Capture-R® Positive Control Serum (Weak) CONTROL +W

Capture-R® Negative Control Serum CONTROL -

Run Controls for Solid Phase Red Cells
Adherence Assays for the Detection of IgG Antibodies to Red Cells

MOLDOVA EUROPEANĂ

IVD

- 1°C – 10°C
- Harmful, Preservative: 0.1% Sodium Azide
- Discard if reagents show evidence of microbial contamination **Rx ONLY**

CAUTION: 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® Positive Control Serum (Weak)

CONTROL +W

Capture-R® Negative Control Serum

CONTROL -

Run Controls for Solid Phase Red Cells Adherence Assays for the Detection of IgG Antibodies to Red Cells

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Intended Use:
Immucor's Capture-R Positive Control Serum (Weak) and Capture-R Negative Control Serum are run controls to be used in Capture-R Solid Phase Assays, including Capture-R® Select, Capture-R® Ready-Screen® and Capture-R® Ready-ID®.

Summary of the Test:
Solid phase red cell adherence assays for the detection of IgG antibodies to red blood cells are indirect antiglobulin tests that employ anti-IgG-coated indicator red cells as the indicator particles.[1,2] The validity of the results obtained with the indicator red cells is dependent on:

1. the anti-IgG activity of the reagent,
2. the thoroughness of washing used to prepare test wells before the addition of indicator red cells,
3. the centrifugation time and speed used to set the reactions, and
4. incubation time and temperature.

The anti-IgG component of the indicator red cells can be neutralized in the vial through contamination with minute amounts of serum proteins. Alternatively, indicator red cells can be neutralized by residual serum proteins remaining after insufficient washing. Capture-R Positive Control (Weak) is an antibody reagent designed to test the activity of the indicator red cells. Negative or weakened positive results obtained with this reagent suggest indicator red cell neutralization.

The Capture-R Positive Control (Weak) can also be used to detect changes in incubation or centrifugation. Incubation at 36-38 C permits binding of antibody to test red cells. Centrifugation is used to facilitate the formation of positive and negative adherence reactions. Changes in incubator performance during use (including incubation at reduced temperatures or for shortened periods of time) will lead to weakened positive or negative results with Capture-R Positive Control (Weak). Similarly, changes in centrifuge performance, leading to overcentrifugation will lead to failure of the Positive Control reagent.

Capture-R Negative Control Serum is used to monitor for undercentrifugation or overincubation, situations that lead to falsely positive test results.

Principle of the Test:
Capture-R Positive Control (Weak) and Capture-R Negative Control are used with each run (or batch) of Capture-R tests to assess the validity of test results of the run. Capture-R Positive Control (Weak) should produce similar positive results from run to run. Capture-R Negative Control should produce negative results with each run. Deviations for the expected control results indicates a run failure and all tests and controls should be repeated.

Reagents:
Capture-R Positive Control Serum (Weak): contains antibodies to red blood cells. Sodium azide is added as a preservative. Store at 1-10 C. Ready for use as supplied.

Capture-R Negative Control Serum: contains no antibodies to red blood cells. Sodium azide is added as a preservative. Store at 1-10 C. Ready for use as supplied.

Precautions:
For in vitro diagnostic use.

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

Do not store frozen or expose to elevated temperatures. Do not use beyond the expiration date. Turbidity may be an indication of microbial contamination. Do not use microbially contaminated reagents.

To be used as run controls with Capture-R tests only.

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

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 (DROPPER BULBS) CONTAINS DRY NATURAL RUBBER.

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 Select Test Wells).

Procedure:
Materials supplied:
Capture-R Positive Control Serum (Weak) in dropper vials
Capture-R Negative Control Serum in dropper vials

Additional materials required:

1. Immucor Capture-R test wells, eg Capture-R® Select, Capture-R® Ready-Screen®, Capture-R® Ready-ID®
2. Immucor Capture LISS
3. Immucor Capture-R Ready Indicator Red Cells
4. Phosphate-buffered (approximately 15 mM) isotonic saline, pH 6.5-7.5
5. Patient or donor specimens
6. 37 C dry heat incubator or water bath

7. Centrifuge with rotor capable of accommodating stripwells and their holders*
8. Automatic microtitration plate washer or semiautomatic microtitration plate washer or wide port saline wash bottle or manual dispensing manifold*
9. Dispensing manifold or pipettors designed for microtitration plates or strips
10. Stopwatch or interval timer
11. Illuminated surface
12. Marking pens
13. Blank strips for balance

*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:

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, add Capture LISS and patient or donor serum/plasma samples according to the applicable test well direction circular.
4. Add 1 drop (50 +/- 5 uL) of each Capture control to appropriate control wells. Each control needs to tested only once per run.
5. Following incubation, wash the test wells manually or using semi automated washing devices according to the direction circular provided with the Capture test wells.
6. Read and record results at test completion.

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

Stability of Reaction:
Following centrifugation, tests 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.

Quality Control:
The performance of Capture-R test systems are 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.

The strength of the result obtained with Capture-R Positive Control Serum (Weak) should be no less than a moderately positive reaction. Reactivity less than this indicates that the procedure, a reagent or an instrument used is not performing. As a consequence, a potential for test failure exists. Weakly positive test results may be missed.

Limitations:

Capture-R Control Sera are used to determine if technical errors or reagent failures have occurred. The reagents cannot be used to validate negative tests performed by other methods. ▲

Specific Performance Characteristics:

Each lot of Capture-R Control Serum is tested prior to release to ensure the product meets reactivity and specificity requirements. 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).

No US standard of potency exists for this product.

Bibliography:

1. Plapp FV, Sinor LT, Rachel JM, et al. A solid phase antibody screen. Am J Clin Pathol 1984;82:719.721.
2. Sinor LT. Advances in solid-phase red cell adherence methods and transfusion serology. Transfusion Med Rev 1992;9:26-31.

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Rev 7/19

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