Capture-R® Ready-Screen® (3)

Solid Phase System for the Detection of Unexpected IgG Antibodies to Red Cells

Rx ONLY

387-5

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IMMUCOR®

Intended Use:

Capture-R® Ready-Screen® (3) is intended for use in the detection of unexpected IgG antibodies to red blood cells by manual, semi-automated or automated solid phase red blood cell adherence methods.

Summary of the Test:

Unexpected antibodies are found in the sera of 0.3 to 3% of donor and patient populations.[1-3] Many antibodies are of clinical importance since they may cause decreased red blood cell survival as the result of hemolytic transfusion reactions, hemolytic disease of the newborn or autoimmune hemolytic anemia. In vitro antibody detection (screening) tests are employed to reveal the presence of these antibodies in patient and donor sera. Selected red blood cells, such as those provided as Capture-R Ready-Screen, are incubated with test sera or plasma under conditions that will facilitate antibody detection.[4]

Capture-R Ready-Screen is manufactured as a three-cell screening set of Group O red blood cells suitable for use in automated and semi-automated solid phase antibody detection methods. The antigens for which these donors have been typed are displayed on the Capture-R Ready-Screen Master List accompanying each lot. Capture-R Ready-Screen (3) is manufactured specifically for laboratories concerned with the optimal detection of antibodies exhibiting dosage.

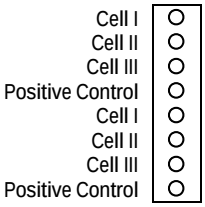
Principle of the Test:

Capture-R Ready-Screen is a modified solid phase antibody detection system based on the procedures of Plapp et al [5], and Juji et al [6]. Membranes of red blood cells have been bound to and dried on the surfaces of polystyrene microwells. The membrane antigens are used to capture red cell-specific antibodies from patient or donor sera or plasmas. Following a brief incubation period, unbound residual immunoglobulins are rinsed from the wells and replaced with a suspension of anti-IgG-coated indicator red blood cells. Centrifugation brings the indicator red cells in contact with antibodies bound to the reagent red blood cell membranes. In the case of a positive test, the migration of the indicator red blood cells to the bottom of the wells is impeded as anti-IgG-IgG complexes are formed on the surface of the immobilized reagent layer. As a consequence of antibody bridging, the indicator cells adhere to the screening cells as a second immobilized layer. In the absence of detectable antigen-antibody interactions (negative test), the indicator red blood cells will not be impeded during their migration and will pellet to the bottom of the wells as tightly agglutinated red blood cell buttons.

Reagents:

1. Capture-R Ready-Screen (3) consisting of 1 x 8 strips of wells carrying the bound and dried red blood cell membranes of three different group O donors, respectively (and a fourth positive control well coated with IgG sensitized red blood cell membranes). The arrangement of reagent red blood cells is illustrated in Figure 1.

Figure 1. Capture-R Ready-Screen (3) strip



Twelve 1 x 8 strips are packaged with a support frame and enclosed in a foil pouch to which a desiccant and moisture indicator have been added. Each strip is ready to be used as supplied. Strips can be used singly or in multiples. Store the strips at 1-30 C (under refrigeration or at room temperature) when not in use. If the humidity indicator enclosed within a pouch shows presence of moisture (by the humidity indicator turning from blue to pink), the strips should not be used. Unused strips, desiccant and humidity indicator should be immediately and carefully resealed within the foil pouch to prevent exposure to moisture that can destroy the red blood cell membranes. Strips within resealed pouches should not be used if the humidity indicator shows the presence of moisture. Strips removed from pouches should be used within eight hours.

2. Master List: provided with each lot of Capture-R Ready-Screen (3) indicates the code and antigenic composition of each donor whose red blood cells are used to prepare the dried reagent monolayers.

Adjunct Reagents to Capture Test Wells:

(purchased separately)
1. Capture LISS
2. Capture-R Ready Indicator Red Cells
3. Capture-R Positive Control Serum (Weak)
4. Capture-R Negative Control Serum
5. WB corQC

Key:
Underline = Addition or significant change; ▲ = Deletion of text

NOTE: The in-date components (Capture-R Ready-Screen wells, Capture-R Ready Indicator Red Cells, Capture-R control sera, WB corQC and Capture LISS) used to perform Capture-R Ready-Screen assays can be used interchangeably with other component lots, provided the components are within their dating periods. NOTE: Master Lists are lot specific.

Precautions:

1. For in vitro diagnostic use.
2. All Capture-R Ready-Screen reagents must be brought to 18-30 C before testing.
3. Capture-R Ready Indicator Red Cells must be suspended before use by gently inverting each vial several times. It is normal for Capture-R Ready Indicator Red Cells to aggregate slightly during 1-10 C storage. Capture-R Ready Indicator Red Cells should not be used if the red blood cells darken from red to brown, if there is hemolysis, or if the red blood cells fail to perform properly in positive and negative control tests. Slight hemolysis may occur with age.
4. Turbidity of Capture LISS and the Capture-R control sera may be an indication of microbial contamination. WB corQC reagent red blood cells should not be used if the red blood cells darken, spontaneously clump, or if there is significant hemolysis. Slight hemolysis may occur with age. Reagents that are contaminated should not be used.
5. Do not use reagents beyond their expiration dates. Leaking vials should not be used.
6. The format for the expiration date is expressed as CCYY-MM-DD (year-month-day).
7. Handle and dispose of reagent as if potentially infectious.
   CAUTION: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE WHEN TESTED IN ACCORDANCE WITH CURRENT FDA RECOMMENDATIONS. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.

Specimen Collection and Preparation:

Plasma or serum: Draw a blood specimen using an acceptable phlebotomy technique. Fresh serum or plasma (EDTA, ACD, CPD, CPDA-1, CP2D) may be used in this assay. All testing should be performed as soon as possible following collection to minimize the chance of false-positive or false-negative reactions due to improper storage or contamination of the specimen. Specimens that cannot be tested within 24 hours should be stored at 1-10 C as soon as possible. Alternatively, specimens can be separated from red blood cells and stored frozen. Weakly reactive antibodies may deteriorate and become undetectable in specimens stored at room temperature for several days before testing or in specimens stored for prolonged periods at 1-10 C. Do not use specimens drawn into tubes containing neutral gel separators. False-positive results may occur with such samples.

Procedure:

A. Materials Provided:

1. Capture-R Ready-Screen (3) strip-wells in resealable foil pouches.

B. Additional Capture Materials Required:

1. Capture LISS in dropper vials
2. Capture-R Ready Indicator Red Cells in dropper vials
3. Capture-R Positive Control Serum (Weak) in dropper vials
4. Capture-R Negative Control Serum in dropper vials

C. Additional Materials Required:

All Methods:

1. Phosphate-buffered (approximately 15mM) isotonic saline, pH 6.5-7.5
2. Donor or patient serum or plasma (automated method may require plasma)

Automated Method:

1. Galileo Echo instrument (as applicable) *
2. Echo Lumena instrument (as applicable) *
3. NEO Iris instrument (as applicable)*
4. WB corQC

Manual or Semi-automated Methods:

1. Transfer pipettes or pipetting system*
2. Centrifuge* with rotor capable of accommodating 1 x 8 strips of wells
3. 37 C heat block* or dry heat incubator*
4. Washing device* or wide port saline wash bottle or manual dispensing manifold
5. Dispensing manifold or pipettors designed for microplates
6. Blank strips of wells for balance
7. Stop watch* or interval timer*
8. Illuminated surface
9. Marking pens
10. Microplate reader* (optional)
11. WB corQC (optional)

* It is the users responsibility to validate an accessory device (either listed or otherwise) for its intended use. Validation results should be maintained as part of the laboratory's records for review by regulatory agencies.

Test Method:

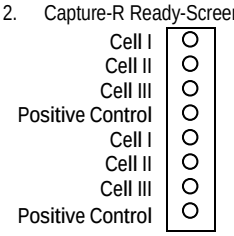
Automated Method

For microplate testing with automated instrumentation, refer to instructions provided in the instrument operator manual.

Manual or Semi-automated Methods:

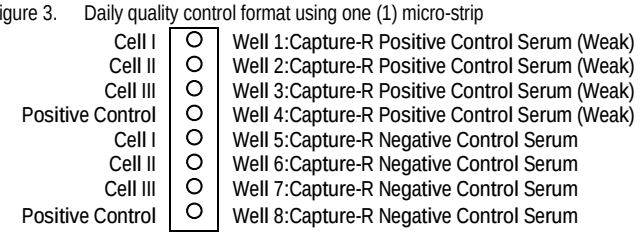
1. Bring all Capture reagents and specimens to 18-30 C before testing.
2. Remove one Capture-R Ready-Screen (3) Strip from its protective pouch. Inspect the humidity indicator enclosed in the pouch. If the humidity indicator shows the presence of moisture, none of the strips within the pouch should be used. In the absence of signs of moisture, return unused strips, desiccant and humidity indicator to the pouch and carefully reseal the pouch.
3. Check the top tab of the strip. Do not use the strip if it is not imprinted to show both the test identification (RS3) and the lot number in eye readable text. The arrangement of Reagent Red Blood Cells is shown in Figure 2.

Figure 2. Capture-R Ready-Screen (3) strip



4. Place the strip in a frame holder. Note: the strip will only fit into the holder in the correct orientation.
5. Add 2 drops (100 +/- 10 uL) of Capture LISS to each test well.
6. Add 1 drop (50+/- 5 uL) of sample plasma or serum into each of the four (4) wells designated for that one specific sample screen (I, II, III and Positive Control well). Continue to add one sample plasma or serum to a designated set of four (4) screen wells (I, II, III and Positive Control well) for any additional patient or donor samples that require testing. NOTE: The purple color of the Capture LISS should change to a sky or turquoise blue in the presence of serum or plasma. The retention of the purple color may indicate that the test specimen has not been added.
7. Daily Quality Control: at a minimum of one (1) time every twenty four (24) hours, add 1 drop (50+/- 5 uL) of Capture-R Positive Control Serum (Weak) to a designated set of four (4) screen wells (I, II, III and Positive Control well) of one (1) micro-strip (well numbers 1, 2, 3 and 4 of 8). Using the same micro-strip, also add 1 drop (50 ± 5 uL) of Capture-R Negative Control Serum to a designated set of four (4) screen wells (well numbers 5, 6, 7 and 8 of 8). Figure 3 below illustrates this quality control format.

Figure 3. Daily quality control format using one (1) micro-strip



8. Incubate the strips at 36-38 C for no less than 15 minutes and no longer than 60 minutes. Add 5 minutes to the incubation period if a dry heat incubator is used.
9. Decant or aspirate the sample-LISS mixture from the wells and wash the wells using a manual or semi-automated washing technique.
   a. Manual Washing Technique
      i. Decant fluid from the wells.
      ii. Fill the wells of the strip with saline dispensed from a multichannel dispenser or manifold designed for microplates. Alternatively, a saline wash bottle can be used to dispense the saline. Saline should not be added with excessive force since this may cause the red cell monolayer to disengage from the plate.
      iii. Decant the wells thoroughly by manually inverting the strip wells over a sink or waste receptacle and with several rapid, sharp motions, decanting the saline from the wells.

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iv. Wash the wells a minimum of six times with saline.

b. Semi-automated Washing Technique

For semi-automated washing, refer to instructions provided in the washer operator manual.

NOTE: The automated washing device must be adjusted such that approximately 4-8 uL of saline remains in each well after aspiration. Wells should not be aspirated until they are dry.

10. Add 1 drop (50 +/- 5 uL) of Capture-R Ready Indicator Red Cells to each of the wells.
11. Immediately centrifuge the strip for 1-3 minutes at 450-600 x g.
    NOTE: The g forces and time given are approximations of forces required to produce the desired degree of adherence. The appropriate g forces (or RPMs) and centrifuge time must be determined individually for each centrifuge used.
12. Place the strip on an illuminated surface (or use an accessory microplate reader) and examine for the presence of or the absence of Indicator Red Cell adherence. For test results of each sample to be considered valid, the fourth Positive Control well (being the internal assay process control well) associated with each sample tested must show adherence of Capture-R Ready Indicator Red Cells to all or part of the reaction surface.
    If the correct reaction is not obtained with the Positive Control well (being the internal assay process control well), test reactions may be invalid and the sample associated with that Positive Control well must be repeated.

Stability of the Reaction:

Following centrifugation, tests can be read immediately. Wells can be covered following centrifugation to prevent evaporation, stored at 1-10 C, and read or reread manually up to 2 days following testing.

Quality Control:

Automated method: For microplate testing with automated instrumentation, refer to instructions provided in the instrument operator manual.

Manual or semi-automated methods: Daily Quality Control of all Capture-R Ready-Screen components is built into the test system by the inclusion of the Capture-R Positive (Weak) and Negative Controls. These controls should be run according to the method described, at a minimum of one (1) time every twenty four (24) hours to ensure that neither equipment malfunction nor reagent failures have occurred. All wells tested with Capture-R Positive (Weak) control must yield a positive result.

Note: Wells I, II and III tested with the Capture-R Negative control must yield a negative result. The associated Positive Control well must still yield a positive result when tested with the Capture-R Negative control.

WB corQC can be used as an alternative set of control material, instead of Capture-R Positive (Weak) and Negative Controls, in this daily quality control process for automated methods.

This antibody screen assay also routinely employs the use of a positive control well with every sample tested. This positive control well is an internal assay process control with every sample tested and is manufactured as an IgG Anti-D sensitized red blood cell membrane in the well. For all sets of the screening wells (I, II and III), the fourth positive control well (associated with each particular set) must yield a positive result to control the blood sample screen result as acceptable.

Repeated failure of the positive control well to perform properly may indicate that one or more of the Capture-R Ready-Screen test reagents have deteriorated, or that tests are consistently being performed incorrectly.

Interpretation of Results:

Negative test: button of Capture-R Ready Indicator Red Cells at the bottom of the test well with no area of adherence.

Positive test: adherence of Capture-R Ready Indicator Red Cells to part or all of reaction surface.

Antibodies that are detected using Capture-R Ready-Screen (3) can be identified using either Capture-R Ready-ID, Capture-R Ready-ID Extend I or II or Capture-R Select (a solid phase system that can be used with selected reagent red blood cells).

Limitations:

1. Erroneous test results can occur from bacterial or chemical contamination of test materials, inadequate incubation periods, improper centrifugation, inadequate washing of test wells, or omission of test reagents or steps.
2. Contamination of Capture-R Ready Indicator Red Cells with IgG-containing serum or plasma proteins will neutralize the anti-IgG component of the Capture-R Ready Indicator Red Cells, leading to falsely negative test results. Failure of the fourth control well is an indication of indicator red cell neutralization in automated testing.
3. Overcentrifugation of the tests, following addition of the Capture-R Ready Indicator Red Cells, may result in falsely negative or doubtful positive reactions due to the collapse of the adherent indicator layer. Undercentrifugation will lead to falsely positive results.
4. Examples of pure IgG4 subclass antibodies may not be detected by the Capture-R Ready Indicator Red Cell reagent. Note, however that pure IgG4 antibodies are very uncommon.
5. The deceleration parameters of the centrifuge in use may affect the type of reactions obtained at the end of the assay. Failure to apply the braking mechanism in units with long deceleration times may result in falsely negative reactions. Conversely, braking of centrifuges with short deceleration times may also cause erroneous test results. It is the user's responsibility to evaluate centrifuge performance through instrument performance qualification. The results of the performance qualification should be maintained as part of the laboratory's records for review by regulatory agencies.
6. Serum or plasma specimens obtained from tubes containing neutral gel separators may produce falsely positive results in antibody screening tests. Tubes with gel separators are not designed for blood bank use.
7. The reactivity of Capture-R Ready-Screen (3) reagent red blood cells may diminish over the dating period. The rate at which antigen reactivity is lost is partially dependent on the individual donor characteristics that are neither controlled nor predicted by the manufacturer.
8. Addition of Capture-R Ready Indicator Red Cells in excess of amounts described in this insert may result in falsely negative or doubtful test reactions.
9. Addition of too few indicator red cells, as might occur with improper mixing of the reagent or through hemolysis of the red cells, will cause weak falsely positive results. Indicator red cells that are colder than 18 C when used will cause weak false-positive results.
10. Low ionic strength solutions (LISS) have been shown to enhance many antigen-antibody interactions. However, sera may be encountered that contain antibodies that are not optimally reactive in LISS test systems including the Capture-R Ready-Screen assay.
11. Antibodies such as anti-M, -P_1, -Le^a and -Le^b frequently react in tube hemagglutination tests at the room temperature phase of testing rather than at 37 C or at the antiglobulin phase. Some workers have interpreted this to mean that the antibodies were composed mostly of saline-reactive IgM molecules. Some examples of these antibodies may be detected in Capture-R assays, even though the test system is designed primarily for the detection of IgG because they contain an IgG component. Others may be detected, not because they are IgG in nature, but because the Indicator Red Cells carry the antigen toward which the IgM antibody is directed. Some IgM antibodies have been found to link Indicator Red Cells to immobilized red blood cell monolayers by binding to antigens on both. Thus, examples of anti-M, -Le^a, -Le^b, -P_1, etc that are detected in Capture-R tests should not be assumed to contain an IgG component without further study. These specificities are regarded as insignificant in most clinical situations. Examples of these antibodies detected in Capture-R tests are not necessarily more significant than examples that fail to react. Specificities of presumed significance, that are wholly IgM in nature (ie, IgM anti-K or IgM anti-E) may fail to react in this assay.
12. Some IgG antibodies have been shown to react poorly in solid phase red blood cell adherence assays. These include examples of antibodies to Bg^a, Bg^b, Kn^a, Cs^a, Yk^a, JMH, McC^a, Ch and Rg. [7,8] Weak examples of clinically relevant antibodies may fail to react by Capture-R Ready Screen, even though the antibodies are detected by an alternative technique. Passively administered anti-D may fail to react by Capture-R Ready-Screen, even though the antibodies are detected by an alternative technique. NO ONE TEST METHOD IS CAPABLE OF DETECTING ALL ANTIBODIES.
13. The genetic background of donors of Reagent Red Cells with phenotypes such as Fy (a+b-), Fy (a-b+), Jk (a+b-), Jk (a-b+), M+N-, M-N+, S+s- or S-s+ is not known. Such red blood cells are assumed to be from genetic homozygotes, but in fact, could have been collected from persons who are genetically heterozygous for the encoding genes.[4] No serological tests have been performed to demonstrate the red blood cells of apparent homozygotes used to prepare Capture-R Ready-Screen or Capture-R Ready-ID carry a double dose of the appropriate antigens.[8]
14. Negative reactions will be obtained if the test serum contains antibodies present in concentrations too low to be detected by the test methods employed.[8]
15. Reactions between an antibody and its antigen may be weakened if acidic or unbuffered saline is used to wash test wells prior to the addition of Indicator Red Cells. Best results will be obtained with saline buffered to pH 6.5-7.5. [9]
16. Incorrect results may be obtained in Capture-R Ready-Screen assays if testing personnel are not adequately trained in proper test performance. A laboratory that institutes Capture-R Ready-Screen technology should have a program that will properly train personnel. After personnel have received sufficient training, but

before existing antibody detection techniques are replaced with Capture-R Ready-Screen, the laboratory should perform parallel evaluations with Capture-R Ready-Screen and the house method (using a large battery of known positive and negative samples) to document that the appropriate results can be obtained.

17. The red blood cells used to prepare this reagent will carry antigens that may not be defined by the manufacturer, therefore, it is possible to obtain positive reactions with this reagent that do not match the profiles of any antigens shown on the Master List.

Specific Performance Characteristics:

Capture-R Ready-Screen was evaluated in parallel with hemagglutination methods in manual studies by five independent laboratories. Tests with 7000 samples show the method is capable of detecting most clinically significant antibodies of the IgG class. Those that are not detected are identified in the Limitations section of this circular.

IgG antibodies not detected are listed in the Limitations section of this circular. Some patient and donor plasmas/sera were evaluated that reacted by Capture-R Ready-Screen, but were nonreactive by reference hemagglutination techniques (most of these samples were shown to contain solid-phase only autoantibodies).

The antiglobulin coating of the Capture-R Ready Indicator Red Cells is evaluated in potency tests with anti-D and anti-Fy^{a}.

Prior to the manufacture of Capture-R Ready-Screen, the red blood cells of each donor are tested by two independent laboratories using no less than two donor sources of antibody (except where precluded by the rarity of the antisera) to confirm the presence or absence of all blood group antigens specified on each Master List. All red blood cells are tested and shown to have a negative direct antiglobulin test by solid phase. Each lot of Capture-R Ready-Screen (3) is evaluated to ensure suitable reactivity and specificity. The performance of this product is dependent upon adhering to the insert's recommended methodology. For additional information or for technical support, contact Immucor at 855-IMMUCOR (466-8267).

Capture-R Ready-Screen (3) meets the requirements of the FDA for reagent red blood cells for use in the detection of unexpected antibodies. No US Standard of potency exists for this product.

The expiration of Capture-R Ready-Screen stripwells is 120 days from the date of manufacture which is the earliest date blood used in this product is withdrawn from any donor.

Performance Characteristics on Galileo Echo and Echo Lumena:

Method comparison studies were performed at four external clinical sites. Specimens were tested on Galileo Echo and/or Echo Lumena and Galileo Neo. Specimens that gave initial equivocal (?) test well results with Capture-R Ready-Screen (3) were retested on the analyzer that gave the initial equivocal results. Test results were evaluated for agreement between analyzers. Combined results from all sites are summarized in the following tables:

Note: Agreement between methods does not indicate which method is correct.

Random Samples N=3166		Galileo Neo				
		Positive	Negative	Equivocal		
Galileo Echo	Positive	36	37	10	Positive % Agreement	90.0%
	Negative	4	3071	2	PPA (95% Lower Bound One-Sided CI)	78.6%
	Equivocal	0	4	2	Negative % Agreement	98.7%
					NPA (95% Lower Bound One-Sided CI)	98.3%

Results are for North America Market assays. Galileo Echo testing performed with software v2.1.

Random Samples N=3166		Resolved Results		PPA (95% Lower Bound One-Sided CI)	100.0%
		Positive	Negative	PPA (95% Lower Bound One-Side CI)	92.6%
Galileo Echo	Positive	39	46	NPA (95% Lower Bound One-Sided CI)	98.4%
	Negative	0	3078		
	Equivocal	0	3	NPA (95% Lower Bound One-Sided CI)	98.0%

Results are for North America Market assays. Galileo Echo testing performed with software v2.1. Discordant and equivocal samples were further tested by manual antibody screen method. PPA lower 95% CI did not meet 99% due to small positive sample (N) size tested. Additional well-characterized antibody positive samples were further tested, see results in table below. NPA lower 95% CI did not meet 99% due to 46 false-positive and 3 equivocal test results.

Well-characterized Samples N=299		Galileo Neo			
		Positive	Negative		
Galileo Echo	Positive	299	0	PPA (95% Lower Bound One-Sided CI)	100.0%
	Negative	0	0		
	Equivocal	0	0	PPA (95% Lower Bound One-Sided CI)	99.0%

Results are for North America Market assays. Galileo Echo testing performed with software v2.1.

Random Samples N=3153		Galileo Neo				
		Positive	Negative	Equivocal		
Echo Lumena	Positive	36	32	4	Positive % Agreement	90.0%
	Negative	5	3070	4	PPA (95% Lower Bound One-Sided CI)	78.6%
	Equivocal	1	1	0	Negative % Agreement	98.7%
					NPA (95% Lower Bound One-Sided CI)	98.3%

Results are for North America Market assays.

Random Samples N=3153		Resolved Results		PPA (95% Lower Bound One-Sided CI)	100.0%
		Positive	Negative	PPA (95% Lower Bound One-Side CI)	92.8%
Echo Lumena	Positive	40	33	NPA (95% Lower Bound One-Sided CI)	98.9%
	Negative	0	3079		
	Equivocal	0	1	NPA (95% Lower Bound One-Sided CI)	98.6%

Results are for North America Market assays. Discordant and equivocal samples were further tested by manual antibody screen method. PPA lower 95% CI did not meet 99% due to small positive sample (N) size tested. Additional well-characterized antibody positive samples were further tested, see results in table below. NPA lower 95% CI did not meet 99% due to 33 false-positive and 1 equivocal test results.

Well-characterized Samples N=300		Galileo Neo			
		Positive	Negative		
Echo Lumena	Positive	299	0	PPA (95% Lower Bound One-Sided CI)	99.7%
	Negative	1	0		

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	Equivocal	0	0	PPA (95% Lower Bound One-Sided CI)	98.4%

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Results are for North America Market assays. PPA lower 95% CI did not meet 99% due to positive sample (N) size tested.

Performance Characteristics on NEO Iris:

Method comparison studies were performed at three external clinical sites, including transfusion services and donor centers. Immucor, Inc., as the manufacturer, was a fourth site. Specimens were tested on NEO Iris and Galileo Neo. Specimens that gave initial equivocal (?) test well results with Capture-R Ready-Screen (3) were retested on the analyzer that gave the initial equivocal results. Test results were evaluated for agreement between analyzers. Combined results from all sites are summarized in the following tables:

Note: Agreement between methods does not indicate which method is correct.

Random Samples N=1791		Galileo Neo			
		Positive	Negative		
NEO Iris	Positive	16	6	Positive % Agreement	100.0%
				PPA (95% Lower Bound One-Sided CI)	53.2%*
	Negative	6	1766	Negative % Agreement	99.7%
				NPA (95% Lower Bound One-Sided CI)	99.3%

* PPA lower 95% CI did not meet 99% due to the low frequency of antibody positive samples in the population. Discordant and equivocal samples were further tested by manual antibody screen method. Additional well-characterized antibody positive samples were further tested, see results in table below.

Results are for North America Market assays.

Well-characterized Samples N=275		Expected Result		
		Positive		
NEO Iris	Positive	275	Positive % Agreement	100.0%
	Negative	0	PPA(95% Lower Bound One-Sided CI)	98.9%

Results are for North America Market assays

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US License 886 applies only to (Capture-R Ready-Screen Test Wells)

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