IgG Sensitized Red Blood Cells II

ALBAcyte®

For the control of the indirect and direct antiglobulin test

REF **Z443U**

- **FOR *IN VITRO* DIAGNOSTIC USE**
- **No U.S. Standard of Potency**
- **Do not freeze**
- **Do not use if obviously discolored or moderately to grossly hemolyzed**
- **3-5% Suspension**
- **Pooled Cells**
- **For Tube Techniques**

- **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 LABELING SYMBOLS

LOT	Batch code
	Use by (YYYY-MM-DD)
REF	Product code
2°C 8°C	Storage temperature limitation (2-8 °C)
IVD	*In vitro* diagnostic medical device
www.quotientbd.com	Consult instructions for use
	Manufacturer
Rx	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 II 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 II 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 TEST

The principle of the test is hemagglutination. The Anti-IgG component of AHG reacts with IgG coated red blood cells, leading to agglutination which:

1. Verifies the presence of active Anti-IgG in the antiglobulin test, thereby acting as a positive control, and a negative control for AHG reagents lacking Anti-IgG.
2. Confirms that neutralization of the Anti-IgG has not occurred.

REAGENT DESCRIPTION

These control red blood cells were prepared from at least four group O R_1r 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 bottle dropper is approximately 40 µL.

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).

STORAGE

Store at 2-8 °C.

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only.
Do not freeze.
Do not use if evidence of contamination is present.
No preparation of the reagent is required.
Do not transfer any of the vial contents to another container as this could result in spillage or contamination.
Do not dilute.
Product should be used by qualified personnel.
Do not use beyond the expiration date.
Do not use if obviously discolored or moderately to grossly hemolyzed.
Replace vial caps when not in use.
The format of the expiration date is expressed as YYYY-MM-DD (Year-Month-Day).

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. APPROPRIATE CARE SHOULD BE TAKEN IN THE USE AND DISPOSAL OF THIS PRODUCT.

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

MATERIALS

Materials provided

- ALBAcyte® IgG Sensitized Red Blood Cells II

Materials required and not provided

- Pipettes
- Centrifuge

PROCEDURES

These control red blood cells have been validated 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 has not been validated.

When using supplemental testing equipment (i.e. centrifuge), follow the procedures that are contained in the operator's manual provided by the device manufacturer.

Tube Technique

1. Invert the vial several times to ensure thorough resuspension of the IgG Sensitized Red Blood Cells II.
2. Add 1 drop of IgG Sensitized Red Blood Cells II to each negative antiglobulin test or directly to two drops of anti-human globulin when confirming reactivity of these reagents.
3. Mix the contents of the test tube well and centrifuge.
   NOTE: Suggested centrifugation: 900-1000 g (approx. 3400 rpm) for 10 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.

Refer to Limitations section for additional guidance on the use of this product

STABILITY OF REACTION

Test results should be read, interpreted and recorded 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, federal and accreditation requirements.

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.

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.

Unexpected negative results may be observed as a result of inadequate washing.

SPECIFIC PERFORMANCE CHARACTERISTICS

These IgG Sensitized Red Blood Cells II 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 II are tested to ensure the product performance specification is achieved.

BIBLIOGRAPHY

1. Roback JD, Grossman BJ, Harris T, *et al*: AABB Technical Manual, 18th ed. AABB, 2014
2. AABB Standards Program Committee: Standards for Blood Banks and Transfusion Services, 29th ed. AABB, 2014
3. Reid ME, Lomas-Francis C, Olsson ML: The Blood Group Antigen FactsBook, ed 3. Academic Press, 2012

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