Capture ® LISS

Low Ionic Strength Solution

For Capture® solid phase antibody detection tests

IVD

MOLDOVA EUROPEANĂ

10°C

1°C

Harmful, Preservative: 0.1% Sodium Azide

- No US standard of potency **Rx ONLY**
- Discard if turbid

CAUTION: THE PACKAGING OF THIS PRODUCT (DROPPER BULBS) CONTAINS DRY NATURAL RUBBER.

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Capture® LISS

Low Ionic Strength Solution

For Capture® solid phase antibody detection tests

IMMUCOR

Intended Use:
Capture LISS is intended for use as a low ionic strength potentiator and sample addition indicator in Capture solid phase tests for the detection of antibodies (Capture-R® Select, Capture-R® Ready-Screen®, Capture-R Ready-ID®, Capture-R Ready-ID Extend, Capture-P®, Capture-P Ready-Screen® and Capture-CMV®).

Summary of the Test:
The ionic strength of a test system is dependent on the amount of dissolved ions in solution. In human serum, 92% of the osmolality is due to dissolved sodium chloride (NaCl) and bicarbonate.[1] In serological test systems, dissolved NaCl contributes positive charges, in the form of sodium ions or Na+, and negative charges as chloride or Cl- ions. These ions, when present in sufficient quantities, can reduce antibody binding.[2]

At the ionic concentration of human serum or plasma (or that of isotonic saline) antigen-antibody interactions occur, but not always with optimal efficiency. In many cases, lowering the ionic strength (decreasing the concentration of salt) of a serologic test system to a point below that of normal physiologic saline, increases the rate of specific antibody uptake.

Several groups of workers have shown that low ionic strength solutions of an appropriate sodium chloride molarity can be used in red cell serological tests to enhance antigen-antibody interactions and decrease the incubation time needed to detect the antibodies. [2-11] Low ionic solutions can serve the same functions in tests to detect antibodies to platelets.[10] Capture LISS contains a dye that changes color in the presence of normal human serum or plasma. Thus, the reagent is also used as an indicator of sample addition to test wells of Capture-R, Capture-P and Capture-CMV tests.

Principle of the Test:
The ionic strength of an antibody detection test is reduced by the addition of a low Ionic additive. The reduction facilitates antibody uptake while reducing the incubation time necessary to detect antibody uptake.

Bromocresol Purple changes color in the presence of protein solutions, such as human serum or plasma. Change in the color of Capture LISS is an indication serum or plasma has been added to a test well.

Reagents:
Capture LISS is a low ionic solution containing glycine and the dye Bromocresol Purple and the preservative sodium azide (0.1%). The reagent will turn from blue-purple to sky blue or turquoise in the presence of normal human serum or plasma. Store at 1-10 C when not in use. Use as supplied.

Precautions:
For in vitro diagnostic use.

Bring Capture LISS to 18-30 C before testing.
Store at 1-10 C when not in use. Do not use beyond expiration date.

Do not use Capture LISS if the reagent becomes turbid or changes color.

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

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.

NOT DESIGNED FOR USE IN TESTS OTHER THAN CAPTURE SOLID PHASE RED CELL ADHERENCE ASSAYS.

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

Specimen Collection and Preparation:
Consult the direction circular of the antibody detection test wells employed to determine specimen collection restrictions (Capture-R Ready-Screen Test Wells, Capture-R Ready-ID Test Wells, Capture-R Ready-ID Extend Test Wells, Capture-R Select Test Wells, Capture-P Test Wells, Capture-P Ready-Screen Test Wells, Capture-CMV Test Wells.)

Procedure:
Materials Provided:
Capture LISS in dropper vials

Additional materials required:

All test methods:

1. Test wells and applicable direction circular: Capture-R Select, Capture-R Ready-Screen, Capture-R Ready-ID, Capture-R Ready-ID Extend, Capture-P, Capture-P Ready-Screen or Capture-CMV.
2. Indicator Red Cells and applicable direction circular: Capture-R Ready (if testing Capture-R Select, Capture-R Ready-Screen, Capture-R Ready-ID, Capture-R Ready-ID Extend), Capture-P (if testing Capture-P or Capture-P Ready-Screen), Capture-CMV Indicator Red Cells.
3. Phosphate-buffered (approximately 15 mM) isotonic saline, pH 6.5-7.5

Manual or tests performed with semiautomated equipment:

1. Capture-R Control Sera (if performing any of the Capture-R family of tests) or Capture-P Control Sera (if performing any of the Capture-P family of tests) or Capture-CMV Control Sera (if performing Capture-CMV).
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 microwells or 96-well, rigid microtitration plates)*
5. Dispensing manifold or pipettors designed for microwells
6. Illuminated reading surface
7. Saline wash bottle or semiautomated 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.

Automated method:

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

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 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 direction circular.
4. Add 2 drops (100 +/- 5 uL) of Capture LISS to each test and control well.
   NOTE: Capture LISS will change color from a blue-purple to a sky blue or turquoise color in the presence of serum or plasma. Failure to observe the color change may indicate the failure to add serum or plasma to a test well.
5. Add patient or donor serum/plasma and incubate the tests for the time and at the temperature described in the directions for the Capture test wells.
6. Following incubation, wash the test wells manually or using semiautomated washing devices according to the direction circular provided with the Capture test wells.
7. Add the appropriate indicator red cells and complete testing according to the directions accompanying the Capture test wells.

Automated method:

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

Stability of Reaction:

Following centrifugation, all tests should be read immediately. Since Capture solid phase positive reactions are permanent, test wells of manual or semiautomated tests can be covered following incubation, stored at 1-10 C and read or reread up to 2 days following testing.

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

Quality Control:

Manual or semiautomated testing: The performance of this reagent is evaluated daily in tests performed with Capture Positive and Negative Control Sera. The controls should be included in each test run to help determine if technical errors or reagent failures have occurred. Continued failure of the Control Sera to perform properly on repeated testing may indicate that Capture LISS or another reagent in the Capture system has deteriorated, or that the test is being performed incorrectly.

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

Interpretation of Results:

Negative test: button of Indicator Red Cells at the bottom of the test well with no readily detectable area of adherence.

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.

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

Limitations:

Erroneous test results can occur from bacterial or chemical contamination of Capture LISS, inadequate washing of test wells, improper storage of the reagent or the omission of the reagent. In addition, failures can occur if the procedures in which Capture LISS is employed are not performed correctly.

The ionic strength of a test system is dependent on the amount of serum used. Addition of serum/plasma in excess of the amounts described in this circular will increase the ionic strength and may decrease test sensitivity.

Specific Performance Characteristics:

Capture LISS has been shown to potentiate antigen-antibody interactions in serological tests, including potency tests and in reactivity (use) tests described in direction circulars accompanying Capture-R Select, Capture-R Ready-Screen, Capture-R Ready-ID, Capture-R Ready-ID Extend, Capture-P, Capture-P Ready-Screen and Capture-CMV. Specificity has been demonstrated in tests with antibody-free sera/plasmas. 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).

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To ensure suitable potency, reactivity and specificity, each lot of Capture LISS is evaluated with reference sera by manual and automated methods.

No US standard of potency.

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