

IgG Sensitized Red Blood Cells

Cells

ALBAcyte®

For the control of the indirect and direct antiglobulin test

REF Z441U

- 3-5% Suspension
- Pooled Cells
- For Tube Techniques
- No U.S. Standard of Potency
- Discard if markedly hemolyzed
- Preservatives: chloramphenicol (0.349 g/L), neomycin sulfate (0.103 g/L)

CAUTION: THE ABSENCE OF ALL VIRUSES HAS NOT BEEN DETERMINED. THIS PRODUCT HAS COMPONENTS (DROPPER BULBS) CONTAINING DRY NATURAL RUBBER.

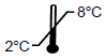
INTERPRETATION OF LABEL SYMBOLS



Batch code



Use by (YYYY-MM-DD)



Storage temperature limitation (2-8 °C)



In vitro diagnostic medical device



Consult instructions for use



Product code



Manufacturer



Rx only

INTENDED USE

These IgG Sensitized Red Blood Cells are for the control of the Indirect Antiglobulin Test (IAT) and Direct Antiglobulin Test (DAT).

SUMMARY AND EXPLANATION

ALBAcyte® IgG Sensitized Red Blood Cells are used to confirm the validity of negative antiglobulin tests by demonstrating the anti-IgG activity of the anti-human globulin (AHG) reagent used in the test.

When ALBAcyte® IgG Sensitized Red Blood Cells are added to a negative antiglobulin test the resultant agglutination indicates both the presence and the activity of the anti-human globulin.

PRINCIPLE OF THE PROCEDURE

The principle of the test is hemagglutination. AHG reacts with IgG coated red blood cells, leading to agglutination and verifies the negative result of the IAT and DAT.

REAGENT DESCRIPTION

These control red blood cells were prepared from at least 4 group O R₁r blood donors, sensitized using a monoclonal IgG antibody of anti-D specificity. The product is presented as a 3-5% suspension of washed red blood cells in Modified Alsever's Solution. The volume delivered by the reagent dropper bottle is approximately 40 µL.

PRECAUTIONS FOR USE AND DISPOSAL

The preservative solution has been specially formulated to preserve red cell integrity and contains the following components - trisodium citrate, citric acid, dextrose, inosine, neomycin sulfate (0.103 g/L) and chloramphenicol (0.349 g/L).

Chloramphenicol is classified as a carcinogen and neomycin sulfate is classified as an irritant.

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.

This product has components (dropper bulbs) containing dry natural rubber.

This reagent is for *in vitro* diagnostic use only.

STORAGE CONDITIONS

Store at 2-8 °C. Use as furnished, Do not dilute. Do not freeze. Do not use if obviously discolored or hemolyzed. Do not use beyond the notified expiry date.

TEST PROCEDURES

General Information

This reagent has been standardized for use by the technique described below and therefore its suitability for use in other techniques cannot be guaranteed.

Materials provided

- ALBAcyte® IgG Sensitized Red Blood Cells

Additional Material and Reagents Required

- Pipettes
- Centrifuge

RECOMMENDED TECHNIQUE

Control of antiglobulin tests

These control red blood cells have been standardized for use in controlling the tube antiglobulin test, described below, where 2 drops of AHG reagent are used. Their suitability for use in other techniques cannot be guaranteed. Users are advised to carefully confirm reagent suitability before using alternative techniques.

Tube Technique

1. Invert the vial several times to ensure thorough resuspension of the IgG Sensitized Red Blood Cells.
2. Add 1 drop of IgG Sensitized Red Blood Cells to each negative antiglobulin test.
3. Mix the contents of the test tube well and centrifuge. Suggested centrifugation: 900-1000g for 10-20 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen, yet allows easy resuspension of negative tests.
4. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.
5. Record results.

STABILITY OF REACTION

Test results should be read and interpreted immediately after centrifugation. Delays may cause dissociation of antigen-antibody complexes resulting in weak positive or false negative reactions.

QUALITY CONTROL

Quality control of AHG reagents is essential and should be confirmed by testing with known positive and negative red blood cells on the day of use and in accordance with local, state and federal regulations.

INTERPRETATION OF RESULTS

Agglutination: The AHG is reactive and therefore the IAT or DAT performed is valid.

No agglutination: The AHG is not reactive and therefore the IAT or DAT performed is not valid.

A positive result indicates that the negative reaction achieved in the antiglobulin test is valid whereas any test which does not show a positive reaction should be considered invalid and repeated.

PERFORMANCE LIMITATIONS

Not for use for the detection or identification of unexpected antibodies.

The reactivity of the product may decrease during the dating period and therefore should not be used after the expiration date. The rate at which the antigen reactivity is lost is partially dependent upon individual donor characteristics that are neither controlled nor predicted by the manufacturer. The recommended conditions of storage and use must be rigidly applied.

False positive or false negative results can occur due to contamination of test materials, improper reaction temperature, improper centrifugation, improper storage of materials, omission of test reagents and certain disease states.

SPECIFIC PERFORMANCE CHARACTERISTICS

These IgG Sensitized Red Blood Cells have been shown to have a positive direct antiglobulin test, indicating that human IgG is detectable on the cell surface.

Prior to release, each lot of ALBAcyte® IgG Sensitized Red Blood Cells are tested to ensure the product performance specification is achieved.

BIBLIOGRAPHY

Technical Manual. 16th ed. Bethesda, MD: American Association of Blood Banks, 2008.

Standards for Blood Banks and Transfusion Services. 26th ed. Bethesda, MD: American Association of Blood Banks, 2009.

For additional information or technical support, contact Product Technical Support at 1-888-228-1990.

DATE OF ISSUE

2025-03



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