	9.00	18.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

HITACHI SERIES®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
Urea	mmol/l	19.8	16.8	22.8	1.50	3.00	BUN
	mg/dl	55.6	47.3	63.9	4.15	8.30	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

ILab 600®/650®/Aries/Taurus

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	30.5	25.9	35.1	2.30	4.60	Bromocresol Green
	g/dl	3.05	2.59	3.51	0.23	0.46	
Alkaline Phosphatase	U/l	380	323	437	28.50	57.00	AMP optimised to IFCC 37°C
	U/l	296	252	340	22.00	44.00	AMP optimised to IFCC 30°C
	U/l	243	206	280	18.50	37.00	AMP optimised to IFCC 25°C
ALT (GPT)	U/l	133	106	160	13.50	27.00	Tris buffer without P5P 37°C
	U/l	98	78	118	10.00	20.00	Tris buffer without P5P 30°C
	U/l	75	60	90	7.50	15.00	Tris buffer without P5P 25°C
Amylase Total	U/l	296	251	341	22.50	45.00	I.L. 2-chloro-pNPG3 37°C
AST (GOT)	U/l	123	98	148	12.50	25.00	Tris buffer without P5P 37°C
	U/l	83	66	100	8.50	17.00	Tris buffer without P5P 30°C
	U/l	59	47	71	6.00	12.00	Tris buffer without P5P 25°C
Bilirubin Total	µmol/l	81.9	64.7	99.1	8.60	17.20	Diazo with Sulphanilic Acid
	mg/dl	4.79	3.78	5.80	0.51	1.01	
	µmol/l	88.5	69.9	107	9.30	18.60	Dichlorophenyl Diazonium (DPD)
	mg/dl	5.18	4.09	6.27	0.55	1.09	
Calcium	mmol/l	3.93	3.54	4.32	0.20	0.39	Cresolphthalein complexone
	mg/dl	15.8	14.2	17.4	0.80	1.60	
	mmol/l	3.99	3.60	4.38	0.20	0.39	Arsenazo III
	mg/dl	16.0	14.4	17.6	0.80	1.60	
Cholesterol	mmol/l	7.35	6.39	8.31	0.48	0.96	Cholesterol Oxidase - Abell Kendall
	mg/dl	284	247	321	18.50	37.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

ILab 600®/650®/Aries/Taurus

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Cholesterol	mmol/l	7.29	6.35	8.23	0.47	0.94	Cholesterol Oxidase - IDMS
	mg/dl	281	245	317	18.00	36.00	
Chloride	mmol/l	111	105	117	3.00	6.00	ISE indirect
Cholinesterase	U/l	5334	4267	6401	533.50	1067.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	506	415	597	45.50	91.00	CK-NAC (IFCC) 37°C
	U/l	317	260	374	28.50	57.00	CK-NAC (IFCC) 30°C
	U/l	215	176	254	19.50	39.00	CK-NAC (IFCC) 25°C
Creatinine	µmol/l	383	307	459	38.00	76.00	Enzymatic UV method
	mg/dl	4.33	3.47	5.19	0.43	0.86	
	µmol/l	373	299	447	37.00	74.00	Creatinine PAP method
	mg/dl	4.21	3.38	5.04	0.42	0.83	
	µmol/l	377	301	453	38.00	76.00	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	4.26	3.40	5.12	0.43	0.86	
gamma-GT	U/l	167	142	192	12.50	25.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	132	112	152	10.00	20.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	103	88	118	7.50	15.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
	U/l	172	146	198	13.00	26.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	136	115	157	10.50	21.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	106	90	122	8.00	16.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
Glucose	mmol/l	15.7	13.4	18.0	1.15	2.30	Glucose oxidase
	mg/dl	283	241	325	21.00	42.00	
HDL - Cholesterol	mmol/l	1.96	1.67	2.25	0.15	0.29	Direct HDL Immunoseparation
	mg/dl	75.7	64.5	86.9	5.60	11.20	
	mmol/l	2.67	2.27	3.07	0.20	0.40	HDL - Ultra
	mg/dl	103	87.6	118	7.70	15.40	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

ILab 600®/650®/Aries/Taurus

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Iron	µmol/l	38.6	31.6	45.6	3.50	7.00	Colorimetric without ppt.
	µg/dl	216	177	255	19.50	39.00	
LD (LDH)	U/l	696	592	800	52.00	104.00	P->L German methods 37°C
	U/l	503	427	579	38.00	76.00	P->L German methods 30°C
	U/l	353	300	406	26.50	53.00	P->L German methods 25°C
	U/l	748	636	860	56.00	112.00	P->L SFBC 37°C
	U/l	540	459	621	40.50	81.00	P->L SFBC 30°C
	U/l	379	322	436	28.50	57.00	P->L SFBC 25°C
Lipase	U/l	76	61	91	7.50	15.00	Other Colorimetric 37°C
Magnesium	mmol/l	2.03	1.78	2.28	0.13	0.25	Enzymatic
	mg/dl	4.93	4.33	5.53	0.30	0.60	
Phosphate Inorganic	mmol/l	2.22	1.88	2.56	0.17	0.34	Phosphomolybdate UV
	mg/dl	6.88	5.83	7.93	0.53	1.05	
Potassium	mmol/l	6.03	5.73	6.33	0.15	0.30	ISE method - indirect
Protein Total	g/l	46.3	37.1	55.5	4.60	9.20	Biuret reaction end point
	g/dl	4.63	3.71	5.55	0.46	0.92	
Sodium	mmol/l	159	151	167	4.00	8.00	ISE method - indirect
Triglycerides	mmol/l	3.06	2.57	3.55	0.25	0.49	Lipase/GPO-PAP no correction
	mg/dl	271	227	315	22.00	44.00	
	mmol/l	3.05	2.56	3.54	0.25	0.49	L/G Kinase EP. no correction
	mg/dl	270	227	313	21.50	43.00	
Uric Acid (Urate)	mmol/l	0.52	0.45	0.58	0.03	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	8.65	7.53	9.77	0.56	1.12	
	mmol/l	0.53	0.46	0.60	0.03	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	8.95	7.80	10.1	0.58	1.15	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

ILab 600®/650®/Aries/Taurus

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Urea	mmol/l	20.5	17.4	23.6	1.55	3.10	Urease end point
	mg/dl	123	105	141	9.00	18.00	
	mmol/l	19.8	16.8	22.8	1.50	3.00	Urease kinetic
	mg/dl	119	101	137	9.00	18.00	
	mmol/l	19.8	16.8	22.8	1.50	3.00	BUN
	mg/dl	55.6	47.3	63.9	4.15	8.30	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Konelab 20/30/60®/Thermo Scientific Indiko Plus ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28 Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Albumin	g/l	30.0	25.5	34.5	2.25	4.50	Bromocresol Green
	g/dl	3.00	2.55	3.45	0.23	0.45	
Alkaline Phosphatase	U/l	351	298	404	26.50	53.00	AMP optimised to IFCC 37°C
	U/l	273	232	314	20.50	41.00	AMP optimised to IFCC 30°C
	U/l	224	190	258	17.00	34.00	AMP optimised to IFCC 25°C
ALT (GPT)	U/l	155	124	186	15.50	31.00	Colorimetric 37°C
	U/l	115	92	138	11.50	23.00	Colorimetric 30°C
	U/l	87	70	104	8.50	17.00	Colorimetric 25°C
	U/l	147	118	176	14.50	29.00	Tris buffer without P5P 37°C
	U/l	109	87	131	11.00	22.00	Tris buffer without P5P 30°C
	U/l	83	66	100	8.50	17.00	Tris buffer without P5P 25°C
AST (GOT)	U/l	145	116	174	14.50	29.00	Tris buffer without P5P 37°C
	U/l	98	78	118	10.00	20.00	Tris buffer without P5P 30°C
	U/l	69	55	83	7.00	14.00	Tris buffer without P5P 25°C
Bilirubin Direct	µmol/l	25.2	19.9	30.5	2.65	5.30	Diazo with Sulphanilic Acid
	mg/dl	1.47	1.16	1.78	0.16	0.31	
	µmol/l	26.7	21.1	32.3	2.80	5.60	Diazo with Dichloroaniline (DCA)
	mg/dl	1.56	1.23	1.89	0.17	0.33	
Bilirubin Total	µmol/l	82.3	65.1	99.5	8.60	17.20	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.81	3.81	5.81	0.50	1.00	
	µmol/l	79.2	62.6	95.8	8.30	16.60	Nitrobenzenediazonium salt
	mg/dl	4.63	3.66	5.60	0.49	0.97	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Konelab 20/30/60®/Thermo Scientific Indiko Plus ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28 Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Calcium	mmol/l	3.75	3.37	4.13	0.19	0.38	Arsenazo III
	mg/dl	15.0	13.5	16.5	0.75	1.50	
Cholesterol	mmol/l	7.31	6.36	8.26	0.48	0.95	Cholesterol Oxidase - Abell Kendall
	mg/dl	282	245	319	18.50	37.00	
	mmol/l	7.50	6.52	8.48	0.49	0.98	Cholesterol Oxidase - IDMS
	mg/dl	290	252	328	19.00	38.00	
Chloride	mmol/l	116	111	121	2.50	5.00	ISE direct
CK Total	U/l	497	407	587	45.00	90.00	CK-NAC (IFCC) 37°C
	U/l	311	255	367	28.00	56.00	CK-NAC (IFCC) 30°C
	U/l	211	173	249	19.00	38.00	CK-NAC (IFCC) 25°C
Creatinine	µmol/l	370	296	444	37.00	74.00	Enzymatic UV method
	mg/dl	4.18	3.34	5.02	0.42	0.84	
	µmol/l	373	299	447	37.00	74.00	Creatinine PAP method
	mg/dl	4.21	3.38	5.04	0.42	0.83	
	µmol/l	352	281	423	35.50	71.00	Jaffe rate blanked
	mg/dl	3.98	3.18	4.78	0.40	0.80	
	µmol/l	334	267	401	33.50	67.00	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	3.77	3.02	4.52	0.38	0.75	
	µmol/l	310	248	372	31.00	62.00	IDMS traceable
	mg/dl	3.50	2.80	4.20	0.35	0.70	
gamma-GT	U/l	180	153	207	13.50	27.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	142	121	163	10.50	21.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	111	94	128	8.50	17.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
Glucose	mmol/l	16.3	13.8	18.8	1.25	2.50	Hexokinase
	mg/dl	294	249	339	22.50	45.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Konelab 20/30/60®/Thermo Scientific Indiko Plus ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Glucose	mmol/l	15.9	13.5	18.3	1.20	2.40	Glucose oxidase
	mg/dl	287	243	331	22.00	44.00	
HDL - Cholesterol	mmol/l	2.82	2.40	3.24	0.21	0.42	Direct HDL PEGME
	mg/dl	109	92.6	125	8.20	16.40	
	mmol/l	2.57	2.18	2.96	0.20	0.39	Direct Clearance Method
	mg/dl	99.2	84.1	114	7.55	15.10	
Iron	µmol/l	40.6	33.3	47.9	3.65	7.30	Colorimetric without ppt.
	µg/dl	227	186	268	20.50	41.00	
LD (LDH)	U/l	376	320	432	28.00	56.00	L->P IFCC 37°C
	U/l	271	231	311	20.00	40.00	L->P IFCC 30°C
	U/l	191	162	220	14.50	29.00	L->P IFCC 25°C
Phosphate Inorganic	mmol/l	2.33	1.98	2.68	0.18	0.35	Phosphomolybdate enzymatic
	mg/dl	7.22	6.14	8.30	0.54	1.08	
	mmol/l	2.31	1.97	2.65	0.17	0.34	Phosphomolybdate UV
	mg/dl	7.16	6.11	8.21	0.53	1.05	
Potassium	mmol/l	5.92	5.63	6.21	0.15	0.29	ISE method - direct
Protein Total	g/l	47.2	37.8	56.6	4.70	9.40	Biuret reaction end point
	g/dl	4.72	3.78	5.66	0.47	0.94	
Sodium	mmol/l	154	146	162	4.00	8.00	ISE method - direct
Triglycerides	mmol/l	3.09	2.60	3.58	0.25	0.49	Lipase/GPO-PAP no correction
	mg/dl	273	230	316	21.50	43.00	
	mmol/l	3.14	2.64	3.64	0.25	0.50	Lipase/Glycerol Dehydrogenase
	mg/dl	278	234	322	22.00	44.00	
Uric Acid (Urate)	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.14	7.96	10.3	0.59	1.18	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Konelab 20/30/60®/Thermo Scientific Indiko Plus ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28 Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Uric Acid (Urate)	mmol/l	0.54	0.47	0.61	0.03	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.02	7.86	10.2	0.58	1.16	
	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.21	8.01	10.4	0.60	1.20	
Urea	mmol/l	19.0	16.1	21.9	1.45	2.90	Urease end point
	mg/dl	114	96.8	131	8.60	17.20	
	mmol/l	18.8	16.0	21.6	1.40	2.80	Urease kinetic
	mg/dl	113	96.2	130	8.40	16.80	
	mmol/l	18.8	16.0	21.6	1.40	2.80	BUN
	mg/dl	52.8	44.9	60.7	3.95	7.90	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

MINDRAY BS SERIES

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
Albumin	g/l	29.9	25.4	34.4	2.25	4.50	Bromocresol Green
	g/dl	2.99	2.54	3.44	0.23	0.45	
	g/l	29.4	24.9	33.9	2.25	4.50	Bromocresol Purple
	g/dl	2.94	2.49	3.39	0.23	0.45	
Alkaline Phosphatase	U/l	384	326	442	29.00	58.00	AMP optimised to IFCC 37°C
	U/l	299	254	344	22.50	45.00	AMP optimised to IFCC 30°C
	U/l	245	208	282	18.50	37.00	AMP optimised to IFCC 25°C
ALT (GPT)	U/l	148	118	178	15.00	30.00	Tris buffer without P5P 37°C
	U/l	110	87	133	11.50	23.00	Tris buffer without P5P 30°C
	U/l	83	66	100	8.50	17.00	Tris buffer without P5P 25°C
Amylase Total	U/l	303	258	348	22.50	45.00	pNP Maltotrioside substrates 37°C
AST (GOT)	U/l	136	109	163	13.50	27.00	Colorimetric 37°C
	U/l	92	74	110	9.00	18.00	Colorimetric 30°C
	U/l	65	52	78	6.50	13.00	Colorimetric 25°C
	U/l	138	110	166	14.00	28.00	Tris buffer without P5P 37°C
	U/l	93	74	112	9.50	19.00	Tris buffer without P5P 30°C
	U/l	66	52	80	7.00	14.00	Tris buffer without P5P 25°C
Bicarbonate	mmol/l	19.3	15.3	23.3	2.00	4.00	Enzymatic
Bilirubin Direct	µmol/l	29.8	23.5	36.1	3.15	6.30	Diazo with Sulphanilic Acid
	mg/dl	1.74	1.37	2.11	0.19	0.37	
	µmol/l	29.1	23.0	35.2	3.05	6.10	Oxidation to Biliverdin/Vanadate
	mg/dl	1.70	1.35	2.05	0.18	0.35	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

MINDRAY BS SERIES

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Bilirubin Total	µmol/l	84.8	67.0	103	8.90	17.80	Diazo with Sulphanilic Acid
	mg/dl	4.96	3.92	6.00	0.52	1.04	
	µmol/l	80.6	63.6	97.6	8.50	17.00	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.72	3.72	5.72	0.50	1.00	
	µmol/l	81.9	64.7	99.1	8.60	17.20	Oxidation to Biliverdin/Vanadate
	mg/dl	4.79	3.78	5.80	0.51	1.01	
Calcium	mmol/l	4.19	3.77	4.61	0.21	0.42	Ion selective electrode
	mg/dl	16.8	15.1	18.5	0.85	1.70	
	mmol/l	3.81	3.43	4.19	0.19	0.38	Arsenazo III
	mg/dl	15.3	13.7	16.9	0.80	1.60	
Cholesterol	mmol/l	7.30	6.35	8.25	0.48	0.95	Cholesterol Oxidase - Abell Kendall
	mg/dl	282	245	319	18.50	37.00	
	mmol/l	7.31	6.36	8.26	0.48	0.95	Cholesterol Oxidase - IDMS
	mg/dl	282	245	319	18.50	37.00	
	mmol/l	7.22	6.28	8.16	0.47	0.94	Cholesterol Dehydrogenase
	mg/dl	279	242	316	18.50	37.00	
Chloride	mmol/l	110	104	116	3.00	6.00	Colorimetric
	mmol/l	115	109	121	3.00	6.00	ISE indirect
Cholinesterase	U/l	5481	4384	6578	548.50	1097.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	541	444	638	48.50	97.00	CK-NAC serum start (DGKC) 37°C
	U/l	339	278	400	30.50	61.00	CK-NAC serum start (DGKC) 30°C
	U/l	230	189	271	20.50	41.00	CK-NAC serum start (DGKC) 25°C
	U/l	560	459	661	50.50	101.00	CK-NAC substrate start (DGKC) 37°C
	U/l	351	287	415	32.00	64.00	CK-NAC substrate start (DGKC) 30°C
	U/l	238	195	281	21.50	43.00	CK-NAC substrate start (DGKC) 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

MINDRAY BS SERIES

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
CK Total	U/l	535	439	631	48.00	96.00	CK-NAC (IFCC) 37°C
	U/l	335	275	395	30.00	60.00	CK-NAC (IFCC) 30°C
	U/l	227	187	267	20.00	40.00	CK-NAC (IFCC) 25°C
Creatinine	µmol/l	352	282	422	35.00	70.00	Alkaline picrate with deproteinization
	mg/dl	3.98	3.19	4.77	0.40	0.79	
	µmol/l	350	280	420	35.00	70.00	Alkaline picrate no deproteinization
	mg/dl	3.96	3.16	4.76	0.40	0.80	
	µmol/l	380	304	456	38.00	76.00	Enzymatic UV method
	mg/dl	4.29	3.44	5.14	0.43	0.85	
	µmol/l	376	300	452	38.00	76.00	Creatinine PAP method
	mg/dl	4.25	3.39	5.11	0.43	0.86	
	µmol/l	354	283	425	35.50	71.00	Jaffe rate blanked
	mg/dl	4.00	3.20	4.80	0.40	0.80	
	µmol/l	372	298	446	37.00	74.00	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	4.20	3.37	5.03	0.42	0.83	
gamma-GT	U/l	178	151	205	13.50	27.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	140	119	161	10.50	21.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	110	93	127	8.50	17.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
	U/l	176	150	202	13.00	26.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	139	118	160	10.50	21.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	109	93	125	8.00	16.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
Glucose	mmol/l	16.1	13.7	18.5	1.20	2.40	Glucose dehydrogenase
	mg/dl	290	247	333	21.50	43.00	
	mmol/l	16.2	13.8	18.6	1.20	2.40	Hexokinase
	mg/dl	292	249	335	21.50	43.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

MINDRAY BS SERIES

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Glucose	mmol/l	16.1	13.7	18.5	1.20	2.40	Glucose oxidase
	mg/dl	290	247	333	21.50	43.00	
HDL - Cholesterol	mmol/l	2.48	2.11	2.85	0.19	0.37	Direct HDL PPD
	mg/dl	95.7	81.4	110	7.15	14.30	
	mmol/l	2.46	2.09	2.83	0.19	0.37	Direct HDL PEGME
	mg/dl	95.0	80.7	109	7.15	14.30	
	mmol/l	2.46	2.09	2.83	0.19	0.37	Direct Clearance Method
	mg/dl	95.0	80.7	109	7.15	14.30	
	mmol/l	2.69	2.28	3.10	0.21	0.41	HDL - Ultra
	mg/dl	104	88.0	120	8.00	16.00	
Iron	µmol/l	37.5	30.8	44.2	3.35	6.70	Colorimetric with ppt.
	µg/dl	210	172	248	19.00	38.00	
	µmol/l	38.6	31.6	45.6	3.50	7.00	Colorimetric without ppt.
	µg/dl	216	177	255	19.50	39.00	
LD (LDH)	U/l	734	624	844	55.00	110.00	P->L German methods 37°C
	U/l	530	451	609	39.50	79.00	P->L German methods 30°C
	U/l	372	316	428	28.00	56.00	P->L German methods 25°C
	U/l	698	593	803	52.50	105.00	P->L SFBC 37°C
	U/l	504	428	580	38.00	76.00	P->L SFBC 30°C
	U/l	354	301	407	26.50	53.00	P->L SFBC 25°C
	U/l	367	312	422	27.50	55.00	L->P IFCC 37°C
	U/l	265	225	305	20.00	40.00	L->P IFCC 30°C
	U/l	186	158	214	14.00	28.00	L->P IFCC 25°C
Lipase	U/l	71	57	85	7.00	14.00	Other Colorimetric 37°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

MINDRAY BS SERIES

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Magnesium	mmol/l	1.98	1.74	2.22	0.12	0.24	Xylidyl Blue
	mg/dl	4.81	4.23	5.39	0.29	0.58	
	mmol/l	2.14	1.89	2.39	0.13	0.25	Enzymatic
	mg/dl	5.20	4.59	5.81	0.31	0.61	
Phosphate Inorganic	mmol/l	2.15	1.83	2.47	0.16	0.32	Phosphomolybdate enzymatic
	mg/dl	6.67	5.67	7.67	0.50	1.00	
	mmol/l	2.12	1.81	2.43	0.16	0.31	Phosphomolybdate UV
	mg/dl	6.57	5.61	7.53	0.48	0.96	
Potassium	mmol/l	6.11	5.80	6.42	0.16	0.31	ISE method - indirect
Protein Total	g/l	48.0	38.4	57.6	4.80	9.60	Biuret reaction end point
	g/dl	4.80	3.84	5.76	0.48	0.96	
	g/l	46.5	37.2	55.8	4.65	9.30	Biuret reaction kinetic
	g/dl	4.65	3.72	5.58	0.47	0.93	
Sodium	mmol/l	160	152	168	4.00	8.00	ISE method - indirect
TIBC	µmol/l	39.3	31.1	47.5	4.10	8.20	FE+UIBC(saturation with iron)
	µg/dl	220	174	266	23.00	46.00	
Triglycerides	mmol/l	2.89	2.43	3.35	0.23	0.46	Lipase/GPO-PAP no correction
	mg/dl	256	215	297	20.50	41.00	
	mmol/l	2.87	2.41	3.33	0.23	0.46	Lipase/GPO-PAP 0.11mmol/l correction
	mg/dl	254	213	295	20.50	41.00	
	mmol/l	2.93	2.46	3.40	0.24	0.47	L/G Kinase EP. no correction
	mg/dl	259	218	300	20.50	41.00	
	mmol/l	2.89	2.43	3.35	0.23	0.46	Lipase/Glycerol Dehydrogenase
	mg/dl	256	215	297	20.50	41.00	
Uric Acid (Urate)	mmol/l	0.54	0.47	0.62	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.14	7.95	10.3	0.60	1.19	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

MINDRAY BS SERIES

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Uric Acid (Urate)	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.09	7.91	10.3	0.59	1.18	
	mmol/l	0.54	0.47	0.61	0.03	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.02	7.86	10.2	0.58	1.16	
Urea	mmol/l	19.5	16.6	22.4	1.45	2.90	Urease end point
	mg/dl	117	99.8	134	8.60	17.20	
	mmol/l	19.6	16.6	22.6	1.50	3.00	Urease kinetic
	mg/dl	118	99.8	136	9.10	18.20	
	mmol/l	19.6	16.7	22.5	1.45	2.90	BUN
	mg/dl	55.0	46.8	63.2	4.10	8.20	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Ortho VITROS®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	29.5	25.1	33.9	2.20	4.40	Ortho Vitros Microslide Systems
	g/dl	2.95	2.51	3.39	0.22	0.44	
Alkaline Phosphatase	U/l	304	259	349	22.50	45.00	Ortho Vitros Microslide Systems 37°C
ALT (GPT)	U/l	152	122	182	15.00	30.00	Ortho Vitros Microslide Systems 37°C
	U/l	152	121	183	15.50	31.00	Ortho Vitros MicroSlide visible 37°C
Amylase Total	U/l	176	149	203	13.50	27.00	Ortho Vitros Microslide Systems 37°C
AST (GOT)	U/l	172	138	206	17.00	34.00	Ortho Vitros Microslide visible slide 37°C
Bicarbonate	mmol/l	21.1	16.7	25.5	2.20	4.40	Ortho Vitros Microslide Systems
Bilirubin Total	µmol/l	74.3	58.7	89.9	7.80	15.60	Vitros 250/500/700/950 Total Bilirubin
Calcium	mmol/l	3.66	3.29	4.03	0.19	0.37	Ortho Vitros Microslide Systems
	mg/dl	14.7	13.2	16.2	0.75	1.50	
Cholesterol	mmol/l	6.99	6.08	7.90	0.46	0.91	Ortho Vitros Microslide Systems
	mg/dl	270	235	305	17.50	35.00	
Chloride	mmol/l	115	109	121	3.00	6.00	Ortho Vitros Microslide Systems
Cholinesterase	U/l	5218	4174	6262	522.00	1044.00	Ortho Vitros Microslide Systems 37°C
Creatinine	µmol/l	374	299	449	37.50	75.00	Vitros DT60/DT60 II/DTSC II
	mg/dl	4.23	3.38	5.08	0.43	0.85	
	µmol/l	370	296	444	37.00	74.00	Vitros IDMS Traceable
	mg/dl	4.18	3.34	5.02	0.42	0.84	
Free T4	pmol/l	92.8	69.6	116	11.60	23.20	Vitros ECi
	ng/dl	7.24	5.43	9.05	0.91	1.81	
	pg/ml	72.4	54.3	90.5	9.05	18.10	Vitros ECi

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Ortho VITROS®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
gamma-GT	U/l	201	171	231	15.00	30.00	Ortho Vitros Microslide Systems 37°C
Glucose	mmol/l	15.1	12.8	17.4	1.15	2.30	Ortho Vitros Microslide Systems
	mg/dl	272	231	313	20.50	41.00	
HDL - Cholesterol	mmol/l	2.51	2.14	2.88	0.19	0.37	Vitros Magnetic HDL
	mg/dl	96.9	82.6	111	7.15	14.30	
	mmol/l	2.51	2.13	2.89	0.19	0.38	Vitros dHDL PTA/MgCl2 direct precipitation
	mg/dl	96.9	82.2	112	7.35	14.70	
Iron	µmol/l	36.2	29.7	42.7	3.25	6.50	Ortho Vitros Microslide Systems
	µg/dl	202	166	238	18.00	36.00	
Lactate	mmol/l	5.50	4.51	6.49	0.50	0.99	Ortho Vitros Microslide Systems
	mg/dl	49.6	40.6	58.6	4.50	9.00	
LD (LDH)	U/l	403	343	463	30.00	60.00	Ortho Vitros IFCC Traceable 37°C
Lipase	U/l	827	663	991	82.00	164.00	Ortho Vitros Microslide Systems 37°C
Lithium	mmol/l	2.41	2.12	2.70	0.15	0.29	Ortho Vitros Microslide Systems
	mg/dl	1.67	1.47	1.87	0.10	0.20	
Magnesium	mmol/l	2.03	1.79	2.27	0.12	0.24	Ortho Vitros Microslide Systems
	mg/dl	4.93	4.35	5.51	0.29	0.58	
Phosphate Inorganic	mmol/l	2.16	1.84	2.48	0.16	0.32	Ortho Vitros Microslide Systems
	mg/dl	6.70	5.70	7.70	0.50	1.00	
Potassium	mmol/l	5.92	5.62	6.22	0.15	0.30	Ortho Vitros Microslide Systems
Protein Total	g/l	47.8	38.3	57.3	4.75	9.50	Ortho Vitros Microslide Systems
	g/dl	4.79	3.83	5.75	0.48	0.96	
PSA Total	ng/ml =	20.1	15.1	25.1	2.50	5.00	Ortho Vitros ECi
Sodium	mmol/l	154	146	162	4.00	8.00	Ortho Vitros Microslide Systems

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Ortho VITROS®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Thyroid Stimulating Hormone	µU/ml =	1.30	1.04	1.56	0.13	0.26	Vitros ECi
TIBC	µmol/l	35.9	28.4	43.4	3.75	7.50	Ortho Vitros Microslide Systems
	µg/dl	201	159	243	21.00	42.00	
Total T3	nmol/l	4.28	3.21	5.35	0.54	1.07	Vitros ECi
	ng/ml	2.79	2.09	3.49	0.35	0.70	
	ng/dl	279	209	349	35.00	70.00	Vitros ECi
Total T4	nmol/l	240	180	300	30.00	60.00	Vitros ECi
	µg/dl	18.7	14.0	23.4	2.35	4.70	
	ng/ml	187	140	234	23.50	47.00	Vitros ECi
Triglycerides	mmol/l	3.49	2.93	4.05	0.28	0.56	Ortho Vitros Microslide Systems
	mg/dl	309	259	359	25.00	50.00	
Uric Acid (Urate)	mmol/l	0.52	0.45	0.58	0.03	0.07	Ortho Vitros Microslide Systems
	mg/dl	8.67	7.54	9.80	0.57	1.13	
Urea	mmol/l	18.7	15.9	21.5	1.40	2.80	Ortho Vitros Microslide Systems
	mg/dl	112	95.6	128	8.20	16.40	
	mmol/l	18.7	15.9	21.5	1.40	2.80	BUN
	mg/dl	52.5	44.6	60.4	3.95	7.90	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

PRESTIGE 24i

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	31.1	26.4	35.8	2.35	4.70	Bromocresol Green
	g/dl	3.11	2.64	3.58	0.24	0.47	
ALT (GPT)	U/l	149	120	178	14.50	29.00	Tris buffer without P5P 37°C
	U/l	110	89	131	10.50	21.00	Tris buffer without P5P 30°C
	U/l	84	68	100	8.00	16.00	Tris buffer without P5P 25°C
AST (GOT)	U/l	137	110	164	13.50	27.00	Tris buffer without P5P 37°C
	U/l	93	74	112	9.50	19.00	Tris buffer without P5P 30°C
	U/l	65	52	78	6.50	13.00	Tris buffer without P5P 25°C
Bilirubin Total	µmol/l	86.0	68.0	104	9.00	18.00	Dichlorophenyl Diazonium (DPD)
	mg/dl	5.03	3.98	6.08	0.53	1.05	
Calcium	mmol/l	3.56	3.21	3.91	0.18	0.35	Arsenazo III
	mg/dl	14.3	12.9	15.7	0.70	1.40	
Cholesterol	mmol/l	7.45	6.48	8.42	0.49	0.97	Cholesterol Oxidase - Abell Kendall
	mg/dl	288	250	326	19.00	38.00	
	mmol/l	7.19	6.26	8.12	0.47	0.93	Cholesterol Oxidase - IDMS
	mg/dl	278	242	314	18.00	36.00	
CK Total	U/l	555	455	655	50.00	100.00	CK-NAC (IFCC) 37°C
	U/l	347	285	409	31.00	62.00	CK-NAC (IFCC) 30°C
	U/l	236	193	279	21.50	43.00	CK-NAC (IFCC) 25°C
Creatinine	µmol/l	331	264	398	33.50	67.00	Alkaline picrate no deproteinization
	mg/dl	3.74	2.98	4.50	0.38	0.76	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

PRESTIGE 24i

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Creatinine	µmol/l	346	277	415	34.50	69.00	Jaffe rate blanked
	mg/dl	3.91	3.13	4.69	0.39	0.78	
gamma-GT	U/l	172	146	198	13.00	26.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	136	115	157	10.50	21.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	106	90	122	8.00	16.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
	U/l	181	154	208	13.50	27.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	143	121	165	11.00	22.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	112	95	129	8.50	17.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
Glucose	mmol/l	16.2	13.7	18.7	1.25	2.50	Glucose oxidase
	mg/dl	292	247	337	22.50	45.00	
Iron	µmol/l	37.0	30.3	43.7	3.35	6.70	Colorimetric without ppt.
	µg/dl	207	169	245	19.00	38.00	
LD (LDH)	U/l	715	608	822	53.50	107.00	P->L German methods 37°C
	U/l	516	439	593	38.50	77.00	P->L German methods 30°C
	U/l	363	308	418	27.50	55.00	P->L German methods 25°C
Magnesium	mmol/l	1.67	1.47	1.87	0.10	0.20	Xylidyl Blue
	mg/dl	4.06	3.57	4.55	0.25	0.49	
Phosphate Inorganic	mmol/l	2.43	2.06	2.80	0.19	0.37	Phosphomolybdate UV
	mg/dl	7.53	6.39	8.67	0.57	1.14	
Protein Total	g/l	47.6	38.1	57.1	4.75	9.50	Biuret reaction end point
	g/dl	4.76	3.81	5.71	0.48	0.95	
Triglycerides	mmol/l	2.92	2.45	3.39	0.24	0.47	Lipase/GPO-PAP no correction
	mg/dl	258	217	299	20.50	41.00	
Uric Acid (Urate)	mmol/l	0.56	0.49	0.63	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.41	8.18	10.6	0.62	1.23	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

PRESTIGE 24i

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Uric Acid (Urate)	mmol/l	0.56	0.48	0.63	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.32	8.10	10.5	0.61	1.22	
Urea	mmol/l	18.5	15.7	21.3	1.40	2.80	Urease kinetic
	mg/dl	111	94.4	128	8.30	16.60	
	mmol/l	18.5	15.7	21.3	1.40	2.80	BUN
	mg/dl	51.9	44.1	59.7	3.90	7.80	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C111®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	31.4	26.7	36.1	2.35	4.70	Bromocresol Green
	g/dl	3.14	2.67	3.61	0.24	0.47	
Alkaline Phosphatase	U/l	338	288	388	25.00	50.00	Roche Integra AMP buffer 37°C
	U/l	263	224	302	19.50	39.00	Roche Integra AMP buffer 30°C
	U/l	216	184	248	16.00	32.00	Roche Integra AMP buffer 25°C
ALT (GPT)	U/l	129	104	154	12.50	25.00	Tris buffer without P5P 37°C
	U/l	95	77	113	9.00	18.00	Tris buffer without P5P 30°C
	U/l	73	59	87	7.00	14.00	Tris buffer without P5P 25°C
Amylase Total	U/l	286	243	329	21.50	43.00	Other Roche 2-chloro-pNPG7 37°C
	U/l	277	235	319	21.00	42.00	Roche liquid stable pNPG7 37°C
AST (GOT)	U/l	125	100	150	12.50	25.00	Tris buffer without P5P 37°C
	U/l	85	68	102	8.50	17.00	Tris buffer without P5P 30°C
	U/l	60	48	72	6.00	12.00	Tris buffer without P5P 25°C
Bilirubin Direct	µmol/l	32.4	25.6	39.2	3.40	6.80	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.90	1.50	2.30	0.20	0.40	
	µmol/l	33.0	26.0	40.0	3.50	7.00	Diazo with Sulphanilic Acid
	mg/dl	1.93	1.52	2.34	0.21	0.41	
	µmol/l	33.0	26.0	40.0	3.50	7.00	Roche DPD JG standardised
	mg/dl	1.93	1.52	2.34	0.21	0.41	
	µmol/l	33.3	26.3	40.3	3.50	7.00	Roche DPD Doumas standardised
	mg/dl	1.95	1.54	2.36	0.21	0.41	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C111®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Bilirubin Total	µmol/l	74.9	59.2	90.6	7.85	15.70	Diazo with Sulphanilic Acid
	mg/dl	4.38	3.46	5.30	0.46	0.92	
	µmol/l	77.6	61.3	93.9	8.15	16.30	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.54	3.59	5.49	0.48	0.95	
	µmol/l	75.3	59.5	91.1	7.90	15.80	Diazonium ion
	mg/dl	4.41	3.48	5.34	0.47	0.93	
Calcium	mmol/l	3.91	3.52	4.30	0.20	0.39	Cresolphthalein complexone
	mg/dl	15.7	14.1	17.3	0.80	1.60	
	mmol/l	3.85	3.46	4.24	0.20	0.39	Arsenazo III
	mg/dl	15.4	13.9	16.9	0.75	1.50	
	mmol/l	3.86	3.48	4.24	0.19	0.38	NM-BAPTA
	mg/dl	15.5	13.9	17.1	0.80	1.60	
Cholesterol	mmol/l	7.31	6.36	8.26	0.48	0.95	Cholesterol Oxidase - Abell Kendall
	mg/dl	282	245	319	18.50	37.00	
	mmol/l	6.88	5.98	7.78	0.45	0.90	Cholesterol Dehydrogenase
	mg/dl	266	231	301	17.50	35.00	
Chloride	mmol/l	116	110	122	3.00	6.00	ISE indirect
CK Total	U/l	502	411	593	45.50	91.00	CK-NAC (IFCC) 37°C
	U/l	314	257	371	28.50	57.00	CK-NAC (IFCC) 30°C
	U/l	213	175	251	19.00	38.00	CK-NAC (IFCC) 25°C
Creatinine	µmol/l	355	284	426	35.50	71.00	Alkaline picrate no deproteinization
	mg/dl	4.01	3.21	4.81	0.40	0.80	
	µmol/l	356	285	427	35.50	71.00	Roche Creatinine Plus
	mg/dl	4.02	3.22	4.82	0.40	0.80	
	µmol/l	356	285	427	35.50	71.00	Jaffe rate blanked
	mg/dl	4.02	3.22	4.82	0.40	0.80	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C111®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Creatinine	µmol/l	352	282	422	35.00	70.00	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	3.98	3.19	4.77	0.40	0.79	
	µmol/l	357	285	429	36.00	72.00	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	4.03	3.22	4.84	0.41	0.81	
gamma-GT	U/l	170	145	195	12.50	25.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	134	114	154	10.00	20.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	105	89	121	8.00	16.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
	U/l	174	148	200	13.00	26.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	137	117	157	10.00	20.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	107	91	123	8.00	16.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
Glucose	mmol/l	16.2	13.7	18.7	1.25	2.50	Hexokinase
	mg/dl	292	247	337	22.50	45.00	
	mmol/l	16.5	14.0	19.0	1.25	2.50	Glucose oxidase
	mg/dl	297	252	342	22.50	45.00	
HDL - Cholesterol	mmol/l	2.95	2.51	3.39	0.22	0.44	Direct HDL PEGME
	mg/dl	114	96.9	131	8.55	17.10	
	mmol/l	3.08	2.62	3.54	0.23	0.46	Direct HDL Roche 4th Generation
	mg/dl	119	101	137	9.00	18.00	
Iron	µmol/l	39.5	32.4	46.6	3.55	7.10	Colorimetric without ppt.
	µg/dl	221	181	261	20.00	40.00	
LD (LDH)	U/l	375	318	432	28.50	57.00	L->P IFCC 37°C
	U/l	271	230	312	20.50	41.00	L->P IFCC 30°C
	U/l	190	161	219	14.50	29.00	L->P IFCC 25°C
Magnesium	mmol/l	2.02	1.77	2.27	0.13	0.25	Xylidyl Blue
	mg/dl	4.91	4.30	5.52	0.31	0.61	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C111®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Magnesium	mmol/l	1.96	1.73	2.19	0.12	0.23	Chlorphosphonazo III
	mg/dl	4.76	4.20	5.32	0.28	0.56	
Phosphate Inorganic	mmol/l	2.23	1.90	2.56	0.17	0.33	Phosphomolybdate enzymatic
	mg/dl	6.91	5.89	7.93	0.51	1.02	
	mmol/l	2.27	1.93	2.61	0.17	0.34	Phosphomolybdate UV
	mg/dl	7.04	5.98	8.10	0.53	1.06	
Potassium	mmol/l	6.05	5.75	6.35	0.15	0.30	ISE method - indirect
Protein Total	g/l	46.6	37.3	55.9	4.65	9.30	Biuret reaction end point
	g/dl	4.66	3.73	5.59	0.47	0.93	
Sodium	mmol/l	155	147	163	4.00	8.00	ISE method - direct
Triglycerides	mmol/l	3.03	2.55	3.51	0.24	0.48	Lipase/GPO-PAP no correction
	mg/dl	268	226	310	21.00	42.00	
	mmol/l	3.11	2.61	3.61	0.25	0.50	Lipase/GPO-PAP 0.11mmol/l correction
	mg/dl	275	231	319	22.00	44.00	
	mmol/l	3.00	2.52	3.48	0.24	0.48	L/G Kinase EP. no correction
	mg/dl	266	223	309	21.50	43.00	
	mmol/l	2.98	2.50	3.46	0.24	0.48	Lipase/Glycerol Dehydrogenase
	mg/dl	264	221	307	21.50	43.00	
Uric Acid (Urate)	mmol/l	0.53	0.46	0.60	0.03	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	8.90	7.74	10.1	0.58	1.16	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.06	7.88	10.2	0.59	1.18	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.12	7.93	10.3	0.60	1.19	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C111®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
Urea	mmol/l	18.3	15.6	21.0	1.35	2.70	Urease kinetic
	mg/dl	110	93.8	126	8.10	16.20	
	mmol/l	18.3	15.6	21.0	1.35	2.70	BUN
	mg/dl	51.4	43.7	59.1	3.85	7.70	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c303/501/502/503

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	31.6	26.9	36.3	2.35	4.70	Bromocresol Green
	g/dl	3.16	2.69	3.63	0.24	0.47	
	g/l	30.7	26.1	35.3	2.30	4.60	Bromocresol Purple
	g/dl	3.07	2.61	3.53	0.23	0.46	
	g/l	28.1	23.9	32.3	2.10	4.20	Turbidimetric Assays
	g/dl	2.81	2.39	3.23	0.21	0.42	
Alkaline Phosphatase	U/l	340	289	391	25.50	51.00	Roche Integra AMP buffer 37°C
	U/l	265	225	305	20.00	40.00	Roche Integra AMP buffer 30°C
	U/l	217	185	249	16.00	32.00	Roche Integra AMP buffer 25°C
	U/l	340	289	391	25.50	51.00	AMP optimised to IFCC 37°C
	U/l	265	225	305	20.00	40.00	AMP optimised to IFCC 30°C
	U/l	217	185	249	16.00	32.00	AMP optimised to IFCC 25°C
	U/l	338	288	388	25.00	50.00	Colorimetric 37°C
	U/l	263	224	302	19.50	39.00	Colorimetric 30°C
	U/l	216	184	248	16.00	32.00	Colorimetric 25°C
ALT (GPT)	U/l	133	106	160	13.50	27.00	Tris buffer without P5P 37°C
	U/l	98	78	118	10.00	20.00	Tris buffer without P5P 30°C
	U/l	75	60	90	7.50	15.00	Tris buffer without P5P 25°C
Amylase Pancreatic	U/l	245	208	282	18.50	37.00	Immunoinhibition EPS substrate 37°C
	U/l	246	209	283	18.50	37.00	Roche EPS Liquid 37°C
Amylase Total	U/l	265	225	305	20.00	40.00	Randox Liquid Ethylidene pNPG7 37°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c303/501/502/503

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Amylase Total	U/l	273	232	314	20.50	41.00	Roche Integra 2-chloro-pNPG7 37°C
	U/l	272	231	313	20.50	41.00	Other Roche 2-chloro-pNPG7 37°C
	U/l	272	231	313	20.50	41.00	Roche liquid stable pNPG7 37°C
	U/l	273	232	314	20.50	41.00	BM/Roche Colorimetric pNPG7 37°C
AST (GOT)	U/l	126	101	151	12.50	25.00	Tris buffer without P5P 37°C
	U/l	85	68	102	8.50	17.00	Tris buffer without P5P 30°C
	U/l	60	48	72	6.00	12.00	Tris buffer without P5P 25°C
Bicarbonate	mmol/l	18.2	14.5	21.9	1.85	3.70	Colorimetric
	mmol/l	18.4	14.6	22.2	1.90	3.80	Enzymatic
Bilirubin Direct	µmol/l	30.9	24.4	37.4	3.25	6.50	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.81	1.43	2.19	0.19	0.38	
	µmol/l	30.9	24.4	37.4	3.25	6.50	Diazo with Sulphanilic Acid
	mg/dl	1.81	1.43	2.19	0.19	0.38	
	µmol/l	31.2	24.6	37.8	3.30	6.60	Roche DPD JG standardised
	mg/dl	1.83	1.44	2.22	0.20	0.39	
	µmol/l	30.5	24.1	36.9	3.20	6.40	Diazo with Dichloroaniline (DCA)
	mg/dl	1.78	1.41	2.15	0.19	0.37	
Bilirubin Total	µmol/l	74.0	58.4	89.6	7.80	15.60	Diazo with Dichloroaniline (DCA)
	mg/dl	4.33	3.42	5.24	0.46	0.91	
	µmol/l	73.4	57.9	88.9	7.75	15.50	Diazo with Sulphanilic Acid
	mg/dl	4.29	3.39	5.19	0.45	0.90	
	µmol/l	73.8	58.3	89.3	7.75	15.50	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.32	3.41	5.23	0.46	0.91	
	µmol/l	74.4	58.7	90.1	7.85	15.70	Diazonium ion
	mg/dl	4.35	3.43	5.27	0.46	0.92	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c303/501/502/503

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Calcium	mmol/l	3.90	3.51	4.29	0.20	0.39	Cresolphthalein complexone
	mg/dl	15.6	14.1	17.1	0.75	1.50	
	mmol/l	3.87	3.48	4.26	0.20	0.39	Arsenazo III
	mg/dl	15.5	13.9	17.1	0.80	1.60	
	mmol/l	3.89	3.50	4.28	0.20	0.39	NM-BAPTA
	mg/dl	15.6	14.0	17.2	0.80	1.60	
Cholesterol	mmol/l	7.32	6.37	8.27	0.48	0.95	Cholesterol Oxidase - Abell Kendall
	mg/dl	283	246	320	18.50	37.00	
	mmol/l	7.32	6.37	8.27	0.48	0.95	Cholesterol Oxidase - IDMS
	mg/dl	283	246	320	18.50	37.00	
	mmol/l	7.35	6.39	8.31	0.48	0.96	Cholesterol Dehydrogenase
	mg/dl	284	247	321	18.50	37.00	
Chloride	mmol/l	111	105	117	3.00	6.00	ISE indirect
Cholinesterase	U/l	5310	4248	6372	531.00	1062.00	Colorimetric Benzoylcholine 37°C
	U/l	5327	4261	6393	533.00	1066.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	507	416	598	45.50	91.00	CK-NAC serum start (DGKC) 37°C
	U/l	317	260	374	28.50	57.00	CK-NAC serum start (DGKC) 30°C
	U/l	215	177	253	19.00	38.00	CK-NAC serum start (DGKC) 25°C
	U/l	498	408	588	45.00	90.00	CK-NAC substrate start (DGKC) 37°C
	U/l	312	255	369	28.50	57.00	CK-NAC substrate start (DGKC) 30°C
	U/l	212	173	251	19.50	39.00	CK-NAC substrate start (DGKC) 25°C
	U/l	504	413	595	45.50	91.00	CK-NAC (IFCC) 37°C
	U/l	316	259	373	28.50	57.00	CK-NAC (IFCC) 30°C
	U/l	214	176	252	19.00	38.00	CK-NAC (IFCC) 25°C
Copper	µmol/l	24.4	19.5	29.3	2.45	4.90	Colorimetric
	µg/dl	155	124	186	15.50	31.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c303/501/502/503

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Creatinine	µmol/l	360	288	432	36.00	72.00	Alkaline picrate with deproteinization
	mg/dl	4.07	3.25	4.89	0.41	0.82	
	µmol/l	367	293	441	37.00	74.00	Alkaline picrate no deproteinization
	mg/dl	4.15	3.31	4.99	0.42	0.84	
	µmol/l	375	300	450	37.50	75.00	Enzymatic UV method
	mg/dl	4.24	3.39	5.09	0.43	0.85	
	µmol/l	381	305	457	38.00	76.00	Creatinine PAP method
	mg/dl	4.31	3.45	5.17	0.43	0.86	
	µmol/l	376	301	451	37.50	75.00	Roche Creatinine Plus
	mg/dl	4.25	3.40	5.10	0.43	0.85	
	µmol/l	369	295	443	37.00	74.00	Jaffe rate blanked
	mg/dl	4.17	3.33	5.01	0.42	0.84	
	µmol/l	366	293	439	36.50	73.00	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	4.14	3.31	4.97	0.42	0.83	
	µmol/l	358	286	430	36.00	72.00	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	4.05	3.23	4.87	0.41	0.82	
	µmol/l	374	299	449	37.50	75.00	IDMS traceable
	mg/dl	4.23	3.38	5.08	0.43	0.85	
Free T4	pmol/l	79.4	59.6	99.2	9.90	19.80	Roche Cobas e601/602
	ng/dl	6.19	4.65	7.73	0.77	1.54	
	pg/ml	61.9	46.5	77.3	7.70	15.40	Roche Cobas e601/602
gamma-GT	U/l	166	142	190	12.00	24.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	131	112	150	9.50	19.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	102	88	116	7.00	14.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c303/501/502/503

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
gamma-GT	U/l	182	154	210	14.00	28.00	Gamma glutamyl-4-nitroanilide 37°C
	U/l	143	121	165	11.00	22.00	Gamma glutamyl-4-nitroanilide 30°C
	U/l	112	95	129	8.50	17.00	Gamma glutamyl-4-nitroanilide 25°C
	U/l	184	156	212	14.00	28.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	145	123	167	11.00	22.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	114	96	132	9.00	18.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
Glucose	mmol/l	15.8	13.4	18.2	1.20	2.40	Glucose dehydrogenase
	mg/dl	285	241	329	22.00	44.00	
	mmol/l	15.9	13.5	18.3	1.20	2.40	Hexokinase
	mg/dl	287	243	331	22.00	44.00	
	mmol/l	15.8	13.4	18.2	1.20	2.40	Glucose oxidase
	mg/dl	285	241	329	22.00	44.00	
HDL - Cholesterol	mmol/l	2.92	2.48	3.36	0.22	0.44	Direct HDL PPD
	mg/dl	113	95.7	130	8.65	17.30	
	mmol/l	2.79	2.37	3.21	0.21	0.42	Direct HDL Immunoseparation
	mg/dl	108	91.5	125	8.25	16.50	
	mmol/l	3.02	2.57	3.47	0.23	0.45	Direct HDL PEGME
	mg/dl	117	99.2	135	8.90	17.80	
	mmol/l	2.99	2.54	3.44	0.23	0.45	Direct HDL Roche 4th Generation
	mg/dl	115	98.0	132	8.50	17.00	
Iron	µmol/l	39.0	31.9	46.1	3.55	7.10	Colorimetric with ppt.
	µg/dl	218	178	258	20.00	40.00	
	µmol/l	39.3	32.2	46.4	3.55	7.10	Colorimetric without ppt.
	µg/dl	220	180	260	20.00	40.00	
Lactate	mmol/l	5.96	4.89	7.03	0.54	1.07	Colorimetric Lactate Oxidase
	mg/dl	53.7	44.1	63.3	4.80	9.60	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c303/501/502/503

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
LD (LDH)	U/l	365	310	420	27.50	55.00	L->P 37°C
	U/l	264	224	304	20.00	40.00	L->P 30°C
	U/l	185	157	213	14.00	28.00	L->P 25°C
	U/l	366	311	421	27.50	55.00	L->P IFCC 37°C
	U/l	264	225	303	19.50	39.00	L->P IFCC 30°C
	U/l	186	158	214	14.00	28.00	L->P IFCC 25°C
Lipase	U/l	78	63	93	7.50	15.00	Other Colorimetric 37°C
	U/l	77	62	92	7.50	15.00	Roche Colorimetric 37°C
	U/l	77	62	92	7.50	15.00	Roche Turbidimetric with colipase 37°C
Lithium	mmol/l	2.01	1.77	2.25	0.12	0.24	Ion selective electrode
	mg/dl	1.40	1.23	1.57	0.09	0.17	
	mmol/l	2.02	1.78	2.26	0.12	0.24	Spectrophotometric
	mg/dl	1.40	1.24	1.56	0.08	0.16	
Magnesium	mmol/l	2.05	1.80	2.30	0.13	0.25	Arsenazo III
	mg/dl	4.98	4.37	5.59	0.31	0.61	
	mmol/l	2.05	1.80	2.30	0.13	0.25	Atomic absorption
	mg/dl	4.98	4.37	5.59	0.31	0.61	
	mmol/l	2.05	1.80	2.30	0.13	0.25	Xylidyl Blue
	mg/dl	4.98	4.37	5.59	0.31	0.61	
	mmol/l	2.00	1.76	2.24	0.12	0.24	Methylthymol blue
	mg/dl	4.86	4.28	5.44	0.29	0.58	
	mmol/l	2.04	1.79	2.29	0.13	0.25	Chlorphosphonazo III
	mg/dl	4.96	4.35	5.57	0.31	0.61	
	mmol/l	2.05	1.80	2.30	0.13	0.25	Enzymatic
	mg/dl	4.98	4.37	5.59	0.31	0.61	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c303/501/502/503

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Osmolality	mOsm/kg	348	279	417	34.50	69.00	Calculated
Phosphate Inorganic	mmol/l	2.23	1.89	2.57	0.17	0.34	Phosphomolybdate enzymatic
	mg/dl	6.91	5.86	7.96	0.53	1.05	
	mmol/l	2.22	1.89	2.55	0.17	0.33	Phosphomolybdate UV
	mg/dl	6.88	5.86	7.90	0.51	1.02	
Potassium	mmol/l	6.07	5.77	6.37	0.15	0.30	ISE method - indirect
Protein Total	g/l	45.6	36.5	54.7	4.55	9.10	Biuret reaction end point
	g/dl	4.56	3.65	5.47	0.46	0.91	
	g/l	45.1	36.1	54.1	4.50	9.00	Biuret reaction kinetic
	g/dl	4.51	3.61	5.41	0.45	0.90	
PSA Total	ng/ml =	21.2	15.9	26.5	2.65	5.30	Roche Cobas 6000/8000
Sodium	mmol/l	158	150	166	4.00	8.00	ISE method - indirect
Thyroid Stimulating Hormone	µU/ml =	1.46	1.17	1.75	0.15	0.29	Roche Cobas e601/602
Total T3	nmol/l	3.56	2.67	4.45	0.45	0.89	Roche Cobas e601/602
	ng/ml	2.32	1.74	2.90	0.29	0.58	
	ng/dl	232	174	290	29.00	58.00	Roche Cobas e601/602
Total T4	nmol/l	229	172	286	28.50	57.00	Roche Cobas e601/602
	µg/dl	17.9	13.4	22.4	2.25	4.50	
	ng/ml	179	134	224	22.50	45.00	Roche Cobas e601/602
Triglycerides	mmol/l	2.99	2.51	3.47	0.24	0.48	Lipase/GPO-PAP no correction
	mg/dl	265	222	308	21.50	43.00	
	mmol/l	2.98	2.50	3.46	0.24	0.48	Lipase/GPO-PAP 0.11mmol/l correction
	mg/dl	264	221	307	21.50	43.00	
	mmol/l	2.98	2.51	3.45	0.24	0.47	L/G Kinase EP. no correction
	mg/dl	264	222	306	21.00	42.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c303/501/502/503

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Triglycerides	mmol/l	3.01	2.53	3.49	0.24	0.48	L/G kinase EP. 0.11 mmol/l correction
	mg/dl	266	224	308	21.00	42.00	
	mmol/l	3.00	2.52	3.48	0.24	0.48	Lipase/Glycerol Dehydrogenase
	mg/dl	266	223	309	21.50	43.00	
Uric Acid (Urate)	mmol/l	0.54	0.47	0.62	0.04	0.07	Uricase catalase 340nm
	mg/dl	9.14	7.95	10.3	0.60	1.19	
	mmol/l	0.53	0.46	0.60	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	8.95	7.78	10.1	0.59	1.17	
	mmol/l	0.53	0.46	0.60	0.03	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	8.89	7.74	10.0	0.58	1.15	
	mmol/l	0.53	0.46	0.60	0.03	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	8.90	7.74	10.1	0.58	1.16	
Urea	mmol/l	19.1	16.2	22.0	1.45	2.90	Urease end point
	mg/dl	115	97.4	133	8.80	17.60	
	mmol/l	19.3	16.4	22.2	1.45	2.90	Urease kinetic
	mg/dl	116	98.6	133	8.70	17.40	
	mmol/l	19.3	16.4	22.2	1.45	2.90	BUN
	mg/dl	54.2	46.1	62.3	4.05	8.10	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C311®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	31.4	26.7	36.1	2.35	4.70	Bromocresol Green
	g/dl	3.14	2.67	3.61	0.24	0.47	
	g/l	30.9	26.3	35.5	2.30	4.60	Bromocresol Purple
	g/dl	3.09	2.63	3.55	0.23	0.46	
Alkaline Phosphatase	U/l	334	284	384	25.00	50.00	Roche Integra AMP buffer 37°C
	U/l	260	221	299	19.50	39.00	Roche Integra AMP buffer 30°C
	U/l	213	181	245	16.00	32.00	Roche Integra AMP buffer 25°C
	U/l	332	282	382	25.00	50.00	AMP optimised to IFCC 37°C
	U/l	259	220	298	19.50	39.00	AMP optimised to IFCC 30°C
	U/l	212	180	244	16.00	32.00	AMP optimised to IFCC 25°C
ALT (GPT)	U/l	134	108	160	13.00	26.00	Tris buffer without P5P 37°C
	U/l	99	80	118	9.50	19.00	Tris buffer without P5P 30°C
	U/l	75	61	89	7.00	14.00	Tris buffer without P5P 25°C
Amylase Pancreatic	U/l	275	234	316	20.50	41.00	Immunoinhibition EPS substrate 37°C
	U/l	249	212	286	18.50	37.00	Roche EPS Liquid 37°C
Amylase Total	U/l	274	232	316	21.00	42.00	Other Roche 2-chloro-pNPG7 37°C
	U/l	276	234	318	21.00	42.00	Roche liquid stable pNPG7 37°C
	U/l	274	233	315	20.50	41.00	BM/Roche Colorimetric pNPG7 37°C
AST (GOT)	U/l	127	102	152	12.50	25.00	Tris buffer without P5P 37°C
	U/l	86	69	103	8.50	17.00	Tris buffer without P5P 30°C
	U/l	60	49	71	5.50	11.00	Tris buffer without P5P 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C311®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Bicarbonate	mmol/l	18.3	14.5	22.1	1.90	3.80	Enzymatic
Bilirubin Direct	µmol/l	30.0	23.7	36.3	3.15	6.30	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.76	1.39	2.13	0.19	0.37	
	µmol/l	30.4	24.0	36.8	3.20	6.40	Roche DPD JG standardised
	mg/dl	1.78	1.40	2.16	0.19	0.38	
	µmol/l	28.2	22.3	34.1	2.95	5.90	Roche DPD Doumas standardised
	mg/dl	1.65	1.30	2.00	0.18	0.35	
Bilirubin Total	µmol/l	74.6	58.9	90.3	7.85	15.70	Diazo with Sulphanilic Acid
	mg/dl	4.36	3.45	5.27	0.46	0.91	
	µmol/l	74.3	58.7	89.9	7.80	15.60	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.35	3.43	5.27	0.46	0.92	
	µmol/l	74.9	59.2	90.6	7.85	15.70	Diazonium ion
	mg/dl	4.38	3.46	5.30	0.46	0.92	
Calcium	mmol/l	3.92	3.53	4.31	0.20	0.39	Cresolphthalein complexone
	mg/dl	15.7	14.1	17.3	0.80	1.60	
	mmol/l	3.93	3.54	4.32	0.20	0.39	Arsenazo III
	mg/dl	15.8	14.2	17.4	0.80	1.60	
	mmol/l	3.91	3.52	4.30	0.20	0.39	NM-BAPTA
	mg/dl	15.7	14.1	17.3	0.80	1.60	
Cholesterol	mmol/l	7.36	6.41	8.31	0.48	0.95	Cholesterol Oxidase - Abell Kendall
	mg/dl	284	247	321	18.50	37.00	
	mmol/l	7.38	6.42	8.34	0.48	0.96	Cholesterol Oxidase - IDMS
	mg/dl	285	248	322	18.50	37.00	
	mmol/l	7.29	6.34	8.24	0.48	0.95	Cholesterol Dehydrogenase
	mg/dl	281	245	317	18.00	36.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C311®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Chloride	mmol/l	111	105	117	3.00	6.00	ISE indirect
Cholinesterase	U/l	5355	4284	6426	535.50	1071.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	504	414	594	45.00	90.00	CK-NAC substrate start (DGKC) 37°C
	U/l	316	259	373	28.50	57.00	CK-NAC substrate start (DGKC) 30°C
	U/l	214	176	252	19.00	38.00	CK-NAC substrate start (DGKC) 25°C
	U/l	506	415	597	45.50	91.00	CK-NAC (IFCC) 37°C
	U/l	317	260	374	28.50	57.00	CK-NAC (IFCC) 30°C
	U/l	215	176	254	19.50	39.00	CK-NAC (IFCC) 25°C
Creatinine	µmol/l	371	297	445	37.00	74.00	Alkaline picrate no deproteinization
	mg/dl	4.19	3.36	5.02	0.42	0.83	
	µmol/l	397	318	476	39.50	79.00	Enzymatic UV method
	mg/dl	4.49	3.59	5.39	0.45	0.90	
	µmol/l	375	300	450	37.50	75.00	Roche Creatinine Plus
	mg/dl	4.24	3.39	5.09	0.43	0.85	
	µmol/l	378	302	454	38.00	76.00	Jaffe rate blanked
	mg/dl	4.27	3.41	5.13	0.43	0.86	
	µmol/l	370	296	444	37.00	74.00	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	4.18	3.34	5.02	0.42	0.84	
	µmol/l	368	294	442	37.00	74.00	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	4.16	3.32	5.00	0.42	0.84	
	µmol/l	363	291	435	36.00	72.00	IDMS traceable
	mg/dl	4.10	3.29	4.91	0.41	0.81	
gamma-GT	U/l	168	143	193	12.50	25.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	132	113	151	9.50	19.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	104	88	120	8.00	16.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C311®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
gamma-GT	U/l	184	156	212	14.00	28.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	145	123	167	11.00	22.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	114	96	132	9.00	18.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
Glucose	mmol/l	16.0	13.6	18.4	1.20	2.40	Hexokinase
	mg/dl	288	245	331	21.50	43.00	
	mmol/l	16.2	13.7	18.7	1.25	2.50	Glucose oxidase
	mg/dl	292	247	337	22.50	45.00	
HDL - Cholesterol	mmol/l	2.79	2.37	3.21	0.21	0.42	Direct HDL PEGME
	mg/dl	108	91.5	125	8.25	16.50	
	mmol/l	3.01	2.56	3.46	0.23	0.45	Direct Clearance Method
	mg/dl	116	98.8	133	8.60	17.20	
	mmol/l	2.96	2.52	3.40	0.22	0.44	Direct HDL Roche 4th Generation
	mg/dl	114	97.3	131	8.35	16.70	
Iron	µmol/l	38.7	31.7	45.7	3.50	7.00	Colorimetric with ppt.
	µg/dl	216	177	255	19.50	39.00	
	µmol/l	39.0	32.0	46.0	3.50	7.00	Colorimetric without ppt.
	µg/dl	218	179	257	19.50	39.00	
Lactate	mmol/l	5.95	4.88	7.02	0.54	1.07	Colorimetric Lactate Oxidase
	mg/dl	53.6	44.0	63.2	4.80	9.60	
LD (LDH)	U/l	366	311	421	27.50	55.00	L->P 37°C
	U/l	264	225	303	19.50	39.00	L->P 30°C
	U/l	186	158	214	14.00	28.00	L->P 25°C
	U/l	366	311	421	27.50	55.00	L->P IFCC 37°C
	U/l	264	225	303	19.50	39.00	L->P IFCC 30°C
	U/l	186	158	214	14.00	28.00	L->P IFCC 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C311®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Lipase	U/l	76	61	91	7.50	15.00	Roche Colorimetric 37°C
	U/l	76	61	91	7.50	15.00	Roche Turbidimetric with colipase 37°C
Magnesium	mmol/l	2.02	1.77	2.27	0.13	0.25	Atomic absorption
	mg/dl	4.91	4.30	5.52	0.31	0.61	
	mmol/l	2.02	1.78	2.26	0.12	0.24	Xylidyl Blue
	mg/dl	4.91	4.33	5.49	0.29	0.58	
	mmol/l	2.01	1.77	2.25	0.12	0.24	Methylthymol blue
	mg/dl	4.88	4.30	5.46	0.29	0.58	
	mmol/l	2.05	1.80	2.30	0.13	0.25	Chlorphosphonazo III
	mg/dl	4.98	4.37	5.59	0.31	0.61	
Phosphate Inorganic	mmol/l	2.25	1.91	2.59	0.17	0.34	Phosphomolybdate enzymatic
	mg/dl	6.98	5.92	8.04	0.53	1.06	
	mmol/l	2.24	1.90	2.58	0.17	0.34	Phosphomolybdate UV
	mg/dl	6.94	5.89	7.99	0.53	1.05	
Potassium	mmol/l	6.06	5.75	6.37	0.16	0.31	ISE method - indirect
Protein Total	g/l	45.5	36.4	54.6	4.55	9.10	Biuret reaction end point
	g/dl	4.55	3.64	5.46	0.46	0.91	
	g/l	45.5	36.4	54.6	4.55	9.10	Biuret reaction kinetic
	g/dl	4.55	3.64	5.46	0.46	0.91	
Sodium	mmol/l	158	150	166	4.00	8.00	ISE method - indirect
TIBC	µmol/l	41.3	32.6	50.0	4.35	8.70	FE+UIBC(saturation with iron)
	µg/dl	231	182	280	24.50	49.00	
	µmol/l	40.5	32.0	49.0	4.25	8.50	Direct Colorimetric
	µg/dl	226	179	273	23.50	47.00	
Triglycerides	mmol/l	3.01	2.53	3.49	0.24	0.48	Lipase/GPO-PAP no correction
	mg/dl	266	224	308	21.00	42.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C311®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Triglycerides	mmol/l	3.00	2.52	3.48	0.24	0.48	Lipase/GPO-PAP 0.11mmol/l correction
	mg/dl	266	223	309	21.50	43.00	
	mmol/l	3.01	2.53	3.49	0.24	0.48	L/G Kinase EP. no correction
	mg/dl	266	224	308	21.00	42.00	
	mmol/l	2.91	2.44	3.38	0.24	0.47	L/G kinase EP. 0.11 mmol/l correction
	mg/dl	258	216	300	21.00	42.00	
	mmol/l	3.01	2.53	3.49	0.24	0.48	Lipase/Glycerol Dehydrogenase
	mg/dl	266	224	308	21.00	42.00	
Uric Acid (Urate)	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase catalase 340nm
	mg/dl	9.21	8.01	10.4	0.60	1.20	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.00	7.83	10.2	0.59	1.17	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	8.99	7.81	10.2	0.59	1.18	
	mmol/l	0.51	0.44	0.58	0.03	0.07	Spectrophotometric at 280-290
	mg/dl	8.55	7.44	9.66	0.56	1.11	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.02	7.85	10.2	0.59	1.17	
Urea	mmol/l	19.4	16.5	22.3	1.45	2.90	Urease end point
	mg/dl	117	99.2	135	8.90	17.80	
	mmol/l	19.4	16.5	22.3	1.45	2.90	Urease kinetic
	mg/dl	117	99.2	135	8.90	17.80	
	mmol/l	19.4	16.5	22.3	1.45	2.90	BUN
	mg/dl	54.4	46.2	62.6	4.10	8.20	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c701 / c702 / c711

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	31.4	26.7	36.1	2.35	4.70	Bromocresol Green
	g/dl	3.14	2.67	3.61	0.24	0.47	
	g/l	28.6	24.3	32.9	2.15	4.30	Bromocresol Purple
	g/dl	2.86	2.43	3.29	0.22	0.43	
Alkaline Phosphatase	U/l	326	277	375	24.50	49.00	Roche Integra AMP buffer 37°C
	U/l	254	216	292	19.00	38.00	Roche Integra AMP buffer 30°C
	U/l	208	177	239	15.50	31.00	Roche Integra AMP buffer 25°C
	U/l	347	295	399	26.00	52.00	AMP optimised to IFCC 37°C
	U/l	270	230	310	20.00	40.00	AMP optimised to IFCC 30°C
	U/l	222	189	255	16.50	33.00	AMP optimised to IFCC 25°C
ALT (GPT)	U/l	135	108	162	13.50	27.00	Tris buffer without P5P 37°C
	U/l	100	80	120	10.00	20.00	Tris buffer without P5P 30°C
	U/l	76	61	91	7.50	15.00	Tris buffer without P5P 25°C
Amylase Pancreatic	U/l	249	212	286	18.50	37.00	Immunoinhibition EPS substrate 37°C
	U/l	248	211	285	18.50	37.00	Roche EPS Liquid 37°C
Amylase Total	U/l	273	232	314	20.50	41.00	Roche liquid stable pNPG7 37°C
AST (GOT)	U/l	127	101	153	13.00	26.00	Tris buffer without P5P 37°C
	U/l	86	68	104	9.00	18.00	Tris buffer without P5P 30°C
	U/l	60	48	72	6.00	12.00	Tris buffer without P5P 25°C
Bile Acids	µmol/l	41.2	32.9	49.5	4.15	8.30	Enzymatic Colorimetric
Bicarbonate	mmol/l	18.8	14.9	22.7	1.95	3.90	Enzymatic

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c701 / c702 / c711

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Bilirubin Direct	µmol/l	30.5	24.1	36.9	3.20	6.40	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.78	1.41	2.15	0.19	0.37	
	µmol/l	31.7	25.0	38.4	3.35	6.70	Roche DPD JG standardised
	mg/dl	1.85	1.46	2.24	0.20	0.39	
Bilirubin Total	µmol/l	74.6	59.0	90.2	7.80	15.60	Diazo with Sulphanilic Acid
	mg/dl	4.36	3.45	5.27	0.46	0.91	
	µmol/l	74.3	58.7	89.9	7.80	15.60	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.35	3.43	5.27	0.46	0.92	
	µmol/l	74.3	58.7	89.9	7.80	15.60	Diazonium ion
	mg/dl	4.35	3.43	5.27	0.46	0.92	
Calcium	mmol/l	3.87	3.49	4.25	0.19	0.38	Cresolphthalein complexone
	mg/dl	15.5	14.0	17.0	0.75	1.50	
	mmol/l	3.87	3.48	4.26	0.20	0.39	NM-BAPTA
	mg/dl	15.5	13.9	17.1	0.80	1.60	
Cholesterol	mmol/l	7.31	6.36	8.26	0.48	0.95	Cholesterol Oxidase - Abell Kendall
	mg/dl	282	245	319	18.50	37.00	
	mmol/l	7.32	6.37	8.27	0.48	0.95	Cholesterol Oxidase - IDMS
	mg/dl	283	246	320	18.50	37.00	
Chloride	mmol/l	112	106	118	3.00	6.00	ISE indirect
Cholinesterase	U/l	5191	4153	6229	519.00	1038.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	480	394	566	43.00	86.00	CK-NAC substrate start (DGKC) 37°C
	U/l	300	247	353	26.50	53.00	CK-NAC substrate start (DGKC) 30°C
	U/l	204	167	241	18.50	37.00	CK-NAC substrate start (DGKC) 25°C
	U/l	498	408	588	45.00	90.00	CK-NAC (IFCC) 37°C
	U/l	312	255	369	28.50	57.00	CK-NAC (IFCC) 30°C
	U/l	212	173	251	19.50	39.00	CK-NAC (IFCC) 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c701 / c702 / c711

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Creatinine	µmol/l	377	301	453	38.00	76.00	Roche Creatinine Plus
	mg/dl	4.26	3.40	5.12	0.43	0.86	
	µmol/l	371	297	445	37.00	74.00	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	4.19	3.36	5.02	0.42	0.83	
	µmol/l	372	298	446	37.00	74.00	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	4.20	3.37	5.03	0.42	0.83	
	µmol/l	369	296	442	36.50	73.00	IDMS traceable
	mg/dl	4.17	3.34	5.00	0.42	0.83	
gamma-GT	U/l	175	149	201	13.00	26.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	138	117	159	10.50	21.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	108	92	124	8.00	16.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
	U/l	181	154	208	13.50	27.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	143	121	165	11.00	22.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	112	95	129	8.50	17.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
Glucose	mmol/l	15.9	13.5	18.3	1.20	2.40	Hexokinase
	mg/dl	287	243	331	22.00	44.00	
HDL - Cholesterol	mmol/l	2.93	2.49	3.37	0.22	0.44	Direct HDL Roche 4th Generation
	mg/dl	113	96.1	130	8.45	16.90	
Iron	µmol/l	38.0	31.1	44.9	3.45	6.90	Colorimetric without ppt.
	µg/dl	212	174	250	19.00	38.00	
Lactate	mmol/l	5.89	4.83	6.95	0.53	1.06	Colorimetric Lactate Oxidase
	mg/dl	53.1	43.5	62.7	4.80	9.60	
LD (LDH)	U/l	364	310	418	27.00	54.00	L->P IFCC 37°C
	U/l	263	224	302	19.50	39.00	L->P IFCC 30°C
	U/l	185	157	213	14.00	28.00	L->P IFCC 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c701 / c702 / c711

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Lipase	U/l	78	62	94	8.00	16.00	Roche Colorimetric 37°C
Lithium	mmol/l	2.05	1.81	2.29	0.12	0.24	Spectrophotometric
	mg/dl	1.42	1.26	1.58	0.08	0.16	
Magnesium	mmol/l	2.05	1.80	2.30	0.13	0.25	Xylidyl Blue
	mg/dl	4.98	4.37	5.59	0.31	0.61	
	mmol/l	2.06	1.81	2.31	0.13	0.25	Chlorphosphonazo III
	mg/dl	5.01	4.40	5.62	0.31	0.61	
Osmolality	mOsm/kg	343	274	412	34.50	69.00	Calculated
Phosphate Inorganic	mmol/l	2.20	1.87	2.53	0.17	0.33	Phosphomolybdate UV
	mg/dl	6.82	5.80	7.84	0.51	1.02	
Potassium	mmol/l	6.08	5.78	6.38	0.15	0.30	ISE method - indirect
Protein Total	g/l	45.5	36.4	54.6	4.55	9.10	Biuret reaction end point
	g/dl	4.55	3.64	5.46	0.46	0.91	
Sodium	mmol/l	158	150	166	4.00	8.00	ISE method - indirect
TIBC	µmol/l	39.9	31.5	48.3	4.20	8.40	FE+UIBC(saturation with iron)
	µg/dl	223	176	270	23.50	47.00	
Triglycerides	mmol/l	2.99	2.51	3.47	0.24	0.48	Lipase/GPO-PAP no correction
	mg/dl	265	222	308	21.50	43.00	
	mmol/l	2.95	2.48	3.42	0.24	0.47	Lipase/GPO-PAP 0.11mmol/l correction
	mg/dl	261	219	303	21.00	42.00	
	mmol/l	3.03	2.54	3.52	0.25	0.49	L/G Kinase EP. no correction
	mg/dl	268	225	311	21.50	43.00	
	mmol/l	3.01	2.52	3.50	0.25	0.49	L/G kinase EP. 0.11 mmol/l correction
	mg/dl	266	223	309	21.50	43.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c701 / c702 / c711

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Triglycerides	mmol/l	3.02	2.54	3.50	0.24	0.48	Lipase/Glycerol Dehydrogenase
	mg/dl	267	225	309	21.00	42.00	
Uric Acid (Urate)	mmol/l	0.51	0.45	0.58	0.03	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	8.64	7.51	9.77	0.57	1.13	
	mmol/l	0.52	0.45	0.59	0.03	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	8.75	7.63	9.87	0.56	1.12	
	mmol/l	0.52	0.46	0.59	0.03	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	8.79	7.64	9.94	0.58	1.15	
Urea	mmol/l	19.1	16.2	22.0	1.45	2.90	Urease kinetic
	mg/dl	115	97.4	133	8.80	17.60	
	mmol/l	19.1	16.2	22.0	1.45	2.90	BUN
	mg/dl	53.6	45.6	61.6	4.00	8.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

RX SERIES®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	30.4	25.8	35.0	2.30	4.60	Bromocresol Green
	g/dl	3.04	2.58	3.50	0.23	0.46	
Alkaline Phosphatase	U/l	564	479	649	42.50	85.00	Diethanolamine buffer DEA 37°C
	U/l	380	323	437	28.50	57.00	AMP optimised to IFCC 37°C
ALT (GPT)	U/l	157	126	188	15.50	31.00	Tris buffer without P5P 37°C
Amylase Pancreatic	U/l	288	245	331	21.50	43.00	Randox Liquid Ethylidene pNPG7 37°C
Amylase Total	U/l	310	264	356	23.00	46.00	Randox Liquid Ethylidene pNPG7 37°C
AST (GOT)	U/l	141	113	169	14.00	28.00	Tris buffer without P5P 37°C
Bicarbonate	mmol/l	21.7	17.2	26.2	2.25	4.50	Enzymatic
Bilirubin Direct	µmol/l	29.7	23.5	35.9	3.10	6.20	Diazo with Sulphanilic Acid
	mg/dl	1.74	1.37	2.11	0.19	0.37	
	µmol/l	28.4	22.4	34.4	3.00	6.00	Oxidation to Biliverdin/Vanadate
	mg/dl	1.66	1.31	2.01	0.18	0.35	
Bilirubin Total	µmol/l	80.2	63.4	97.0	8.40	16.80	Diazo with Sulphanilic Acid
	mg/dl	4.69	3.71	5.67	0.49	0.98	
	µmol/l	87.1	68.8	105	9.15	18.30	Oxidation to Biliverdin/Vanadate
	mg/dl	5.10	4.02	6.18	0.54	1.08	
Calcium	mmol/l	3.75	3.38	4.12	0.19	0.37	Arsenazo III
	mg/dl	15.0	13.5	16.5	0.75	1.50	
Cholesterol	mmol/l	7.87	6.85	8.89	0.51	1.02	Cholesterol Oxidase - Abell Kendall
	mg/dl	304	264	344	20.00	40.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

RX SERIES®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Chloride	mmol/l	111	105	117	3.00	6.00	ISE direct
CK Total	U/l	575	472	678	51.50	103.00	CK-NAC substrate start (DGKC) 37°C
	U/l	587	481	693	53.00	106.00	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	330	264	396	33.00	66.00	Alkaline picrate no deproteinization
	mg/dl	3.73	2.98	4.48	0.38	0.75	
	µmol/l	382	306	458	38.00	76.00	Enzymatic UV method
	mg/dl	4.32	3.46	5.18	0.43	0.86	
gamma-GT	U/l	187	159	215	14.00	28.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
Glucose	mmol/l	15.7	13.3	18.1	1.20	2.40	Hexokinase
	mg/dl	283	240	326	21.50	43.00	
	mmol/l	16.0	13.6	18.4	1.20	2.40	Glucose oxidase
	mg/dl	288	245	331	21.50	43.00	
Iron	µmol/l	39.7	32.6	46.8	3.55	7.10	Colorimetric without ppt.
	µg/dl	222	182	262	20.00	40.00	
Lactate	mmol/l	6.02	4.94	7.10	0.54	1.08	Colorimetric Lactate Oxidase
	mg/dl	54.2	44.5	63.9	4.85	9.70	
LD (LDH)	U/l	718	610	826	54.00	108.00	P->L German methods 37°C
	U/l	360	306	414	27.00	54.00	L->P IFCC 37°C
Lipase	U/l	102	82	122	10.00	20.00	Randox Colorimetric 37°C
Magnesium	mmol/l	2.01	1.77	2.25	0.12	0.24	Xylidyl Blue
	mg/dl	4.88	4.30	5.46	0.29	0.58	
Phosphate Inorganic	mmol/l	2.15	1.83	2.47	0.16	0.32	Phosphomolybdate UV
	mg/dl	6.67	5.67	7.67	0.50	1.00	
Potassium	mmol/l	6.18	5.87	6.49	0.16	0.31	Enzymatic
	mmol/l	5.98	5.68	6.28	0.15	0.30	ISE method - direct

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

RX SERIES®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Protein Total	g/l	47.5	38.0	57.0	4.75	9.50	Biuret reaction end point
	g/dl	4.75	3.80	5.70	0.48	0.95	
Sodium	mmol/l	157	149	165	4.00	8.00	Enzymatic
	mmol/l	159	151	167	4.00	8.00	ISE method - direct
TIBC	µmol/l	47.2	37.3	57.1	4.95	9.90	Direct Colorimetric
	µg/dl	264	209	319	27.50	55.00	
Triglycerides	mmol/l	3.01	2.53	3.49	0.24	0.48	Lipase/GPO-PAP no correction
	mg/dl	266	224	308	21.00	42.00	
Uric Acid (Urate)	mmol/l	0.58	0.51	0.66	0.04	0.08	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.79	8.52	11.1	0.64	1.27	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.07	7.90	10.2	0.59	1.17	
Urea	mmol/l	17.9	15.2	20.6	1.35	2.70	Urease kinetic
	mg/dl	108	91.4	125	8.30	16.60	
	mmol/l	17.9	15.2	20.6	1.35	2.70	BUN
	mg/dl	50.2	42.7	57.7	3.75	7.50	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS ADVIA 1200/1650/1800/2400®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	29.6	25.1	34.1	2.25	4.50	Bromocresol Green
	g/dl	2.96	2.51	3.41	0.23	0.45	
Alkaline Phosphatase	U/l	323	274	372	24.50	49.00	AMP optimised to IFCC 37°C
ALT (GPT)	U/l	153	123	183	15.00	30.00	Tris buffer without P5P 37°C
Amylase Pancreatic	U/l	260	221	299	19.50	39.00	Immunoinhibition EPS substrate 37°C
Amylase Total	U/l	285	242	328	21.50	43.00	Siemens - blocked pNPG7 37°C
AST (GOT)	U/l	140	112	168	14.00	28.00	Tris buffer without P5P 37°C
Bile Acids	µmol/l	40.2	32.2	48.2	4.00	8.00	Enzymatic Colorimetric
Bicarbonate	mmol/l	19.7	15.6	23.8	2.05	4.10	Enzymatic
Bilirubin Direct	µmol/l	29.5	23.3	35.7	3.10	6.20	Oxidation to Biliverdin/Vanadate
	mg/dl	1.73	1.36	2.10	0.19	0.37	
Bilirubin Total	µmol/l	87.6	69.2	106	9.20	18.40	Diazo with Sulphanilic Acid
	mg/dl	5.12	4.05	6.19	0.54	1.07	
	µmol/l	91.1	71.9	110	9.60	19.20	Oxidation to Biliverdin/Vanadate
	mg/dl	5.33	4.21	6.45	0.56	1.12	
Calcium	mmol/l	3.76	3.38	4.14	0.19	0.38	Arsenazo III
	mg/dl	15.1	13.5	16.7	0.80	1.60	
Cholesterol	mmol/l	7.37	6.41	8.33	0.48	0.96	Cholesterol Oxidase - Abell Kendall
	mg/dl	284	247	321	18.50	37.00	
	mmol/l	7.37	6.41	8.33	0.48	0.96	Cholesterol Oxidase - IDMS
	mg/dl	284	247	321	18.50	37.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS ADVIA 1200/1650/1800/2400®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Chloride	mmol/l	115	109	121	3.00	6.00	ISE indirect
CK Total	U/l	517	424	610	46.50	93.00	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	349	279	419	35.00	70.00	Alkaline picrate with deproteinization
	mg/dl	3.94	3.15	4.73	0.40	0.79	
	µmol/l	357	286	428	35.50	71.00	Alkaline picrate no deproteinization
	mg/dl	4.03	3.23	4.83	0.40	0.80	
	µmol/l	376	301	451	37.50	75.00	Enzymatic UV method
	mg/dl	4.25	3.40	5.10	0.43	0.85	
	µmol/l	366	293	439	36.50	73.00	Creatinine PAP method
	mg/dl	4.14	3.31	4.97	0.42	0.83	
	µmol/l	371	297	445	37.00	74.00	Jaffe rate blanked
	mg/dl	4.19	3.36	5.02	0.42	0.83	
	µmol/l	364	291	437	36.50	73.00	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	4.11	3.29	4.93	0.41	0.82	
	µmol/l	377	302	452	37.50	75.00	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	4.26	3.41	5.11	0.43	0.85	
gamma-GT	U/l	179	152	206	13.50	27.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	164	140	188	12.00	24.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
Glucose	mmol/l	15.7	13.3	18.1	1.20	2.40	Hexokinase
	mg/dl	283	240	326	21.50	43.00	
	mmol/l	15.9	13.5	18.3	1.20	2.40	Glucose oxidase
	mg/dl	287	243	331	22.00	44.00	
HDL - Cholesterol	mmol/l	2.37	2.01	2.73	0.18	0.36	Direct HDL Immunoseparation
	mg/dl	91.5	77.6	105	6.95	13.90	
	mmol/l	2.41	2.05	2.77	0.18	0.36	Direct Clearance Method
	mg/dl	93.0	79.1	107	6.95	13.90	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS ADVIA 1200/1650/1800/2400®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Iron	µmol/l	38.6	31.7	45.5	3.45	6.90	Colorimetric without ppt.
	µg/dl	216	177	255	19.50	39.00	
Lactate	mmol/l	5.78	4.74	6.82	0.52	1.04	Colorimetric Lactate Oxidase
	mg/dl	52.1	42.7	61.5	4.70	9.40	
LD (LDH)	U/l	369	314	424	27.50	55.00	L->P 37°C
	U/l	362	308	416	27.00	54.00	L->P IFCC 37°C
Lipase	U/l	88	71	105	8.50	17.00	Other Colorimetric 37°C
Lithium	mmol/l	1.98	1.74	2.22	0.12	0.24	Spectrophotometric
	mg/dl	1.37	1.21	1.53	0.08	0.16	
Magnesium	mmol/l	1.91	1.68	2.14	0.12	0.23	Xylidyl Blue
	mg/dl	4.64	4.08	5.20	0.28	0.56	
Phosphate Inorganic	mmol/l	2.32	1.98	2.66	0.17	0.34	Phosphomolybdate UV
	mg/dl	7.19	6.14	8.24	0.53	1.05	
Potassium	mmol/l	6.10	5.79	6.41	0.16	0.31	ISE method - indirect
Protein Total	g/l	45.6	36.5	54.7	4.55	9.10	Biuret reaction end point
	g/dl	4.56	3.65	5.47	0.46	0.91	
	g/l	45.8	36.6	55.0	4.60	9.20	Biuret reaction kinetic
	g/dl	4.58	3.66	5.50	0.46	0.92	
Sodium	mmol/l	160	152	168	4.00	8.00	ISE method - indirect
TIBC	µmol/l	45.2	35.7	54.7	4.75	9.50	FE+UIBC(saturation with iron)
	µg/dl	253	200	306	26.50	53.00	
	µmol/l	44.5	35.1	53.9	4.70	9.40	Direct Colorimetric
	µg/dl	249	196	302	26.50	53.00	
Triglycerides	mmol/l	3.04	2.56	3.52	0.24	0.48	Lipase/GPO-PAP no correction
	mg/dl	269	227	311	21.00	42.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS ADVIA 1200/1650/1800/2400®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Triglycerides	mmol/l	2.99	2.51	3.47	0.24	0.48	L/G Kinase EP. no correction
	mg/dl	265	222	308	21.50	43.00	
Uric Acid (Urate)	mmol/l	0.55	0.48	0.63	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.31	8.10	10.5	0.61	1.21	
	mmol/l	0.55	0.47	0.62	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.16	7.96	10.4	0.60	1.20	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.00	7.83	10.2	0.59	1.17	
Urea	mmol/l	19.5	16.5	22.5	1.50	3.00	Urease end point
	mg/dl	117	99.2	135	8.90	17.80	
	mmol/l	19.4	16.5	22.3	1.45	2.90	Urease kinetic
	mg/dl	117	99.2	135	8.90	17.80	
	mmol/l	19.4	16.5	22.3	1.45	2.90	BUN
	mg/dl	54.4	46.2	62.6	4.10	8.20	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Siemens Atellica Solution

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	29.5	25.0	34.0	2.25	4.50	Bromocresol Green
	g/dl	2.95	2.50	3.40	0.23	0.45	
	g/l	29.2	24.8	33.6	2.20	4.40	Bromocresol Purple
	g/dl	2.92	2.48	3.36	0.22	0.44	
Alkaline Phosphatase	U/l	324	275	373	24.50	49.00	AMP optimised to IFCC 37°C
ALT (GPT)	U/l	155	124	186	15.50	31.00	Tris buffer without P5P 37°C
	U/l	156	125	187	15.50	31.00	Siemens Dade Standard Non IFCC Correlated 37°C
Amylase Pancreatic	U/l	288	245	331	21.50	43.00	Immunoinhibition EPS substrate 37°C
Amylase Total	U/l	319	272	366	23.50	47.00	Siemens - blocked pNPG7 37°C
AST (GOT)	U/l	139	112	166	13.50	27.00	Tris buffer without P5P 37°C
	U/l	140	112	168	14.00	28.00	Siemens Dade Standard Non IFCC Correlated 37°C
Bicarbonate	mmol/l	20.3	16.1	24.5	2.10	4.20	Enzymatic
Bilirubin Direct	µmol/l	31.1	24.6	37.6	3.25	6.50	Oxidation to Biliverdin/Vanadate
	mg/dl	1.82	1.44	2.20	0.19	0.38	
Bilirubin Total	µmol/l	91.3	72.1	111	9.60	19.20	Oxidation to Biliverdin/Vanadate
	mg/dl	5.34	4.22	6.46	0.56	1.12	
Calcium	mmol/l	4.04	3.63	4.45	0.21	0.41	Cresolphthalein complexone
	mg/dl	16.2	14.5	17.9	0.85	1.70	
	mmol/l	3.78	3.41	4.15	0.19	0.37	Arsenazo III
	mg/dl	15.2	13.7	16.7	0.75	1.50	
Cholesterol	mmol/l	7.32	6.37	8.27	0.48	0.95	Cholesterol Oxidase - Abell Kendall
	mg/dl	283	246	320	18.50	37.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Siemens Atellica Solution

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Cholesterol	mmol/l	7.34	6.39	8.29	0.48	0.95	Cholesterol Oxidase - IDMS
	mg/dl	283	247	319	18.00	36.00	
Chloride	mmol/l	115	109	121	3.00	6.00	ISE indirect
Cholinesterase	U/l	6761	5409	8113	676.00	1352.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	507	416	598	45.50	91.00	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	366	293	439	36.50	73.00	Alkaline picrate no deproteinization
	mg/dl	4.14	3.31	4.97	0.42	0.83	
	µmol/l	375	300	450	37.50	75.00	Enzymatic UV method
	mg/dl	4.24	3.39	5.09	0.43	0.85	
	µmol/l	375	300	450	37.50	75.00	Creatinine PAP method
	mg/dl	4.24	3.39	5.09	0.43	0.85	
	µmol/l	363	290	436	36.50	73.00	Jaffe rate blanked
	mg/dl	4.10	3.28	4.92	0.41	0.82	
	µmol/l	363	291	435	36.00	72.00	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	4.10	3.29	4.91	0.41	0.81	
gamma-GT	U/l	167	142	192	12.50	25.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	164	140	188	12.00	24.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
Glucose	mmol/l	15.7	13.3	18.1	1.20	2.40	Hexokinase
	mg/dl	283	240	326	21.50	43.00	
	mmol/l	15.9	13.5	18.3	1.20	2.40	Glucose oxidase
	mg/dl	287	243	331	22.00	44.00	
HDL - Cholesterol	mmol/l	2.83	2.40	3.26	0.22	0.43	Direct HDL PPD
	mg/dl	109	92.6	125	8.20	16.40	
	mmol/l	2.86	2.43	3.29	0.22	0.43	Direct HDL Immunoseparation
	mg/dl	110	93.8	126	8.10	16.20	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Siemens Atellica Solution

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
HDL - Cholesterol	mmol/l	2.92	2.48	3.36	0.22	0.44	Direct Clearance Method
	mg/dl	113	95.7	130	8.65	17.30	
Iron	µmol/l	39.0	31.9	46.1	3.55	7.10	Colorimetric with ppt.
	µg/dl	218	178	258	20.00	40.00	
	µmol/l	38.8	31.8	45.8	3.50	7.00	Colorimetric without ppt.
	µg/dl	217	178	256	19.50	39.00	
Lactate	mmol/l	6.01	4.93	7.09	0.54	1.08	Colorimetric Lactate Oxidase
	mg/dl	54.2	44.4	64.0	4.90	9.80	
LD (LDH)	U/l	362	307	417	27.50	55.00	L->P 37°C
	U/l	361	307	415	27.00	54.00	L->P IFCC 37°C
Lipase	U/l	88	70	106	9.00	18.00	Other Colorimetric 37°C
Lithium	mmol/l	1.98	1.74	2.22	0.12	0.24	Spectrophotometric
	mg/dl	1.37	1.21	1.53	0.08	0.16	
Magnesium	mmol/l	1.99	1.75	2.23	0.12	0.24	Xylidyl Blue
	mg/dl	4.84	4.25	5.43	0.30	0.59	
Osmolality	mOsm/kg	345	276	414	34.50	69.00	Calculated
Phosphate Inorganic	mmol/l	2.30	1.96	2.64	0.17	0.34	Phosphomolybdate UV
	mg/dl	7.13	6.08	8.18	0.53	1.05	
Potassium	mmol/l	5.98	5.68	6.28	0.15	0.30	ISE method - indirect
Protein Total	g/l	46.1	36.9	55.3	4.60	9.20	Biuret reaction end point
	g/dl	4.61	3.69	5.53	0.46	0.92	
Sodium	mmol/l	157	149	165	4.00	8.00	ISE method - indirect
Thyroid Stimulating Hormone	µU/ml =	1.23	0.98	1.48	0.12	0.25	Siemens Atellica IM
TIBC	µmol/l	47.0	37.1	56.9	4.95	9.90	Direct Colorimetric
	µg/dl	263	207	319	28.00	56.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Siemens Atellica Solution

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Triglycerides	mmol/l	3.03	2.55	3.51	0.24	0.48	Lipase/GPO-PAP no correction
	mg/dl	268	226	310	21.00	42.00	
	mmol/l	3.08	2.58	3.58	0.25	0.50	L/G Kinase EP. no correction
	mg/dl	273	228	318	22.50	45.00	
Uric Acid (Urate)	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.19	8.00	10.4	0.60	1.19	
	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.19	8.00	10.4	0.60	1.19	
	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.22	8.03	10.4	0.60	1.19	
Urea	mmol/l	19.2	16.3	22.1	1.45	2.90	Urease end point
	mg/dl	115	98.0	132	8.50	17.00	
	mmol/l	19.0	16.1	21.9	1.45	2.90	Urease kinetic
	mg/dl	114	96.8	131	8.60	17.20	
	mmol/l	19.1	16.2	22.0	1.45	2.90	Urease hypochlorite
	mg/dl	115	97.4	133	8.80	17.60	
	mmol/l	19.0	16.2	21.8	1.40	2.80	BUN
	mg/dl	53.3	45.3	61.3	4.00	8.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS DIMENSION EXL®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	27.6	23.5	31.7	2.05	4.10	Bromocresol Green
	g/dl	2.76	2.35	3.17	0.21	0.41	
	g/l	28.2	24.0	32.4	2.10	4.20	Bromocresol Purple
	g/dl	2.82	2.40	3.24	0.21	0.42	
Alkaline Phosphatase	U/l	332	282	382	25.00	50.00	Siemens Dimension AMP buffer 37°C
	U/l	333	283	383	25.00	50.00	AMP optimised to IFCC 37°C
ALT (GPT)	U/l	153	122	184	15.50	31.00	Tris buffer with P5P 37°C
	U/l	155	124	186	15.50	31.00	Siemens Dade Standard Non IFCC Correlated 37°C
Amylase Total	U/l	327	278	376	24.50	49.00	Siemens - maltopenta/hexaoside 37°C
	U/l	329	279	379	25.00	50.00	Siemens 2-chloro-pNPG3 37°C
AST (GOT)	U/l	158	127	189	15.50	31.00	Tris buffer with P5P 37°C
	U/l	162	130	194	16.00	32.00	Siemens Dade Standard Non IFCC Correlated 37°C
Bicarbonate	mmol/l	20.7	16.4	25.0	2.15	4.30	Enzymatic
Bilirubin Direct	µmol/l	19.1	15.1	23.1	2.00	4.00	Diazo with Sulphanilic Acid
	mg/dl	1.12	0.883	1.36	0.12	0.24	
	µmol/l	19.0	15.0	23.0	2.00	4.00	Diazo/Sulphanilic Siemens Dimension
	mg/dl	1.11	0.878	1.34	0.12	0.23	
Bilirubin Total	µmol/l	80.8	63.8	97.8	8.50	17.00	Diazo with Sulphanilic Acid
	mg/dl	4.73	3.73	5.73	0.50	1.00	
Calcium	mmol/l	3.85	3.46	4.24	0.20	0.39	Cresolphthalein complexone
	mg/dl	15.4	13.9	16.9	0.75	1.50	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS DIMENSION EXL®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Cholesterol	mmol/l	7.00	6.09	7.91	0.46	0.91	Cholesterol Oxidase - Abell Kendall
	mg/dl	270	235	305	17.50	35.00	
	mmol/l	7.07	6.15	7.99	0.46	0.92	Dimension-Siemens reagents
	mg/dl	273	237	309	18.00	36.00	
Chloride	mmol/l	113	108	118	2.50	5.00	ISE indirect
Cholinesterase	U/l	9320	7456	11184	932.00	1864.00	Colorimetric - Butyrythiochol. Dimension 37°C
CK Total	U/l	500	410	590	45.00	90.00	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	374	300	448	37.00	74.00	Alkaline picrate with deproteinization
	mg/dl	4.23	3.39	5.07	0.42	0.84	
	µmol/l	375	300	450	37.50	75.00	Alkaline picrate no deproteinization
	mg/dl	4.24	3.39	5.09	0.43	0.85	
	µmol/l	376	301	451	37.50	75.00	Enzymatic UV method
	mg/dl	4.25	3.40	5.10	0.43	0.85	
	µmol/l	373	298	448	37.50	75.00	Creatinine PAP method
	mg/dl	4.21	3.37	5.05	0.42	0.84	
	µmol/l	374	299	449	37.50	75.00	Jaffe rate blanked
	mg/dl	4.23	3.38	5.08	0.43	0.85	
	µmol/l	371	297	445	37.00	74.00	IDMS traceable
	mg/dl	4.19	3.36	5.02	0.42	0.83	
Free T4	pmol/l	81.0	60.8	101	10.10	20.20	Siemens Dimension Exl LOCI
	ng/dl	6.32	4.74	7.90	0.79	1.58	
	pg/ml	63.2	47.4	79.0	7.90	15.80	Siemens Dimension Exl LOCI
gamma-GT	U/l	186	158	214	14.00	28.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	214	182	246	16.00	32.00	Siemens Dimension (non IFCC) 37°C
Glucose	mmol/l	16.0	13.6	18.4	1.20	2.40	Hexokinase
	mg/dl	288	245	331	21.50	43.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS DIMENSION EXL®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Glucose	mmol/l	15.8	13.4	18.2	1.20	2.40	Oxygen electrode
	mg/dl	285	241	329	22.00	44.00	
HDL - Cholesterol	mmol/l	2.96	2.51	3.41	0.23	0.45	Direct HDL PPD
	mg/dl	114	96.9	131	8.55	17.10	
	mmol/l	2.92	2.48	3.36	0.22	0.44	Direct HDL PEGME
	mg/dl	113	95.7	130	8.65	17.30	
Iron	µmol/l	36.9	30.2	43.6	3.35	6.70	Colorimetric with ppt.
	µg/dl	206	169	243	18.50	37.00	
	µmol/l	36.5	29.9	43.1	3.30	6.60	Colorimetric without ppt.
	µg/dl	204	167	241	18.50	37.00	
Lactate	mmol/l	5.63	4.62	6.64	0.51	1.01	UV LDH
	mg/dl	50.7	41.6	59.8	4.55	9.10	
LD (LDH)	U/l	346	294	398	26.00	52.00	Siemens Dimension L-P Non IFCC 37°C
	U/l	352	299	405	26.50	53.00	L->P IFCC 37°C
Lipase	U/l	77	61	93	8.00	16.00	Siemens Dimension Colorimetric (LIP Kit) 37°C
Magnesium	mmol/l	2.02	1.78	2.26	0.12	0.24	Methylthymol blue
	mg/dl	4.91	4.33	5.49	0.29	0.58	
Osmolality	mOsm/kg	338	270	406	34.00	68.00	Calculated
Phosphate Inorganic	mmol/l	2.31	1.96	2.66	0.18	0.35	Phosphomolybdate enzymatic
	mg/dl	7.16	6.08	8.24	0.54	1.08	
	mmol/l	2.32	1.97	2.67	0.18	0.35	Phosphomolybdate UV
	mg/dl	7.19	6.11	8.27	0.54	1.08	
Potassium	mmol/l	6.03	5.73	6.33	0.15	0.30	ISE method - indirect
Protein Total	g/l	47.2	37.8	56.6	4.70	9.40	Biuret reaction end point
	g/dl	4.72	3.78	5.66	0.47	0.94	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS DIMENSION EXL®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
PSA Total	ng/ml =	19.9	14.9	24.9	2.50	5.00	Siemens Dimension
Sodium	mmol/l	158	150	166	4.00	8.00	ISE method - indirect
Thyroid Stimulating Hormone	µU/ml =	1.18	0.95	1.41	0.12	0.23	Siemens Dimension ExI LOCI
TIBC	µmol/l	36.3	28.6	44.0	3.85	7.70	Removal of excess free iron
	µg/dl	203	160	246	21.50	43.00	
	µmol/l	36.3	28.7	43.9	3.80	7.60	FE+UIBC(saturation with iron)
	µg/dl	203	160	246	21.50	43.00	
	µmol/l	37.6	29.7	45.5	3.95	7.90	Direct Colorimetric
	µg/dl	210	166	254	22.00	44.00	
Triglycerides	mmol/l	2.96	2.49	3.43	0.24	0.47	Lipase/GPO-PAP no correction
	mg/dl	262	220	304	21.00	42.00	
	mmol/l	2.96	2.48	3.44	0.24	0.48	L/G Kinase EP. no correction
	mg/dl	262	219	305	21.50	43.00	
	mmol/l	2.94	2.47	3.41	0.24	0.47	Lipase/Glycerol Dehydrogenase
	mg/dl	260	219	301	20.50	41.00	
Uric Acid (Urate)	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase catalase 340nm
	mg/dl	9.11	7.91	10.3	0.60	1.20	
	mmol/l	0.55	0.48	0.62	0.04	0.07	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.21	8.01	10.4	0.60	1.20	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.06	7.88	10.2	0.59	1.18	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Spectrophotometric at 280-290
	mg/dl	9.11	7.93	10.3	0.59	1.18	
Urea	mmol/l	19.5	16.5	22.5	1.50	3.00	Urease end point
	mg/dl	117	99.2	135	8.90	17.80	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS DIMENSION EXL®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Urea	mmol/l	20.0	17.0	23.0	1.50	3.00	Urease kinetic
	mg/dl	120	102	138	9.00	18.00	
	mmol/l	20.0	17.0	23.0	1.50	3.00	BUN
	mg/dl	56.1	47.7	64.5	4.20	8.40	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS DIMENSION RxL/Max/Xpand®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	27.6	23.5	31.7	2.05	4.10	Bromocresol Green
	g/dl	2.76	2.35	3.17	0.21	0.41	
	g/l	28.2	24.0	32.4	2.10	4.20	Bromocresol Purple
	g/dl	2.82	2.40	3.24	0.21	0.42	
Alkaline Phosphatase	U/l	329	280	378	24.50	49.00	Siemens Dimension AMP buffer 37°C
	U/l	332	282	382	25.00	50.00	AMP optimised to IFCC 37°C
ALT (GPT)	U/l	153	123	183	15.00	30.00	Tris buffer with P5P 37°C
	U/l	153	123	183	15.00	30.00	Siemens Dade Standard Non IFCC Correlated 37°C
Amylase Total	U/l	331	281	381	25.00	50.00	Siemens 2-chloro-pNPG3 37°C
AST (GOT)	U/l	161	129	193	16.00	32.00	Tris buffer with P5P 37°C
	U/l	159	127	191	16.00	32.00	Siemens Dade Standard Non IFCC Correlated 37°C
Bicarbonate	mmol/l	21.5	17.0	26.0	2.25	4.50	Enzymatic
Bilirubin Direct	µmol/l	20.1	15.9	24.3	2.10	4.20	Diazo with Sulphanilic Acid
	mg/dl	1.18	0.930	1.43	0.13	0.25	
	µmol/l	18.9	14.9	22.9	2.00	4.00	Diazo/Sulphanilic Siemens Dimension
	mg/dl	1.11	0.872	1.35	0.12	0.24	
Bilirubin Total	µmol/l	80.3	63.4	97.2	8.45	16.90	Diazo with Sulphanilic Acid
	mg/dl	4.70	3.71	5.69	0.50	0.99	
Calcium	mmol/l	3.86	3.48	4.24	0.19	0.38	Cresolphthalein complexone
	mg/dl	15.5	13.9	17.1	0.80	1.60	
Cholesterol	mmol/l	7.16	6.23	8.09	0.47	0.93	Cholesterol Oxidase - Abell Kendall
	mg/dl	276	240	312	18.00	36.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS DIMENSION RxL/Max/Xpand®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Cholesterol	mmol/l	6.98	6.08	7.88	0.45	0.90	Dimension-Siemens reagents
	mg/dl	269	235	303	17.00	34.00	
Chloride	mmol/l	114	108	120	3.00	6.00	ISE indirect
CK Total	U/l	507	416	598	45.50	91.00	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	375	300	450	37.50	75.00	Alkaline picrate no deproteinization
	mg/dl	4.24	3.39	5.09	0.43	0.85	
	µmol/l	377	301	453	38.00	76.00	Creatinine PAP method
	mg/dl	4.26	3.40	5.12	0.43	0.86	
	µmol/l	367	293	441	37.00	74.00	Jaffe rate blanked
	mg/dl	4.15	3.31	4.99	0.42	0.84	
	µmol/l	377	301	453	38.00	76.00	IDMS traceable
	mg/dl	4.26	3.40	5.12	0.43	0.86	
gamma-GT	U/l	192	164	220	14.00	28.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	206	175	237	15.50	31.00	Siemens Dimension (non IFCC) 37°C
Glucose	mmol/l	16.1	13.6	18.6	1.25	2.50	Hexokinase
	mg/dl	290	245	335	22.50	45.00	
HDL - Cholesterol	mmol/l	3.01	2.56	3.46	0.23	0.45	Direct HDL PPD
	mg/dl	116	98.8	133	8.60	17.20	
	mmol/l	2.93	2.49	3.37	0.22	0.44	Direct HDL PEGME
	mg/dl	113	96.1	130	8.45	16.90	
Iron	µmol/l	36.8	30.2	43.4	3.30	6.60	Colorimetric with ppt.
	µg/dl	206	169	243	18.50	37.00	
	µmol/l	37.1	30.4	43.8	3.35	6.70	Colorimetric without ppt.
	µg/dl	207	170	244	18.50	37.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS DIMENSION RxL/Max/Xpand®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
LD (LDH)	U/l	341	290	392	25.50	51.00	Siemens Dimension L-P Non IFCC 37°C
	U/l	352	299	405	26.50	53.00	L->P IFCC 37°C
Magnesium	mmol/l	2.03	1.79	2.27	0.12	0.24	Methylthymol blue
	mg/dl	4.93	4.35	5.51	0.29	0.58	
Phosphate Inorganic	mmol/l	2.27	1.93	2.61	0.17	0.34	Phosphomolybdate enzymatic
	mg/dl	7.04	5.98	8.10	0.53	1.06	
	mmol/l	2.32	1.97	2.67	0.18	0.35	Phosphomolybdate UV
	mg/dl	7.19	6.11	8.27	0.54	1.08	
Potassium	mmol/l	5.99	5.69	6.29	0.15	0.30	ISE method - indirect
Protein Total	g/l	47.2	37.7	56.7	4.75	9.50	Biuret reaction end point
	g/dl	4.72	3.77	5.67	0.48	0.95	
Sodium	mmol/l	157	149	165	4.00	8.00	ISE method - indirect
TIBC	µmol/l	37.6	29.7	45.5	3.95	7.90	Removal of excess free iron
	µg/dl	210	166	254	22.00	44.00	
	µmol/l	36.0	28.4	43.6	3.80	7.60	FE+UIBC(saturation with iron)
	µg/dl	201	159	243	21.00	42.00	
	µmol/l	36.3	28.6	44.0	3.85	7.70	Direct Colorimetric
	µg/dl	203	160	246	21.50	43.00	
Triglycerides	mmol/l	2.93	2.46	3.40	0.24	0.47	Lipase/GPO-PAP no correction
	mg/dl	259	218	300	20.50	41.00	
	mmol/l	2.95	2.47	3.43	0.24	0.48	L/G Kinase EP. no correction
	mg/dl	261	219	303	21.00	42.00	
	mmol/l	2.89	2.43	3.35	0.23	0.46	Lipase/Glycerol Dehydrogenase
	mg/dl	256	215	297	20.50	41.00	
Uric Acid (Urate)	mmol/l	0.54	0.47	0.61	0.04	0.07	Uricase catalase 340nm
	mg/dl	9.06	7.88	10.2	0.59	1.18	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS DIMENSION RxL/Max/Xpand®

ASSAYED HUMAN SERA LEVEL 3 (HUM ASY CONTROL 3)

Lot. No. 1328UE Cat. No. HE1532 / HS2611

Size 20 x 5 ml / 5 x 5 ml Expiry 2027-03-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
Uric Acid (Urate)	mmol/l	0.53	0.46	0.60	0.04	0.07	Uricase peroxidase no ascorbate oxidase
	mg/dl	8.97	7.80	10.1	0.59	1.17	
	mmol/l	0.54	0.47	0.61	0.04	0.07	Spectrophotometric at 280-290
	mg/dl	9.09	7.90	10.3	0.60	1.19	
Urea	mmol/l	20.6	17.5	23.7	1.55	3.10	Urease end point
	mg/dl	124	105	143	9.50	19.00	
	mmol/l	20.1	17.1	23.1	1.50	3.00	Urease kinetic
	mg/dl	121	103	139	9.00	18.00	
	mmol/l	20.1	17.1	23.1	1.50	3.00	BUN
	mg/dl	56.4	47.9	64.9	4.25	8.50	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

PRODUCT INFORMATION

HN1530 / HS2611

1592UN

Please note that for Human Assayed Multi-Sera Level 2, lot 1592UN, the stability of Alkaline Phosphatase **4 hours** at +15°C to +25°C.

Alkaline Phosphatase is also stable for 7 days at +2°C to +8°C, or 28 days when frozen once at -18°C to -24°C

CCS INC 194

FORM NO. 8373-GP
REVISION (2)
2 Aug 2019

HUMAN ASSAYED MULTI-SERA - LEVEL 2 (HUM ASY CONTROL 2)

CAT. NO. HN1530 **GTIN:** 05055273203783 **SIZE:** 20 x 5ml
CAT. NO. HS2611 **GTIN:** 05055273203813 **SIZE:** 5 x 5ml
LOT NO. 1592UN **EXPIRY:** 2026-01-28

INTENDED USE
This product is intended for *in vitro* diagnostic use, in the quality control of diagnostic assays. The Human Assayed Multi-sera is for the control of accuracy.

DEVICE DESCRIPTION
The Human Assayed Multi-sera is supplied at 2 levels, level 2 and 3. Target values and ranges are supplied for the analytes listed in the values section at both levels.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.
However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY
OPENED: Store refrigerated (+2°C to +8°C). Reconstituted serum is stable for 8 hours at +15°C to +25°C or 7 days at +2°C to +8°C, and 28 days when frozen once at –18°C to –24°C. (See Limitations)

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

LIMITATIONS
For Total & Prostatic Acid Phosphatase, the material should be stabilised by adding 1 drop (25µl - 30µl) of 0.7M Acetic acid solution to 1ml of the serum exactly 30 minutes after reconstitution. After stabilisation Total and Prostatic Acid Phosphatase is stable for 2 hours at +15°C to +25°C, 2 days at +2°C to +8°C, and 28 days when frozen once at –18°C to –24°C.
Alkaline Phosphatase levels in the reconstituted serum will rise over the stability period. It is recommended that the reconstituted serum is allowed to stand for 1 hour at +15°C to +25°C before measurement.
Once reconstituted, Alkaline Phosphatase is stable for 7 days at +2°C to +8°C, 4 hours at +15°C to +25°C and 28 days when frozen once at -18°C to -24°C.
Bilirubin in the serum is light sensitive and it is recommended that the serum is stored in the dark. Stored in the dark, it is stable for 4 days at +2°C to +8°C. Do not store at +15°C to +25°C. Do not freeze.
GLDH is stable for 2 days at 2-8°C.
NEFA is stable for 1 day at +2°C to +8°C.
Total PSA is stable for 4 days at +2°C to +8°C, or 28 days in aliquots frozen at –18°C to –24°C.
Bacterial contamination of the reconstituted serum will cause reductions in the stability of many components.
Different lot numbers of this control should not be interchanged, as the values assigned to the controls vary from lot to lot.
The control should not be used as a calibration material.
Due to the zinc content in some batches of rubber stoppers, the QC and calibrator material should be aliquoted into polypropylene tubes and stored at +2°C to +8°C to ensure stable zinc levels throughout the stability period.

PREPARATION FOR USE
The Human Assayed Multi-sera is supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised serum with exactly 5ml of distilled water at +15°C to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.

2. Refer to the Control section of the individual analyser application.

3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED
Human Assayed Multi-sera - Level 2 20 x 5ml / 5 x 5ml

MATERIALS REQUIRED BUT NOT PROVIDED
Volumetric pipette

ASSIGNED VALUES
Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

Each batch of assayed human serum is submitted to reference laboratories for assignment against international Reference Standards. Where international Reference Standards are unavailable, Reference Methods are used. Values are also collected from approx. 3000 laboratories worldwide and using a unique statistical analysis, a value is assigned.

With each batch, a control range is provided for individual parameters and each parameter method. The control range is equivalent to the assigned mean ±2S.D.

If an instrument specific value is not available, refer to the Method section. If necessary, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

NOTES
® All trademarks recognised.

(1) Applies only in Germany. Ranges established according to the Guidelines of the Federal Chamber of Physicians in Germany.
(2) Values established by reference laboratories officially recognised by the Federal Chamber of Physicians in Germany.
(3) DGKC: German Society for Clinical Chemistry.
(4) IFCC: International Federation of Clinical Chemistry.
(5) SCE: Scandinavian Committee on Enzymes.

EC REP Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

Rev. 26 Sep '23 me

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	42.1	35.8	48.4	3.15	6.30	Bromocresol Green
	g/dl	4.21	3.58	4.84	0.32	0.63	
	g/l	42.4	36.1	48.7	3.15	6.30	Bromocresol Purple
	g/dl	4.24	3.61	4.87	0.32	0.63	
	g/l	41.9	35.6	48.2	3.15	6.30	Ortho Vitros Microslide Systems
	g/dl	4.19	3.56	4.82	0.32	0.63	
	g/l	40.1	34.1	46.1	3.00	6.00	Turbidimetric Assays
	g/dl	4.01	3.41	4.61	0.30	0.60	
Alkaline Phosphatase	U/l	170	145	195	12.50	25.00	Ortho Vitros Microslide Systems 37°C
	U/l	291	248	334	21.50	43.00	Diethanolamine buffer DEA 37°C
	U/l	227	193	261	17.00	34.00	Diethanolamine buffer DEA 30°C
	U/l	186	158	214	14.00	28.00	Diethanolamine buffer DEA 25°C
	U/l	193	164	222	14.50	29.00	AMP optimised to IFCC 37°C
	U/l	150	128	172	11.00	22.00	AMP optimised to IFCC 30°C
	U/l	123	105	141	9.00	18.00	AMP optimised to IFCC 25°C
	U/l	185	157	213	14.00	28.00	AMP non-optimised 37°C
	U/l	144	122	166	11.00	22.00	AMP non-optimised 30°C
	U/l	118	100	136	9.00	18.00	AMP non-optimised 25°C
	U/l	176	150	202	13.00	26.00	Colorimetric 37°C
	U/l	137	117	157	10.00	20.00	Colorimetric 30°C
	U/l	112	96	128	8.00	16.00	Colorimetric 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
ALT (GPT)	U/l	31	25	37	3.00	6.00	Colorimetric 37°C
	U/l	23	19	27	2.00	4.00	Colorimetric 30°C
	U/l	17	14	20	1.50	3.00	Colorimetric 25°C
	U/l	37	29	45	4.00	8.00	Tris buffer with P5P 37°C
	U/l	27	21	33	3.00	6.00	Tris buffer with P5P 30°C
	U/l	21	16	26	2.50	5.00	Tris buffer with P5P 25°C
	U/l	32	26	38	3.00	6.00	Tris buffer without P5P 37°C
	U/l	24	19	29	2.50	5.00	Tris buffer without P5P 30°C
	U/l	18	15	21	1.50	3.00	Tris buffer without P5P 25°C
	U/l	43	34	52	4.50	9.00	Tris buffer with P5P NVKC 37°C
	U/l	32	25	39	3.50	7.00	Tris buffer with P5P NVKC 30°C
	U/l	24	19	29	2.50	5.00	Tris buffer with P5P NVKC 25°C
	U/l	37	29	45	4.00	8.00	Ortho Vitros MicroSlide visible 37°C
Amylase Pancreatic	U/l	66	56	76	5.00	10.00	Immunoinhibition EPS substrate 37°C
	U/l	66	56	76	5.00	10.00	Roche EPS Liquid 37°C
	U/l	76	64	88	5.90	11.80	Randox Liquid Ethylidene pNPG7 37°C
Amylase Total	U/l	94	80	108	7.00	14.00	pNP Maltotrioside substrates 37°C
	U/l	97	83	111	7.00	14.00	Siemens - blocked pNPG7 37°C
	U/l	77	66	88	5.55	11.10	Randox Lyo. Ethylidene pNPG7 37°C
	U/l	105	89	121	8.00	16.00	Randox Liquid Ethylidene pNPG7 37°C
	U/l	91	78	104	6.50	13.00	BM/Roche Colorimetric pNPG7 37°C
	U/l	87	74	100	6.50	13.00	Beckman Synchron CX4/CX5/CX7 37°C
	U/l	92	79	105	6.50	13.00	Roche Integra 2-chloro-pNPG7 37°C
	U/l	77	65	89	6.00	12.00	Ortho Vitros Microslide Systems 37°C
	U/l	90	77	103	6.50	13.00	Other Roche 2-chloro-pNPG7 37°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Amylase Total	U/l	92	78	106	7.00	14.00	Roche liquid stable pNPG7 37°C
	U/l	98	83	113	7.50	15.00	Siemens 2-chloro-pNPG3 37°C
	U/l	96	81	111	7.50	15.00	Beckman Coulter - blocked pNPG7 37°C
	U/l	94	80	108	7.00	14.00	Beckman Synchron AMY7 37°C
	U/l	96	81	111	7.50	15.00	Abbott Architect Non-IFCC Cal. 37°C
	U/l	110	93	127	8.50	17.00	Abbott Architect IFCC Cal. 37°C
	U/l	84	71	97	6.50	13.00	Beckman CNPG3 (Extinction Coeff) 37°C
Apolipoprotein A-1	g/l	1.21	0.99	1.43	0.11	0.22	Immunoturbidimetric
	mg/dl	121	99.2	143	10.90	21.80	
Apolipoprotein B	g/l	0.67	0.55	0.79	0.06	0.12	Immunoturbidimetric
	mg/dl	66.9	54.9	78.9	6.00	12.00	
Acid Phosphatase (Total)	U/l	17.9	12.0	23.8	2.95	5.90	1-Naphthyl Phosphate substrate Kinetic 37°C
AST (GOT)	U/l	31	25	38	3.15	6.30	Colorimetric 37°C
	U/l	21	17	25	2.00	4.00	Colorimetric 30°C
	U/l	15	12	18	1.50	3.00	Colorimetric 25°C
	U/l	49	39	59	5.00	10.00	Ortho Vitros Microslide visible slide 37°C
	U/l	51	41	61	5.00	10.00	Tris buffer with P5P 37°C
	U/l	34	28	40	3.00	6.00	Tris buffer with P5P 30°C
	U/l	24	20	28	2.00	4.00	Tris buffer with P5P 25°C
	U/l	32	25	39	3.50	7.00	Tris buffer without P5P 37°C
	U/l	22	17	27	2.50	5.00	Tris buffer without P5P 30°C
	U/l	15	12	18	1.50	3.00	Tris buffer without P5P 25°C
	U/l	48	39	57	4.50	9.00	Tris buffer with P5P NVKC 37°C
	U/l	32	26	38	3.00	6.00	Tris buffer with P5P NVKC 30°C
	U/l	23	19	27	2.00	4.00	Tris buffer with P5P NVKC 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Bile Acids	µmol/l	24.5	19.6	29.4	2.45	4.90	Enzymatic Colorimetric
	µmol/l	27.3	21.8	32.8	2.75	5.50	4th Generation Colorimetric
	µmol/l	25.7	20.6	30.8	2.55	5.10	5th Generation Colorimetric
Bicarbonate	mmol/l	13.9	11.1	16.7	1.40	2.80	Colorimetric
	mmol/l	15.7	12.5	18.9	1.60	3.20	Ortho Vitros Microslide Systems
	mmol/l	14.2	11.2	17.2	1.50	3.00	Enzymatic
	mmol/l	14.8	11.8	17.8	1.50	3.00	Ion selective electrode
Bilirubin Direct	µmol/l	20.7	16.4	25.0	2.15	4.30	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.21	0.959	1.46	0.13	0.25	
	µmol/l	20.7	16.4	25.0	2.15	4.30	Diazo with Sulphanilic Acid
	mg/dl	1.21	0.959	1.46	0.13	0.25	
	µmol/l	20.9	16.5	25.3	2.20	4.40	Diazo with Dichloroaniline (DCA)
	mg/dl	1.22	0.965	1.48	0.13	0.26	
	µmol/l	18.8	14.8	22.8	2.00	4.00	Oxidation to Biliverdin/Vanadate
	mg/dl	1.10	0.866	1.33	0.12	0.23	
	µmol/l	18.0	14.2	21.8	1.90	3.80	Modified Jendrassik
	mg/dl	1.05	0.831	1.27	0.11	0.22	
Bilirubin Total	µmol/l	25.0	19.8	30.2	2.60	5.20	Vitros 250/500/700/950 Total Bilirubin
	mg/dl	1.46	1.16	1.76	0.15	0.30	
	µmol/l	28.5	22.5	34.5	3.00	6.00	Diazo with Dichloroaniline (DCA)
	mg/dl	1.67	1.32	2.02	0.18	0.35	
	µmol/l	29.5	23.3	35.7	3.10	6.20	Diazo with Sulphanilic Acid
	mg/dl	1.73	1.36	2.10	0.19	0.37	
	µmol/l	27.2	21.5	32.9	2.85	5.70	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.59	1.26	1.92	0.17	0.33	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Bilirubin Total	µmol/l	27.9	22.1	33.7	2.90	5.80	Nitrobenzenediazonium salt
	mg/dl	1.63	1.29	1.97	0.17	0.34	
	µmol/l	27.5	21.7	33.3	2.90	5.80	Diazonium ion
	mg/dl	1.61	1.27	1.95	0.17	0.34	
	µmol/l	32.2	25.4	39.0	3.40	6.80	Oxidation to Biliverdin/Vanadate
	mg/dl	1.88	1.49	2.27	0.20	0.39	
	µmol/l	36.9	29.2	44.6	3.85	7.70	Modified Jendrassik
	mg/dl	2.16	1.71	2.61	0.23	0.45	
Calcium	mmol/l	2.14	1.93	2.35	0.11	0.21	Cresolphthalein complexone
	mg/dl	8.58	7.74	9.42	0.42	0.84	
	mmol/l	2.14	1.93	2.35	0.11	0.21	Ortho Vitros Microslide Systems
	mg/dl	8.58	7.74	9.42	0.42	0.84	
	mmol/l	2.09	1.89	2.29	0.10	0.20	Ion selective electrode
	mg/dl	8.38	7.58	9.18	0.40	0.80	
	mmol/l	2.17	1.95	2.39	0.11	0.22	Arsenazo III
	mg/dl	8.70	7.82	9.58	0.44	0.88	
	mmol/l	2.16	1.95	2.37	0.11	0.21	NM-BAPTA
	mg/dl	8.66	7.82	9.50	0.42	0.84	
Cholesterol	mmol/l	4.07	3.54	4.60	0.27	0.53	Ortho Vitros Microslide Systems
	mg/dl	157	137	177	10.00	20.00	
	mmol/l	4.16	3.62	4.70	0.27	0.54	Cholesterol Oxidase - Abell Kendall
	mg/dl	161	140	182	10.50	21.00	
	mmol/l	4.20	3.65	4.75	0.28	0.55	Cholesterol Oxidase - IDMS
	mg/dl	162	141	183	10.50	21.00	
	mmol/l	4.06	3.54	4.58	0.26	0.52	Cholesterol Dehydrogenase
	mg/dl	157	137	177	10.00	20.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
Chloride	mmol/l	95.3	87.7	103	3.80	7.60	Ortho Vitros Microslide Systems
	mmol/l	93.6	86.1	101	3.75	7.50	ISE indirect
	mmol/l	95.2	87.6	103	3.80	7.60	ISE direct
Cholinesterase	U/l	5985	4788	7182	598.50	1197.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	172	141	203	15.50	31.00	Ortho Vitros Microslide Systems 37°C
	U/l	184	151	217	16.50	33.00	CK-NAC serum start (DGKC) 37°C
	U/l	115	95	135	10.00	20.00	CK-NAC serum start (DGKC) 30°C
	U/l	78	64	92	7.00	14.00	CK-NAC serum start (DGKC) 25°C
	U/l	197	162	232	17.50	35.00	CK-NAC substrate start (DGKC) 37°C
	U/l	123	101	145	11.00	22.00	CK-NAC substrate start (DGKC) 30°C
	U/l	84	69	99	7.50	15.00	CK-NAC substrate start (DGKC) 25°C
	U/l	190	155	225	17.50	35.00	CK-NAC (IFCC) 37°C
	U/l	119	97	141	11.00	22.00	CK-NAC (IFCC) 30°C
	U/l	81	66	96	7.50	15.00	CK-NAC (IFCC) 25°C
Copper	µmol/l	16.3	13.1	19.5	1.60	3.20	Atomic absorption
	µg/dl	104	83.3	125	10.35	20.70	
	µmol/l	16.0	12.8	19.2	1.60	3.20	Colorimetric
	µg/dl	102	81.4	123	10.30	20.60	
Cortisol	nmol/l	494	371	617	61.50	123.00	Roche Cobas 6000/8000
	µg/dl	17.8	13.4	22.2	2.20	4.40	
Creatinine	µmol/l	119	95.5	143	11.75	23.50	Alkaline picrate with deproteinization
	mg/dl	1.34	1.08	1.60	0.13	0.26	
	µmol/l	124	99.1	149	12.45	24.90	Alkaline picrate no deproteinization
	mg/dl	1.40	1.12	1.68	0.14	0.28	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Creatinine	µmol/l	126	101	151	12.50	25.00	Enzymatic UV method
	mg/dl	1.42	1.14	1.70	0.14	0.28	
	µmol/l	125	100	150	12.50	25.00	Creatinine PAP method
	mg/dl	1.41	1.13	1.69	0.14	0.28	
	µmol/l	128	102	154	13.00	26.00	Jaffe rate blanked
	mg/dl	1.45	1.15	1.75	0.15	0.30	
	µmol/l	125	99.9	150	12.55	25.10	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	1.41	1.13	1.69	0.14	0.28	
	µmol/l	121	97.2	145	11.90	23.80	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	1.37	1.10	1.64	0.14	0.27	
	µmol/l	119	95.6	142	11.70	23.40	Vitros IDMS Traceable
	mg/dl	1.34	1.08	1.60	0.13	0.26	
	µmol/l	123	98.3	148	12.35	24.70	IDMS traceable
	mg/dl	1.39	1.11	1.67	0.14	0.28	
D-3-Hydroxybutyrate	mmol/l	0.30	0.25	0.34	0.02	0.04	Tris buffer 100mmol pH 8.5
Digoxin	nmol/l	1.74	1.39	2.09	0.18	0.35	Immunoturbidimetric
	ng/ml	1.36	1.09	1.63	0.14	0.27	
Folate	nmol/l	20.6	15.7	25.6	2.47	4.94	Roche Cobas 6000/8000
	ng/ml	9.10	6.92	11.3	1.09	2.18	
Free T4	pmol/l	16.6	12.5	20.7	2.05	4.10	Abbott Architect
	ng/dl	1.29	0.975	1.61	0.16	0.32	
	pg/ml	12.9	9.75	16.1	1.58	3.15	Abbott Architect
	pmol/l	19.3	14.5	24.1	2.40	4.80	Siemens Centaur XP/XPT/Classic
	ng/dl	1.51	1.13	1.89	0.19	0.38	
	pg/ml	15.1	11.3	18.9	1.90	3.80	Siemens Centaur XP/XPT/Classic

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Free T4	pmol/l	18.3	13.7	22.9	2.30	4.60	Beckman Access
	ng/dl	1.43	1.07	1.79	0.18	0.36	
	pg/ml	14.3	10.7	17.9	1.80	3.60	Beckman Access
	pmol/l	16.5	12.4	20.6	2.05	4.10	Beckman DxI800
	ng/dl	1.29	0.967	1.61	0.16	0.32	
	pg/ml	12.9	9.67	16.1	1.62	3.23	Beckman DxI800
	pmol/l	36.7	27.5	45.9	4.60	9.20	Vitros ECi
	ng/dl	2.86	2.15	3.57	0.36	0.71	
	pg/ml	28.6	21.5	35.7	3.55	7.10	Vitros ECi
	pmol/l	22.2	16.6	27.8	2.80	5.60	Roche Cobas 4000/E411
	ng/dl	1.73	1.29	2.17	0.22	0.44	
	pg/ml	17.3	12.9	21.7	2.20	4.40	Roche Cobas 4000/E411
	pmol/l	22.0	16.5	27.5	2.75	5.50	Roche Cobas e601/602
	ng/dl	1.72	1.29	2.15	0.22	0.43	
	pg/ml	17.2	12.9	21.5	2.15	4.30	Roche Cobas e601/602
	pmol/l	18.9	14.2	23.6	2.35	4.70	Biomerieux Vidas FT4N Kit
	ng/dl	1.47	1.11	1.83	0.18	0.36	
	pg/ml	14.7	11.1	18.3	1.80	3.60	Biomerieux Vidas FT4N Kit
	pmol/l	21.4	16.0	26.8	2.70	5.40	Roche Cobas e402/e801
	ng/dl	1.67	1.25	2.09	0.21	0.42	
	pg/ml	16.7	12.5	20.9	2.10	4.20	Roche Cobas e402/e801
Gentamicin	µmol/l	7.11	5.69	8.53	0.71	1.42	Gravimetric
	µg/ml	3.40	2.72	4.08	0.34	0.68	
gamma-GT	U/l	45	38	52	3.50	7.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	35	30	40	2.50	5.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	28	23	33	2.50	5.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
gamma-GT	U/l	56	48	64	4.00	8.00	Ortho Vitros Microslide Systems 37°C
	U/l	46	39	53	3.50	7.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	36	31	41	2.50	5.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	28	24	32	2.00	4.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
	U/l	48	41	55	3.50	7.00	Randox Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	38	32	44	3.00	6.00	Randox Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	30	25	35	2.50	5.00	Randox Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
GLDH	U/l	16	13	19	1.50	3.00	Triethanolamine buffer 50 mmol 37°C
	U/l	12	10	14	1.00	2.00	Triethanolamine buffer 50 mmol 30°C
	U/l	10	8	12	1.00	2.00	Triethanolamine buffer 50 mmol 25°C
Glucose	mmol/l	6.25	5.31	7.19	0.47	0.94	Ortho Vitros Microslide Systems
	mg/dl	113	95.7	130	8.65	17.30	
	mmol/l	6.31	5.37	7.25	0.47	0.94	Glucose dehydrogenase
	mg/dl	114	96.8	131	8.60	17.20	
	mmol/l	6.22	5.29	7.15	0.47	0.93	Hexokinase
	mg/dl	112	95.3	129	8.35	16.70	
	mmol/l	6.35	5.40	7.30	0.48	0.95	Glucose oxidase
	mg/dl	114	97.3	131	8.35	16.70	
alpha-HBDH	U/l	222	175	269	23.50	47.00	Oxobutyrate < 10 mmol/l 37°C
	U/l	168	132	204	18.00	36.00	Oxobutyrate < 10 mmol/l 30°C
	U/l	126	99	153	13.50	27.00	Oxobutyrate < 10 mmol/l 25°C
HDL - Cholesterol	mmol/l	1.50	1.28	1.72	0.11	0.22	Direct HDL PPD
	mg/dl	57.9	49.4	66.4	4.25	8.50	
	mmol/l	1.33	1.13	1.53	0.10	0.20	Direct HDL Immunoseparation
	mg/dl	51.3	43.6	59.0	3.85	7.70	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
HDL - Cholesterol	mmol/l	1.42	1.21	1.63	0.11	0.21	Vitros Magnetic HDL
	mg/dl	54.8	46.7	62.9	4.05	8.10	
	mmol/l	1.45	1.23	1.67	0.11	0.22	Direct HDL PEGME
	mg/dl	56.0	47.5	64.5	4.25	8.50	
	mmol/l	1.33	1.13	1.53	0.10	0.20	Direct Clearance Method
	mg/dl	51.3	43.6	59.0	3.85	7.70	
	mmol/l	1.41	1.20	1.62	0.11	0.21	Vitros dHDL PTA/MgCl2 direct precipitation
	mg/dl	54.4	46.3	62.5	4.05	8.10	
	mmol/l	1.49	1.27	1.71	0.11	0.22	HDL - Ultra
	mg/dl	57.5	49.0	66.0	4.25	8.50	
	mmol/l	1.39	1.18	1.60	0.11	0.21	Direct HDL Roche 4th Generation
	mg/dl	53.7	45.5	61.9	4.10	8.20	
Immunoglobulin A	g/l	2.07	1.55	2.59	0.26	0.52	Immunoturbidimetric
	mg/dl	207	155	259	26.00	52.00	
Immunoglobulin G	g/l	7.13	5.85	8.41	0.64	1.28	Immunoturbidimetric
	mg/dl	713	585	841	64.00	128.00	
Immunoglobulin M	g/l	1.10	0.88	1.32	0.11	0.22	Immunoturbidimetric
	mg/dl	110	88.0	132	11.00	22.00	
Iron	µmol/l	19.4	15.9	22.9	1.75	3.50	Colorimetric with ppt.
	µg/dl	108	88.9	127	9.55	19.10	
	µmol/l	19.5	16.0	23.0	1.75	3.50	Colorimetric without ppt.
	µg/dl	109	89.4	129	9.80	19.60	
	µmol/l	19.2	15.7	22.7	1.75	3.50	Ortho Vitros Microslide Systems
	µg/dl	107	87.8	126	9.60	19.20	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Lactate	mmol/l	1.63	1.34	1.92	0.15	0.29	Ion selective electrode
	mg/dl	14.7	12.1	17.3	1.30	2.60	
	mmol/l	1.61	1.32	1.90	0.15	0.29	Colorimetric Lactate Oxidase
	mg/dl	14.5	11.9	17.1	1.30	2.60	
	mmol/l	1.50	1.23	1.77	0.14	0.27	Ortho Vitros Microslide Systems
	mg/dl	13.5	11.1	15.9	1.20	2.40	
	mmol/l	1.52	1.25	1.79	0.14	0.27	Enzymatic Electrode
	mg/dl	13.7	11.3	16.1	1.20	2.40	
	mmol/l	1.52	1.24	1.80	0.14	0.28	UV LDH
	mg/dl	13.7	11.2	16.2	1.25	2.50	
LD (LDH)	U/l	206	175	237	15.50	31.00	L->P 37°C
	U/l	149	126	172	11.50	23.00	L->P 30°C
	U/l	104	89	119	7.50	15.00	L->P 25°C
	U/l	451	383	519	34.00	68.00	P->L Scandinavian & Dutch 37°C
	U/l	326	277	375	24.50	49.00	P->L Scandinavian & Dutch 30°C
	U/l	229	194	264	17.50	35.00	P->L Scandinavian & Dutch 25°C
	U/l	422	358	486	32.00	64.00	P->L German methods 37°C
	U/l	305	258	352	23.50	47.00	P->L German methods 30°C
	U/l	214	182	246	16.00	32.00	P->L German methods 25°C
	U/l	421	358	484	31.50	63.00	P->L SFBC 37°C
	U/l	304	258	350	23.00	46.00	P->L SFBC 30°C
	U/l	213	182	244	15.50	31.00	P->L SFBC 25°C
	U/l	216	184	248	16.00	32.00	L->P IFCC 37°C
	U/l	156	133	179	11.50	23.00	L->P IFCC 30°C
	U/l	110	93	127	8.50	17.00	L->P IFCC 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
LD (LDH)	U/l	237	201	273	18.00	36.00	Ortho Vitros IFCC Traceable 37°C
Lipase	U/l	34	28	40	3.00	6.00	Other Colorimetric 37°C
	U/l	231	185	277	23.00	46.00	Ortho Vitros Microslide Systems 37°C
	U/l	35	28	42	3.50	7.00	Roche Colorimetric 37°C
	U/l	42	34	50	4.00	8.00	Randox Colorimetric 37°C
Lithium	mmol/l	0.98	0.86	1.09	0.06	0.12	Ion selective electrode
	mg/dl	0.677	0.596	0.758	0.04	0.08	
	mmol/l	0.99	0.87	1.11	0.06	0.12	Spectrophotometric
	mg/dl	0.687	0.604	0.770	0.04	0.08	
Magnesium	mmol/l	0.88	0.78	0.99	0.05	0.11	Arsenazo III
	mg/dl	2.14	1.89	2.39	0.13	0.25	
	mmol/l	0.89	0.79	1.00	0.05	0.11	Ortho Vitros Microslide Systems
	mg/dl	2.17	1.91	2.43	0.13	0.26	
	mmol/l	0.94	0.83	1.06	0.06	0.11	Calmagite
	mg/dl	2.29	2.02	2.56	0.14	0.27	
	mmol/l	0.92	0.81	1.04	0.06	0.11	Xylidyl Blue
	mg/dl	2.25	1.98	2.52	0.14	0.27	
	mmol/l	0.95	0.84	1.06	0.06	0.11	Methylthymol blue
	mg/dl	2.30	2.03	2.57	0.14	0.27	
	mmol/l	0.93	0.82	1.04	0.06	0.11	Chlorphosphonazo III
	mg/dl	2.25	1.98	2.52	0.14	0.27	
	mmol/l	0.89	0.78	0.99	0.05	0.11	Enzymatic
	mg/dl	2.16	1.90	2.42	0.13	0.26	
NEFA	mmol/l	1.41	1.13	1.69	0.14	0.28	Colorimetric
Osmolality	mOsm/kg	295	236	354	29.50	59.00	Calculated

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Osmolality	mOsm/kg	298	238	358	30.00	60.00	Freezing point depression
Paracetamol	mmol/l	0.09	0.07	0.10	0.01	0.02	Gravimetric
	mg/l	13.0	10.4	15.6	1.30	2.60	
Phosphate Inorganic	mmol/l	1.52	1.29	1.75	0.12	0.23	Ortho Vitros Microslide Systems
	mg/dl	4.71	4.00	5.42	0.36	0.71	
	mmol/l	1.46	1.24	1.68	0.11	0.22	Phosphomolybdate enzymatic
	mg/dl	4.53	3.84	5.22	0.35	0.69	
	mmol/l	1.47	1.25	1.69	0.11	0.22	Phosphomolybdate UV
	mg/dl	4.56	3.88	5.24	0.34	0.68	
Potassium	mmol/l	3.90	3.59	4.21	0.16	0.31	Ortho Vitros Microslide Systems
	mmol/l	3.83	3.52	4.14	0.16	0.31	ISE method - direct
	mmol/l	3.90	3.59	4.21	0.16	0.31	ISE method - indirect
	mmol/l	4.10	3.77	4.43	0.17	0.33	Enzymatic
Protein Total	g/l	60.4	48.4	72.4	6.00	12.00	Ortho Vitros Microslide Systems
	g/dl	6.04	4.84	7.24	0.60	1.20	
	g/l	59.6	47.7	71.5	5.95	11.90	Biuret reaction end point
	g/dl	5.96	4.77	7.15	0.60	1.19	
	g/l	59.9	47.9	71.9	6.00	12.00	Biuret reaction kinetic
	g/dl	5.99	4.79	7.19	0.60	1.20	
PSA Total	ng/ml =	9.69	7.27	12.1	1.21	2.42	Beckman Access standardised to Hybritech
	ng/ml =	10.2	7.67	12.7	1.27	2.53	bioMerieux VIDAS TPSA
	ng/ml =	8.62	6.47	10.8	1.08	2.15	Siemens Centaur XP/XPT/Classic
	ng/ml =	8.15	6.11	10.2	1.02	2.04	Abbott Architect
	ng/ml =	10.7	8.01	13.4	1.35	2.69	Cobas E411
	ng/ml =	10.1	7.60	12.6	1.25	2.50	Roche Cobas 6000/8000

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Salicylate	mmol/l	0.43	0.35	0.52	0.04	0.09	Gravimetric
	mg/dl	5.99	4.79	7.19	0.60	1.20	
Sodium	mmol/l	139	132	146	3.50	7.00	Ortho Vitros Microslide Systems
	mmol/l	139	132	146	3.50	7.00	ISE method - direct
	mmol/l	141	134	148	3.50	7.00	ISE method - indirect
	mmol/l	145	138	152	3.50	7.00	Enzymatic
Theophylline	µmol/l	28.3	22.6	34.0	2.85	5.70	Gravimetric
	µg/ml	5.10	4.07	6.13	0.52	1.03	
Thyroid Stimulating Hormone	µU/ml =	1.24	0.99	1.49	0.12	0.25	Abbott Architect
	µU/ml =	1.66	1.33	1.99	0.17	0.33	bioMerieux VIDAS TSH
	µU/ml =	1.64	1.32	1.96	0.16	0.32	bioMerieux VIDAS TSH3 Ultrasensitive
	µU/ml =	1.72	1.38	2.06	0.17	0.34	Roche Cobas 4000/E411
	µU/ml =	1.71	1.37	2.05	0.17	0.34	Roche Cobas e601/602
	µU/ml =	1.39	1.11	1.67	0.14	0.28	Siemens Centaur XP/XPT/Classic TSH3-Ultra
	µU/ml =	1.48	1.18	1.78	0.15	0.30	Beckman DxI 600/800 Access (3rd IS)
	µU/ml =	1.69	1.35	2.03	0.17	0.34	Roche Cobas e402/e801

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Tobramycin	µmol/l	6.30	5.04	7.56	0.63	1.26	Gravimetric
	µg/ml	2.95	2.36	3.54	0.30	0.59	
Total T3	nmol/l	1.86	1.40	2.32	0.23	0.46	Abbott Architect
	ng/ml	1.21	0.911	1.51	0.15	0.30	
	ng/dl	121	91.1	151	14.95	29.90	Abbott Architect
	nmol/l	2.01	1.51	2.51	0.25	0.50	BioMerieux Vidas
	ng/ml	1.31	0.983	1.64	0.16	0.33	
	ng/dl	131	98.3	164	16.35	32.70	BioMerieux Vidas
	nmol/l	2.27	1.70	2.84	0.29	0.57	Roche Cobas 4000/E411
	ng/ml	1.48	1.11	1.85	0.19	0.37	
	ng/dl	148	111	185	18.50	37.00	Roche Cobas 4000/E411
	nmol/l	2.23	1.67	2.79	0.28	0.56	Roche Cobas e601/602
	ng/ml	1.45	1.09	1.81	0.18	0.36	
	ng/dl	145	109	181	18.00	36.00	Roche Cobas e601/602
Total T4	nmol/l	91.9	68.9	115	11.50	23.00	Abbott Architect
	µg/dl	7.17	5.37	8.97	0.90	1.80	
	ng/ml	71.7	53.7	89.7	9.00	18.00	Abbott Architect
	nmol/l	97.7	73.2	122	12.25	24.50	Roche Cobas 4000/E411
	µg/dl	7.62	5.71	9.53	0.96	1.91	
	ng/ml	76.2	57.1	95.3	9.55	19.10	Roche Cobas 4000/E411
	nmol/l	97.5	73.1	122	12.20	24.40	Roche Cobas e601/602
	µg/dl	7.61	5.70	9.52	0.96	1.91	
	ng/ml	76.1	57.0	95.2	9.55	19.10	Roche Cobas e601/602

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Total T4	nmol/l	105	79.1	131	12.95	25.90	Microgenics DRI assay
	µg/dl	8.19	6.17	10.2	1.01	2.02	
	ng/ml	81.9	61.7	102	10.10	20.20	Microgenics DRI assay
Transferrin	g/l	2.00	1.60	2.40	0.20	0.40	Immunoturbidimetric
	mg/dl	200	160	240	20.00	40.00	
Triglycerides	mmol/l	1.15	0.96	1.34	0.09	0.19	Lipase/GPO-PAP no correction
	mg/dl	102	85.3	119	8.35	16.70	
	mmol/l	1.16	0.97	1.35	0.09	0.19	Lipase/GPO-PAP 0.11mmol/l correction
	mg/dl	103	86.0	120	8.50	17.00	
	mmol/l	1.14	0.96	1.32	0.09	0.18	L/G Kinase EP. no correction
	mg/dl	101	84.6	117	8.20	16.40	
	mmol/l	1.15	0.97	1.33	0.09	0.18	L/G kinase EP. 0.11 mmol/l correction
	mg/dl	102	85.5	119	8.25	16.50	
	mmol/l	1.14	0.96	1.32	0.09	0.18	Lipase/Glycerol Dehydrogenase
	mg/dl	101	84.6	117	8.20	16.40	
	mmol/l	1.36	1.14	1.58	0.11	0.22	Ortho Vitros Microslide Systems
	mg/dl	120	101	139	9.50	19.00	
Uric Acid (Urate)	mmol/l	0.33	0.29	0.38	0.02	0.04	Ortho Vitros Microslide Systems
	mg/dl	5.59	4.87	6.31	0.36	0.72	
	mmol/l	0.34	0.29	0.38	0.02	0.04	Uricase catalase 340nm
	mg/dl	5.66	4.92	6.40	0.37	0.74	
	mmol/l	0.35	0.30	0.39	0.02	0.05	Uricase peroxidase with ascorbate oxidase
	mg/dl	5.85	5.09	6.61	0.38	0.76	
	mmol/l	0.35	0.30	0.39	0.02	0.05	Uricase peroxidase no ascorbate oxidase
	mg/dl	5.83	5.07	6.59	0.38	0.76	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Uric Acid (Urate)	mmol/l	0.35	0.30	0.39	0.02	0.05	Spectrophotometric at 280-290
	mg/dl	5.86	5.11	6.61	0.38	0.75	
	mmol/l	0.35	0.30	0.39	0.02	0.05	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	5.81	5.06	6.56	0.38	0.75	
Urea	mmol/l	7.12	6.05	8.19	0.54	1.07	Ortho Vitros Microslide Systems
	mg/dl	42.8	36.4	49.2	3.20	6.40	
	mmol/l	7.17	6.10	8.24	0.54	1.07	Urease end point
	mg/dl	43.1	36.7	49.5	3.20	6.40	
	mmol/l	7.28	6.19	8.37	0.55	1.09	Urease kinetic
	mg/dl	43.8	37.2	50.4	3.30	6.60	
	mmol/l	7.18	6.10	8.26	0.54	1.08	Urease - hypochlorite
	mg/dl	43.2	36.7	49.7	3.25	6.50	
	mmol/l	7.28	6.19	8.37	0.55	1.09	BUN
	mg/dl	20.4	17.3	23.5	1.55	3.10	
Vitamin B12	pmol/l	411	329	493	41.00	82.00	Roche Cobas 6000/8000
	pg/ml	557	446	668	55.50	111.00	
Zinc	µmol/l	27.4	21.9	32.9	2.75	5.50	Colorimetric with deproteinisation
	µg/dl	179	143	215	18.00	36.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

METHOD (Elec.)

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
alpha-1-globulin		4.6	3.5	5.7	0.55	1.10	% of total Protein (Beckman Capillary)
alpha-2-globulin		7.0	5.3	8.7	0.84	1.68	% of total Protein (Beckman Capillary)
Albumin (electrophoresis)		67.5	60.8	74.2	3.35	6.70	% of total Protein (Beckman Capillary)
beta-globulin		10.3	7.8	12.8	1.24	2.47	% of total Protein (Beckman Capillary)
gamma-globulin		10.6	8.1	13.1	1.27	2.54	% of total Protein (Beckman Capillary)

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Abbott Alinity/ Architect c/ci Systems®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	41.7	35.4	48.0	3.15	6.30	Bromocresol Green
	g/dl	4.17	3.54	4.80	0.32	0.63	
	g/l	42.8	36.4	49.2	3.20	6.40	Bromocresol Purple
	g/dl	4.28	3.64	4.92	0.32	0.64	
Alkaline Phosphatase	U/l	190	162	218	14.00	28.00	p-Nitrophenylphosphate AMP 37°C
	U/l	184	156	212	14.00	28.00	AMP optimised to IFCC 37°C
	U/l	184	157	211	13.50	27.00	AMP non-optimised 37°C
ALT (GPT)	U/l	33	27	39	3.00	6.00	Tris buffer without P5P 37°C
Amylase Pancreatic	U/l	65	55	75	5.00	10.00	Immunoinhibition EPS substrate 37°C
Amylase Total	U/l	95	81	109	7.00	14.00	Abbott Architect Non-IFCC Cal. 37°C
	U/l	110	93	127	8.50	17.00	Abbott Architect IFCC Cal. 37°C
AST (GOT)	U/l	32	26	38	3.00	6.00	Tris buffer without P5P 37°C
Bile Acids	µmol/l	25.1	20.1	30.1	2.50	5.00	Enzymatic Colorimetric
Bicarbonate	mmol/l	13.2	10.5	15.9	1.35	2.70	Enzymatic
Bilirubin Direct	µmol/l	20.7	16.4	25.0	2.15	4.30	Diazo with Sulphanilic Acid
	mg/dl	1.21	0.959	1.46	0.13	0.25	
	µmol/l	20.8	16.5	25.1	2.15	4.30	Diazo with Dichloroaniline (DCA)
	mg/dl	1.22	0.965	1.48	0.13	0.26	
Bilirubin Total	µmol/l	28.1	22.2	34.0	2.95	5.90	Diazo with Dichloroaniline (DCA)
	mg/dl	1.64	1.30	1.98	0.17	0.34	
	µmol/l	28.3	22.4	34.2	2.95	5.90	Diazo with Sulphanilic Acid
	mg/dl	1.66	1.31	2.01	0.18	0.35	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Abbott Alinity/ Architect c/ci Systems®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Bilirubin Total	µmol/l	28.0	22.1	33.9	2.95	5.90	Diazonium ion
	mg/dl	1.64	1.29	1.99	0.18	0.35	
Calcium	mmol/l	2.13	1.92	2.34	0.11	0.21	Arsenazo III
	mg/dl	8.54	7.70	9.38	0.42	0.84	
Cholesterol	mmol/l	4.15	3.61	4.69	0.27	0.54	Cholesterol Oxidase - Abell Kendall
	mg/dl	160	139	181	10.50	21.00	
	mmol/l	4.10	3.56	4.64	0.27	0.54	Cholesterol Oxidase - IDMS
	mg/dl	158	137	179	10.50	21.00	
Chloride	mmol/l	95.9	88.3	104	3.80	7.60	ISE indirect
Cholinesterase	U/l	6887	5509	8265	689.00	1378.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	187	153	221	17.00	34.00	CK-NAC serum start (DGKC) 37°C
	U/l	191	156	226	17.50	35.00	CK-NAC (IFCC) 37°C
	U/l	195	160	230	17.50	35.00	Abbott CK-NAC (IFCC) 37°C
Copper	µmol/l	11.8	9.46	14.1	1.17	2.34	Colorimetric
	µg/dl	75.0	60.2	89.8	7.40	14.80	
Creatinine	µmol/l	127	102	152	12.50	25.00	Alkaline picrate no deproteinization
	mg/dl	1.44	1.15	1.73	0.15	0.29	
	µmol/l	126	101	151	12.50	25.00	Enzymatic UV method
	mg/dl	1.42	1.14	1.70	0.14	0.28	
gamma-GT	U/l	45	39	51	3.00	6.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	44	38	50	3.00	6.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
Glucose	mmol/l	6.14	5.22	7.06	0.46	0.92	Hexokinase
	mg/dl	111	94.1	128	8.45	16.90	
	mmol/l	6.45	5.49	7.41	0.48	0.96	Glucose oxidase
	mg/dl	116	98.9	133	8.55	17.10	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Abbott Alinity/ Architect c/ci Systems®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
HDL - Cholesterol	mmol/l	1.50	1.28	1.72	0.11	0.22	Direct HDL PPD
	mg/dl	57.9	49.4	66.4	4.25	8.50	
	mmol/l	1.51	1.28	1.74	0.12	0.23	Direct Clearance Method
	mg/dl	58.3	49.4	67.2	4.45	8.90	
	mmol/l	1.48	1.26	1.70	0.11	0.22	HDL - Ultra
	mg/dl	57.1	48.6	65.6	4.25	8.50	
Iron	µmol/l	20.4	16.7	24.1	1.85	3.70	Colorimetric with ppt.
	µg/dl	114	93.4	135	10.30	20.60	
	µmol/l	20.3	16.7	23.9	1.80	3.60	Colorimetric without ppt.
	µg/dl	113	93.4	133	9.80	19.60	
Lactate	mmol/l	1.67	1.37	1.97	0.15	0.30	Colorimetric Lactate Oxidase
	mg/dl	15.0	12.3	17.7	1.35	2.70	
LD (LDH)	U/l	206	175	237	15.50	31.00	L->P 37°C
	U/l	207	176	238	15.50	31.00	L->P IFCC 37°C
Lipase	U/l	33	27	39	3.00	6.00	Other Colorimetric 37°C
Lithium	mmol/l	1.00	0.88	1.12	0.06	0.12	Spectrophotometric
	mg/dl	0.694	0.611	0.777	0.04	0.08	
Magnesium	mmol/l	0.88	0.78	0.99	0.05	0.11	Arsenazo III
	mg/dl	2.14	1.89	2.39	0.13	0.25	
	mmol/l	0.89	0.78	0.99	0.05	0.11	Enzymatic
	mg/dl	2.15	1.89	2.41	0.13	0.26	
Osmolality	mOsm/kg	301	241	361	30.00	60.00	Calculated
Phosphate Inorganic	mmol/l	1.45	1.23	1.67	0.11	0.22	Phosphomolybdate enzymatic
	mg/dl	4.50	3.81	5.19	0.35	0.69	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Abbott Alinity/ Architect c/ci Systems®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Phosphate Inorganic	mmol/l	1.46	1.24	1.68	0.11	0.22	Phosphomolybdate UV
	mg/dl	4.53	3.84	5.22	0.35	0.69	
Potassium	mmol/l	3.91	3.59	4.23	0.16	0.32	ISE method - indirect
Protein Total	g/l	61.0	48.8	73.2	6.10	12.20	Biuret reaction end point
	g/dl	6.10	4.88	7.32	0.61	1.22	
	g/l	60.8	48.7	72.9	6.05	12.10	Biuret reaction kinetic
	g/dl	6.08	4.87	7.29	0.61	1.21	
Sodium	mmol/l	142	135	149	3.50	7.00	ISE method - indirect
TIBC	µmol/l	43.2	34.1	52.3	4.55	9.10	FE+UIBC(saturation with iron)
	µg/dl	241	191	291	25.00	50.00	
	µmol/l	49.0	38.7	59.3	5.15	10.30	Calculated from Transferrin
	µg/dl	274	216	332	29.00	58.00	
Triglycerides	mmol/l	1.10	0.92	1.28	0.09	0.18	Lipase/GPO-PAP no correction
	mg/dl	97.4	81.8	113	7.80	15.60	
	mmol/l	1.13	0.95	1.31	0.09	0.18	L/G Kinase EP. no correction
	mg/dl	100	83.9	116	8.05	16.10	
	mmol/l	1.13	0.95	1.31	0.09	0.18	Lipase/Glycerol Dehydrogenase
	mg/dl	100	83.8	116	8.10	16.20	
Uric Acid (Urate)	mmol/l	0.35	0.30	0.39	0.02	0.05	Uricase peroxidase with ascorbate oxidase
	mg/dl	5.83	5.07	6.59	0.38	0.76	
	mmol/l	0.35	0.30	0.39	0.02	0.05	Uricase peroxidase no ascorbate oxidase
	mg/dl	5.83	5.07	6.59	0.38	0.76	
	mmol/l	0.33	0.29	0.38	0.02	0.04	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	5.58	4.86	6.30	0.36	0.72	
Urea	mmol/l	7.38	6.27	8.49	0.56	1.11	Urease kinetic
	mg/dl	44.4	37.7	51.1	3.35	6.70	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Abbott Alinity/ Architect c/ci Systems®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Urea	mmol/l	7.38	6.27	8.49	0.56	1.11	BUN
	mg/dl	20.7	17.6	23.8	1.55	3.10	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman Coulter AU Series®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	40.3	34.2	46.4	3.05	6.10	Bromocresol Green
	g/dl	4.03	3.42	4.64	0.31	0.61	
Alkaline Phosphatase	U/l	290	246	334	22.00	44.00	Diethanolamine buffer DEA 37°C
	U/l	212	180	244	16.00	32.00	AMP optimised to IFCC 37°C
ALT (GPT)	U/l	35	28	42	3.50	7.00	Beckman Mod. IFCC Ref. without P5P 37°C
	U/l	34	28	40	3.00	6.00	Beckman (Extinction Coefficient) 37°C
Amylase Total	U/l	87	74	100	6.50	13.00	Beckman Synchron CX4/CX5/CX7 37°C
	U/l	96	81	111	7.50	15.00	Beckman Coulter - blocked pNPG7 37°C
	U/l	93	79	107	7.00	14.00	Beckman Synchron AMY7 37°C
	U/l	84	71	97	6.50	13.00	Beckman CNPG3 (Extinction Coeff) 37°C
AST (GOT)	U/l	35	28	42	3.50	7.00	Beckman Mod. IFCC Ref. without P5P 37°C
	U/l	34	27	41	3.50	7.00	Beckman (Extinction Coefficient) 37°C
Bile Acids	µmol/l	24.4	19.5	29.3	2.45	4.90	Enzymatic Colorimetric
Bicarbonate	mmol/l	14.4	11.5	17.3	1.45	2.90	
Bilirubin Direct	µmol/l	20.6	16.3	24.9	2.15	4.30	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.21	0.954	1.47	0.13	0.26	
Bilirubin Total	µmol/l	31.4	24.8	38.0	3.30	6.60	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.84	1.45	2.23	0.20	0.39	
	µmol/l	31.9	25.2	38.6	3.35	6.70	DPD (Beckman AU)
	mg/dl	1.87	1.47	2.27	0.20	0.40	
Calcium	mmol/l	2.17	1.95	2.39	0.11	0.22	Cresolphthalein complexone
	mg/dl	8.70	7.82	9.58	0.44	0.88	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman Coulter AU Series®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Calcium	mmol/l	2.18	1.97	2.39	0.11	0.21	Arsenazo III
	mg/dl	8.74	7.90	9.58	0.42	0.84	
Cholesterol	mmol/l	4.15	3.61	4.69	0.27	0.54	Cholesterol Oxidase - Abell Kendall
	mg/dl	160	139	181	10.50	21.00	
	mmol/l	4.27	3.72	4.82	0.28	0.55	Cholesterol Oxidase - IDMS
	mg/dl	165	144	186	10.50	21.00	
	mmol/l	4.06	3.53	4.59	0.27	0.53	Cholesterol Dehydrogenase
	mg/dl	157	136	178	10.50	21.00	
Chloride	mmol/l	93.4	86.0	101	3.70	7.40	ISE indirect
Cholinesterase	U/l	5549	4439	6659	555.00	1110.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	207	170	244	18.50	37.00	CK-NAC (IFCC) 37°C
	U/l	194	159	229	17.50	35.00	Beckman CK-NAC (Extinction Coeff) 37°C
Creatinine	µmol/l	123	98.1	148	12.45	24.90	Alkaline picrate no deproteinization
	mg/dl	1.39	1.11	1.67	0.14	0.28	
	µmol/l	127	102	152	12.50	25.00	Enzymatic UV method
	mg/dl	1.44	1.15	1.73	0.15	0.29	
	µmol/l	127	102	152	12.50	25.00	Jaffe rate blanked
	mg/dl	1.44	1.15	1.73	0.15	0.29	
	µmol/l	118	94.1	142	11.95	23.90	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	1.33	1.06	1.60	0.14	0.27	
	µmol/l	123	98.2	148	12.40	24.80	IDMS traceable
	mg/dl	1.39	1.11	1.67	0.14	0.28	
D-3-Hydroxybutyrate	mmol/l	0.28	0.24	0.32	0.02	0.04	Tris buffer 100mmol pH 8.5
gamma-GT	U/l	48	40	56	4.00	8.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman Coulter AU Series®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
gamma-GT	U/l	47	40	54	3.50	7.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	46	39	53	3.50	7.00	Beckman Szasz (Extinction Coeff) 37°C
GLDH	U/l	16	13	19	1.50	3.00	Triethanolamine buffer 50 mmol 37°C
Glucose	mmol/l	6.26	5.32	7.20	0.47	0.94	Glucose dehydrogenase
	mg/dl	113	95.9	130	8.55	17.10	
	mmol/l	6.23	5.29	7.17	0.47	0.94	Hexokinase
	mg/dl	112	95.3	129	8.35	16.70	
	mmol/l	6.22	5.29	7.15	0.47	0.93	Glucose oxidase
	mg/dl	112	95.3	129	8.35	16.70	
HDL - Cholesterol	mmol/l	1.33	1.13	1.53	0.10	0.20	Direct HDL Immunoseparation
	mg/dl	51.3	43.6	59.0	3.85	7.70	
	mmol/l	1.54	1.31	1.77	0.12	0.23	Direct Clearance Method
	mg/dl	59.4	50.6	68.2	4.40	8.80	
	mmol/l	1.51	1.28	1.74	0.12	0.23	HDL - Ultra
	mg/dl	58.3	49.4	67.2	4.45	8.90	
Iron	µmol/l	20.0	16.4	23.6	1.80	3.60	Colorimetric with ppt.
	µg/dl	112	91.7	132	10.15	20.30	
	µmol/l	19.7	16.1	23.3	1.80	3.60	Colorimetric without ppt.
	µg/dl	110	90.0	130	10.00	20.00	
Lactate	mmol/l	1.47	1.20	1.74	0.14	0.27	Colorimetric Lactate Oxidase
	mg/dl	13.2	10.8	15.6	1.20	2.40	
LD (LDH)	U/l	203	173	233	15.00	30.00	L->P 37°C
	U/l	450	383	517	33.50	67.00	P->L Scandinavian & Dutch 37°C
	U/l	209	178	240	15.50	31.00	L->P IFCC 37°C
	U/l	194	165	223	14.50	29.00	L to P Beckman (Extinction Coeff) 37°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman Coulter AU Series®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
Lipase	U/l	34	27	41	3.50	7.00	Other Colorimetric 37°C
	U/l	45	36	54	4.50	9.00	Randox Colorimetric 37°C
Lithium	mmol/l	0.96	0.84	1.07	0.06	0.12	Spectrophotometric
	mg/dl	0.664	0.584	0.744	0.04	0.08	
Magnesium	mmol/l	0.92	0.81	1.03	0.06	0.11	Calmagite
	mg/dl	2.24	1.98	2.50	0.13	0.26	
	mmol/l	0.92	0.81	1.03	0.06	0.11	Xylidyl Blue
	mg/dl	2.25	1.98	2.52	0.14	0.27	
Phosphate Inorganic	mmol/l	1.47	1.25	1.69	0.11	0.22	Phosphomolybdate UV
	mg/dl	4.56	3.88	5.24	0.34	0.68	
Potassium	mmol/l	3.86	3.55	4.17	0.16	0.31	ISE method - indirect
Protein Total	g/l	59.1	47.3	70.9	5.90	11.80	Biuret reaction end point
	g/dl	5.91	4.73	7.09	0.59	1.18	
	g/l	59.1	47.2	71.0	5.95	11.90	Biuret reaction kinetic
	g/dl	5.91	4.72	7.10	0.60	1.19	
Sodium	mmol/l	141	134	148	3.50	7.00	ISE method - indirect
TIBC	µmol/l	47.3	37.4	57.2	4.95	9.90	FE+UIBC(saturation with iron)
	µg/dl	264	209	319	27.50	55.00	
	µmol/l	46.6	36.8	56.4	4.90	9.80	Direct Colorimetric
	µg/dl	260	206	314	27.00	54.00	
Triglycerides	mmol/l	1.14	0.96	1.32	0.09	0.18	Lipase/GPO-PAP no correction
	mg/dl	101	84.7	117	8.15	16.30	
	mmol/l	1.13	0.95	1.31	0.09	0.18	L/G Kinase EP. no correction
	mg/dl	100	84.3	116	7.85	15.70	
Uric Acid (Urate)	mmol/l	0.35	0.31	0.40	0.02	0.05	Uricase peroxidase with ascorbate oxidase
	mg/dl	5.91	5.14	6.68	0.39	0.77	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman Coulter AU Series®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
Uric Acid (Urate)	mmol/l	0.35	0.30	0.39	0.02	0.05	Uricase peroxidase no ascorbate oxidase
	mg/dl	5.86	5.11	6.61	0.38	0.75	
	mmol/l	0.36	0.31	0.41	0.02	0.05	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	6.01	5.22	6.80	0.40	0.79	
Urea	mmol/l	7.18	6.10	8.26	0.54	1.08	Urease end point
	mg/dl	43.2	36.7	49.7	3.25	6.50	
	mmol/l	7.41	6.30	8.52	0.56	1.11	Urease kinetic
	mg/dl	44.5	37.9	51.1	3.30	6.60	
	mmol/l	7.41	6.30	8.52	0.56	1.11	BUN
	mg/dl	20.8	17.7	23.9	1.55	3.10	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman DxC600/800®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	43.9	37.3	50.5	3.30	6.60	Bromocresol Purple
	g/dl	4.39	3.73	5.05	0.33	0.66	
Amylase Total	U/l	95	81	109	7.00	14.00	Beckman Synchron AMY7 37°C
Bilirubin Direct	µmol/l	13.5	10.6	16.4	1.45	2.90	Diazo with Sulphanilic Acid
	mg/dl	0.790	0.620	0.960	0.09	0.17	
	µmol/l	14.0	11.0	17.0	1.50	3.00	Diazo/ Sulphanilic Beckman DxC
	mg/dl	0.819	0.644	0.994	0.09	0.18	
Bilirubin Total	µmol/l	31.8	25.1	38.5	3.35	6.70	Diazo with Sulphanilic Acid
	mg/dl	1.86	1.47	2.25	0.20	0.39	
Calcium	mmol/l	2.09	1.88	2.30	0.11	0.21	Ion selective electrode
	mg/dl	8.38	7.54	9.22	0.42	0.84	
Cholesterol	mmol/l	4.03	3.51	4.55	0.26	0.52	Cholesterol Oxidase - Abell Kendall
	mg/dl	156	135	177	10.50	21.00	
Chloride	mmol/l	94.1	86.6	102	3.75	7.50	ISE indirect
Creatinine	µmol/l	116	92.8	139	11.60	23.20	Alkaline picrate no deproteinization
	mg/dl	1.31	1.05	1.57	0.13	0.26	
Glucose	mmol/l	6.00	5.10	6.90	0.45	0.90	Glucose oxidase
	mg/dl	108	91.9	124	8.05	16.10	
HDL - Cholesterol	mmol/l	1.64	1.39	1.89	0.13	0.25	HDL - Ultra
	mg/dl	63.3	53.7	72.9	4.80	9.60	
Magnesium	mmol/l	0.92	0.81	1.03	0.06	0.11	Calmagite
	mg/dl	2.24	1.97	2.51	0.14	0.27	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Beckman DxC600/800®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Potassium	mmol/l	3.75	3.45	4.05	0.15	0.30	ISE method - indirect
Protein Total	g/l	60.9	48.7	73.1	6.10	12.20	Biuret reaction end point
	g/dl	6.09	4.87	7.31	0.61	1.22	
Sodium	mmol/l	137	130	144	3.50	7.00	ISE method - indirect
Triglycerides	mmol/l	1.15	0.96	1.34	0.09	0.19	Lipase/GPO-PAP no correction
	mg/dl	102	85.3	119	8.35	16.70	
Uric Acid (Urate)	mmol/l	0.34	0.29	0.38	0.02	0.04	Uricase peroxidase no ascorbate oxidase
	mg/dl	5.66	4.92	6.40	0.37	0.74	
Urea	mmol/l	7.50	6.38	8.62	0.56	1.12	Urease kinetic
	mg/dl	45.1	38.3	51.9	3.40	6.80	
	mmol/l	7.50	6.38	8.62	0.56	1.12	BUN
	mg/dl	21.1	17.9	24.3	1.60	3.20	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Biotecnica/Wiener BT and CB Series

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	40.3	34.2	46.4	3.05	6.10	Bromocresol Green
	g/dl	4.03	3.42	4.64	0.31	0.61	
ALT (GPT)	U/l	36	29	43	3.50	7.00	Tris buffer without P5P 37°C
	U/l	27	21	33	3.00	6.00	Tris buffer without P5P 30°C
	U/l	20	16	24	2.00	4.00	Tris buffer without P5P 25°C
AST (GOT)	U/l	31	25	37	3.00	6.00	Tris buffer without P5P 37°C
	U/l	21	17	25	2.00	4.00	Tris buffer without P5P 30°C
	U/l	15	12	18	1.50	3.00	Tris buffer without P5P 25°C
Bilirubin Direct	µmol/l	16.6	13.1	20.1	1.75	3.50	Dichlorophenyl Diazonium (DPD)
	mg/dl	0.971	0.766	1.18	0.10	0.21	
Calcium	mmol/l	2.22	2.00	2.44	0.11	0.22	Arsenazo III
	mg/dl	8.90	8.02	9.78	0.44	0.88	
Cholesterol	mmol/l	3.99	3.47	4.51	0.26	0.52	Cholesterol Oxidase - Abell Kendall
	mg/dl	154	134	174	10.00	20.00	
Creatinine	µmol/l	116	93.1	139	11.45	22.90	Alkaline picrate no deproteinization
	mg/dl	1.31	1.05	1.57	0.13	0.26	
Glucose	mmol/l	5.96	5.06	6.86	0.45	0.90	Glucose oxidase
	mg/dl	107	91.2	123	7.90	15.80	
Phosphate Inorganic	mmol/l	1.60	1.36	1.84	0.12	0.24	Phosphomolybdate UV
	mg/dl	4.96	4.22	5.70	0.37	0.74	
Protein Total	g/l	60.6	48.5	72.7	6.05	12.10	Biuret reaction end point
	g/dl	6.06	4.85	7.27	0.61	1.21	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Biotecnica/Wiener BT and CB Series

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Triglycerides	mmol/l	1.13	0.95	1.31	0.09	0.18	Lipase/GPO-PAP no correction
	mg/dl	100	84.0	116	8.00	16.00	
Uric Acid (Urate)	mmol/l	0.36	0.31	0.41	0.02	0.05	Uricase peroxidase no ascorbate oxidase
	mg/dl	6.06	5.28	6.84	0.39	0.78	
Urea	mmol/l	7.28	6.19	8.37	0.55	1.09	Urease kinetic
	mg/dl	43.8	37.2	50.4	3.30	6.60	
	mmol/l	7.28	6.19	8.37	0.55	1.09	BUN
	mg/dl	20.4	17.3	23.5	1.55	3.10	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

COBAS INTEGRA®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	43.4	36.9	49.9	3.25	6.50	Bromocresol Green
	g/dl	4.34	3.69	4.99	0.33	0.65	
	g/l	39.2	33.4	45.0	2.90	5.80	Turbidimetric Assays
	g/dl	3.92	3.34	4.50	0.29	0.58	
Alkaline Phosphatase	U/l	181	154	208	13.50	27.00	Roche Integra AMP buffer 37°C
	U/l	141	120	162	10.50	21.00	Roche Integra AMP buffer 30°C
	U/l	116	98	134	9.00	18.00	Roche Integra AMP buffer 25°C
ALT (GPT)	U/l	30	24	36	3.00	6.00	Tris buffer without P5P 37°C
	U/l	22	18	26	2.00	4.00	Tris buffer without P5P 30°C
	U/l	17	14	20	1.50	3.00	Tris buffer without P5P 25°C
Amylase Total	U/l	94	80	108	7.00	14.00	BM/Roche Colorimetric pNPG7 37°C
	U/l	93	79	107	7.00	14.00	Roche Integra 2-chloro-pNPG7 37°C
	U/l	94	80	108	7.00	14.00	Roche liquid stable pNPG7 37°C
AST (GOT)	U/l	30	24	36	3.00	6.00	Tris buffer without P5P 37°C
	U/l	20	16	24	2.00	4.00	Tris buffer without P5P 30°C
	U/l	14	11	17	1.50	3.00	Tris buffer without P5P 25°C
Bicarbonate	mmol/l	13.7	10.9	16.5	1.40	2.80	Enzymatic
Bilirubin Direct	µmol/l	20.7	16.4	25.0	2.15	4.30	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.21	0.959	1.46	0.13	0.25	
	µmol/l	19.9	15.7	24.1	2.10	4.20	Diazo with Sulphanilic Acid
	mg/dl	1.16	0.918	1.40	0.12	0.24	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

COBAS INTEGRA®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Bilirubin Direct	µmol/l	20.2	16.0	24.4	2.10	4.20	Roche DPD JG standardised
	mg/dl	1.18	0.936	1.42	0.12	0.24	
Bilirubin Total	µmol/l	28.4	22.5	34.3	2.95	5.90	Diazo with Sulphanilic Acid
	mg/dl	1.66	1.32	2.00	0.17	0.34	
	µmol/l	28.0	22.2	33.8	2.90	5.80	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.64	1.30	1.98	0.17	0.34	
	µmol/l	28.8	22.8	34.8	3.00	6.00	Diazonium ion
	mg/dl	1.68	1.33	2.03	0.18	0.35	
Calcium	mmol/l	2.15	1.93	2.37	0.11	0.22	Cresolphthalein complexone
	mg/dl	8.62	7.74	9.50	0.44	0.88	
	mmol/l	2.13	1.92	2.34	0.11	0.21	NM-BAPTA
	mg/dl	8.54	7.70	9.38	0.42	0.84	
Cholesterol	mmol/l	4.12	3.59	4.65	0.27	0.53	Cholesterol Oxidase - Abell Kendall
	mg/dl	159	139	179	10.00	20.00	
	mmol/l	4.10	3.57	4.63	0.27	0.53	Cholesterol Oxidase - IDMS
	mg/dl	158	138	178	10.00	20.00	
Chloride	mmol/l	94.4	86.8	102	3.80	7.60	ISE indirect
CK Total	U/l	182	149	215	16.50	33.00	CK-NAC (IFCC) 37°C
	U/l	114	93	135	10.50	21.00	CK-NAC (IFCC) 30°C
	U/l	77	63	91	7.00	14.00	CK-NAC (IFCC) 25°C
Creatinine	µmol/l	117	93.5	141	11.75	23.50	Alkaline picrate with deproteinization
	mg/dl	1.32	1.06	1.58	0.13	0.26	
	µmol/l	126	101	151	12.50	25.00	Alkaline picrate no deproteinization
	mg/dl	1.42	1.14	1.70	0.14	0.28	
	µmol/l	128	102	154	13.00	26.00	Roche Creatinine Plus
	mg/dl	1.45	1.15	1.75	0.15	0.30	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

COBAS INTEGRA®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Creatinine	µmol/l	116	93.1	139	11.45	22.90	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	1.31	1.05	1.57	0.13	0.26	
	µmol/l	122	97.5	147	12.25	24.50	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	1.38	1.10	1.66	0.14	0.28	
gamma-GT	U/l	42	36	48	3.00	6.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	33	28	38	2.50	5.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	26	22	30	2.00	4.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
	U/l	47	40	54	3.50	7.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	37	32	42	2.50	5.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	29	25	33	2.00	4.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
Glucose	mmol/l	6.33	5.38	7.28	0.48	0.95	Hexokinase
	mg/dl	114	96.9	131	8.55	17.10	
HDL - Cholesterol	mmol/l	1.39	1.18	1.60	0.11	0.21	Direct HDL Roche 4th Generation
	mg/dl	53.7	45.5	61.9	4.10	8.20	
Iron	µmol/l	20.1	16.4	23.8	1.85	3.70	Colorimetric with ppt.
	µg/dl	112	91.7	132	10.15	20.30	
	µmol/l	19.9	16.3	23.5	1.80	3.60	Colorimetric without ppt.
	µg/dl	111	91.1	131	9.95	19.90	
Lactate	mmol/l	1.60	1.31	1.89	0.15	0.29	Colorimetric Lactate Oxidase
	mg/dl	14.4	11.8	17.0	1.30	2.60	
LD (LDH)	U/l	223	190	256	16.50	33.00	L->P IFCC 37°C
	U/l	161	137	185	12.00	24.00	L->P IFCC 30°C
	U/l	113	96	130	8.50	17.00	L->P IFCC 25°C
Lipase	U/l	36	29	43	3.50	7.00	Roche Colorimetric 37°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

COBAS INTEGRA®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Lipase	U/l	36	29	43	3.50	7.00	
Lithium	mmol/l	0.96	0.84	1.07	0.06	0.12	Ion selective electrode
	mg/dl	0.665	0.585	0.745	0.04	0.08	
Magnesium	mmol/l	0.93	0.81	1.04	0.06	0.11	Xylidyl Blue
	mg/dl	2.25	1.98	2.52	0.14	0.27	
	mmol/l	0.93	0.82	1.04	0.06	0.11	Chlorphosphonazo III
	mg/dl	2.26	1.99	2.53	0.14	0.27	
Phosphate Inorganic	mmol/l	1.53	1.30	1.76	0.12	0.23	Phosphomolybdate enzymatic
	mg/dl	4.74	4.03	5.45	0.36	0.71	
	mmol/l	1.53	1.30	1.76	0.12	0.23	Phosphomolybdate UV
	mg/dl	4.74	4.03	5.45	0.36	0.71	
Potassium	mmol/l	3.86	3.55	4.17	0.16	0.31	ISE method - indirect
Protein Total	g/l	57.0	45.6	68.4	5.70	11.40	Biuret reaction end point
	g/dl	5.70	4.56	6.84	0.57	1.14	
	g/l	59.2	47.3	71.1	5.95	11.90	Biuret reaction kinetic
	g/dl	5.92	4.73	7.11	0.60	1.19	
Sodium	mmol/l	139	132	146	3.50	7.00	ISE method - indirect
TIBC	µmol/l	43.1	34.1	52.1	4.50	9.00	FE+UIBC(saturation with iron)
	µg/dl	241	191	291	25.00	50.00	
Triglycerides	mmol/l	1.15	0.97	1.33	0.09	0.18	Lipase/GPO-PAP no correction
	mg/dl	102	85.7	118	8.15	16.30	
	mmol/l	1.17	0.98	1.36	0.09	0.19	Lipase/GPO-PAP 0.11mmol/l correction
	mg/dl	104	87.0	121	8.50	17.00	
	mmol/l	1.17	0.98	1.36	0.09	0.19	Lipase/Glycerol Dehydrogenase
	mg/dl	104	86.8	121	8.60	17.20	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

COBAS INTEGRA®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Uric Acid (Urate)	mmol/l	0.36	0.31	0.40	0.02	0.05	Uricase peroxidase with ascorbate oxidase
	mg/dl	6.00	5.22	6.78	0.39	0.78	
	mmol/l	0.35	0.31	0.40	0.02	0.05	Uricase peroxidase no ascorbate oxidase
	mg/dl	5.91	5.14	6.68	0.39	0.77	
	mmol/l	0.35	0.31	0.40	0.02	0.05	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	5.93	5.16	6.70	0.39	0.77	
Urea	mmol/l	6.98	5.93	8.03	0.53	1.05	Urease kinetic
	mg/dl	41.9	35.6	48.2	3.15	6.30	
	mmol/l	6.98	5.93	8.03	0.53	1.05	BUN
	mg/dl	19.6	16.7	22.5	1.45	2.90	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Elitech/Vitalab Selectra Series

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	42.2	35.9	48.5	3.15	6.30	Bromocresol Green
	g/dl	4.22	3.59	4.85	0.32	0.63	
ALT (GPT)	U/l	37	29	45	4.00	8.00	Tris buffer without P5P 37°C
AST (GOT)	U/l	37	30	44	3.50	7.00	Tris buffer without P5P 37°C
Calcium	mmol/l	2.27	2.04	2.50	0.12	0.23	Arsenazo III
	mg/dl	9.10	8.18	10.0	0.46	0.92	
Cholesterol	mmol/l	4.33	3.77	4.89	0.28	0.56	Cholesterol Oxidase - Abell Kendall
	mg/dl	167	146	188	10.50	21.00	
CK Total	U/l	206	169	243	18.50	37.00	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	118	94.1	142	11.95	23.90	Alkaline picrate no deproteinization
	mg/dl	1.33	1.06	1.60	0.14	0.27	
	µmol/l	123	98.7	147	12.15	24.30	Creatinine PAP method
	mg/dl	1.39	1.12	1.66	0.14	0.27	
Glucose	mmol/l	6.73	5.72	7.74	0.51	1.01	Glucose oxidase
	mg/dl	121	103	139	9.00	18.00	
Protein Total	g/l	60.5	48.4	72.6	6.05	12.10	Biuret reaction end point
	g/dl	6.05	4.84	7.26	0.61	1.21	
Triglycerides	mmol/l	1.21	1.02	1.40	0.10	0.19	Lipase/GPO-PAP no correction
	mg/dl	107	90.3	124	8.35	16.70	
Uric Acid (Urate)	mmol/l	0.41	0.36	0.46	0.03	0.05	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	6.90	6.01	7.79	0.45	0.89	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Elitech/Vitalab Selectra Series

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Urea	mmol/l	7.26	6.17	8.35	0.55	1.09	Urease kinetic
	mg/dl	43.6	37.1	50.1	3.25	6.50	
	mmol/l	7.26	6.17	8.35	0.55	1.09	BUN
	mg/dl	20.4	17.3	23.5	1.55	3.10	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Konelab 20/30/60®/Thermo Scientific Indiko Plus ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	39.5	33.6	45.4	2.95	5.90	Bromocresol Green
	g/dl	3.95	3.36	4.54	0.30	0.59	
Alkaline Phosphatase	U/l	199	169	229	15.00	30.00	AMP optimised to IFCC 37°C
	U/l	155	132	178	11.50	23.00	AMP optimised to IFCC 30°C
	U/l	127	108	146	9.50	19.00	AMP optimised to IFCC 25°C
ALT (GPT)	U/l	37	30	44	3.50	7.00	Tris buffer without P5P 37°C
	U/l	27	22	32	2.50	5.00	Tris buffer without P5P 30°C
	U/l	21	17	25	2.00	4.00	Tris buffer without P5P 25°C
AST (GOT)	U/l	38	30	46	4.00	8.00	Tris buffer without P5P 37°C
	U/l	26	20	32	3.00	6.00	Tris buffer without P5P 30°C
	U/l	18	14	22	2.00	4.00	Tris buffer without P5P 25°C
Bilirubin Total	µmol/l	32.8	25.9	39.7	3.45	6.90	Diazo with Sulphanilic Acid
	mg/dl	1.92	1.52	2.32	0.20	0.40	
	µmol/l	26.4	20.9	31.9	2.75	5.50	Nitrobenzenediazonium salt
	mg/dl	1.54	1.22	1.86	0.16	0.32	
Calcium	mmol/l	2.13	1.91	2.35	0.11	0.22	Arsenazo III
	mg/dl	8.54	7.66	9.42	0.44	0.88	
Cholesterol	mmol/l	4.12	3.58	4.66	0.27	0.54	Cholesterol Oxidase - Abell Kendall
	mg/dl	159	138	180	10.50	21.00	
CK Total	U/l	194	159	229	17.50	35.00	CK-NAC (IFCC) 37°C
	U/l	121	100	142	10.50	21.00	CK-NAC (IFCC) 30°C
	U/l	82	68	96	7.00	14.00	CK-NAC (IFCC) 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Konelab 20/30/60®/Thermo Scientific Indiko Plus ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Creatinine	µmol/l	124	99.5	149	12.25	24.50	Alkaline picrate no deproteinization
	mg/dl	1.40	1.12	1.68	0.14	0.28	
gamma-GT	U/l	45	38	52	3.50	7.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	35	30	40	2.50	5.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	28	23	33	2.50	5.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
Glucose	mmol/l	6.02	5.12	6.92	0.45	0.90	Glucose oxidase
	mg/dl	108	92.3	124	7.85	15.70	
HDL - Cholesterol	mmol/l	1.34	1.14	1.54	0.10	0.20	Direct HDL PEGME
	mg/dl	51.7	44.0	59.4	3.85	7.70	
Iron	µmol/l	21.6	17.7	25.5	1.95	3.90	Colorimetric without ppt.
	µg/dl	121	98.9	143	11.05	22.10	
Magnesium	mmol/l	0.90	0.80	1.01	0.05	0.11	Xylidyl Blue
	mg/dl	2.20	1.93	2.47	0.14	0.27	
Phosphate Inorganic	mmol/l	1.47	1.25	1.69	0.11	0.22	Phosphomolybdate UV
	mg/dl	4.56	3.88	5.24	0.34	0.68	
Potassium	mmol/l	3.78	3.48	4.08	0.15	0.30	ISE method - direct
Protein Total	g/l	60.8	48.6	73.0	6.10	12.20	Biuret reaction end point
	g/dl	6.08	4.86	7.30	0.61	1.22	
Sodium	mmol/l	137	130	144	3.50	7.00	ISE method - direct
Triglycerides	mmol/l	1.16	0.97	1.35	0.09	0.19	Lipase/GPO-PAP no correction
	mg/dl	103	86.2	120	8.40	16.80	
Uric Acid (Urate)	mmol/l	0.36	0.31	0.41	0.02	0.05	Uricase peroxidase with ascorbate oxidase
	mg/dl	6.06	5.28	6.84	0.39	0.78	
Urea	mmol/l	7.37	6.26	8.48	0.56	1.11	Urease kinetic
	mg/dl	44.3	37.6	51.0	3.35	6.70	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Konelab 20/30/60®/Thermo Scientific Indiko Plus ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28 Range

Analyte	unit	Target	low	high	1SD	2SD	methods
Urea	mmol/l	7.37	6.26	8.48	0.56	1.11	BUN
	mg/dl	20.7	17.6	23.8	1.55	3.10	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Ortho VITROS®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	41.9	35.6	48.2	3.15	6.30	Ortho Vitros Microslide Systems
	g/dl	4.19	3.56	4.82	0.32	0.63	
Alkaline Phosphatase	U/l	170	145	195	12.50	25.00	Ortho Vitros Microslide Systems 37°C
ALT (GPT)	U/l	36	29	43	3.50	7.00	Ortho Vitros Microslide Systems 37°C
	U/l	37	29	45	4.00	8.00	Ortho Vitros MicroSlide visible 37°C
Amylase Total	U/l	77	65	89	6.00	12.00	Ortho Vitros Microslide Systems 37°C
AST (GOT)	U/l	49	39	59	5.00	10.00	Ortho Vitros Microslide visible slide 37°C
Bicarbonate	mmol/l	15.7	12.5	18.9	1.60	3.20	Ortho Vitros Microslide Systems
Bilirubin Total	µmol/l	25.0	19.8	30.2	2.60	5.20	Vitros 250/500/700/950 Total Bilirubin
	mg/dl	1.46	1.16	1.76	0.15	0.30	
Calcium	mmol/l	2.14	1.93	2.35	0.11	0.21	Ortho Vitros Microslide Systems
	mg/dl	8.58	7.74	9.42	0.42	0.84	
Cholesterol	mmol/l	4.07	3.54	4.60	0.27	0.53	Ortho Vitros Microslide Systems
	mg/dl	157	137	177	10.00	20.00	
Chloride	mmol/l	95.3	87.7	103	3.80	7.60	Ortho Vitros Microslide Systems
CK Total	U/l	172	141	203	15.50	31.00	Ortho Vitros Microslide Systems 37°C
Creatinine	µmol/l	119	95.6	142	11.70	23.40	Vitros IDMS Traceable
	mg/dl	1.34	1.08	1.60	0.13	0.26	
Free T4	pmol/l	36.7	27.5	45.9	4.60	9.20	Vitros ECi
	ng/dl	2.86	2.15	3.57	0.36	0.71	
	pg/ml	28.6	21.5	35.7	3.55	7.10	Vitros ECi

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Ortho VITROS®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

Analyte	unit	Target	Range low	Range high	1SD	2SD	methods
gamma-GT	U/l	56	48	64	4.00	8.00	Ortho Vitros Microslide Systems 37°C
Glucose	mmol/l	6.25	5.31	7.19	0.47	0.94	Ortho Vitros Microslide Systems
	mg/dl	113	95.7	130	8.65	17.30	
HDL - Cholesterol	mmol/l	1.41	1.20	1.62	0.11	0.21	Vitros dHDL PTA/MgCl2 direct precipitation
	mg/dl	54.4	46.3	62.5	4.05	8.10	
Iron	µmol/l	19.2	15.7	22.7	1.75	3.50	Ortho Vitros Microslide Systems
	µg/dl	107	87.8	126	9.60	19.20	
Lactate	mmol/l	1.50	1.23	1.77	0.14	0.27	Ortho Vitros Microslide Systems
	mg/dl	13.5	11.1	15.9	1.20	2.40	
LD (LDH)	U/l	237	201	273	18.00	36.00	Ortho Vitros IFCC Traceable 37°C
Lipase	U/l	231	185	277	23.00	46.00	Ortho Vitros Microslide Systems 37°C
	U/l	35	28	42	3.50	7.00	
Magnesium	mmol/l	0.89	0.79	1.00	0.05	0.11	Ortho Vitros Microslide Systems
	mg/dl	2.17	1.91	2.43	0.13	0.26	
Phosphate Inorganic	mmol/l	1.52	1.29	1.75	0.12	0.23	Ortho Vitros Microslide Systems
	mg/dl	4.71	4.00	5.42	0.36	0.71	
Potassium	mmol/l	3.90	3.59	4.21	0.16	0.31	Ortho Vitros Microslide Systems
Protein Total	g/l	60.4	48.4	72.4	6.00	12.00	Ortho Vitros Microslide Systems
	g/dl	6.04	4.84	7.24	0.60	1.20	
Sodium	mmol/l	139	132	146	3.50	7.00	Ortho Vitros Microslide Systems
Triglycerides	mmol/l	1.36	1.14	1.58	0.11	0.22	Ortho Vitros Microslide Systems
	mg/dl	120	101	139	9.50	19.00	
Uric Acid (Urate)	mmol/l	0.33	0.29	0.38	0.02	0.04	Ortho Vitros Microslide Systems
	mg/dl	5.59	4.87	6.31	0.36	0.72	
Urea	mmol/l	7.12	6.05	8.19	0.54	1.07	Ortho Vitros Microslide Systems
	mg/dl	42.8	36.4	49.2	3.20	6.40	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C111®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	43.5	37.0	50.0	3.25	6.50	Bromocresol Green
	g/dl	4.35	3.70	5.00	0.33	0.65	
Alkaline Phosphatase	U/l	182	155	209	13.50	27.00	Roche Integra AMP buffer 37°C
	U/l	142	121	163	10.50	21.00	Roche Integra AMP buffer 30°C
	U/l	116	99	133	8.50	17.00	Roche Integra AMP buffer 25°C
ALT (GPT)	U/l	30	24	36	3.00	6.00	Tris buffer without P5P 37°C
	U/l	22	18	26	2.00	4.00	Tris buffer without P5P 30°C
	U/l	17	14	20	1.50	3.00	Tris buffer without P5P 25°C
Amylase Total	U/l	95	81	109	7.00	14.00	Roche liquid stable pNPG7 37°C
AST (GOT)	U/l	32	25	39	3.50	7.00	Tris buffer without P5P 37°C
	U/l	22	17	27	2.50	5.00	Tris buffer without P5P 30°C
	U/l	15	12	18	1.50	3.00	Tris buffer without P5P 25°C
Bilirubin Direct	µmol/l	20.1	15.9	24.3	2.10	4.20	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.18	0.930	1.43	0.13	0.25	
	µmol/l	20.2	16.0	24.4	2.10	4.20	Roche DPD JG standardised
	mg/dl	1.18	0.936	1.42	0.12	0.24	
Bilirubin Total	µmol/l	27.6	21.8	33.4	2.90	5.80	Diazo with Sulphanilic Acid
	mg/dl	1.61	1.28	1.94	0.17	0.33	
	µmol/l	27.8	22.0	33.6	2.90	5.80	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.63	1.29	1.97	0.17	0.34	
	µmol/l	28.6	22.6	34.6	3.00	6.00	Diazonium ion
	mg/dl	1.67	1.32	2.02	0.18	0.35	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C111®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Calcium	mmol/l	2.14	1.93	2.35	0.11	0.21	NM-BAPTA
	mg/dl	8.58	7.74	9.42	0.42	0.84	
Cholesterol	mmol/l	4.17	3.63	4.71	0.27	0.54	Cholesterol Oxidase - Abell Kendall
	mg/dl	161	140	182	10.50	21.00	
	mmol/l	4.10	3.57	4.63	0.27	0.53	Cholesterol Oxidase - IDMS
	mg/dl	158	138	178	10.00	20.00	
CK Total	U/l	186	153	219	16.50	33.00	CK-NAC (IFCC) 37°C
	U/l	116	96	136	10.00	20.00	CK-NAC (IFCC) 30°C
	U/l	79	65	93	7.00	14.00	CK-NAC (IFCC) 25°C
Creatinine	µmol/l	124	99.4	149	12.30	24.60	Alkaline picrate no deproteinization
	mg/dl	1.40	1.12	1.68	0.14	0.28	
	µmol/l	127	101	153	13.00	26.00	Roche Creatinine Plus
	mg/dl	1.44	1.14	1.74	0.15	0.30	
	µmol/l	121	97.1	145	11.95	23.90	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	1.37	1.10	1.64	0.14	0.27	
	µmol/l	121	96.9	145	12.05	24.10	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	1.37	1.09	1.65	0.14	0.28	
Glucose	mmol/l	6.45	5.49	7.41	0.48	0.96	Hexokinase
	mg/dl	116	98.9	133	8.55	17.10	
HDL - Cholesterol	mmol/l	1.39	1.18	1.60	0.11	0.21	Direct HDL Roche 4th Generation
	mg/dl	53.7	45.5	61.9	4.10	8.20	
LD (LDH)	U/l	221	188	254	16.50	33.00	L->P IFCC 37°C
	U/l	160	136	184	12.00	24.00	L->P IFCC 30°C
	U/l	112	95	129	8.50	17.00	L->P IFCC 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C111®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Magnesium	mmol/l	0.91	0.80	1.02	0.05	0.11	Xylidyl Blue
	mg/dl	2.22	1.95	2.49	0.14	0.27	
Phosphate Inorganic	mmol/l	1.57	1.33	1.81	0.12	0.24	Phosphomolybdate UV
	mg/dl	4.87	4.12	5.62	0.38	0.75	
Protein Total	g/l	58.3	46.6	70.0	5.85	11.70	Biuret reaction end point
	g/dl	5.83	4.66	7.00	0.59	1.17	
Triglycerides	mmol/l	1.16	0.98	1.34	0.09	0.18	Lipase/GPO-PAP no correction
	mg/dl	103	86.4	120	8.30	16.60	
Uric Acid (Urate)	mmol/l	0.34	0.30	0.39	0.02	0.04	Uricase peroxidase with ascorbate oxidase
	mg/dl	5.73	4.99	6.47	0.37	0.74	
	mmol/l	0.34	0.30	0.38	0.02	0.04	Uricase peroxidase no ascorbate oxidase
	mg/dl	5.71	4.97	6.45	0.37	0.74	
	mmol/l	0.36	0.31	0.41	0.02	0.05	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	6.01	5.22	6.80	0.40	0.79	
Urea	mmol/l	6.87	5.84	7.90	0.52	1.03	Urease kinetic
	mg/dl	41.3	35.1	47.5	3.10	6.20	
	mmol/l	6.87	5.84	7.90	0.52	1.03	BUN
	mg/dl	19.3	16.4	22.2	1.45	2.90	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c303/501/502/503

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	43.0	36.6	49.4	3.20	6.40	Bromocresol Green
	g/dl	4.30	3.66	4.94	0.32	0.64	
	g/l	40.9	34.8	47.0	3.05	6.10	Turbidimetric Assays
	g/dl	4.09	3.48	4.70	0.31	0.61	
Alkaline Phosphatase	U/l	181	154	208	13.50	27.00	Roche Integra AMP buffer 37°C
	U/l	141	120	162	10.50	21.00	Roche Integra AMP buffer 30°C
	U/l	116	98	134	9.00	18.00	Roche Integra AMP buffer 25°C
ALT (GPT)	U/l	31	25	37	3.00	6.00	Tris buffer without P5P 37°C
	U/l	23	19	27	2.00	4.00	Tris buffer without P5P 30°C
	U/l	17	14	20	1.50	3.00	Tris buffer without P5P 25°C
Amylase Pancreatic	U/l	66	56	76	5.00	10.00	Roche EPS Liquid 37°C
Amylase Total	U/l	91	77	105	7.00	14.00	BM/Roche Colorimetric pNPG7 37°C
	U/l	91	78	104	6.50	13.00	Roche Integra 2-chloro-pNPG7 37°C
	U/l	92	78	106	7.00	14.00	Roche liquid stable pNPG7 37°C
AST (GOT)	U/l	31	24	38	3.50	7.00	Tris buffer without P5P 37°C
	U/l	21	16	26	2.50	5.00	Tris buffer without P5P 30°C
	U/l	15	11	19	2.00	4.00	Tris buffer without P5P 25°C
Bile Acids	µmol/l	24.2	19.3	29.1	2.45	4.90	Enzymatic Colorimetric
Bicarbonate	mmol/l	14.0	11.1	16.9	1.45	2.90	Colorimetric
	mmol/l	13.8	10.9	16.7	1.45	2.90	Enzymatic
Bilirubin Direct	µmol/l	20.7	16.4	25.0	2.15	4.30	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.21	0.959	1.46	0.13	0.25	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c303/501/502/503

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Bilirubin Direct	µmol/l	20.2	16.0	24.4	2.10	4.20	Diazo with Sulphanilic Acid
	mg/dl	1.18	0.936	1.42	0.12	0.24	
	µmol/l	20.8	16.5	25.1	2.15	4.30	Roche DPD JG standardised
	mg/dl	1.22	0.965	1.48	0.13	0.26	
Bilirubin Total	µmol/l	27.5	21.7	33.3	2.90	5.80	Diazo with Dichloroaniline (DCA)
	mg/dl	1.61	1.27	1.95	0.17	0.34	
	µmol/l	26.5	20.9	32.1	2.80	5.60	Diazo with Sulphanilic Acid
	mg/dl	1.55	1.22	1.88	0.17	0.33	
	µmol/l	26.8	21.1	32.5	2.85	5.70	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.57	1.23	1.91	0.17	0.34	
	µmol/l	26.8	21.2	32.4	2.80	5.60	Diazonium ion
	mg/dl	1.57	1.24	1.90	0.17	0.33	
Calcium	mmol/l	2.16	1.94	2.38	0.11	0.22	Cresolphthalein complexone
	mg/dl	8.66	7.78	9.54	0.44	0.88	
	mmol/l	2.17	1.95	2.39	0.11	0.22	NM-BAPTA
	mg/dl	8.70	7.82	9.58	0.44	0.88	
Cholesterol	mmol/l	4.18	3.64	4.72	0.27	0.54	Cholesterol Oxidase - Abell Kendall
	mg/dl	161	141	181	10.00	20.00	
	mmol/l	4.20	3.65	4.75	0.28	0.55	Cholesterol Oxidase - IDMS
	mg/dl	162	141	183	10.50	21.00	
Chloride	mmol/l	91.3	84.0	98.6	3.65	7.30	ISE indirect
Cholinesterase	U/l	5575	4460	6690	557.50	1115.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	189	155	223	17.00	34.00	CK-NAC substrate start (DGKC) 37°C
	U/l	118	97	139	10.50	21.00	CK-NAC substrate start (DGKC) 30°C
	U/l	80	66	94	7.00	14.00	CK-NAC substrate start (DGKC) 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c303/501/502/503

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
CK Total	U/l	187	153	221	17.00	34.00	CK-NAC (IFCC) 37°C
	U/l	117	96	138	10.50	21.00	CK-NAC (IFCC) 30°C
	U/l	79	65	93	7.00	14.00	CK-NAC (IFCC) 25°C
Creatinine	µmol/l	125	99.9	150	12.55	25.10	Alkaline picrate no deproteinization
	mg/dl	1.41	1.13	1.69	0.14	0.28	
	µmol/l	130	104	156	13.00	26.00	Roche Creatinine Plus
	mg/dl	1.47	1.18	1.76	0.15	0.29	
	µmol/l	124	99.4	149	12.30	24.60	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	1.40	1.12	1.68	0.14	0.28	
	µmol/l	128	103	153	12.50	25.00	Jaffe rate blanked compensated (-18 µmol/l)
	mg/dl	1.45	1.16	1.74	0.15	0.29	
D-3-Hydroxybutyrate	mmol/l	0.27	0.23	0.31	0.02	0.04	Tris buffer 100mmol pH 8.5
Free T4	pmol/l	22.7	17.0	28.4	2.85	5.70	Roche Cobas e601/602
	ng/dl	1.77	1.33	2.21	0.22	0.44	
	pg/ml	17.7	13.3	22.1	2.20	4.40	Roche Cobas e601/602
gamma-GT	U/l	42	36	48	3.00	6.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	33	28	38	2.50	5.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	26	22	30	2.00	4.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
	U/l	47	40	54	3.50	7.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	37	32	42	2.50	5.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	29	25	33	2.00	4.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
GLDH	U/l	15	12	18	1.50	3.00	Triethanolamine buffer 50 mmol 37°C
	U/l	12	9	15	1.50	3.00	Triethanolamine buffer 50 mmol 30°C
	U/l	9	7	11	1.00	2.00	Triethanolamine buffer 50 mmol 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c303/501/502/503

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Glucose	mmol/l	6.20	5.27	7.13	0.47	0.93	Hexokinase
	mg/dl	112	95.0	129	8.50	17.00	
HDL - Cholesterol	mmol/l	1.39	1.18	1.60	0.11	0.21	Direct HDL Roche 4th Generation
	mg/dl	53.7	45.5	61.9	4.10	8.20	
Iron	µmol/l	19.2	15.7	22.7	1.75	3.50	Colorimetric with ppt.
	µg/dl	107	87.8	126	9.60	19.20	
	µmol/l	19.2	15.7	22.7	1.75	3.50	Colorimetric without ppt.
	µg/dl	107	87.8	126	9.60	19.20	
Lactate	mmol/l	1.60	1.31	1.89	0.15	0.29	Colorimetric Lactate Oxidase
	mg/dl	14.4	11.8	17.0	1.30	2.60	
LD (LDH)	U/l	213	181	245	16.00	32.00	L->P 37°C
	U/l	154	131	177	11.50	23.00	L->P 30°C
	U/l	108	92	124	8.00	16.00	L->P 25°C
	U/l	218	186	250	16.00	32.00	L->P IFCC 37°C
	U/l	157	134	180	11.50	23.00	L->P IFCC 30°C
	U/l	111	94	128	8.50	17.00	L->P IFCC 25°C
Lipase	U/l	35	28	42	3.50	7.00	Roche Colorimetric 37°C
	U/l	35	28	42	3.50	7.00	
Lithium	mmol/l	0.99	0.87	1.11	0.06	0.12	Spectrophotometric
	mg/dl	0.690	0.607	0.773	0.04	0.08	
Magnesium	mmol/l	0.93	0.82	1.04	0.06	0.11	Xylidyl Blue
	mg/dl	2.26	1.99	2.53	0.14	0.27	
	mmol/l	0.93	0.82	1.04	0.06	0.11	Chlorphosphonazo III
	mg/dl	2.26	1.99	2.53	0.14	0.27	
Osmolality	mOsm/kg	286	228	344	29.00	58.00	Calculated

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c303/501/502/503

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Phosphate Inorganic	mmol/l	1.46	1.24	1.68	0.11	0.22	Phosphomolybdate enzymatic
	mg/dl	4.53	3.84	5.22	0.35	0.69	
	mmol/l	1.47	1.25	1.69	0.11	0.22	Phosphomolybdate UV
	mg/dl	4.56	3.88	5.24	0.34	0.68	
Potassium	mmol/l	3.92	3.61	4.23	0.16	0.31	ISE method - indirect
Protein Total	g/l	59.2	47.4	71.0	5.90	11.80	Biuret reaction end point
	g/dl	5.92	4.74	7.10	0.59	1.18	
	g/l	58.9	47.1	70.7	5.90	11.80	Biuret reaction kinetic
	g/dl	5.89	4.71	7.07	0.59	1.18	
PSA Total	ng/ml =	9.66	7.24	12.1	1.21	2.42	Roche Cobas 6000/8000
Sodium	mmol/l	141	134	148	3.50	7.00	ISE method - indirect
Thyroid Stimulating Hormone	µU/ml =	1.70	1.36	2.04	0.17	0.34	Roche Cobas e601/602
TIBC	µmol/l	41.6	32.8	50.4	4.40	8.80	FE+UIBC(saturation with iron)
	µg/dl	233	183	283	25.00	50.00	
	µmol/l	49.4	39.0	59.8	5.20	10.40	Calculated from Transferrin
	µg/dl	276	218	334	29.00	58.00	
Total T3	nmol/l	2.21	1.65	2.77	0.28	0.56	Roche Cobas e601/602
	ng/ml	1.44	1.07	1.81	0.19	0.37	
	ng/dl	144	107	181	18.50	37.00	Roche Cobas e601/602
Total T4	nmol/l	99.1	74.3	124	12.40	24.80	Roche Cobas e601/602
	µg/dl	7.73	5.80	9.66	0.97	1.93	
	ng/ml	77.3	58.0	96.6	9.65	19.30	Roche Cobas e601/602
Triglycerides	mmol/l	1.17	0.98	1.36	0.09	0.19	Lipase/GPO-PAP no correction
	mg/dl	104	87.0	121	8.50	17.00	
	mmol/l	1.15	0.97	1.33	0.09	0.18	Lipase/GPO-PAP 0.11mmol/l correction
	mg/dl	102	85.7	118	8.15	16.30	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c303/501/502/503

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Triglycerides	mmol/l	1.16	0.97	1.35	0.09	0.19	L/G Kinase EP. no correction
	mg/dl	103	86.0	120	8.50	17.00	
Uric Acid (Urate)	mmol/l	0.34	0.29	0.38	0.02	0.04	Uricase catalase 340nm
	mg/dl	5.63	4.89	6.37	0.37	0.74	
	mmol/l	0.34	0.30	0.38	0.02	0.04	Uricase peroxidase with ascorbate oxidase
	mg/dl	5.71	4.97	6.45	0.37	0.74	
	mmol/l	0.34	0.30	0.38	0.02	0.04	Uricase peroxidase no ascorbate oxidase
	mg/dl	5.71	4.97	6.45	0.37	0.74	
	mmol/l	0.34	0.30	0.39	0.02	0.05	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	5.76	5.01	6.51	0.38	0.75	
Urea	mmol/l	7.24	6.15	8.33	0.55	1.09	Urease kinetic
	mg/dl	43.5	37.0	50.0	3.25	6.50	
	mmol/l	7.24	6.15	8.33	0.55	1.09	BUN
	mg/dl	20.3	17.3	23.3	1.50	3.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C311®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	42.9	36.5	49.3	3.20	6.40	Bromocresol Green
	g/dl	4.29	3.65	4.93	0.32	0.64	
	g/l	41.7	35.4	48.0	3.15	6.30	Bromocresol Purple
	g/dl	4.17	3.54	4.80	0.32	0.63	
Alkaline Phosphatase	U/l	178	152	204	13.00	26.00	Roche Integra AMP buffer 37°C
	U/l	139	118	160	10.50	21.00	Roche Integra AMP buffer 30°C
	U/l	114	97	131	8.50	17.00	Roche Integra AMP buffer 25°C
ALT (GPT)	U/l	32	25	39	3.50	7.00	Tris buffer without P5P 37°C
	U/l	24	19	29	2.50	5.00	Tris buffer without P5P 30°C
	U/l	18	14	22	2.00	4.00	Tris buffer without P5P 25°C
Amylase Pancreatic	U/l	69	59	79	5.00	10.00	Roche EPS Liquid 37°C
Amylase Total	U/l	90	77	103	6.50	13.00	BM/Roche Colorimetric pNPG7 37°C
	U/l	94	80	108	7.00	14.00	Roche liquid stable pNPG7 37°C
AST (GOT)	U/l	32	25	39	3.50	7.00	Tris buffer without P5P 37°C
	U/l	22	17	27	2.50	5.00	Tris buffer without P5P 30°C
	U/l	15	12	18	1.50	3.00	Tris buffer without P5P 25°C
Bicarbonate	mmol/l	13.8	11.0	16.6	1.40	2.80	Enzymatic
Bilirubin Direct	µmol/l	21.3	16.9	25.7	2.20	4.40	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.25	0.989	1.51	0.13	0.26	
	µmol/l	21.4	16.9	25.9	2.25	4.50	Diazo with Sulphanilic Acid
	mg/dl	1.25	0.989	1.51	0.13	0.26	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C311®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Bilirubin Direct	µmol/l	21.1	16.7	25.5	2.20	4.40	Roche DPD JG standardised
	mg/dl	1.23	0.977	1.48	0.13	0.25	
Bilirubin Total	µmol/l	27.3	21.5	33.1	2.90	5.80	Diazo with Sulphanilic Acid
	mg/dl	1.60	1.26	1.94	0.17	0.34	
	µmol/l	27.0	21.3	32.7	2.85	5.70	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.58	1.25	1.91	0.17	0.33	
	µmol/l	27.0	21.3	32.7	2.85	5.70	Diazonium ion
	mg/dl	1.58	1.25	1.91	0.17	0.33	
Calcium	mmol/l	2.17	1.96	2.38	0.11	0.21	Cresolphthalein complexone
	mg/dl	8.70	7.86	9.54	0.42	0.84	
	mmol/l	2.18	1.96	2.40	0.11	0.22	NM-BAPTA
	mg/dl	8.74	7.86	9.62	0.44	0.88	
Cholesterol	mmol/l	4.20	3.66	4.74	0.27	0.54	Cholesterol Oxidase - Abell Kendall
	mg/dl	162	141	183	10.50	21.00	
	mmol/l	4.25	3.69	4.81	0.28	0.56	Cholesterol Oxidase - IDMS
	mg/dl	164	142	186	11.00	22.00	
Chloride	mmol/l	91.5	84.2	98.8	3.65	7.30	ISE indirect
CK Total	U/l	190	156	224	17.00	34.00	CK-NAC (IFCC) 37°C
	U/l	119	98	140	10.50	21.00	CK-NAC (IFCC) 30°C
	U/l	81	66	96	7.50	15.00	CK-NAC (IFCC) 25°C
Creatinine	µmol/l	135	108	162	13.50	27.00	Alkaline picrate no deproteinization
	mg/dl	1.53	1.22	1.84	0.16	0.31	
	µmol/l	132	106	158	13.00	26.00	Roche Creatinine Plus
	mg/dl	1.49	1.20	1.78	0.15	0.29	
	µmol/l	129	103	155	13.00	26.00	Jaffe rate blanked
	mg/dl	1.46	1.16	1.76	0.15	0.30	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C311®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Creatinine	µmol/l	125	100	150	12.50	25.00	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	1.41	1.13	1.69	0.14	0.28	
gamma-GT	U/l	42	36	48	3.00	6.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	33	28	38	2.50	5.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	26	22	30	2.00	4.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
	U/l	47	40	54	3.50	7.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	37	32	42	2.50	5.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	29	25	33	2.00	4.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
Glucose	mmol/l	6.23	5.30	7.16	0.47	0.93	Hexokinase
	mg/dl	112	95.5	129	8.25	16.50	
	mmol/l	6.22	5.28	7.16	0.47	0.94	Glucose oxidase
	mg/dl	112	95.1	129	8.45	16.90	
HDL - Cholesterol	mmol/l	1.39	1.18	1.60	0.11	0.21	Direct HDL Roche 4th Generation
	mg/dl	53.7	45.5	61.9	4.10	8.20	
Iron	µmol/l	19.2	15.7	22.7	1.75	3.50	Colorimetric with ppt.
	µg/dl	107	87.8	126	9.60	19.20	
	µmol/l	19.3	15.9	22.7	1.70	3.40	Colorimetric without ppt.
	µg/dl	108	88.9	127	9.55	19.10	
Lactate	mmol/l	1.63	1.34	1.92	0.15	0.29	Colorimetric Lactate Oxidase
	mg/dl	14.7	12.1	17.3	1.30	2.60	
LD (LDH)	U/l	220	187	253	16.50	33.00	L->P IFCC 37°C
	U/l	159	135	183	12.00	24.00	L->P IFCC 30°C
	U/l	112	95	129	8.50	17.00	L->P IFCC 25°C
Lipase	U/l	35	28	42	3.50	7.00	Roche Colorimetric 37°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas C311®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Magnesium	mmol/l	0.92	0.81	1.03	0.06	0.11	Xylidyl Blue
	mg/dl	2.24	1.97	2.51	0.14	0.27	
	mmol/l	0.93	0.82	1.04	0.06	0.11	Chlorphosphonazo III
	mg/dl	2.26	1.99	2.53	0.14	0.27	
Phosphate Inorganic	mmol/l	1.49	1.26	1.72	0.12	0.23	Phosphomolybdate UV
	mg/dl	4.62	3.91	5.33	0.36	0.71	
Potassium	mmol/l	3.93	3.62	4.24	0.16	0.31	ISE method - indirect
Protein Total	g/l	59.3	47.5	71.1	5.90	11.80	Biuret reaction end point
	g/dl	5.93	4.75	7.11	0.59	1.18	
Sodium	mmol/l	141	134	148	3.50	7.00	ISE method - indirect
Triglycerides	mmol/l	1.18	0.99	1.37	0.09	0.19	Lipase/GPO-PAP no correction
	mg/dl	104	87.7	120	8.15	16.30	
	mmol/l	1.14	0.96	1.32	0.09	0.18	Lipase/Glycerol Dehydrogenase
	mg/dl	101	84.8	117	8.10	16.20	
Uric Acid (Urate)	mmol/l	0.35	0.30	0.40	0.02	0.05	Uricase peroxidase with ascorbate oxidase
	mg/dl	5.86	5.09	6.63	0.39	0.77	
	mmol/l	0.35	0.31	0.40	0.02	0.05	Uricase peroxidase no ascorbate oxidase
	mg/dl	5.90	5.12	6.68	0.39	0.78	
	mmol/l	0.35	0.30	0.40	0.02	0.05	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	5.88	5.11	6.65	0.39	0.77	
Urea	mmol/l	7.44	6.32	8.56	0.56	1.12	Urease kinetic
	mg/dl	44.7	38.0	51.4	3.35	6.70	
	mmol/l	7.44	6.32	8.56	0.56	1.12	BUN
	mg/dl	20.9	17.8	24.0	1.55	3.10	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c701 / c702 / c711

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	43.2	36.7	49.7	3.25	6.50	Bromocresol Green
	g/dl	4.32	3.67	4.97	0.33	0.65	
	g/l	41.3	35.1	47.5	3.10	6.20	Bromocresol Purple
	g/dl	4.13	3.51	4.75	0.31	0.62	
	g/l	42.3	35.9	48.7	3.20	6.40	Turbidimetric Assays
	g/dl	4.23	3.59	4.87	0.32	0.64	
Alkaline Phosphatase	U/l	173	147	199	13.00	26.00	Roche Integra AMP buffer 37°C
	U/l	135	115	155	10.00	20.00	Roche Integra AMP buffer 30°C
	U/l	111	94	128	8.50	17.00	Roche Integra AMP buffer 25°C
	U/l	178	151	205	13.50	27.00	Colorimetric 37°C
	U/l	139	118	160	10.50	21.00	Colorimetric 30°C
	U/l	114	96	132	9.00	18.00	Colorimetric 25°C
ALT (GPT)	U/l	31	25	37	3.00	6.00	Tris buffer without P5P 37°C
	U/l	23	19	27	2.00	4.00	Tris buffer without P5P 30°C
	U/l	17	14	20	1.50	3.00	Tris buffer without P5P 25°C
Amylase Pancreatic	U/l	67	57	77	5.00	10.00	Roche EPS Liquid 37°C
Amylase Total	U/l	92	78	106	7.00	14.00	Roche liquid stable pNPG7 37°C
AST (GOT)	U/l	30	24	36	3.00	6.00	Tris buffer without P5P 37°C
	U/l	20	16	24	2.00	4.00	Tris buffer without P5P 30°C
	U/l	14	11	17	1.50	3.00	Tris buffer without P5P 25°C
Bile Acids	µmol/l	24.1	19.3	28.9	2.40	4.80	Enzymatic Colorimetric

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c701 / c702 / c711

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Bicarbonate	mmol/l	14.1	11.2	17.0	1.45	2.90	Enzymatic
Bilirubin Direct	µmol/l	20.5	16.2	24.8	2.15	4.30	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.20	0.948	1.45	0.13	0.25	
	µmol/l	19.1	15.1	23.1	2.00	4.00	Diazo with Sulphanilic Acid
	mg/dl	1.12	0.883	1.36	0.12	0.24	
	µmol/l	20.7	16.4	25.0	2.15	4.30	Roche DPD JG standardised
	mg/dl	1.21	0.959	1.46	0.13	0.25	
	µmol/l	17.1	13.5	20.7	1.80	3.60	Oxidation to Biliverdin/Vanadate
	mg/dl	1.00	0.790	1.21	0.11	0.21	
Bilirubin Total	µmol/l	27.0	21.3	32.7	2.85	5.70	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.58	1.25	1.91	0.17	0.33	
	µmol/l	26.5	20.9	32.1	2.80	5.60	Diazonium ion
	mg/dl	1.55	1.22	1.88	0.17	0.33	
Calcium	mmol/l	2.13	1.91	2.35	0.11	0.22	Cresolphthalein complexone
	mg/dl	8.54	7.66	9.42	0.44	0.88	
	mmol/l	2.16	1.94	2.38	0.11	0.22	NM-BAPTA
	mg/dl	8.66	7.78	9.54	0.44	0.88	
Cholesterol	mmol/l	4.20	3.66	4.74	0.27	0.54	Cholesterol Oxidase - Abell Kendall
	mg/dl	162	141	183	10.50	21.00	
	mmol/l	4.17	3.63	4.71	0.27	0.54	Cholesterol Oxidase - IDMS
	mg/dl	161	140	182	10.50	21.00	
Chloride	mmol/l	91.7	84.3	99.1	3.70	7.40	ISE indirect
Cholinesterase	U/l	5472	4378	6566	547.00	1094.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	191	156	226	17.50	35.00	CK-NAC (IFCC) 37°C
	U/l	120	98	142	11.00	22.00	CK-NAC (IFCC) 30°C
	U/l	81	66	96	7.50	15.00	CK-NAC (IFCC) 25°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c701 / c702 / c711

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Creatinine	µmol/l	132	106	158	13.00	26.00	Roche Creatinine Plus
	mg/dl	1.49	1.20	1.78	0.15	0.29	
	µmol/l	131	105	157	13.00	26.00	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	1.48	1.19	1.77	0.15	0.29	
gamma-GT	U/l	42	35	49	3.50	7.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	33	28	38	2.50	5.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	26	22	30	2.00	4.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
	U/l	47	40	54	3.50	7.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	37	32	42	2.50	5.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	29	25	33	2.00	4.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
Glucose	mmol/l	6.19	5.26	7.12	0.47	0.93	Hexokinase
	mg/dl	112	94.8	129	8.60	17.20	
HDL - Cholesterol	mmol/l	1.38	1.17	1.59	0.11	0.21	Direct HDL Roche 4th Generation
	mg/dl	53.3	45.2	61.4	4.05	8.10	
Iron	µmol/l	18.2	14.9	21.5	1.65	3.30	Colorimetric with ppt.
	µg/dl	102	83.3	121	9.35	18.70	
	µmol/l	18.6	15.3	21.9	1.65	3.30	Colorimetric without ppt.
	µg/dl	104	85.5	123	9.25	18.50	
Lactate	mmol/l	1.59	1.30	1.88	0.15	0.29	Colorimetric Lactate Oxidase
	mg/dl	14.3	11.7	16.9	1.30	2.60	
LD (LDH)	U/l	216	184	248	16.00	32.00	L->P IFCC 37°C
	U/l	156	133	179	11.50	23.00	L->P IFCC 30°C
	U/l	110	93	127	8.50	17.00	L->P IFCC 25°C
Lipase	U/l	34	28	40	3.00	6.00	Roche Colorimetric 37°C

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c701 / c702 / c711

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Lithium	mmol/l	0.98	0.87	1.10	0.06	0.12	Spectrophotometric
	mg/dl	0.683	0.601	0.765	0.04	0.08	
Magnesium	mmol/l	0.94	0.83	1.05	0.06	0.11	Xylidyl Blue
	mg/dl	2.29	2.01	2.57	0.14	0.28	
Phosphate Inorganic	mmol/l	1.46	1.24	1.68	0.11	0.22	Phosphomolybdate UV
	mg/dl	4.53	3.84	5.22	0.35	0.69	
Potassium	mmol/l	3.93	3.62	4.24	0.16	0.31	ISE method - indirect
Protein Total	g/l	58.9	47.1	70.7	5.90	11.80	Biuret reaction end point
	g/dl	5.89	4.71	7.07	0.59	1.18	
Sodium	mmol/l	141	134	148	3.50	7.00	ISE method - indirect
TIBC	µmol/l	42.8	33.8	51.8	4.50	9.00	FE+UIBC(saturation with iron)
	µg/dl	239	189	289	25.00	50.00	
Triglycerides	mmol/l	1.16	0.98	1.35	0.09	0.19	Lipase/GPO-PAP no correction
	mg/dl	103	86.3	120	8.35	16.70	
	mmol/l	1.20	1.01	1.39	0.10	0.19	Lipase/GPO-PAP 0.11mmol/l correction
	mg/dl	106	89.4	123	8.30	16.60	
	mmol/l	1.15	0.96	1.34	0.09	0.19	L/G Kinase EP. no correction
	mg/dl	102	85.2	119	8.40	16.80	
Uric Acid (Urate)	mmol/l	0.34	0.29	0.38	0.02	0.04	Uricase peroxidase with ascorbate oxidase
	mg/dl	5.63	4.89	6.37	0.37	0.74	
	mmol/l	0.34	0.30	0.39	0.02	0.04	Uricase peroxidase no ascorbate oxidase
	mg/dl	5.75	5.01	6.49	0.37	0.74	
	mmol/l	0.34	0.29	0.38	0.02	0.04	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	5.68	4.94	6.42	0.37	0.74	
Urea	mmol/l	7.12	6.06	8.18	0.53	1.06	Urease kinetic
	mg/dl	42.8	36.4	49.2	3.20	6.40	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Roche Cobas c701 / c702 / c711

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Urea	mmol/l	7.12	6.05	8.19	0.54	1.07	BUN
	mg/dl	20.0	17.0	23.0	1.50	3.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

RX SERIES®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	42.1	35.8	48.4	3.15	6.30	Bromocresol Green
	g/dl	4.21	3.58	4.84	0.32	0.63	
Alkaline Phosphatase	U/l	304	258	350	23.00	46.00	Diethanolamine buffer DEA 37°C
	U/l	188	159	217	14.50	29.00	AMP optimised to IFCC 37°C
ALT (GPT)	U/l	33	26	40	3.50	7.00	Tris buffer without P5P 37°C
Amylase Pancreatic	U/l	76	64	88	5.90	11.80	Randox Liquid Ethylidene pNPG7 37°C
Amylase Total	U/l	105	89	121	8.00	16.00	Randox Liquid Ethylidene pNPG7 37°C
AST (GOT)	U/l	35	28	42	3.50	7.00	Tris buffer without P5P 37°C
Bile Acids	µmol/l	25.7	20.6	30.8	2.55	5.10	5th Generation Colorimetric
Bicarbonate	mmol/l	15.3	12.1	18.5	1.60	3.20	Enzymatic
Bilirubin Direct	µmol/l	20.0	15.8	24.2	2.10	4.20	Diazo with Sulphanilic Acid
	mg/dl	1.17	0.924	1.42	0.12	0.25	
	µmol/l	18.3	14.4	22.2	1.95	3.90	Oxidation to Biliverdin/Vanadate
	mg/dl	1.07	0.842	1.30	0.11	0.23	
Bilirubin Total	µmol/l	31.7	25.0	38.4	3.35	6.70	Diazo with Sulphanilic Acid
	mg/dl	1.85	1.46	2.24	0.20	0.39	
	µmol/l	31.7	25.1	38.3	3.30	6.60	Oxidation to Biliverdin/Vanadate
	mg/dl	1.85	1.47	2.23	0.19	0.38	
Calcium	mmol/l	2.29	2.06	2.52	0.12	0.23	Arsenazo III
	mg/dl	9.18	8.26	10.1	0.46	0.92	
Cholesterol	mmol/l	4.24	3.69	4.79	0.28	0.55	Cholesterol Oxidase - Abell Kendall
	mg/dl	164	142	186	11.00	22.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

RX SERIES®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Chloride	mmol/l	92.1	84.8	99.4	3.65	7.30	ISE direct
CK Total	U/l	220	180	260	20.00	40.00	CK-NAC substrate start (DGKC) 37°C
	U/l	212	174	250	19.00	38.00	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	115	91.6	138	11.70	23.40	Alkaline picrate no deproteinization
	mg/dl	1.30	1.04	1.56	0.13	0.26	
	µmol/l	134	107	161	13.50	27.00	Enzymatic UV method
	mg/dl	1.51	1.21	1.81	0.15	0.30	
gamma-GT	U/l	48	41	55	3.50	7.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
Glucose	mmol/l	6.40	5.44	7.36	0.48	0.96	Hexokinase
	mg/dl	115	98.0	132	8.50	17.00	
	mmol/l	6.47	5.50	7.44	0.49	0.97	Glucose oxidase
	mg/dl	117	99.1	135	8.95	17.90	
Iron	µmol/l	20.2	16.5	23.9	1.85	3.70	Colorimetric without ppt.
	µg/dl	113	92.2	134	10.40	20.80	
Lactate	mmol/l	1.53	1.25	1.81	0.14	0.28	Colorimetric Lactate Oxidase
	mg/dl	13.8	11.3	16.3	1.25	2.50	
LD (LDH)	U/l	422	359	485	31.50	63.00	P->L German methods 37°C
	U/l	194	165	223	14.50	29.00	L->P IFCC 37°C
Lipase	U/l	42	34	50	4.00	8.00	Randox Colorimetric 37°C
Magnesium	mmol/l	0.95	0.84	1.07	0.06	0.12	Xylidyl Blue
	mg/dl	2.31	2.03	2.59	0.14	0.28	
Phosphate Inorganic	mmol/l	1.48	1.26	1.70	0.11	0.22	Phosphomolybdate UV
	mg/dl	4.59	3.91	5.27	0.34	0.68	
Potassium	mmol/l	3.90	3.59	4.21	0.16	0.31	ISE method - direct

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

RX SERIES®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Potassium	mmol/l	4.10	3.77	4.43	0.17	0.33	Enzymatic
Protein Total	g/l	61.8	49.5	74.1	6.15	12.30	Biuret reaction end point
	g/dl	6.18	4.95	7.41	0.62	1.23	
Sodium	mmol/l	140	133	147	3.50	7.00	ISE method - direct
	mmol/l	145	138	152	3.50	7.00	Enzymatic
TIBC	µmol/l	51.4	40.6	62.2	5.40	10.80	Direct Colorimetric
	µg/dl	287	227	347	30.00	60.00	
Triglycerides	mmol/l	1.16	0.98	1.34	0.09	0.18	Lipase/GPO-PAP no correction
	mg/dl	103	86.5	120	8.25	16.50	
Uric Acid (Urate)	mmol/l	0.36	0.31	0.40	0.02	0.05	Uricase peroxidase no ascorbate oxidase
	mg/dl	5.98	5.21	6.75	0.39	0.77	
	mmol/l	0.36	0.31	0.40	0.02	0.05	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	6.00	5.22	6.78	0.39	0.78	
Urea	mmol/l	7.08	6.02	8.14	0.53	1.06	Urease kinetic
	mg/dl	42.6	36.2	49.0	3.20	6.40	
	mmol/l	7.08	6.02	8.14	0.53	1.06	BUN
	mg/dl	19.9	16.9	22.9	1.50	3.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS ADVIA 1200/1650/1800/2400®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	41.1	34.9	47.3	3.10	6.20	Bromocresol Green
	g/dl	4.11	3.49	4.73	0.31	0.62	
	g/l	42.6	36.2	49.0	3.20	6.40	Bromocresol Purple
	g/dl	4.26	3.62	4.90	0.32	0.64	
Alkaline Phosphatase	U/l	178	152	204	13.00	26.00	AMP optimised to IFCC 37°C
ALT (GPT)	U/l	39	31	47	4.00	8.00	Tris buffer without P5P 37°C
Amylase Total	U/l	95	81	109	7.00	14.00	Siemens - blocked pNPG7 37°C
AST (GOT)	U/l	38	30	46	4.00	8.00	Tris buffer without P5P 37°C
Bile Acids	µmol/l	28.1	22.5	33.7	2.80	5.60	Enzymatic Colorimetric
Bicarbonate	mmol/l	16.7	13.2	20.2	1.75	3.50	Enzymatic
Bilirubin Direct	µmol/l	18.4	14.5	22.3	1.95	3.90	Oxidation to Biliverdin/Vanadate
	mg/dl	1.08	0.848	1.31	0.12	0.23	
Bilirubin Total	µmol/l	32.1	25.4	38.8	3.35	6.70	Oxidation to Biliverdin/Vanadate
	mg/dl	1.88	1.49	2.27	0.20	0.39	
Calcium	mmol/l	2.11	1.90	2.32	0.11	0.21	Cresolphthalein complexone
	mg/dl	8.46	7.62	9.30	0.42	0.84	
	mmol/l	2.23	2.01	2.45	0.11	0.22	Arsenazo III
	mg/dl	8.94	8.06	9.82	0.44	0.88	
Cholesterol	mmol/l	4.18	3.64	4.72	0.27	0.54	Cholesterol Oxidase - Abell Kendall
	mg/dl	161	141	181	10.00	20.00	
Chloride	mmol/l	95.2	87.6	103	3.80	7.60	ISE indirect

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS ADVIA 1200/1650/1800/2400®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
CK Total	U/l	203	166	240	18.50	37.00	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	125	100	150	12.50	25.00	Enzymatic UV method
	mg/dl	1.41	1.13	1.69	0.14	0.28	
	µmol/l	125	99.7	150	12.65	25.30	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	1.41	1.13	1.69	0.14	0.28	
gamma-GT	U/l	42	36	48	3.00	6.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
Glucose	mmol/l	6.08	5.17	6.99	0.46	0.91	Hexokinase
	mg/dl	110	93.2	127	8.40	16.80	
	mmol/l	6.31	5.36	7.26	0.48	0.95	Glucose oxidase
	mg/dl	114	96.6	131	8.70	17.40	
HDL - Cholesterol	mmol/l	1.23	1.05	1.41	0.09	0.18	Direct Clearance Method
	mg/dl	47.5	40.5	54.5	3.50	7.00	
Iron	µmol/l	18.9	15.5	22.3	1.70	3.40	Colorimetric without ppt.
	µg/dl	106	86.6	125	9.70	19.40	
Lactate	mmol/l	1.47	1.20	1.74	0.14	0.27	Colorimetric Lactate Oxidase
	mg/dl	13.2	10.8	15.6	1.20	2.40	
LD (LDH)	U/l	434	369	499	32.50	65.00	P->L German methods 37°C
	U/l	217	184	250	16.50	33.00	L->P IFCC 37°C
Lipase	U/l	40	32	48	4.00	8.00	Other Colorimetric 37°C
Magnesium	mmol/l	0.88	0.77	0.98	0.05	0.11	Xylidyl Blue
	mg/dl	2.13	1.88	2.38	0.13	0.25	
Phosphate Inorganic	mmol/l	1.49	1.26	1.72	0.12	0.23	Phosphomolybdate UV
	mg/dl	4.62	3.91	5.33	0.36	0.71	
Potassium	mmol/l	3.92	3.61	4.23	0.16	0.31	ISE method - indirect
Protein Total	g/l	58.8	47.1	70.5	5.85	11.70	Biuret reaction end point
	g/dl	5.88	4.71	7.05	0.59	1.17	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS ADVIA 1200/1650/1800/2400®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Sodium	mmol/l	142	135	149	3.50	7.00	ISE method - indirect
TIBC	µmol/l	46.3	36.6	56.0	4.85	9.70	Calculated from Transferrin
	µg/dl	259	205	313	27.00	54.00	
Triglycerides	mmol/l	1.20	1.01	1.39	0.10	0.19	Lipase/GPO-PAP no correction
	mg/dl	106	89.4	123	8.30	16.60	
	mmol/l	1.22	1.03	1.41	0.10	0.19	L/G Kinase EP. no correction
	mg/dl	108	91.2	125	8.40	16.80	
Uric Acid (Urate)	mmol/l	0.35	0.31	0.40	0.02	0.05	Uricase peroxidase no ascorbate oxidase
	mg/dl	5.95	5.17	6.73	0.39	0.78	
Urea	mmol/l	7.63	6.49	8.77	0.57	1.14	Urease kinetic
	mg/dl	45.9	39.0	52.8	3.45	6.90	
	mmol/l	7.63	6.49	8.77	0.57	1.14	BUN
	mg/dl	21.4	18.2	24.6	1.60	3.20	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Siemens Atellica Solution

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	40.9	34.7	47.1	3.10	6.20	Bromocresol Green
	g/dl	4.09	3.47	4.71	0.31	0.62	
	g/l	42.0	35.7	48.3	3.15	6.30	Bromocresol Purple
	g/dl	4.20	3.57	4.83	0.32	0.63	
Alkaline Phosphatase	U/l	180	153	207	13.50	27.00	AMP optimised to IFCC 37°C
ALT (GPT)	U/l	38	30	46	4.00	8.00	Tris buffer without P5P 37°C
Amylase Pancreatic	U/l	70	60	80	5.00	10.00	Immunoinhibition EPS substrate 37°C
Amylase Total	U/l	101	86	116	7.50	15.00	Siemens - blocked pNPG7 37°C
AST (GOT)	U/l	37	30	44	3.50	7.00	Tris buffer without P5P 37°C
Bicarbonate	mmol/l	16.0	12.7	19.3	1.65	3.30	Enzymatic
Bilirubin Direct	µmol/l	19.0	15.0	23.0	2.00	4.00	Oxidation to Biliverdin/Vanadate
	mg/dl	1.11	0.878	1.34	0.12	0.23	
Bilirubin Total	µmol/l	32.9	26.0	39.8	3.45	6.90	Oxidation to Biliverdin/Vanadate
	mg/dl	1.92	1.52	2.32	0.20	0.40	
Calcium	mmol/l	2.13	1.91	2.35	0.11	0.22	Cresolphthalein complexone
	mg/dl	8.54	7.66	9.42	0.44	0.88	
	mmol/l	2.21	1.98	2.44	0.12	0.23	Arsenazo III
	mg/dl	8.86	7.94	9.78	0.46	0.92	
Cholesterol	mmol/l	4.21	3.67	4.75	0.27	0.54	Cholesterol Oxidase - Abell Kendall
	mg/dl	163	142	184	10.50	21.00	
	mmol/l	4.12	3.58	4.66	0.27	0.54	Cholesterol Oxidase - IDMS
	mg/dl	159	138	180	10.50	21.00	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Siemens Atellica Solution

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Chloride	mmol/l	97.1	89.4	105	3.85	7.70	ISE indirect
CK Total	U/l	190	156	224	17.00	34.00	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	118	94.3	142	11.85	23.70	Alkaline picrate no deproteinization
	mg/dl	1.33	1.07	1.59	0.13	0.26	
	µmol/l	124	98.9	149	12.55	25.10	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	1.40	1.12	1.68	0.14	0.28	
gamma-GT	U/l	44	38	50	3.00	6.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
Glucose	mmol/l	6.17	5.24	7.10	0.47	0.93	Hexokinase
	mg/dl	111	94.4	128	8.30	16.60	
	mmol/l	6.23	5.30	7.16	0.47	0.93	Glucose oxidase
	mg/dl	112	95.5	129	8.25	16.50	
HDL - Cholesterol	mmol/l	1.27	1.08	1.46	0.10	0.19	Direct Clearance Method
	mg/dl	49.0	41.7	56.3	3.65	7.30	
Iron	µmol/l	19.0	15.6	22.4	1.70	3.40	Colorimetric without ppt.
	µg/dl	106	87.2	125	9.40	18.80	
Lactate	mmol/l	1.46	1.20	1.72	0.13	0.26	Colorimetric Lactate Oxidase
	mg/dl	13.2	10.8	15.6	1.20	2.40	
LD (LDH)	U/l	211	180	242	15.50	31.00	Siemens Dimension L-P Non IFCC 37°C
	U/l	216	184	248	16.00	32.00	L->P IFCC 37°C
Lipase	U/l	39	32	46	3.50	7.00	Other Colorimetric 37°C
Lithium	mmol/l	1.05	0.92	1.18	0.06	0.13	Spectrophotometric
	mg/dl	0.729	0.640	0.818	0.04	0.09	
Magnesium	mmol/l	0.86	0.76	0.96	0.05	0.10	Xylidyl Blue
	mg/dl	2.09	1.84	2.34	0.13	0.25	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

Siemens Atellica Solution

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Phosphate Inorganic	mmol/l	1.50	1.27	1.73	0.12	0.23	Phosphomolybdate UV
	mg/dl	4.65	3.94	5.36	0.36	0.71	
Potassium	mmol/l	3.76	3.46	4.06	0.15	0.30	ISE method - indirect
Protein Total	g/l	58.7	47.0	70.4	5.85	11.70	Biuret reaction end point
	g/dl	5.87	4.70	7.04	0.59	1.17	
Sodium	mmol/l	140	133	147	3.50	7.00	ISE method - indirect
TIBC	µmol/l	47.5	37.5	57.5	5.00	10.00	Direct Colorimetric
	µg/dl	266	210	322	28.00	56.00	
Triglycerides	mmol/l	1.23	1.04	1.42	0.10	0.19	Lipase/GPO-PAP no correction
	mg/dl	109	92.0	126	8.50	17.00	
Uric Acid (Urate)	mmol/l	0.35	0.31	0.40	0.02	0.05	Uricase peroxidase with ascorbate oxidase
	mg/dl	5.95	5.17	6.73	0.39	0.78	
	mmol/l	0.35	0.31	0.40	0.02	0.05	Uricase peroxidase no ascorbate oxidase
	mg/dl	5.93	5.16	6.70	0.39	0.77	
Urea	mmol/l	7.55	6.41	8.69	0.57	1.14	Urease kinetic
	mg/dl	45.4	38.5	52.3	3.45	6.90	
	mmol/l	7.55	6.42	8.68	0.57	1.13	BUN
	mg/dl	21.2	18.0	24.4	1.60	3.20	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS DIMENSION EXL®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Albumin	g/l	42.5	36.1	48.9	3.20	6.40	Bromocresol Purple
	g/dl	4.25	3.61	4.89	0.32	0.64	
Alkaline Phosphatase	U/l	176	149	203	13.50	27.00	Siemens Dimension AMP buffer 37°C
ALT (GPT)	U/l	41	33	49	4.00	8.00	Tris buffer with P5P 37°C
	U/l	43	34	52	4.50	9.00	Tris buffer with P5P NVKC 37°C
	U/l	40	32	48	4.00	8.00	Siemens Dade Standard Non IFCC Correlated 37°C
Amylase Total	U/l	99	84	114	7.50	15.00	Siemens 2-chloro-pNPG3 37°C
AST (GOT)	U/l	47	38	56	4.50	9.00	Tris buffer with P5P 37°C
	U/l	48	39	57	4.50	9.00	Tris buffer with P5P NVKC 37°C
	U/l	49	40	58	4.50	9.00	Siemens Dade Standard Non IFCC Correlated 37°C
Bilirubin Direct	µmol/l	14.1	11.1	17.1	1.50	3.00	Diazo/Sulphanilic Siemens Dimension
	mg/dl	0.825	0.649	1.00	0.09	0.18	
Bilirubin Total	µmol/l	30.7	24.3	37.1	3.20	6.40	Diazo with Sulphanilic Acid
	mg/dl	1.80	1.42	2.18	0.19	0.38	
Calcium	mmol/l	2.06	1.85	2.27	0.11	0.21	Cresolphthalein complexone
	mg/dl	8.26	7.41	9.11	0.43	0.85	
Cholesterol	mmol/l	3.74	3.25	4.23	0.25	0.49	Dimension-Siemens reagents
	mg/dl	144	125	163	9.50	19.00	
Chloride	mmol/l	94.6	87.0	102	3.80	7.60	ISE indirect
CK Total	U/l	184	151	217	16.50	33.00	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	132	105	159	13.50	27.00	Alkaline picrate no deproteinization
	mg/dl	1.49	1.19	1.79	0.15	0.30	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS DIMENSION EXL®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Creatinine	µmol/l	129	103	155	13.00	26.00	Creatinine PAP method
	mg/dl	1.46	1.16	1.76	0.15	0.30	
	µmol/l	131	105	157	13.00	26.00	Jaffe rate blanked
	mg/dl	1.48	1.19	1.77	0.15	0.29	
gamma-GT	U/l	53	45	61	4.00	8.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	59	50	68	4.50	9.00	Siemens Dimension (non IFCC) 37°C
Glucose	mmol/l	6.34	5.39	7.29	0.48	0.95	Hexokinase
	mg/dl	114	97.1	131	8.45	16.90	
HDL - Cholesterol	mmol/l	1.46	1.24	1.68	0.11	0.22	Direct HDL PEGME
	mg/dl	56.4	47.9	64.9	4.25	8.50	
Iron	µmol/l	18.6	15.2	22.0	1.70	3.40	Colorimetric with ppt.
	µg/dl	104	85.0	123	9.50	19.00	
	µmol/l	18.8	15.5	22.1	1.65	3.30	Colorimetric without ppt.
	µg/dl	105	86.6	123	9.20	18.40	
LD (LDH)	U/l	207	176	238	15.50	31.00	L->P IFCC 37°C
Lipase	U/l	110	88	132	11.00	22.00	Colorimetric Siemens Dimension (LIPL Kit) 37°C
Magnesium	mmol/l	0.95	0.83	1.06	0.06	0.11	Methylthymol blue
	mg/dl	2.30	2.02	2.58	0.14	0.28	
Phosphate Inorganic	mmol/l	1.57	1.34	1.80	0.12	0.23	Phosphomolybdate enzymatic
	mg/dl	4.87	4.15	5.59	0.36	0.72	
	mmol/l	1.53	1.30	1.76	0.12	0.23	Phosphomolybdate UV
	mg/dl	4.74	4.03	5.45	0.36	0.71	
Potassium	mmol/l	3.81	3.50	4.12	0.16	0.31	ISE method - indirect
Protein Total	g/l	61.0	48.8	73.2	6.10	12.20	Biuret reaction end point
	g/dl	6.10	4.88	7.32	0.61	1.22	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS DIMENSION EXL®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Sodium	mmol/l	141	134	148	3.50	7.00	ISE method - indirect
Triglycerides	mmol/l	1.11	0.93	1.29	0.09	0.18	Lipase/GPO-PAP no correction
	mg/dl	98.2	82.7	114	7.75	15.50	
Uric Acid (Urate)	mmol/l	0.34	0.30	0.38	0.02	0.04	Uricase peroxidase no ascorbate oxidase
	mg/dl	5.70	4.96	6.44	0.37	0.74	
	mmol/l	0.35	0.30	0.39	0.02	0.05	Spectrophotometric at 280-290
	mg/dl	5.81	5.06	6.56	0.38	0.75	
Urea	mmol/l	7.43	6.31	8.55	0.56	1.12	Urease kinetic
	mg/dl	44.7	37.9	51.5	3.40	6.80	
	mmol/l	7.43	6.32	8.54	0.56	1.11	BUN
	mg/dl	20.9	17.8	24.0	1.55	3.10	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS DIMENSION RxL/Max/Xpand®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Amylase Total	U/l	98	83	113	7.50	15.00	Siemens 2-chloro-pNPG3 37°C
AST (GOT)	U/l	49	39	59	5.00	10.00	Tris buffer with P5P 37°C
Bilirubin Direct	µmol/l	13.8	10.9	16.7	1.45	2.90	Diazo/Sulphanilic Siemens Dimension
	mg/dl	0.807	0.638	0.976	0.08	0.17	
Bilirubin Total	µmol/l	28.5	22.5	34.5	3.00	6.00	Diazo with Sulphanilic Acid
	mg/dl	1.67	1.32	2.02	0.18	0.35	
Calcium	mmol/l	2.12	1.91	2.33	0.11	0.21	Cresolphthalein complexone
	mg/dl	8.50	7.66	9.34	0.42	0.84	
Cholesterol	mmol/l	3.80	3.31	4.29	0.25	0.49	Dimension-Siemens reagents
	mg/dl	147	128	166	9.50	19.00	
Chloride	mmol/l	92.0	84.6	99.4	3.70	7.40	ISE indirect
CK Total	U/l	191	157	225	17.00	34.00	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	131	104	158	13.50	27.00	Alkaline picrate no deproteinization
	mg/dl	1.48	1.18	1.78	0.15	0.30	
gamma-GT	U/l	54	46	62	4.00	8.00	Siemens Dimension (non IFCC) 37°C
Glucose	mmol/l	6.26	5.32	7.20	0.47	0.94	Hexokinase
	mg/dl	113	95.9	130	8.55	17.10	
HDL - Cholesterol	mmol/l	1.55	1.31	1.79	0.12	0.24	Direct HDL PEGME
	mg/dl	59.8	50.6	69.0	4.60	9.20	
Potassium	mmol/l	3.79	3.49	4.09	0.15	0.30	ISE method - indirect
Protein Total	g/l	61.1	48.9	73.3	6.10	12.20	Biuret reaction end point
	g/dl	6.11	4.89	7.33	0.61	1.22	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

RANDOX

SIEMENS DIMENSION RxL/Max/Xpand®

ASSAYED HUMAN SERA LEVEL 2 (HUM ASY CONTROL 2)

Lot. No. 1592UN Cat. No. HN1530 / HS2611

Size 20 x 5ml / 5 x 5ml Expiry 2026-01-28

			Range				
Analyte	**unit**	**Target**	**low**	**high**	**1SD**	**2SD**	**methods**
Sodium	mmol/l	138	131	145	3.50	7.00	ISE method - indirect
Triglycerides	mmol/l	1.13	0.95	1.31	0.09	0.18	Lipase/GPO-PAP no correction
	mg/dl	100	83.8	116	8.10	16.20	
Uric Acid (Urate)	mmol/l	0.34	0.30	0.38	0.02	0.04	Spectrophotometric at 280-290
	mg/dl	5.70	4.96	6.44	0.37	0.74	
Urea	mmol/l	7.34	6.24	8.44	0.55	1.10	Urease kinetic
	mg/dl	44.1	37.5	50.7	3.30	6.60	
	mmol/l	7.34	6.24	8.44	0.55	1.10	BUN
	mg/dl	20.6	17.5	23.7	1.55	3.10	

Randox Laboratories Ltd., 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
Tel: +44 (0) 28 9442 2413 Fax: +44 (0) 28 9445 2912
Email: applications@randox.com Website: www.randox.com

CE IVD

zybio

q h h Bnt Cs

Bsn u C

y

µmm	µ	
9: 79E7997 9A7RO79:	d: <9 ≥ Z < d; C7A ≥ Z <	l t µ Rj O; 998 ; 9
9: 79E7997 9A7RO79<	d: @D ≥ Z ; d; : ; ≥ Z ;	U~suz~C: D9 l t µ Rj O@998@; 9

q

\Δ ~ µ w xµ zw sΔ ~s ~ w v w w ≥ -Δs µ-Δ µx s≤sΔ-Δw s≥ -Δµ sΔ xw s wsu ~ ~ -Δ z ≥ sΔ s≥ ≤sv 1 w ≥ µ ≤s ≥ s27 O≤Δ-us≤≤ 5 ~ ~ ≥ s-Δ≤ w s sΔ s-v µ v-syΔµ ~ µxzw s µt-≤ss v~ w s w 7

f z w w Δ ≥ w s ≤s Δ-Δ w s ≥ -Δµ sΔ xw s w 1MZf 2 z s t w w Δ -v w ≤ w µ w s w w Δ -Δ s s-w µx ~ w 7 f z w ≥ s'µ µ uw µx MZf ~ z w ≤-w 5 z-uz z s ≤sw µ z w ≥ w s w≥ w Δ µx MZf su ~ ~ xµ z w v-syΔµ ~ µx z w s ≤-u v ~ w s w 7 R≤sv s w w ≥ MZf ~ xµ Δv -Δ z w s ~ ~ 5 u ~ zµ ~ 5 µt u ~ w 's Δv-uw5 us u-Δµ≥ s µx z w ≤-w 5 sΔv uz µΔ-u s≤ µµzµ≤≤st w7 MZf ~ µΔ≤ ≤yz ≤ w≤v s w -Δ s -w Δ zµ z s w sΔ Δuµ≥ ≤us w ≥ µus v-s≤ -Δ≤s u-µΔ7 M≤zµ yz t µ z w ≥ s s s w s≥ -Δµ sΔ xw s w 1Mef 2 sΔv MZf t wuµ≥ w w≤v s w zwΔw w v ~ w s w µuw w sxwu ≤-w uw≤≤ -Δ wy ~ 5 MZf ~ z w ≥ µ w ≤-w 6 wu-xu w Δ ≥ w7 [µ wµ w5 w≤v s -µΔ µx MZf su ~ ~ w ~ ≤µΔyw z sΔ w≤v s -µΔ µx Mef su ~ ~ 7\Δ s -w Δ ~z ~s≥ -Δ NB v w x-u-w Δu 5 w ≥ s≥ -Δµ sΔ xw s w su ~ ~ ≥ s t w v wu ws w 7 f z w s s w Δ w u -µΔ -Δ s≥ -Δµ sΔ xw s w su ~ ~ ≥ s t w ws w µ v wu ws w -vµ s≤ z µ z s w5 z w µ z w-u y µ xµ s≥ -Δµ sΔ xw s w 5 w ≤-Δy -Δ sΔ -Δu ws w-Δ z w s -µ µx s µw Δ ≥ w µ z µ≤µw Δ ≥ w7

y

f z~ x~ w z w ≥ w z µv wuµ≥ ≥ w Δ v w t z w \Δ w Δs -µΔs≤Sw w s -µΔ µx O≤Δ-us≤ Ozw≥ ~ 1MSOO2F

: 7 Ms Δ-Δw 4 α 6Xwµy≤ s -u Mu-v MZf b -u Mu-v 4 Z6T ≤ s≥ -u Mu-v

; 7b -u Mu-v 4] MPU 4 U⁴ ZPU Z6Z su -u Mu-v 4] MP⁴ 4 U¡a

a -vs -µΔ µx] MPU µ] MP⁴ us w s v wu ws w-Δ st µ t sΔuw s <@9 Δ≥ 5 z-uz ~ v ~ wu ≤ µ µ -µΔs≤ µ z w MZf su ~ ~ -Δ z w s≥ ≤sw7

µ k k

Oµ≥ µΔw Δ	[s-Δ OµΔ ~ w Δ	OµΔuw Δ s -µΔ
d:	f µ≥ w s≥ µ≤¶ ~ 2t xw	B; ≥ ≥ µ≤8Z
	] -uµ -Δs≥ -v w s v w Δ-Δw v-Δ u s≤µ -v w 1] MPU2	97@≥ ≥ µ≤8Z
d;	f µ≥ w s≥ µ≤¶ ~ 2t xw	A: ; ≥ ≥ µ≤8Z
	α 6Xwµy≤ s -u Mu-v	CE7B ≥ ≥ µ≤8Z
	Z6Ms Δ-Δw	DED ≥ ≥ µ≤8Z
	Zsu s wPwz v µyw Δs w1ZPU2	D7A xg 8Z

f z w uµ≥ µΔw Δ -Δ v-xw w Δ t s uzw s w Δ µΔ6Δ w uzs Δywst ≤sw7

: 7 f z w w s y w Δ zµ ≤sv t w µ w s ; 6D °C sΔv xw s s xµ≥ v~wu ≤yz sΔv xw w -Δy7 f z w Δµ w Δw w s y w Δ s w s≤v xµ : ; ≥ µΔ z 7

; 7a Δuw µ w Δw w5 z w w s y w Δ s w st ≤sv xµ @ w w x s ; 6D °C 7Sµ w s y w Δ Δµ -Δ w5 z w us zµ ≤sv t w -yz w Δw µ s µ-v uµΔ s≥ -Δs -µΔ7

<7f z w µv u -µΔ vs ws Δv w ~s -µΔ vs ws ws s-≤st ≤svµΔ su x syw-Δ w 7

q

U~suz~C: D95 l t -µ Rj O@998@; 95 l t -µ Rj O; 998 ; 9 Ozw≥ ~ MΔs≤ w7a z w ≥ µvw≤ us Δ t w w sx w w-xus -µΔ7

q

] µΔ6zw≥ µ≤ -u w ≥ µ ≤s ≥ s ~ ~st ≤sv xµ s≥ ≤sv 5 z-uz s w st ≤sv xµ < vs s ; 6D °C 7M µ-v w ws w xw w-Δy sΔv zs -Δy7

y

: 7 Sµ -Δ ~ µ v-syΔµ -u w µΔ≤7 \Δ us w µx uµΔ su 5 -≥ ≥ w v-s w≤ x≤ z z w sxwu w s ws ~z ≤sv Δ µx s w7

; 7 f z w vµ syw µx w s y w Δ sΔv s≥ ≤sv us Δ t w s µ -s w≤ -Δu ws w µ vwu ws w suuµ v-Δy µ s -µ -Δ ≥ w Δ 5 Δv w zwuµΔv ~ µΔ zs zw µ≤≥ w µ µ -µΔ µx w s y w Δ sΔv s≥ ≤sv ~ -Δ s -st ≤sw7

<7f z w Δwuw s wus -µΔ zµ ≤sv t w s x w Δ µ w zw w s y w Δ 7f z w t µ ≤sv us zµ ≤sv t w -yz w Δw -≥ ≥ w v-s w≤ s x w w µ s µ-v uµΔ s≥ -Δs -µΔ7

@7i z w Δ w s y w Δ t wuµ≥ w t-v µ z w t s Δ x st µ t sΔuw H: 7 9995 zw w s y w Δ ~ xs-≤sw sΔv zµ ≤sv t wv ~ us v w w7

A7M≤s ≥ ≤sv sΔv w su -µΔ s w zµ ≤sv t w ws w s µ uw µx-Δx wu -µΔ7 f z w s w≤-v y w Δws w v -Δy z w w w≥ w Δ sΔv zw w su x sy-Δy ≥ s w-s≤ zs≤st wuµ≤sw uw sΔv v~ µ w -Δ suuµ vsΔuw ~z ws v sΔ wy s -µΔ 7

B7f z w s≥ w s≥ ≤sv w w ~z w s y w Δ x µ≥ v-xw v Δ ≥ s Δ x su w ≥ s ≤sv s µ v-xw v Δ ≥ w s w s≤w 7

C7 i s Δ-Δy F f z~ µv u uµΔ s-Δ -Δy w v-w Δ µx z ≥ s Δ µ sΔ≥ s≤ µ -y-Δ7 M w w Δ 5 z w w ~ Δµ s µ uµ≥ ≤sv w≤ y s sΔ w w zs ~ ~ x w w x µ≥ -Δx wu -µ t sΔuw sΔv ≥ s t w uµΔ s≥ -Δs w v -Δy w7 f z~ µv u sΔv s≥ ≤sv zs≤≤ t w uµΔ -v w w s µ w Δ -s≤ µ uw µx -Δx wu -µΔ5 sΔv µ w s µ zµ ≤sv s x w µ wu ~ w≥ w s w sΔv uµ≥ ≤ ~z ≤st µ s µ sx w wy s -µΔ 7M≤s s w zs≤≤ t w v~ µ w µx-Δ suuµ vsΔuw ~z ≤µus≤ wy s -µΔ 7

y

OK y

u	ds w [wzµv	Lµ	B8 ; A
u	<@9 Δ≥	µ	<C °C
	@9A Δ≥	µ	: 9 ≥ -Δ
µ l	6		

PK x

h	i	k	l
BtC	8	8	: ;
k BtC	8	: ;	8
y BtC	: ;	8	8
µ OBtC	; 99	; 99	; 99
[~ w≤5 -Δu t s w s <C °C xµ A ≥ -Δ			
µ PBtC	B9	B9	B9
[~ w≤5 sx w ; ≥ -Δ5 suu s w≤ ≥ w s w zw st µ t sΔuw uzsΔyw s w 8≥ -Δ ~z-Δ < ≥ -Δ7			

OK k

g w l t -µ O≤Δ-us≤ Ozw≥ ~ [≤-6sΔs≤ w Os≤t s µ µ ds Δvµ ≥ ≤-6sΔs≤ w us≤t s µ 7Os≤t s -µΔ u usvFdw6us≤t s -µΔ ~ Δwwvw -Δ us wµx w s≤uw≥ wΔ µx zw w s y w Δ t s uz5vw -s -µΔ µx s≤ uµΔ µ≤5µ zw ≥ s'µ w s~ sΔv ≥ s-Δ w Δs Δuw µx w ~ ≥ w Δ 7

CE IVD

zybio

RK z k

f µ wΔ w zw wsst ≤ µx zw w w ≤ 5 s≤ uµΔ µ≤~ w ~ww sxw wsuz us≤t s ÷µΔ5sΔv zw s≤ uµΔ µ≤ s≤w zµ sv t w ~z÷Δ zw wu÷xww sΔyw7Vk~ ~ µ µx zw wu÷xww sΔyw5 zw w zµ sv uzwu× zw≥ ws w≥ wΔ w≥ sΔv wus≤t s w ~ ÷xΔwuw s 7V ~ wuµ≥≥wΔvww zs w uµΔv u wy ≤s s≤ uµΔ µ≤suuµ v÷Δy µ zw~ µ ΔΔwww µ wΔ w zwsuu su µx zw≥ws w≥ wΔ w≥ sΔv zw wsst ≤ µx zw w w ≤ 7

SK k

Z÷Δws us≤t s ÷µΔ s ww µ v s zw µ x÷Δy u w7 fzw uµΔuwΔ s ÷µΔ µx s≤sΔ÷Δw s≥ ÷Δµ sΔ xws w1MZf2÷Δ zw s≥ sv wus Δ t w us≤u ≤s ww µΔ zw µ x÷Δy u wt s ww µΔ~ st µ t sΔuwuzsΔyw s w7

µ q

[s≤vFE A9 g8Z

Sw≥ s≤vFC @9 g8Z

f z~ wxwwΔuw÷Δ w s≤~ v ww ≥÷Δww t s ww µΔ EA v~ ÷t ÷µΔ ÷Δ w s≤µt s÷Δww xµ≥ ;99 zws≤z ≥ s≤v sΔv ;99 zws≤z xw≥ s≤w wu÷≥ wΔ ~zµ ws ww v~ws w5 sΔv ~ xµ wxwwΔuw µΔ≤7V ~ wuµ≥≥wΔvww zs wsuz ≤st µ s µ w st ≤÷z ~ µ Δ wxwwΔuw sΔyw7

m µ

Vk zwuµΔuwΔ s ÷µΔ µx MZf ÷Δ zw s≥ ≤vw uwww :999 g8Z5 zw ww u ÷µΔ ≥ µvwµx zw uzw≥ ~ sΔs≤ w ÷≤≤t w ww5 µ zw z÷yz uµΔuwΔ s ÷µΔ s≥ ≤v zs≤≤t w v≤ ww ~z Δµ ≥ s≤ s≤Δw5 ~z ~ w µ w ≤ ≥ ≤÷≤ww t zwv≤ ÷µΔ xsu µ 7 f zw µxw ÷µΔs≤~ w µΔ ÷t≤v xµ zw w÷w µx zw w w ≤5 z÷uz ≥ s t w sxwwu ww t zw t'wu 0 syw5 w 5µ wyz 7 f zw w s≤w ~z÷Δ zw u ~÷us≤ sΔyw zµ sv t w uµΔx÷≥ ww t w≥ ws ÷Δy5÷x~ ~ µt ÷µ ≤ t w µΔv zw wxwwΔuw s≤w sΔyw µ ÷x~ ~ ÷≤≤t w µΔv zw wxwwΔuw sΔyw sxw uµΔx÷≥ s ÷µΔ vww u ÷µΔ5 zw s yw uµΔuwΔ s ÷µΔ ÷Δ zw s≥ ≤v ~ uµΔ ÷vww µ t w st Δµ ≥ s≤7Vk zw w w ≤ ~ ÷ΔuµΔ ~ wΔ ~z µ w wΔ uµΔ s µ zw u≤Δ÷us≤ ~ s ÷µΔ5us ws Δs≤ ~ zµ sv t w wxµ ≥ ww uµ w µΔv÷Δy≤7

t

:7 f zw vw ÷s ÷µΔ µx w w ≤ us ww t ÷Δ w xwwΔ ~ ≤v zs Δ :9. ÷x zw uµΔuwΔ s ÷µΔ µx zw xµ≤µ ÷Δy ÷Δ w xwwΔ s ws µ t w≤µ zwy~ wΔ s≤w F

	k
Uw≥ µy≤µt ÷Δ	A y8Z
Oz ≤v	97<9.
N÷≤ t ÷Δ	<99 ≥ µ≤8Z
f ÷y≤uw÷vw	: :7< ≥ ≥ µ≤8Z

;7 f zw w w ≤ µx z~ µv u s wµΔ≤ xµ u≤Δ÷us≤ wxwwΔuws Δv us ΔΔµ t w ww s zw t s ~ xµ v÷sy Δµ ~ µ w u≤ ÷µΔ µx us w 7 f zw u≤Δ÷us≤ v÷sy Δµ ~ s Δv ws ≥ wΔ µx s ÷wΔ zµ sv t w uµ≥ t ÷Δww ~z zw~ ≥ µ≥ 8 ÷yΔ 5 ≥ ww÷us≤ z~ µ 5 µ zw ≤st µ s µ w s Δv ws ≥ wΔ w µΔ w7 Sµ suz÷w w v÷sy Δµ ÷u µ w5 zw w w ≤ zµ sv t w uµ≥ t ÷Δww ~z u≤Δ÷us≤ w 5 ≥ ww÷us≤ z~ µ s Δv µ zw w w ≤ 7

y k

:7 f zw wsywΔ t ≤sΔ× st µ t sΔuw :7999G zw wsywΔ t ≤sΔ× st µ t sΔuw uzsΔyw s w1 8≥ ÷Δ2 9799@7

;7 MΔs≤ ÷us≤ wΔ ~~~ F s zw w uµΔuwΔ s ÷µΔ µx :<9 g8Z5 zw wsywΔ st µ t sΔuwuzsΔyw s w1 8≥ ÷Δ2 979:7

<7Muu su F ws ~ wvw ÷s ÷µΔ :9. 7

@7b wu~ ÷µΔF ~z÷Δ6 Δ A. 5t w wwΔ6 Δ ws ~ w sΔyw :9. 7

A7Z÷Δws ds ΔywF

mA5: 999og8Z5 zwuµ ws ÷µΔ uµwx÷u÷wΔ 12 97EE97

mA5@9og8Z5 zwst µ≤ wvw ÷s ÷µΔ @g8ZG

1@95: 999og8Z5 zw ws ~ wvw ÷s ÷µΔ :9. 7

u µ B C

Ozw≥ ~ sΔs≤ w5 l t ÷µ O≤Δ÷us≤Ozw≥ ~ [≤÷6sΔs≤ w Os≤t s µ µ ds Δvµ ≥ ≤÷6sΔs≤ wus≤t s µ 5OµΔ µ≤5T wΔws≤≤st w ~≥ wΔ sΔv uµΔ ≥ st ≤w7

µ

mob s ~P5 f s÷µ≤÷R5 l sΔwss M5 w s≤7g vs ww vwx÷Δ~÷µΔ µx zws≤z sΔyw xµ w ≥ s≤sΔ÷Δws≥ ÷Δµ sΔ xws w≤v ws÷MM7MΔΔ VΔ w Δ [ww5; 99; 5: <CF: 6: 97

q

IVD	VΔ h~ µ P÷sy Δµ ÷u [wv÷us≤Pw ÷uw	LOT	Ns uz Oµvw
	OµΔ ≤ VΔ u ÷µΔ xµ g w		g w6N Ps w
REF	Os s≤µy w] ≥ t w		[sΔ xsu w
	f w≥ ws wZ÷≥ ~		Ps wµx[sΔ xsu w
CE	OR ≥ s x÷Δy µx uµΔxµ ≥ ~	EC REP	M zµ ~ ww dw w wΔ s ~ w÷Δ zw R µ ws Δ Oµ≥ ≥ Δ~

l t ÷µ VΔu7

S≤µµ : µ S≤µµ A5N ÷sv÷Δy <95] µ7B µx f s÷x sΔy d µsv5N≤µu× O µx Ws Δ ÷s µ VΔv ÷s≤bs x5 Psv xµ P~ ÷u 5@999D; Ozµ Δy ÷Δy5 bRa bZR e dRbg NZVO a S OUV] M7

i wt F 7 t ÷µ7uµ≥

R6≥ s÷≤F÷Δx µL t ÷µ7uµ≥

f w≤F4DB192, < BDBA AA9E

Ss F4DB192, < BDBE ECCE

EC REP Zµ] Z N7h7

XµΔ÷Δy÷Δ W ≤sΔs ≤wΔ :95 : w hwv5 ;AEAMM5 f zw Usy w5

] wzw≤sΔv 7

O wΔ hw ÷µΔF9< Ps wµx V wFM ÷5; 9; <

S≤µµ : µ S≤µµ A5N ÷sv÷Δy <95] µ7B µx f s÷x sΔy d µsv5N≤µu× O µx Ws Δ ÷s µ VΔv ÷s≤bs x5 Psv xµ P~ ÷u 5@999D; Ozµ Δy ÷Δy5 bRa bZR e dRbg NZVO a S OUV] M f w≤F4DB192, < BDBA AA9E Ss F4DB192, < BDBE ECCE R6≥ s÷≤F÷Δx µL t ÷µ7uµ≥ i wt F 7 t ÷µ7uµ≥

CE IVD

zybio

Instructions for Use of Aspartate Aminotransferase (AST) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.00.16.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.00.16.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of aspartate aminotransferase activity in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of viral hepatitis, obstructive jaundice, and myocardial infarction.

Summary

The enzyme aspartate aminotransferase (AST) is widely distributed in tissue, principally hepatic, cardiac, muscle, and kidney. Elevated serum levels are found in diseases involving these tissues. Hepatobiliary diseases, such as cirrhosis, metastatic carcinoma, and viral hepatitis also increase serum AST levels. Following myocardial infarction, serum AST is elevated and reaches a peak two days after onset. In patients undergoing renal dialysis or those with vitamin B6 deficiency, serum AST may be decreased. The apparent reduction in AST may be related to decreased pyridoxal phosphate, the prosthetic group for AST, resulting in an increase in the ratio of apoenzyme to holoenzyme. Two isoenzymes of AST have been detected, cytoplasmic and mitochondrial. Only the cytoplasmic isoenzyme occurs in normal serum, while the mitochondrial, together with the cytoplasmic isoenzyme, has been detected in the serum of patients with coronary and hepatobiliary disease.

Principle

This kit uses the method recommended by the International Federation of Clinical Chemistry (IFCC):

1. Aspartic Acid + α-Ketoglutaric Acid $\xrightarrow{AST}$ Oxaloacetic Acid + L-Glutamic Acid

2. Oxaloacetic Acid + NADH + H^+ $\xrightarrow{MDH}$ L-Lactic Acid + NAD^+ + H_2O

Oxidation of NADH to NAD^+ causes a decrease in absorbance at 340 nm, which is directly proportional to the AST activity in the sample.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Trometamol (Tris) buffer	62 mmol/L
	Nicotinamide adenine dinucleotide (NADH)	0.4 mmol/L
R2	Trometamol (Tris) buffer	439 mmol/L
	α-Ketoglutaric Acid	37.1 mmol/L
	L-Aspartic Acid	>800 mmol/L
	Malate Dehydrogenase (MDH)	>2.5 kU/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.

2. Once opened, the reagents are stable for 4 weeks at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.

3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Non-hemolytic serum or plasma is suitable for samples, which are stable for 3 days at 2 - 8 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.

2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.

3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.

4. When reagent becomes turbid or the blank absorbance < 1.000, the reagent is failed and should be discarded.

5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.

6. The same sample tested with reagents from different manufacturers may lead to different measured values.

7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	Sample/Reagent	6/125
Main Wavelength	340 nm	Reaction Temperature	37 ℃
Sub Wavelength	405 nm	Reaction Time	10 min
Reaction Direction	-		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	12
Calibrator (μL)	/	12	/
Purified Water (μL)	12	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	50	50	50
Mix well, after 2 min, measure the average absorbance change rate ΔA/min within 3 min.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA
Tel: +86 (0)23 6865 5509 Fax: +86 (0)23 6869 9779 E-mail: info@zybio.com Web: www.zybio.com

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of aspartate aminotransferase (AST) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

≤ 40 U/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of AST in the sample exceeds 1000 U/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Chyle	0.30%
Bilirubin	300 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≥ 1.000; the reagent blank absorbance change rate (Δ*A*/min) ≤ 0.004.

2. Analytical sensitivity: at the test concentration of 130.0 U/L, the reagent absorbance change rate (Δ*A*/min) ≥ 0.01.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 10%.

5. Linear Range:

[10, 1000] U/L, the correlation coefficient (*r*) ≥ 0.990.

[10, 100] U/L, the absolute deviation ≤ 10 U/L;

(100, 1000] U/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Abdalla D. Clinical chemistry: theory, analysis, correlations[J]. Revista Brasileira de Ciências Farmacêuticas, 2003, 39:348-349.

[2] Tietz N. Fundamentals of clinical chemistry[M]. Saunders, 1987.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

Zybio Inc.

Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.

Web: www.zybio.com

E-mail: info@zybio.com

Tel: +86 (0)23 6865 5509

Fax: +86 (0)23 6869 9779

EC REP Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Current Version: 02 Date of Issue: May, 2022

CE IVD

zybio

Instructions for Use of Calcium (Ca) Kit (Arsenazo III Method)

Package Specification

REF	Reagent	Systems
01.09.0C.01.EC.01	R 30 mL × 6	Zybio EXC200/220
01.09.0C.01.EC.02	R 60 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of calcium (Ca) concentration in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of calcium metabolism disorders.

Summary

Calcium is the most abundant mineral element in the body with about 99% in the bones primarily as hydroxyapatite. The remaining calcium is distributed between the various tissues and the extracellular fluids where it performs a vital role for many life sustaining processes. Among the extra skeletal functions of calcium are involvement in blood coagulation, neuromuscular conduction, excitability of skeletal and cardiac muscle, enzyme activation, and the preservation of cell membrane integrity and permeability. Serum calcium levels and hence the body content are controlled by parathyroid hormone (PTH), calcitonin, and vitamin D. An imbalance in any of these modulators leads to alterations of the body and serum calcium levels. Increases in serum PTH or vitamin D are usually associated with hypercalcemia. Increased serum calcium levels may also be observed in multiple myeloma and other neoplastic diseases. Hypocalcemia may be observed e g. in hypoparathyroidism, nephrosis, and pancreatitis.

Principle

The Arsenazo III is combined with calcium ions, forming a purple-colored complex. The color of the complex is proportional to the concentration of calcium ion in the sample, which can be calculated by measuring the absorbance change at 660 nm.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R	Arsenazo III	129 μmol/L
	MES Buffer	4.25 g/L
	Surfactant	0.2% (v/v)

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 4 weeks at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

1. Fresh and nonhemolytic serum or plasma (heparin) is suitable for samples.
2. Samples should be analyzed as soon as possible after collection, which can be stable for 2 days at 20 - 25 ℃, for 14 days at 2 - 8 ℃, and for 3 months at - 20 ℃. Repeated freezing and thawing should be avoided.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. Strict measures shall be taken to avoid contamination since calcium ion is almost omnipresent.
4. When reagent becomes turbid or the blank absorbance > 1.500, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. Trace chelating agents (such as EDTA) present in the detergent can hinder the generation of chromogens. It is recommended to use disposable tubes and pipettes, etc.
7. The same sample tested with reagents from different manufacturers may lead to different measured values.
8. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/100
Main Wavelength	660 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Direction**	+

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent (μL)	300	300	300
Mix well, incubate at 37 ℃ for 2 min, then zero the system at 660 nm as blank and measure absorbance *A*.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA
Tel: +86 (0)23 6865 5509 Fax: +86 (0)23 6869 9779 E-mail: info@zybio.com Web: www.zybio.com

5. Calculation

Linear calibration was used to draw the working curve. The concentration of calcium ion (Ca) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

Adults Serum: 2.10 - 2.60 mmol/L

Children Serum: 2.50 - 3.00 mmol/L

This reference interval is determined based on 95% distribution interval obtained from 210 healthy human specimens without related diseases per group, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of Ca in the sample exceeds 4.00 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is within ± 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Bilirubin	280 μmol/L
Mg^{2+}	3 mmol/L
K^{+}	8 mmol/L
Na^{+}	180 mmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 1.500.
2. Analytical sensitivity: at the test concentration of 2.50 mmol/L, the absorbance change (ΔA) ≥ 0.20.
3. Accuracy: relative deviation ≤ 5%.
4. Precision: within-run *CV* ≤ 3%, between-run relative range ≤ 5%.
5. Linear range:

[1.00, 4.00] mmol/L, the correlation coefficient (r) ≥ 0.990.

Within the specified test range, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Massry S, Coburn J, Chapman L, et al. Role of serum Ca, parathyroid hormone, and NaCl infusion on renal Ca and Na clearances[J]. Am J Physiol, 1968, 214:1403-1409.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

Zybio Inc.
Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.
Web: www.zybio.com
E-mail: info@zybio.com
Tel: +86 (0)23 6865 5509
Fax: +86 (0)23 6869 9779

EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Current Version: 02 Date of Issue: May, 2022

Instructions for Use of Total Cholesterol (CHOL) Kit (Single) (Enzymatic Method)

Package Specification

REF	Reagent
01.09.02.11. EC. 01	R 30 mL × 6
01.09.02.11. EC. 02	R 60 mL × 2

Intended Use

In vitro test for the quantitative determination of cholesterol concentration in human samples (serum). Clinically, it is mainly used as an aid to diagnosis of hypercholesterolemia.

Summary

Cholesterol is a steroid with a secondary hydroxyl group in the C3 position. It is synthesized in many types of tissue, but particularly in the liver and intestinal wall. Approximately three quarters of cholesterol is newly synthesized and a quarter originates from dietary intake. Cholesterol assays are used for screening for atherosclerotic risk and in the diagnosis and treatment of disorders involving elevated cholesterol levels as well as lipid and lipoprotein metabolic disorders. Cholesterol analysis was first reported by Liebermann in 1885 followed by Burchard in 1889. In the Liebermann-Burchard reaction, cholesterol forms a blue-green dye from polymeric unsaturated carbohydrates in an acetic acid/acetic anhydride/concentrated sulfuric acid medium. The Abell and Kendall method is specific for cholesterol, but is technically complex and requires the use of corrosive reagents. In 1974, Roeschlau and Allain described the first fully enzymatic method. This method is based on the determination of Δ4-cholestenone after enzymatic cleavage of the cholesterol ester by cholesterol esterase, conversion of cholesterol by cholesterol oxidase, and subsequent measurement by the Trinder reaction of the hydrogen peroxide formed. Optimization of ester cleavage (> 99.5%) allows standardization using primary and secondary standards and a direct comparison with the CDC and NIST reference methods. Nonfasting sample results may be slightly lower than fasting results. The Roche cholesterol assay meets the 1992 National Institutes of Health (NIH) goal of less than or equal to 3% for both precision and bias. The assay is optionally standardized against Abell/Kendall and isotope dilution/mass spectrometry. The performance claims and data presented here are independent of the standardization.

Principle

Cholesteryl Ester $\xrightarrow{\text{Cholesterol Esterase}}$ Cholesterol + Fatty Acid

Cholesterol + O_2 $\xrightarrow{\text{Cholesterol Oxidase}}$ 3-cholestenone + H_2O_2

H_2O_2 +4-AAP + Phenol $\xrightarrow{\text{Peroxidase}}$ Quinonimine + H_2O

The content of total cholesterol in the sample could be calculated by comparing the absorbance change measured at 505 nm with calibrator treated in the same manner.

Reagents Components and Concentration

Composition: R

R	Hepes Buffer	50 mmol/L
	$MgCl_2$	10 mmol/L
	4-AAP	0.3 mmol/L
	Peroxidase	2000 U/L
	Cholesterol Esterase	3000 U/L
	Cholesterol Oxidase	300 U/L
	Phenol	1.5 mmol/L

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The reagents could be stable for 2 weeks at 2 - 8 ℃ in transportation.
4. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

1. Serum is suitable for samples and is stable for 3 days at 2 - 8 ℃ and for 30 days at -20 ℃.
2. Repeated freezing and thawing should be avoided.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or blank absorbance > 0.100, the reagent is invalid and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. **Parameters**

Method	End-Point Method	**Sample / Reagent**	1/100
Main Wavelength	505 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. **Operations**

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water	3	/	/

Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.
Tel: +86 (0)23 6865 5509 Fax: +86 (0)23 6869 9779 E-mail: info@zybio.com Web: www.zybio.com

Reagent (μL)	300	300	300
Mix well, incubate at 37 ℃ for 10 min, and measure absorbance *A*.			

3. Calibration

Use Zybio clinical chemistry multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

Indoor quality control is recommended. Values obtained should fall within the limited range. If there is a failure of any of controls, the laboratory should take appropriate corrective measures.

5. Calculation

CHOL (mmol/L) = (*A* Sample / *A* Calibrator) × C Calibrator

Reference Intervals

≤ 5.2 mmol/L (≤ 200 mg/dL)

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration exceeds 20.0 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, gender or weight. The measured values within the critical range should be re-determined and confirmed, if it is obviously beyond the reference range or if it is still beyond the reference range after confirmation, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations-Interference

The deviation of test results caused by interferents is within ± 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
VC	500 mg/L
Hemoglobin	5 g/L
Bilirubin	342 μmol/L

Performance Characteristics

1. The reagent blank absorbance: ≤ 0.100.
2. Analytical sensitivity: at the test concentration of 5.0 mmol/L, the absorbance change (Δ*A*) > 0.10.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 4%, between-run relative range ≤ 6%.
5. Linear range:

[1.0, 20.0] mmol/L, the correlation coefficient (*r*) ≥ 0.990.

[1.0, 4.0] mmol/L, the absolute deviation ≤ 0.4 mmol/L;

(4.0, 20.0] mmol/L, the relative deviation ≤ 10%.

References

[1] Allain C C, Poon L S, Chan C S G, et al. Enzymatic Determination of Total Serum Cholesterol[J]. Clinical Chemistry, 1974, 20(4):470-475.

[2] Trinder, P. Determination of Glucose in Blood Using Glucose Oxidase with an Alternative Oxygen Acceptor[J]. Ann.clin.biochem, 1969, 6(1):24-27.

[3] Siedel J, EO Hägele, Ziegenhorn J et al. Reagent for the enzymatic determination of serum total cholesterol with improved lipolytic efficiency[J]. Clinical Chemistry, 2019(6):6.

[4] Wiebe D A Bernert J T Influence of incomplete cholesteryl ester hydrolysis on enzymic measurements of cholesterol [J]. Clinical Chemistry, 1984(3):352-356.

[5] Cohn J S, Mcnamara J R, Schaefer E J. Lipoprotein cholesterol concentrations in the plasma of human subjects as measured in the fed and fasted states [J]. Clinical Chemistry, 1988(12):2456-2459.

Label Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture

Manufacturer Information

Zybio Inc.

Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.

Web: www.zybio.com

E-mail: info@zybio.com

Tel: +86 (0)23 6865 5509

Fax: +86 (0)23 6869 9779

CE IVD

zybio

Instructions for Use of Creatinine (CREA) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.01.05.EC.01	R1 30 mL × 2 R2 10 mL × 2	Zybio EXC200/220
01.09.01.05.EC.02	R1 30 mL × 1 R2 10 mL × 1	Zybio EXC200/220
01.09.01.05.EC.03	R1 45 mL × 2 R2 15 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of creatinine (CREA) concentration in human samples (serum, plasma or urine). Clinically, it is mainly used as one of the evaluation indicators of renal function.

Summary

Chronic kidney disease is a worldwide problem that carries a substantial risk for cardiovascular morbidity and death. Current guidelines define chronic kidney disease as kidney damage or glomerular filtration rate (GFR) less than 60 mL/min per 1.73 m^2 for three months or more, regardless of cause. The assay of creatinine in serum or plasma is the most commonly used test to assess renal function. Creatinine is a break-down product of creatine phosphate in muscle, and is usually produced at a fairly constant rate by the body (depending on muscle mass). It is freely filtered by the glomeruli and, under normal conditions, is not re-absorbed by the tubules to any appreciable extent. A small but significant amount is also actively secreted. Since a rise in blood creatinine is observed only with marked damage of the nephrons, it is not suited to detect early stage kidney disease. A considerably more sensitive test and better estimation of glomerular filtration rate (GFR) is given by the creatinine clearance test based on creatinine's concentration in urine and serum or plasma, and urine flow rate. For this test a precisely timed urine collection (usually 24 hours) and a blood sample are needed. However, since this test is prone to error due to the inconvenient collection of timed urine, mathematical attempts to estimate GFR based only on the creatinine concentration in serum or plasma have been made. Among the various approaches suggested, two have found wide recognition: that of Cockroft and Gault and that based on the results of the MDRD trial. While the first equation was derived from data obtained with the conventional Jaffé method, a newer version of the second is usable for IDMS-traceable creatinine methods. Both are applicable for adults. In children, the Schwartz formula should be used. In addition to the diagnosis and treatment of renal disease, the monitoring of renal dialysis, creatinine measurements are used for the calculation of the fractional excretion of other urine analytes (e g, albumin, α -amylase). Numerous methods were described for determining creatinine. Automated assays established in the routine laboratory include the Jaffé alkalinepicrate method in various modifications, as well as enzymatic tests.

Principle

This kit uses an enzymatic method to determine the concentration of creatinine (CREA) in samples.

Creatinine (CREA) in the sample is hydrolyzed by creatininase to creatine, which is hydrolyzed to sarcosine and carbamide catalyzed by creatinase. Sarcosine is oxidized to glycine, formaldehyde, and H_2O_2 catalyzed by sarcosine oxidase, and finally coupled with Trinder reaction to form colored quinonimine, causing an increase in absorbance. The degree of increase is proportional to the concentration of CREA in the sample. By monitoring the change of absorbance and comparing it with that of the calibrator treated in the same manner, the concentration of CREA in the sample can be calculated according to the working curve.

1. Creatinine + H_2O $\xrightarrow{\text{Creatininase}}$ Creatine
2. Creatine + H_2O $\xrightarrow{\text{Creatinase}}$ Sarcosine + Carbamide
3. Sarcosine + H_2O + O_2 $\xrightarrow{\text{Sarcosine Oxidase}}$ Glycine + HCHO + H_2O_2
4. $2H_2O_2$ + 4-AAP + TOOS $\xrightarrow{\text{Peroxidase}}$ Quinonimine + $4H_2O$

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Creatinase	≥10 kU/L
	Sarcosine Oxidase	≥7.5 kU/L
	Sodium 3-(N-Ethyl-3-Methylanilino)-2-Hydroxypro Panesulfonate（TOOS）	≥1 mmol/L
R2	Creatininase	≥100 kU/L
	4-Aminoantipyrine (4-AAP)	≥1 mmol/L
	Peroxidase	≥2 kU/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from freezing. The unopened reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum, plasma (heparin for anticoagulation) or urine is suitable for samples, which shall be separated as soon as possible after collection to avoid hemolysis.

Serum or plasma (heparin for anticoagulation) are stable for 7 days at 2 - 8 ℃ and for 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Urine are stable for 3 days at room temperature, for 6 days at 2 - 8 ℃ and for 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When the blank absorbance > 0.300, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

(1) Basic parameters (Blood)

Method	End-Point Method	Sample/Reagent	1/60
Main Wavelength	540 nm	Reaction Temperature	37 ℃
Sub Wavelength	700 nm	Reaction Time	10 min
Reaction Direction	+		

(2) Basic parameters (Urine)

Method	End-Point Method	Sample/Reagent	1/160
Main Wavelength	600 nm	Reaction Temperature	37 ℃
Sub Wavelength	700 nm	Reaction Time	10 min
Reaction Direction	+		

Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA
Tel: +86 (0)23 6865 5509 Fax: +86 (0)23 6869 9779 E-mail: info@zybio.com Web: www.zybio.com

CE IVD

zybio

2. Operation

(1) Operation (Blood)

Addition	Blank	Calibration	Detection
Sample (Blood) (μL)	/	/	5
Calibrator (μL)	/	5	/
Purified Water (μL)	5	/	/
Reagent 1 (μL)	225	225	225
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	75	75	75
Mix well, incubate at 37 ℃ for 5 min, then measure absorbance A_2, calculate $\Delta A = A_2 - A_1$.			

(2) Operation (Urine)

Addition	Blank	Calibration	Detection
Sample (Urine) (μL)	/	/	2
Calibrator (μL)	/	2	/
Purified Water (μL)	2	/	/
Reagent 1 (μL)	240	240	240
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	80	80	80
Mix well, incubate at 37 ℃ for 5 min, then measure absorbance A_2, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of creatinine (CREA) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

Serum: Male: 44~97 μmol/L; Female: 35~80 μmol/L;
Morning urine: Male: 3540~24600 μmol/L; Female: 2550~20000 μmol/L;
24-hour urine: Male: 9000~19000 μmol/L; Female: 6000~13000 μmol/L;

Explanation of Results

1. If the concentration of CREA in the blood sample exceeds 2000 μmol/L or the concentration of CREA in the urine sample exceeds 40000 μmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.
2. The system can be configured to initiate automatic repetition, and setting the automatic repetition conditions (when the test result exceeds 40000 μmol/L, it is recommended to use a triple dilution for automatic repeated detection) can extend the urine detection range to 120000 μmol/L. Automatic repetition results will be marked as automatic repetition.
3. The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is ≤ 10% if the concentrations of the following interferents are at or below the given values:

Sample	Substances	Concentrations
Blood	Bilirubin	342 μmol/L
	Hemoglobin	1 g/L
	Triglyceride	10 mmol/L
	Vc	500 mg/L
Urine	Bilirubin	342 μmol/L
	Hemoglobin	5 g/L
	Triglyceride	11 mmol/L
	Vc	4 g/L
	Glucose	150 mmol/L
	Urea	1600 mmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.300.
2. Analytical sensitivity:
Blood: at the test concentration of 100 μmol/L, the reagent absorbance change (ΔA) ≥ 0.010.
Urine: at the test concentration of 2000 μmol/L, the reagent absorbance change (ΔA) ≥ 0.040.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run CV ≤ 3%, between-run relative range ≤ 6%.
5. Linear Range:
Correlation coefficient:
Blood: [20, 2000] μmol/L, the correlation coefficient (r) ≥ 0.990.
Urine: [100, 40000] μmol/L, the correlation coefficient (r) ≥ 0.990.
Linearity deviation:
Blood: [20, 70) μmol/L, the absolute deviation ≤ 7 μmol/L;
[70, 2000] μmol/L, the relative deviation ≤ 10%.
Urine: [100, 3000) μmol/L, the absolute deviation ≤ 300 μmol/L;
[3000, 40000] μmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Huidobro E, Tagle R, Guzmán A. Estimation of glomerular filtration rate with creatinine[J]. Rev Med Chil, 2018, 146:344-350.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

Zybio Inc.
Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.
Web: www.zybio.com
E-mail: info@zybio.com
Tel: +86 (0)23 6865 5509
Fax: +86 (0)23 6869 9779

EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Current Version: 02 Date of Issue: May, 2022

CE IVD

Instructions for Use of Direct Bilirubin (DBIL) Kit (Vanadate Oxidation Method)

Package Specification

REF	Reagent	Systems
01.09.00.20.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.00.20.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of direct bilirubin concentration in human samples (serum or plasma). Clinically, it is mainly used as an evaluation indicator of bilirubin metabolism disorders.

Summary

Bilirubin is formed in the reticuloendothelial system during the degradation of aged erythrocytes. The heme portion from hemoglobin and from other heme-containing proteins is removed, metabolized to bilirubin, and transported as a complex with serum albumin to the liver. In the liver, bilirubin is conjugated with glucuronic acid for solubilization and subsequent transport through the bile duct and elimination via the digestive tract.

Diseases or conditions which, through hemolytic processes, produce bilirubin faster than the liver can metabolize it, cause the levels of unconjugated (indirect) bilirubin to increase in the circulation. Liver immaturity and several other diseases in which the bilirubin conjugation mechanism is impaired cause similar elevations of circulating unconjugated bilirubin. Bile duct obstruction or damage to hepatocellular structure causes increases in the levels of both conjugated (direct) and unconjugated (indirect) bilirubin in the circulation.

Principle

The direct bilirubin in the sample is oxidized to biliverdin, which causes a decrease in absorbance at 450 nm.

1. Bilirubin $\xrightarrow{\text{Vanadate}}$ Biliverdin

The concentration of direct bilirubin in the sample shall be calculated by measuring the absorbance change at 450 nm and comparing with that in calibrator treated in the same manner.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Citric Acid buffer	100 mmol/L
	Surfactant 1	>0.1% (v/v)
R2	Citric Acid buffer	4.9 mmol/L
	Sodium Metavanadate	>5 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.

2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.

3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma (heparin anticoagulation) is suitable for samples, which are stable for 3 days at 2 - 8 ℃. Samples should be protected from direct light.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.

2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.

3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.

4. When reagent becomes turbid or the blank absorbance > 0.300, the reagent is failed and should be discarded.

5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.

6. The same sample tested with reagents from different manufacturers may lead to different measured values.

7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/35
Main Wavelength	450 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	546 nm	**Reaction Time**	10 min
Reaction Direction	-		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	10
Calibrator (μL)	/	10	/
Purified Water (μL)	10	/	/
Reagent 1 (μL)	280	280	280
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	70	70	70
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is

Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA
Tel: +86 (0)23 6865 5509 Fax: +86 (0)23 6869 9779 E-mail: info@zybio.com Web: www.zybio.com

out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of direct bilirubin (DBIL) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

≤ 6.89 μmol/L (≤ 0.4mg/dL)

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of DBIL in the sample exceeds 300.00 μmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Hemoglobin	5 g/L
Chyle	0.30%

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.300.
2. Analytical sensitivity: at the test concentration of 15.00 μmol/L, the reagent absorbance change (ΔA) ≥ 0.008.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 10%.
5. Linear Range:

[2.00, 300.00] μmol/L, the correlation coefficient (r) ≥ 0.990.

[2.00, 20.00] μmol/L, the absolute deviation ≤ 2.00 μmol/L;

(20.00, 300.00] μmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Gu D, Wang Y, Ren B, et al. Comparison of Three Routine Methods for the Measurement of Serum Bilirubin in a China Laboratory[J]. Clin Lab, 2018, 64:1485-1490.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

Zybio Inc.
Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.
Web: www.zybio.com
E-mail: info@zybio.com
Tel: +86 (0)23 6865 5509
Fax: +86 (0)23 6869 9779

EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Current Version: 02 Date of Issue: May, 2022

CE IVD

Instructions for Use of Glucose (GLU) Kit (Hexokinase Method)

Package Specification

REF	Reagent	Systems
01.09.06.00.EC.02	R1 30 mL × 1 R2 7.5 mL × 1	Zybio EXC200/220
01.09.06.00.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
1080203	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of glucose in human samples (serum or plasma). Clinically, the measurements are used as an aid to diagnosis of diabetes mellitus.

Summary

Glucose(GLU) is a kind of hexose containing aldehyde group, whose molecular formula is $C_6H_{12}O_6$, and it is the most important monosaccharide in organisms. Its main function is to provide energy needed for physiological activities.

Glucose and energy homeostasis are maintained through multiple interacting complex feed-back systems that involves neuronal, hormonal, and metabolic components.

Glucose is of central metabolic importance in virtually all organisms, from microbes to humans. Glycolytic metabolism of glucose is a major pathway for the generation of energy (ATP). The phosphorylation of glucose is the first step in glycolysis. A family of hexose phosphorylating enzymes, the hexokinases, carry out this important process. Glucose, glucose 6-phosphate (G-6-P), and α-glucose 1-phosphate (α-G1P) are three essential molecules. When glucose enters a cell, it is first converted to G-6-P upon phosphorylation at C6 by hexokinase (HK).

Principle

The kit uses hexokinase method to determine glucose in serum or plasma.

1. GLU + ATP $\xrightarrow{\text{Hexokinase}}$ G-6-P + ADP

2. G-6-P + NAD^+ $\xrightarrow{\text{G6PDH}}$ 6-Phosphogluconic Acid + NADH + H^+

The glucose content in the sample could be calculated by comparing the variation value of NADH absorbance measured at 340 nm with calibrator treated by the same way.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Adenosine triphosphate (ATP)	8-10 mmol/L
R2	Nicotinamide adenine dinucleotide (NAD^+)	5-8 mmol/L
	Hexokinase	5-10 kU/L
	Glucose-6-phosphate dehydrogenase (G6PDH)	8-15 kU/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 18 months.

2. Once opened, the reagents are stable for 35 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.

3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum and plasma (Na-heparin or K_2-EDTA) are the recommended specimen types. The serum and plasma (Na-heparin) samples are stable for 24 hours at 2 - 8 °C, for 30 days at - 20 °C, and for 3 freezing-thawing cycles.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.

2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.

3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.

4. When reagent becomes turbid or the blank absorbance > 0.600, the reagent is failed and should be discarded.

5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.

6. The same sample tested with reagents from different manufacturers may lead to different measured values.

7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/100
Main Wavelength	340 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	405 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent 1 (μL)	240	240	240
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	60	60	60
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA
Tel: +86 (0)23 6865 5509 Fax: +86 (0)23 6869 9779 E-mail: info@zybio.com Web: www.zybio.com

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of glucose (GLU) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

3.9~6.1 mmol/L

This reference interval is determined based on 95% distribution interval obtained from 132 healthy human specimens without related diseases and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of GLU in the sample exceeds 40.0 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is within ± 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Hemoglobin	5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests, and treatment response. To achieve diagnostic purposes, the test results should be combined with clinical tests, medical history, and other test results.

Performance Characteristics

1. The product has a limit of blank (LoB) of 0.06 mmol/L.
2. The product has a limit of detection (LoD) of 0.13 mmol/L.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: ≤ 5%CV for specimen from 2.0 - 7.0 mmol/L, and ≤ 4%CV for specimen > 7.0 mmol/L.
5. Linear Range:

[2.0, 40.0] mmol/L, the correlation coefficient (r) ≥ 0.990.

[2.0, 4.0) mmol/L, the absolute deviation ≤ 0.4 mmol/L;

[4.0, 40.0] mmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Marco V, Zhao F. Viriyapong R, et al. The impact of ageing, fasting and high-fat diet on central and peripheral glucose tolerance and glucose-sensing neural networks in the arcuate nucleus [J]. J Neuroendocrinol, 2017, 29:10.1111/jne.12528.

[2] Wilson J. Isozymes of mammalian hexokinase: structure, subcellular localization and metabolic function[J]. J Exp Biol, 2003, 206:2049-2057.

[3] Middleton R. Hexokinases and glucokinases[J]. Biochem Soc Trans, 1990, 18: 180-183.

[4] Tang Y, Cheng F, Feng Z, et al. Stereostructural Elucidation of Glucose Phosphorylation by Raman Optical Activity[J]. J Phys Chem B, 2019, 123:7794-7800.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

Zybio Inc.
Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.
Web: www.zybio.com
E-mail: info@zybio.com
Tel: +86 (0)23 6865 5509
Fax: +86 (0)23 6869 9779

EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Current Version: 02 Date of Issue: May, 2022

CE IVD

zybio

Instructions for Use of Low Density Lipoprotein Cholesterol (LDL-C) Kit (Enzymatic Method)

Package Specification

REF	Reagent	Systems
01.09.02.00.EC.01	R1 30 mL × 3 R2 10 mL ×3 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Zybio EXC200/220
01.09.02.00.EC.02	R1 45 mL × 2 R2 15 mL × 2 Calibrator 1 Level × 1.0 mL × 1 Control 2 Levels × 1.0 mL × 1	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of low density lipoprotein cholesterol (LDL-C) concentration in human samples (serum). Clinically, it is mainly used as an aid to diagnosis of hypercholesterolemia, coronary heart disease, and atherosclerosis.

Summary

Low Density Lipoprotein (LDL) play a key role in causing and influencing the progression of atherosclerosis and, in particular, coronary sclerosis. The LDLs are derived from VLDLs (Very Low Density Lipoproteins) rich in triglycerides by the action of various lipolytic enzymes and are synthesized in the liver. The elimination of LDL from plasma takes place mainly by liver parenchymal cells via specific LDL receptors. Elevated LDL concentrations in blood and an increase in their residence time coupled with an increase in the biological modification rate results in the destruction of the endothelial function and a higher LDL-cholesterol uptake in the monocyte/macrophage system as well as by smooth muscle cells in vessel walls. The majority of cholesterol stored in atherosclerotic plaques originates from LDL. The LDL-cholesterol value is the most powerful clinical predictor among all of the single parameters with respect to coronary atherosclerosis.

Therefore, therapies focusing on lipid reduction primarily target the reduction of LDL-cholesterol which is then expressed in an improvement of the endothelial function, prevention of atherosclerosis and reducing its progression as well as preventing plaque rupture.

Principle

1. The surface-active ingredients in R1 inhibit low density lipoprotein in serum, while high-density lipoprotein and very low-density lipoprotein are consumed by the reaction catalyzed by cholesterol enzyme.

$$\text{Cholesteryl Ester} + H_2O \xrightarrow{\text{Cholesterol Esterase}} \text{Cholesterol} + \text{Fatty acid}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{Cholesterol Oxidase}} \text{Cholestenone} + H_2O_2$$

$$2H_2O_2 \xrightarrow{\text{Peroxidase}} 2H_2O + O_2$$

2. LDL-C is only measured after the surfactant in R2 has released low-density lipoprotein.

$$\text{Cholesteryl Ester} + H_2O \xrightarrow{\text{Cholesterol Esterase}} \text{Cholesterol} + \text{Fatty acid}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{Cholesterol Oxidase}} \text{Cholestenone} + H_2O_2$$

$$2H_2O_2 + \text{4-AAP} + \text{TOOS} \xrightarrow{\text{Peroxidase}} \text{Quinonimine} + 4H_2O$$

3. The absorbance of quinonimine is directly proportional to the content of cholesterol. The content of low-density lipoprotein cholesterol (LDL-C) in the sample can be calculated by measuring the absorbance change value at 546 nm.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Ascorbate Oxidase	> 3000 U/L
	Cholesterol Oxidase	> 400 U/L
	Cholesterol Esterase	> 500 U/L
	Sodium 3-(N-ethyl-3-methylanilino)-2-hydroxypropanesulfonate（TOOS）	0.8 mmol/L
	1,4-Piperazinebis (ethanesulfonic acid) buffer (PIPES)	100 mmol/L
R2	4-Aminoantipyrine (4-AAP)	4 mmol/L
	1,4-Piperazinebis (ethanesulfonic acid) buffer (PIPES)	100 mmol/L
	Peroxidase	> 1500 U/L
	Surfactant	Appropriate amount
Calibrator	Sucrose	10 g/L
	Bovine Serum	Refer to the label for marked value of LDL-C concentration
Control	Sucrose	10 g/L
	Bovine Serum	Refer to the label for marked value of LDL-C concentration

The measurement system can be traceable to JCCRM 224-16.

The components in different batches are non-interchangeable.

The target value of control has batch specificity.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 18 months. Summer transportation with attention to refrigeration.
2. Once opened, the reagents are stable for 1 month at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.
3. To ensure accuracy, calibrator and control are stored at 2 - 8 ℃ after reconstitution and used only on the same day.
4. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum is suitable for samples, which shall be separated in time after collection to avoid hemolysis. Samples are stable for 6 days at 2 - 8 ℃ and 3 weeks at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or the blank absorbance > 0.05, the reagent is failed and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. Dedicated calibrator is recommended for use to ensure the accuracy of test values.
7. The same sample tested with reagents from different manufacturers may lead to different measured values.
8. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA
Tel: +86 (0)23 6865 5509 Fax: +86 (0)23 6869 9779 E-mail: info@zybio.com Web: www.zybio.com

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	3/320
Main Wavelength	546 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	**Blank**	**Calibration**	**Detection**
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent 1 (μL)	240	240	240
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	80	80	80
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio matched calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

Calibrator reconstitution: Reconstitution with the amount of purified water labeled on the bottle accurately absorbed, leave for 30 minutes, and mix well before use.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

Control reconstitution: Reconstitution with the amount of purified water labeled on the bottle accurately absorbed, leave for 30 minutes, and mix well before use.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of low density lipoprotein cholesterol (LDL-C) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

≤3.36 mmol/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of LDL-C in the sample exceeds 11.60 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is ≤ 10% if the concentrations of the following interferents are at or below the given values:

Substances	**Concentrations**
Vc	0.5 g/L
Hemoglobin	5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L
Intralipid	1000 mg/dL

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.05.
2. Analytical sensitivity: at the test concentration of 1.00 mmol/L, the reagent absorbance change (ΔA) ≥ 0.03.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run CV ≤ 3%, between-run relative range ≤ 10%.
5. Linear Range:

[0.20, 11.60] mmol/L, the correlation coefficient (r) ≥ 0.995.

[0.20, 3.00) mmol/L, the absolute deviation ≤ 0.30 mmol/L;

[3.00, 11.60] mmol/L, the relative deviation ≤ 10%.

6. Calibrator accuracy: relative deviation ≤ 10%.
7. Calibrator homogeneity: between-vial CV ≤ 10%.
8. Control accuracy: test value is within the allowable range of the marked value.
9. Control homogeneity: between-vial CV ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, General lab equipment and consumable.

References

[1] Davidson M. Low-density lipoprotein cholesterol, non-high-density lipoprotein, apolipoprotein, or low-density lipoprotein particle: what should clinicians measure?[J]. J Am Coll Cardiol, 2012, 60:2616-2617.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

Zybio Inc.
Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.
Web: www.zybio.com
E-mail: info@zybio.com
Tel: +86 (0)23 6865 5509
Fax: +86 (0)23 6869 9779

EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Current Version: 02 Date of Issue: May, 2022

CE IVD

zybio

Instructions for Use of Total Bilirubin (TBIL) Kit (Vanadate Oxidation Method)

Package Specification

REF	Reagent	Systems
01.09.00.21.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.00.21.EC.03	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of total bilirubin concentration in human samples (serum or plasma). Clinically, it is mainly used as one of the evaluation indicators for bilirubin metabolism diseases.

Summary

Measurement of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, is used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder blockage.

Bilirubin is formed in the reticuloendothelial system during the degradation of aged erythrocytes. The heme portion from hemoglobin and from other heme-containing proteins is removed, metabolized to bilirubin, and transported as a complex with serum albumin to the liver. In the liver, bilirubin is conjugated with glucuronic acid for solubilization and subsequent transport through the bile duct and elimination via the digestive tract.

Diseases or conditions which, through hemolytic processes, produce bilirubin faster than the liver can metabolize it, cause the levels of unconjugated (indirect) bilirubin to increase in the circulation. Liver immaturity and several other diseases in which the bilirubin conjugation mechanism is impaired cause similar elevations of circulating unconjugated bilirubin. Bile duct obstruction or damage to hepatocellular structure causes increases in the levels of both conjugated (direct) and unconjugated (indirect) bilirubin in the circulation.

Principle

The total bilirubin in the sample is oxidized to biliverdin, which causes a decrease in absorbance at 450 nm.

1. Bilirubin $\xrightarrow{\text{Vanadate}}$ Biliverdin

The concentration of total bilirubin in the sample shall be calculated by measuring the absorbance change at 450 nm and comparing with that in calibrator treated in the same manner.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Citric Acid buffer	100 mmol/L
	Surfactant 1	0.2% (v/v)
R2	Citrate Buffer	18.36 mmol/L
	Sodium Metavanadate	6.56 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.

2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.

3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma (heparin anticoagulation) is suitable for samples, which are stable for 3 days at 2 - 8 ℃. Samples should be protected from direct light.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.

2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.

3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.

4. When reagent becomes turbid or the blank absorbance > 0.050, the reagent is failed and should be discarded.

5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.

6. The same sample tested with reagents from different manufacturers may lead to different measured values.

7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample/Reagent**	1/35
Main Wavelength	450 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	546 nm	**Reaction Time**	10 min
Reaction Direction	-		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	10
Calibrator (μL)	/	10	/
Purified Water (μL)	10	/	/
Reagent 1 (μL)	280	280	280
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	70	70	70
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA
Tel: +86 (0)23 6865 5509 Fax: +86 (0)23 6869 9779 E-mail: info@zybio.com Web: www.zybio.com

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of total bilirubin (TBIL) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

3.4~20.5 μmol/L (0.2~1.2mg/dL)

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of TBIL in the sample exceeds 500 μmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Hemoglobin	5 g/L
Chyle	0.30%

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.050.

2. Analytical sensitivity: at the test concentration of 30 μmol/L, the reagent absorbance change (ΔA) > 0.003.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run *CV* ≤ 4%, between-run relative range ≤ 10%.

5. Linear Range:

[3, 500] μmol/L, the correlation coefficient (r) ≥ 0.990.

[3, 20] μmol/L, the absolute deviation ≤ 2 μmol/L;

(20, 500] μmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Doumas B, Cheung P, Perry B. Candidate reference method for determination of total bilirubin in serum: development and validation[J]. Clin Chem, 1985, 31:1779-1789.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

Zybio Inc.
Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.
Web: www.zybio.com
E-mail: info@zybio.com
Tel: +86 (0)23 6865 5509
Fax: +86 (0)23 6869 9779

EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Current Version: 02 Date of Issue: May, 2022

Instructions for Use of Triglyceride (TG) Kit (Single) (Enzymatic Method)

Package Specification

REF	Reagent
01.09.02.01. EC. 01	R 30 mL × 6
01.09.02.01. EC. 02	R 60 mL × 2

Intended Use

In vitro test for the quantitative determination of triglyceride in human samples (serum). Clinically, it is mainly used as an aid to diagnosis of hypertriglyceridemia.

Summary

Triglycerides are esters of the trihydric alcohol glycerol with 3 long-chain fatty acids. They are partly synthesized in the liver and partly ingested in food. The determination of triglycerides is utilized in the diagnosis and treatment of patients having diabetes mellitus, nephrosis, liver obstruction, lipid metabolism disorders and numerous other endocrine diseases. The enzymatic triglycerides assay as described by Eggstein and Kreutz still required saponification with potassium hydroxide. Numerous attempts were subsequently made to replace alkaline saponification by enzymatic hydrolysis with lipase. Bucolo and David tested a lipase/protease mixture; Wahlefeld used an esterase from the liver in combination with a particularly effective lipase from Rhizopus arrhizus for hydrolysis. This method is based on the work by Wahlefeld using a lipoprotein lipase from microorganisms for the rapid and complete hydrolysis of triglycerides to glycerol followed by oxidation to dihydroxyacetone phosphate and hydrogen peroxide. The hydrogen peroxide produced then reacts with 4-aminophenazone and 4-chlorophenol under the catalytic action of peroxidase to form a red dyestuff (Trinder endpoint reaction). The color intensity of the red dyestuff formed is directly proportional to the triglyceride concentration and can be measured photometrically.

Principle

$$TG + H_2O \xrightarrow{\text{Lipase}} \text{Glycerol} + \text{Fatty Acid}$$

$$\text{Glycerol} + ATP \xrightarrow{\text{Glycerol Kinase}} \text{Glycerin-3- Phosphoric Acid} + ADP$$

$$\text{Glycerin-3-Phosphoric Acid} + O_2 \xrightarrow{\text{GPO}} \text{Dihydroxyacetone Phosphate} + H_2O_2$$

$$H_2O_2 + \text{4-AAP} + \text{Phenol} \xrightarrow{\text{Peroxidase}} \text{Quinonimine} + H_2O$$

The TG content in the sample could be calculated by comparing the absorbance change measured at 505 nm with calibrator treated in the same way.

Reagents Components and Concentration

Composition: R

R	Lipoprotein Lipase	2.5 KU/L
	Peroxidase	1.2 KU/L
	GPO	7.5 KU/L
	Glycerol Kinase	5.0 KU/L
	ATP	50 mmol/L
	4-AAP	0.5 mmol/L
	Phenol	2 mmol/L
	MOPS Buffer	80 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The reagents are valid for 12 months.
2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃ For reagents not in use, the cap should be tightened to avoid contamination.
3. The reagents could be stable for 2 weeks at 2 - 8 ℃ in transportation.
4. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400, Zybio EXC200/220 Chemistry Analyzer. Other models shall be used after verification.

Specimen Information

1. Non-hemolyzed serum is suitable for samples.
2. The serum is stable for 3 days at 2 - 8 ℃ and for 30 days at -20 ℃.
3. Repeated freezing and thawing should be avoided.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.
2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.
3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.
4. When reagent becomes turbid or blank absorbance > 0.200, the reagent is invalid and should be discarded.
5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.
6. The same sample tested with reagents from different manufacturers may lead to different measured values.
7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	**Sample / Reagent**	1/100
Main Wavelength	505 nm	**Reaction Temperature**	37 ℃
Sub Wavelength	700 nm	**Reaction Time**	10 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent (μL)	300	300	300
Mix well, incubate at 37 ℃ for 10 min, and measure absorbance *A*			

3. Calibration

Use Zybio clinical chemistry multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

Indoor quality control is recommended. Values obtained should fall within the

Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.
Tel: +86 (0)23 6865 5509 Fax: +86 (0)23 6869 9779 E-mail: info@zybio.com Web: www.zybio.com

limited range. If there is a failure of any of controls, the laboratory should take appropriate corrective measures.

5. Calculation

TG (mmol/L) = (*A* Sample / *A* Calibrator) × C Calibrator

Reference Intervals

≤ 2.30 mmol/L

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration exceeds 10.00 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional shall be responsible for the review of the test result, which may be affected by the subject's age, gender, or weight. The measured values within the critical range should be re-determined and confirmed, if it is obviously beyond the reference range or if it is still beyond the reference range after confirmation, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations-Interference

The deviation of test results caused by interferents is within ± 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
VC	500 mg/L
Hemoglobin	5 g/L
Bilirubin	342 μmol/L

Performance Characteristics

1. The reagent blank absorbance: ≤ 0.200.
2. Analytical sensitivity: at the test concentration of 1.0 mmol/L, the reagent absorbance change $\Delta A > 0.03$.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 8%.
5. Linear Range:

[0.50, 10.00] mmol/L, the correlation coefficient (*r*) ≥ 0.990.

[0.50, 2.00) mmol/L, the absolute deviation ≤ 0.20 mmol/L;

[2.00, 10.00] mmol/L, the relative deviation ≤ 10%.

References

[1] Peter T. Triglyceride-rich lipoproteins as a causal factor for cardiovascular disease[J]. Vascular Health & Risk Management, 2016, 12:171-183.

[2] Shen Mengyuan, Niu Xiaohan, Wang Lixin. Application of blood lipid monitoring in diagnosis of cardiovascular and cerebrovascular diseases. China Journal of Laboratory Medicine, 2018, 41 (11): 893.

[3] Giovanni B, Harold D. Quantitative Determination of Serum Triglycerides by the Use of Enzymes[J]. Clinical Chemistry, 1973(5):476-482.

[4] Trinder, P. Determination of Glucose in Blood Using Glucose Oxidase with an Alternative Oxygen Acceptor[J]. Ann.clin.biochem, 1969, 6(1):24-27.

Label Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture

Manufacturer Information

Zybio Inc.

Floor 1 to Floor 5, Building 30, No.6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.

Web: www.zybio.com

E-mail: info@zybio.com

Tel: +86 (0)23 6865 5509

Fax: +86 (0)23 6869 9779

CE IVD

zybio

Instructions for Use of Uric Acid (UA) Kit (Uricase Method)

Package Specification

REF	Reagent	Systems
01.09.01.07.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.01.07.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of uric acid concentration in human samples (serum or plasma). Clinically, it is mainly used as an aid to diagnosis of hyperuricemia.

Summary

Uric acid is the final product of purine metabolism in the human organism. Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

The oxidation of uric acid provides the basis for two approaches to the quantitative determination of this purine metabolite. One approach is the reduction of phosphotungstic acid in an alkaline solution to tungsten blue, which is measured photometrically. The method is, however, subject to interferences from drugs and reducing substances other than uric acid.

A second approach, described by Praetorius and Poulson, utilizes the enzyme uricase to oxidize uric acid; this method eliminates the interferences intrinsic to chemical oxidation. Uricase can be employed in methods that involve the UV measurement of the consumption of uric acid or in combination with other enzymes to provide a colorimetric assay.

Another method is the colorimetric method developed by Town et al. The sample is initially incubated with a reagent mixture containing ascorbate oxidase and a clearing system. In this test system it is important that any ascorbic acid present in the sample is eliminated in the preliminary reaction; this precludes any ascorbic acid interference with the subsequent POD indicator reaction. Upon addition of the starter reagent, oxidation of uric acid by uricase begins.

Principle

1. Uric acid + O_2 + H_2O $\xrightarrow{\text{Uricase}}$ Allantoin + CO_2 + H_2O_2

2. H_2O_2 + 4-AAP + TOOS $\xrightarrow{\text{Peroxidase}}$ Quinoneimine + H_2O

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Sodium 3-(N-ethyl-3-methylanilino)-2-hydroxypropanesulfonate (TOOS)	1.11 mmol/L
	Ascorbate Oxidase	10 kU/L
R2	Trometamol (Tris) buffer	200 mmol/L
	Uricase	1.5 kU/L
	Peroxidase	5 kU/L
	4-Aminoantipyrine (4-AAP)	4 mmol/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.

2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.

3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma (heparin or EDTA anticoagulation) is suitable for samples, which are stable for 3 days at 2 - 8 ℃ and for 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.

2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.

3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.

4. When reagent becomes turbid or the blank absorbance > 0.200, the reagent is failed and should be discarded.

5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.

6. The same sample tested with reagents from different manufacturers may lead to different measured values.

7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	End-Point Method	Sample/Reagent	1/50
Main Wavelength	546 nm	Reaction Temperature	37 ℃
Sub Wavelength	700 nm	Reaction Time	10 min
Reaction Direction	+		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	5
Calibrator (μL)	/	5	/
Purified Water (μL)	5	/	/
Reagent 1 (μL)	200	200	200
Mix well, incubate at 37 ℃ for 5 min, and measure absorbance A_1			
Reagent 2 (μL)	50	50	50
Mix well, measure absorbance A_2 after 5 min, calculate $\Delta A = A_2 - A_1$.			

Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA
Tel: +86 (0)23 6865 5509 Fax: +86 (0)23 6869 9779 E-mail: info@zybio.com Web: www.zybio.com

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of uric acid (UA) in the sample can be calculated on the working curve based on its absorbance change value.

Reference Intervals

Male: 202~416 μmol/L

Female: 140~380 μmol/L

This reference interval is determined based on 95% distribution interval obtained from 210 healthy males and 210 healthy females specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of UA in the sample exceeds 1190 μmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Hemoglobin	5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≤ 0.200.

2. Analytical sensitivity: at the test concentration of 360 μmol/L, the reagent absorbance change (ΔA) ≥ 0.03.

3. Accuracy: relative deviation ≤ 10%.

4. Precision: within-run *CV* ≤ 4%, between-run relative range ≤ 6%.

5. Linear Range:

[100, 1190] μmol/L, the correlation coefficient (*r*) ≥ 0.990.

[100, 300] μmol/L, the absolute deviation ≤ 30 μmol/L;

(300, 1190] μmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Young D. Effects of drugs on clinical laboratory tests[J]. Ann Clin Biochem, 1997, 34:579-581.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

Zybio Inc.
Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.
Web: www.zybio.com
E-mail: info@zybio.com
Tel: +86 (0)23 6865 5509
Fax: +86 (0)23 6869 9779

EC REP Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Current Version: 02 Date of Issue: May, 2022

CE IVD

Instructions for Use of Urea (UREA) Kit (Urease-GLDH Method)

Package Specification

REF	Reagent	Systems
01.09.01.06.EC.01	R1 30 mL × 3 R2 7.5 mL × 3	Zybio EXC200/220
01.09.01.06.EC.02	R1 48 mL × 2 R2 12 mL × 2	Hitachi 7180 Zybio EXC400/420

Intended Use

In vitro test for the quantitative determination of urea concentration in human samples (serum or plasma). Clinically, it is mainly used as one of the evaluation indicators of renal function.

Summary

Urea is the major end product of protein nitrogen metabolism. It is synthesized by the urea cycle in the liver from ammonia which is produced by amino acid deamination. Urea is excreted mostly by the kidneys but minimal amounts are also excreted in sweat and degraded in the intestines by bacterial action. Determination of blood urea nitrogen is the most widely used screening test for renal function. When used in conjunction with serum creatinine determinations it can aid in the differential diagnosis of the three types of azotemia: prerenal, renal and postrenal. Elevations in blood urea nitrogen concentration are seen in inadequate renal perfusion, shock, diminished blood volume (prerenal causes), chronic nephritis, nephrosclerosis, tubular necrosis, glomerular nephritis (renal causes) and urinary tract obstruction (postrenal causes). Transient elevations may also be seen during periods of high protein intake. Unpredictable levels occur with liver diseases.

Principle

1. $Urea + H_2O \xrightarrow{Urease} 2NH_3 + CO_2$

2. $NH_3 + \alpha\text{-Ketoglutaric Acid} + NADH + H^+ \xrightarrow{GLDH} Glutamic\ Acid + NAD^+ + H_2O$

Oxidation of NADH to NAD^+ causes a decrease in absorbance at 340 nm, which is directly proportional to the Urea concentration in the sample.

Reagents Components and Concentration

Components	Main Constituents	Concentration
R1	Trometamol (Tris) buffer	100 mmol/L
	Nicotinamide adenine dinucleotide (NADH)	0.3 mmol/L
R2	α-Ketoglutaric Acid	10 mmol/L
	Urease	6.0 kU/L
	Glutamate dehydrogenase (GLDH)	2.0 kU/L

The components in different batches are non-interchangeable.

Storage and Validity

1. The reagents should be stored at 2 - 8 ℃ and kept away from direct light and freezing. The unopened reagents are valid for 12 months.

2. Once opened, the reagents are stable for 30 days at 2 - 8 ℃. For reagents not in use, the cap should be tightened to avoid contamination.

3. The production date and expiration date are available on package insert.

System Information

Hitachi 7180, Zybio EXC400/420, Zybio EXC200/220 Chemistry Analyzer. Other models can be used after verification.

Specimen Information

Serum or plasma (heparin or EDTA anticoagulation) is suitable for samples, which are stable for 3 days at 2 - 8 ℃ and for 30 days at - 20 ℃. Avoid repeated freezing and thawing.

Warnings and Precautions

1. For in vitro diagnostic use only. In case of contact, immediately flush the affected area with plenty of water.

2. The dosage of reagents and samples can be appropriately increased or decreased according to various instruments, under the condition that the volume proportion of reagents and samples is invariable.

3. The necessary precautions should be taken to use the reagents. The bottle cap should be tightened immediately after use to avoid contamination.

4. When reagent becomes turbid or the blank absorbance < 1.000, the reagent is failed and should be discarded.

5. All samples and reaction wastes should be treated as sources of infection. The waste liquid generated during the experiment and the used packaging materials shall be collected and disposed in accordance with relevant regulations.

6. The same sample tested with reagents from different manufacturers may lead to different measured values.

7. Warning: This product contains ingredients of human or animal origin. At present, there is no way to completely guarantee that it is free from infectious substances and may be contaminated during use. This product and samples shall be considered as potential sources of infection, and operators should take protective measures and comply with laboratory safety regulations. All waste shall be disposed of in accordance with local regulations.

Test Process

1. Parameters

Method	Rate Method	Sample/Reagent	1/100
Main Wavelength	340 nm	Reaction Temperature	37 ℃
Sub Wavelength	405 nm	Reaction Time	10 min
Reaction Direction	-		

2. Operation

Addition	Blank	Calibration	Detection
Sample (μL)	/	/	3
Calibrator (μL)	/	3	/
Purified Water (μL)	3	/	/
Reagent 1 (μL)	240	240	240
Mix well, incubate at 37 ℃ for 5 min			
Reagent 2 (μL)	60	60	60
Mix well, after 1 min, measure the absorbance change within 2 min, and calculate the absorbance change rate ΔA/ min.			

3. Calibration

Use Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator. Calibration cycle: Re-calibration is needed in case of replacement of the reagent batch, deviation of quality control, or the major repair and maintenance of equipment.

Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA
Tel: +86 (0)23 6865 5509 Fax: +86 (0)23 6869 9779 E-mail: info@zybio.com Web: www.zybio.com

4. Quality Control

To ensure the reliability of the test results, quality control is required after each calibration, and the quality control value should be within the specified range. If it is out of the specified range, the user should check the measurement system and recalibrate it if necessary. It is recommended that users conduct regular quality control according to their own needs to ensure the accuracy of the measurement system and the reliability of the test results.

5. Calculation

Linear calibration was used to draw the working curve. The concentration of urea (UREA) in the sample can be calculated on the working curve based on its absorbance change rate.

Reference Intervals

1.7~8.3 mmol/L (10~50 mg/dL)

This reference interval is determined based on 95% distribution interval obtained from 200 healthy human specimens without related diseases, and is for reference only. It is recommended that each laboratory establish its own reference range.

Explanation of Results

If the concentration of UREA in the sample exceeds 40.0 mmol/L, the reduction mode of the chemistry analyzer will be used, or the high concentration sample shall be diluted with normal saline, with its report result multiplied by the dilution factor.

The professional is responsible for the review of the test result, which may be affected by the subject's age, sex, or weight. The test values within the critical range should be confirmed by remeasuring, if it is obviously beyond the reference value range or if it is still beyond the reference range after confirmation detection, the target concentration in the sample is considered to be abnormal. If the test result is inconsistent with or even contrary to the clinical situation, cause analysis should be performed correspondingly.

Limitations

1. The deviation of test results caused by interferents is less than 10% if the concentrations of the following interferents are at or below the given values:

Substances	Concentrations
Vc	0.5 g/L
Hemoglobin	5 g/L
Chyle	0.30%
Bilirubin	342 μmol/L

2. The test results of this product are only for clinical reference and cannot be used as the basis for diagnosis or exclusion of cases. The clinical diagnosis and treatment of patients should be combined with their symptoms/signs, medical history, other laboratory tests and treatment response. For achieve diagnostic purposes, the test results should be combined with clinical tests, medical history and other test results.

Performance Characteristics

1. The reagent blank absorbance ≥ 1.000; the reagent blank absorbance change rate (ΔA/min) ≤ 0.04.
2. Analytical sensitivity: at the test concentration of 7.5 mmol/L, the reagent absorbance change rate (ΔA/min) ≥ 0.008.
3. Accuracy: relative deviation ≤ 10%.
4. Precision: within-run *CV* ≤ 5%, between-run relative range ≤ 6%.
5. Linear Range:

[0.5, 40.0] mmol/L, the correlation coefficient (*r*) ≥ 0.990.

[0.5, 5.0] mmol/L, the absolute deviation ≤ 0.5 mmol/L;

(5.0, 40.0] mmol/L, the relative deviation ≤ 10%.

Materials Required (but not provided)

Chemistry analyzer, Zybio Clinical Chemistry Multi-analyte Calibrator or Randox multi-analyte calibrator, Control, General lab equipment and consumable.

References

[1] Ai H, Chen K. Diagnostic Value of Blood Urea Nitrogen and Serum Creatinine in the Diagnosis of Early Diabetic Nephropathy[J]. Journal of Practical Medical Techniques, 2008, 15:431-433.

Symbol Interpretation

IVD	In Vitro Diagnostic Medical Device	LOT	Batch Code
	Consult Instructions for Use		Use-By Date
REF	Catalogue Number		Manufacturer
	Temperature Limit		Date of Manufacture
CE	CE marking of conformity	EC REP	Authorized Representative in the European Community

Zybio Inc.

Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA.

Web: www.zybio.com

E-mail: info@zybio.com

Tel: +86 (0)23 6865 5509

Fax: +86 (0)23 6869 9779

EC REP

Lotus NL B.V.

Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Current Version: 02 Date of Issue: May, 2022