Capture-R® Ready-Screen® (Pooled Cells)
Solid Phase System for the Detection of Unexpected IgG Antibodies to Red Cells

Rx ONLY
346-13

Intended Use:
Capture-R Ready-Screen® (Pooled Cells) is intended for use in the detection of unexpected IgG antibodies to red blood cells by manual, semiautomated 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.2 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. Capture-R Ready-Screen (Pooled Cells) is not recommended for pretransfusion tests done in lieu of a major crossmatch to detect unexpected antibodies in patients’ samples.

Principle of the Test:
Capture-R Ready-Screen is a modified solid phase antibody detection systems based on the procedures of Flipp et al.3 and Juil et al.4 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 blood cell-specific antibodies from patient or donor sera or plasmas. Following a brief incubation period, unbound residual immunoglobulin 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 binding, the indicator red 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 cell buttons.

Reagents:
1. Capture-R Ready-Screen (Pooled Cells) consisting of 1 x 8 strips carrying the bound and dried red blood cell membranes prepared from a pool of two group O donors. 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 the presence of moisture (by the humidity indicator turning from blue to pink), the strips should not be used. Unused strips, desiccant and moisture indicator should be carefully returned within the foil pouch to prevent exposure to moisture that can destroy the red blood cell membranes. Strips within sealed 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 indicates the code and antigen composition of each donor whose red blood cells are used to prepare the dried reagent monolayers.

Adjunct Reagents to Capture Test Wells:
1. Capture LSS: a low ionic strength solution containing glycine, bromosalol purple dye and the preservative sodium azide (0.1%). Store at 1-10°C.
2. Capture-R Ready Indicator Red Cells: a suspension of red blood cells coated with murine monoclonal anti-human IgG molecules. The reagent is suspended in a buffered preservative solution to which chloramphenicol (0.1% w/v) and gentamicin sulfate (0.05 mg/mL) have been added as preservatives. Store at 1-10°C.
3. Capture-R Positive Control Serum (Wash): contains antibodies to red blood cells. Sodium azide (0.1%) is added as a preservative*. Store at 1-10°C.
4. Capture-R Negative Control Serum: contains no antibodies to red blood cells. Sodium azide (0.1%) is added as a preservative*. Store at 1-10°C.

NOTE: The in-date components (Capture-R Ready-Screen wells, Capture-R Ready Indicator Red Cells, Capture LSS and Capture-R Control Serum) 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. This reagent contains 0.1% sodium azide. Warning: H302 Harmful if swallowed.
Sodium azide may react with lead and copper plumbing to form explosive compounds. If discarded into the sink, flush with a large volume of water to prevent azide build-up.
3. All Capture-R Ready-Screen reagents must be brought to 18-30°C before testing.
4. 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 cells fail to perform properly in positive and negative control tests. Slight hemolysis may occur with age.
5. Turbidity of Capture LSS and Capture Control Reagents may be an indication of microbial contamination. Reagents that are contaminated should not be used.
6. Do not use reagents beyond their expiration dates. Leaking vials should not be used.
7. The format for the expiration date is expressed as YY/MM/DD (year-month-day).
8. 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 REQUIRED TESTS. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.

The packaging of this product (shipped bulks) contains dry natural nuclide.

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, CPD2) 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

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* = Addition or significant change; ▲ = Deletion of text.
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 specimens.

Procedure:
A. Materials Provided:
1. Capture-R Ready-Screen (Pooled Cells)/Microwells in resellable 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 (Week) in dropper vials
4. Capture-R Negative Control Serum in dropper vials
C. Additional materials required:
1. Donor or patient serum or plasma
2. Marking pens
3. Transfer pipettes or pipetting system
4. Alginate* with reconstituted by accommodating 1 x 8 and 2 x 8 strips of walls
5. or C heat block or dry heat incubator
6. Phosphate-buffered saline, (approximately 15 mL), pH 5.5-7.5
7. Washing device or wide pipette saline wash bottle or manual dispensing manifold
8. Dispensing manifold or pipettors designed for microplates
9. Blunt tips of vials for balance
10. Microscope slides (optional)
* it is the user’s 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:
1. Bring all Capture reagents and specimens to 18-20°C before testing.
2. Remove one Capture-R Ready-Screen 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 bottom tab of the strip. Do not use the strip if it is not imprinted to show
the test identification. The arrangement of Reagent Blood Cells is shown in
Fig. 1.
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 µL) of Capture LISS to each test and control well.
6. Add 1 drop of Capture-R Positive Control Serum (Pooled Cells) to each well.
7. Incubate the strips at 36-38°C for no less than 15 minutes and no longer than 60
minutes. Add 1 drop of Capture-R Negative Control Serum to another well.
8. Decant or aspirate the samples LISS mixture from the wells and wash the wells
using a manual or automated washing technique.
a. Manual Washing Technique
i. Discard 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,
dumping the saline from the wells.
iv. Wash the wells a minimum of six times with saline.
b. Automated Washing Technique
i. Prime the instrument and make lines with isotonic saline according to
the instrument manufacturer’s directions.
NOTE: When using strips on automated washers, the strip wash holder (frame) must
be full of test and/or empty strips.
ii. To remove sample from the wells, aspirate the contents of each well
with a vacuum device.
iii. Sequential aspiration process: Wash each well a minimum of
three times by filling each well with at least 300 µL of saline and
then aspirating the well contents with a vacuum device. Consult the
instrument manufacturer’s operating manual for a description of
the proper use of the microplate washing device. After the first three
washes, rotate the strip 180 degrees and wash a minimum of three
more times. In the event that one of the dispensing or aspirating
probes of the washer has become clogged, this increases the
likelihood that all test wells will be washed sufficiently.
NOTE: The automated washing device must be adjusted such that approximately
4-8 µL of saline remains in each well after aspiration. Wells should not be aspirated
until they are dry.
9. Add 1 drop (50 +/- 5 µL) of Capture-R Ready Indicator Red Cells to each of the
wells.
10. Immediately centrifuge the strip for 1-3 minutes at:
450-600 g
NOTE: The g force and time given are approximations of forces required to produce the
desired degree of adherence. The appropriate g forces or rpm time must be determined
individually for each centrifuge used.
11. Place the strip on an illuminated surface and examine for adherence or the absence
of indicator Red Cell adherence. For test results to be considered valid, the
following reactions must be obtained with the Capture-R Control Serum limit line a
plate is tested.
• Positive Control (Weak) = adherence of Capture-R Ready Indicator Red
Cells to all or part of the reaction surface.
• Negative Control Serum = absence of Capture-R Ready Indicator Red
Cells at the bottom of the test well.
If the correct reactions are not obtained with the Capture-R Control Serum, test
reactions may be invalid and the tests of that run must be repeated.

Stability of Reaction:
Following centrifugation, manual and semiautomated tests can be read immediately. Wells
be covered following centrifugation to prevent evaporation, stored at 1-10°C, and read
or retested manually up to 2 days following testing.

Quality Control:
Daily Quality Control of all Capture-R Ready-Screen components is built into the test
systems by the inclusion of the Capture-R Positive and Negative Controls. These
Controls should be included with each centrifugation run, whether or not it consists of one
strip, or more than one strip, to ensure that neither technical errors (e.g. improper washing
or centrifugation), nor reagent failures, have occurred. Continued failure of the Controls
in test strips on repeat testing 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 at the bottom of the test well with
no area of adherence.
Positive test: adherence of Capture-R Ready Indicator Red Cells to all or part of
the reaction surface.
Antibodies that are detected using Capture-R Ready-Screen can be identified using either
Capture-R Ready-ID, Capture-R Ready-ID Extend I and II, or Capture-R Select, a solid
phase system that can be used with reagent red blood cells of all manufacturers.

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 oxidation 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 blood cells, leading to falsely negative test results. Failure of the

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Capture-R® Positive Control is an indicator of indicator red cell neutralization in manual or semiautomated testing.

3. Overcorrection of the tests, following addition of the Capture-R® Fiebey Indicator Red Cells, may result in falsely negative or doubtful positive results due to the collapse of the adherent indicator layer. Undercorrection will lead to falsely positive results.

4. Examples of pure IgG subclass antibodies may not be detected by the Capture-R® Ready Indicator Red Cell reagent. Nasa, 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 users responsibility to evaluate centrifuge performance before use to identify optimum rpm speeds, spin times and acceleration/deceleration settings. The results of the performance evaluation should be maintained as part of the laboratorys 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 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 either controlled or provided by the manufacturer.

8. Addition of Capture-R® Ready Indicator Fed 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 blood cells, will cause weaker falsely negative results. Indicator red cells that are colder than 18°C when used will cause weaker false-positive results.

10. Low toxic strength solutions (LSS) have been shown to enhance many antigen-antibody interactions. However, sera may be encountered that contain antibodies that are not optimally reactive in LSS test systems including the Capture-R® Ready Screen assay.

11. Antibodies such as anti-M, -P, -Lea and -Leb frequently react in tube hemagglutination tests at the room temperature phase of testing rather than at 37°C or at the antihemofluor phase. Some workers have interpreted this to mean that the antibodies were composed mostly of autologous 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, -Le, -F, -A etc that are detected in Capture-R® tests should not be assumed to contain an IgM 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 weakly IgM in nature (i.e., IgM anti-K or IgM anti-D) may fail to react in this assay.

12. Some IgG antibodies have been shown to read poorly in solid phase red blood cell adherence assays. These include examples of antibodies to K, D, A, B, C, Cw, Dw, Jk(a), Rh and Ha, which may fail to react by Capture-R® Ready Screen, even though the antibodies are detected by an alternative technique. Positively administered anti-D may fail to react with Capture-R® Ready Screen. NO ONE TEST METHOD IS CAPABLE OF DETECTING ALL ANTIBODIES.

13. Antibody screening tests employing pooled reagent red blood cells will not be as sensitive as those incorporating the red blood cells of untyped single donors. Pooled reagent red blood cells should not be used when the antiglobulin antibody screen is performed in place of the antiglobulin crossmatch.

14. The red blood cells used to prepare the reagent can carry antigens that are not defined by the manufacturer. Therefore, it is possible to obtain positive reactions with this product that do not match the profiles of any antigens shown on the Master List.

15. The genetic background of donors of Reagent Red Cells with phenotypes such as Fy(a+b), Fy(a+s), Jk(a+b), Jk(a+b), M(N), Mn(N), M(N), S- or St+ or 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. No serological tests have been performed to demonstrate the red blood cells of apparent homozygotes used to prepare Capture-R® Ready Screen carry a double dose of the appropriate antigens.

16. Negative reactions will be obtained if the test specimens contain antibodies present in concentrations too low to be detected by the test methods employed.

17. Reactions between an antigen and its antibody 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 6.5-7.0.

18. 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 this house method using a large battery of known positive and negative samples) to document that the appropriate results can be obtained.

Specific Performance Characteristics: Clinical evaluations of over 7,000 samples performed by two separate microbiologists demonstrated that the Capture-R® Ready Screen assays were capable of detecting clinically important IgG antibodies to red blood cells. Each laboratory involved in the study used plasma or serum specimens that were tested by a reference hemagglutination assay in parallel. Capture-R® Ready Screen has been shown to detect most clinically significant antibodies of the IgG subclass. IgG antibody specificities not readily detected in these studies are listed in the LIMITATIONS section of this insert. Some patient and donor specimens were evaluated that reacted by Capture-R® Ready Screen, but were nonreactive by reference hemagglutination techniques. Most of these specimens 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.

Prior to the manufacture of 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 those precluded by the rarity of the antigen) to confirm the presence or absence of all blood group antigens specified on the Master List. All red blood cells are tested and shown to have a negative direct antiglobulin test using polyspecific anti-human globulin.

For additional information or for technical support, contact Immucor at 866-MMMUCOR (666-6688).

Capture-R® Ready Screen 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 these products.

The expiration date of Capture-R® Ready Screen strips will be stated on the expiration date of manufacture which is the earliest date that blood is withdrawn from any donor used in this component.

Bibliography:

US License 866 only applies to (Capture-R® Ready Screen Test Waits)

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