Capture-R® Ready Indicator Red Cells

Anti-IgG-Coated Indicator Red Cells for use in Solid Phase Assays for the Detection of IgG Antibodies

IVD

10°C

1°C

- Discard if hemolyzed or discolored

MOLDOVA EUROPEANA

- Preservative: Chloramphenicol (0.25 mg/mL) Neomycin sulfate (0.1 mg/mL) Gentamycin sulfate (0.05 mg/mL)

Rx ONLY

CAUTION: DO NOT PIPETTE THIS PRODUCT BY MOUTH, AS THE ABSENCE OF MURINE VIRUS HAS NOT BEEN DETERMINED. ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. THE PACKAGING OF THIS PRODUCT (DROPPER BULBS) CONTAINS DRY NATURAL RUBBER.

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Capture-R® Ready Indicator Red Cells

IMMUCOR

Intended Use:

Anti-IgG-coated Indicator Red Cells for use in Capture-R Ready-Screen®, Capture-R Ready-ID® or Capture-R® Select Solid Phase Assays for the detection of IgG antibodies to red blood cells.

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 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 Capture-R Ready products, are incubated with test sera or plasma under test conditions that will facilitate antibody detection. Capture-R Ready Indicator Red Cells are used as the indicator reagent for the detection of IgG antibodies bound to the red blood cells.

Principle of the Test:

Capture-R Ready-Screen, Capture-R Ready-ID and Capture-R Select assays are based on the procedures of Plapp et al.[4] Red blood cells are first bound to the surfaces of polystyrene microtitration test wells. The membrane antigens are used to capture red blood cell-specific IgG antibodies from patient or donor sera or plasmas. Serum/plasma is added to the red blood cell-coated test wells and the wells are incubated at 37 C. Following incubation, unbound residual immunoglobulins are rinsed from the wells and a suspension of anti-IgG-coated indicator red cells is added. Centrifugation brings the indicator red cells in contact with antibodies bound to the immobilized reagent red cells. In the case of a positive test, the migration of the indicator red cells to the bottom of the wells is impeded as anti-IgG-IgG complexes form between the indicator red cells and the sensitized immobilized reagent cell layer. As a consequence of antibody bridging, the indicator cells adhere to the immobilized cells as a second immobilized layer. In the absence of detectable antigen-antibody interactions (negative test), the indicator red cells do not bind to the immobilized cells and pellet to the bottom of the wells as tightly packed red blood cell buttons.

Reagents:

Capture-R Ready Indicator Red Cells: Single donor or pooled red blood cells coated with murine monoclonal anti-human IgG. The reagent is prepared as a dilute suspension in a buffered preservative solution containing adenosine and adenine to retard hemolysis and loss of antigenicity during the dating period. Chloramphenicol (0.25 mg/mL), neomycin sulfate (0.1 mg/mL), and gentamycin sulfate (0.05 mg/mL) are added as preservatives. Store at 1-10 C when not in use. It is normal for Indicator Red Cells to aggregate slightly during storage at 1-10 C. The reagent is supplied in dropper vials and is ready for use.

Precautions:

For in vitro diagnostic use.
Do not freeze or expose to elevated temperatures. Do not use beyond the expiration date. Do not use if the reagent is hemolyzed or discolored.

The format for the expiration date is expressed as CCYY-MM-DD (year-month-day).

DESIGNED FOR USE ONLY IN CAPTURE-R READY-SCREEN, CAPTURE-R READY-ID AND CAPTURE-R SELECT SOLID PHASE RED CELL ADHERENCE ASSAYS.

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

Handle and dispose of reagent as if potentially infectious.
CAUTION: DO NOT PIPETTE THIS PRODUCT BY MOUTH, AS THE ABSENCE OF MURINE VIRUS HAS NOT BEEN DETERMINED. 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 (DROPPER BULBS) CONTAINS DRY NATURAL RUBBER.

Capture-R Ready Indicator Red Cells should be allowed to warm to 18-30 C before use in tests. Failure to warm this reagent properly will result in aberrant test results

Specimen Collection and Preparation:

Consult the package insert of the Capture test wells to be used to determine specimen collection restrictions (Capture-R Ready-Screen, Capture-R Ready-ID, Capture-R Select).

Procedure:

Materials supplied:
Capture-R Ready Indicator Red Cells in dropper vials

Additional materials required:
All test methods:

1. Test wells and applicable package insert (Capture-R Ready-Screen, Capture-R Ready-ID, Capture-R Select)
2. Immucor Capture LISS
3. Phosphate-buffered (approximately 15 mM) isotonic saline, pH 6.5-7.5
4. Patient or donor specimens

Manual or tests performed with semiautomated equipment:

1. Capture-R Control Sera (Positive Control Weak, Negative Control)
2. Interval timer
3. 37 C dry heat incubator, heat block or water bath
4. Centrifuge capable of accommodating 1 x 8 or 2 x 8 strips of Capture microwells *
5. Dispensing manifold or pipettors designed for microwells
6. Illuminated reading surface
7. Saline wash bottle or automated washing device

* 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.

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

Test method:

Antibody detection by manual or semiautomated methods:

1. Bring all reagents and samples to 18-30 C before testing.
2. Prepare donor or patient red blood cells or serum/plasma samples according to the directions supplied with the Capture test wells in use.

3. Prepare Capture test wells according to the applicable package insert.
4. Proceed with testing according to the package insert for the Capture test wells.
5. Following the final wash add one drop (50 +/- 5 uL) of Capture-R Ready Indicator Red Cells to each test and control well.
6. Centrifuge test wells according to the applicable test well package insert.
7. Read and record results.

Automated method:

For microplate testing with automated instrumentation, refer to instructions provided in the instrument operator manual.
Capture-R Ready Indicator Cells should be used not more than 24 hours after a stir ball or stir bar has been added to the vial. Longer use of the cells may compromise the integrity of the reagent.

Stability of Reaction:
Following centrifugation, tests performed manually or with semiautomated equipment can be read immediately. Since positive reactions are permanent, wells can be covered following centrifugation to prevent evaporation, stored at 1-10 C, and read or reread up to 2 days following testing. Automated tests cannot be stored or read off the instruments.

Quality Control:
Manual or semiautomated testing: The performance of this reagent is evaluated at each test run with Capture-R Positive and Negative Control Sera. The controls help to determine if technical errors or reagent failures have occurred. Continued failure of the control sera to give the expected results on repeat testing may indicate that Capture-R Ready Indicator Red Cells or another reagent in the Capture system has deteriorated, or that the test is consistently being performed incorrectly.

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

Interpretation of Results:

Positive test: adherence of indicator red cells to part or all of the reaction surface or enlargement of the cell button over that of the negative control.

Negative test: button of indicator red cells at the bottom of the test well with no readily detectable area of adherence.

Limitations:

Erroneous test results can occur from bacterial or chemical contamination of Capture-R Ready Indicator Red Cells, inadequate washing of test wells, improper storage of this reagent or the omission of the reagent.
Overcentrifugation of manual or semiautomated 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.

The deceleration parameters of the centrifuge in use may effect 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.

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. 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 weak falsely positive results. Indicator red cells that are colder than 18 C when used will cause weak false-positive results.

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 Capture-R Positive Control Serum is an indication of neutralization in manual or semiautomated testing. Automated methods employ Capture-R Control Cells to detect neutralization. These cells should agglutinate in the presence of active Indicator Red Cells.

Examples of pure IgG4 subclass antibodies may not be detected by the Capture-R Ready Indicator Red Cells reagent. Note, however that pure IgG4 antibodies are very uncommon.

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. Examples of these antibodies may be detected in Capture-R assays, even though the test system is designed primarily for the detection of IgG. Some of these antibodies may be detected by Capture-R Ready Indicator Red Cells 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 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 entirely IgM in nature (ie, IgM anti-K or IgM anti-E) may fail to react in this assay.

Specific Performance Characteristics:

To ensure suitable potency, reactivity and specificity, each lot of Capture-R Ready Indicator Red Cells is tested prior to release against reference sera containing IgG antibodies or reference sera free of red cell antibodies. The antiglobulin coating of Capture-R Ready Indicator Red Cells is evaluated in potency tests with dilutions of anti-D and anti-Fy^a. This product is evaluated by manual and automated methods before release. 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).
The expiration date is set at 45 days from the date of manufacture which is the earliest date that blood is withdrawn from any donor used in a component of the product.

Bibliography:

1. Boral LI, Henry JB. The type and screen: a safe alternative and supplement in selected surgical procedures. Transfusion 1977;17:163.
2. Giblett ER. Blood group alloantibodies: an assessment of laboratory practices. Transfusion 1977;17:299.
3. Roualt CL. Appropriate pretransfusion testing, In: Pretransfusion testing for the '80's. Washington DC: American Association of Blood Banks, 1980:125.
4. Plapp FV, Sinor LT, Rachel JM, et al. A solid phase antibody screen. Am J Clin Pathol 1984;82:719.721.

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