C3 Coated Red Blood Cells

ALBAcyte®

For control of the indirect and direct antiglobulin test

REF **Z482U**

- **2-4% Suspension**
- **Discard if markedly hemolyzed**
- **Preservatives:**
  - **Trimethoprim (0.032 g/L)**
  - **Sulfamethoxazole (0.16 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)
2°C 8°C	Storage temperature limitation (2 - 8 °C)
IVD	*In vitro* diagnostic medical device
REF	Product code
www.quotientbd.com	Consult instructions for use
	Manufacturer

INTENDED USE

ALBAcyte® C3 Coated Red Blood Cells is used as a control to confirm the presence or absence of Anti-C3 reactivity of Anti-Human Globulin Reagent and as indicator cells in AHG testing.

SUMMARY AND EXPLANATION

The antiglobulin test is a highly sensitive method for the detection of human globulin bound to red blood cells. Positive reactivity may be due to sensitization by immunoglobulin, complement or both. Depending on the specificity of the AHG utilized, reactivity may vary. It is important to use complement coated red cells as a control to confirm the presence or absence of active Anti-C3 in the test.

PRINCIPLE OF THE TEST

The principle of the test is hemagglutination. The Anti-C3 component of AHG reacts with C3 coated red blood cells, leading to agglutination which:

1. Verifies the presence of active Anti-C3 in the antiglobulin test, thereby acting as a positive control, and a negative control for AHG reagents lacking Anti-C3.
2. Confirms that neutralization of the Anti-C3 has not occurred.

REAGENT DESCRIPTION

ALBAcyte® C3 Coated Red Blood Cells are prepared from whole blood donations and are sensitized with C3b (C3c/C3d). The product is presented as a 2-4% suspension of washed red blood cells in a red cell preservative solution.

The volume delivered by the reagent dropper bottle is approximately 40 µL. Bearing this in mind, care should be taken to ensure that appropriate serum: cell ratios are maintained in all test systems.

STORAGE CONDITIONS

The reagent should be stored at 2 - 8°C. Do not freeze. Do not use beyond the expiration date stated on the product label.

PRECAUTIONS FOR USE AND DISPOSAL

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 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.

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

Do not use if obviously discolored or hemolyzed.

MATERIALS

Materials Provided

- ALBAcyte® C3 Coated Red Blood Cells

Materials required but not provided

- Test tubes (12 x 75 mm or 10 x 75 mm)
- Centrifuge
- Anti-Human Globulin (AHG)
- Timer
- Pipettes
- Optical Aid

TEST PROCEDURES

General Information

This reagent has been standardized for use by the techniques described below where the use of two drops of AHG reagent is directed. Therefore, its suitability for use in other techniques cannot be guaranteed.

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

Testing should be performed in accordance with local, state and federal regulations.

RECOMMENDED TECHNIQUES

Tube Technique – QC of AHG Reagents

1. Invert the vial several times to ensure thorough re-suspension of the ALBAcyte® C3 Coated Red Blood Cells.
2. Add 1 drop of ALBAcyte® C3 Coated Red Blood Cells to each tube, as required.
3. Add 2 drops of AHG reagent as per the manufacturer's instructions for use. Steps 2 and 3 may be performed in either order.
4. Mix the contents of the test tube and centrifuge.
5. 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 positive tests yet allows easy re-suspension of negative tests.
   NOTE: Weak or negative complement/anti-complement reactions may be enhanced by an additional short incubation (5 minutes) at room temperature. The AHG manufacturer's instructions for use should be followed.
6. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination, following the manufacturer's instructions for use.

Tube Technique – Use of C3 Coated Cells as Indicator Cells for Control of AHG Testing

1. Invert the vial several times to ensure thorough re-suspension of the ALBAcyte® C3 Coated Red Blood Cells.
2. Add 1 drop of ALBAcyte® C3 Coated Red Blood Cells to each negative antiglobulin test performed using AHG containing anti-C3b, -C3d.
3. Mix the contents of the test tube and centrifuge.
4. Suggested centrifugation: 900-1000 g (approx. 3400 rpm) for 10 - 20 seconds or a time and speed appropriate for the centrifuge used that

produces the strongest reaction of positive tests, yet allows easy re-suspension of negative tests.
NOTE: Weak or negative complement/anti-complement reactions may be enhanced by an additional short incubation (5 minutes) at room temperature. The AHG manufacturer's instructions for use should be followed.

5. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.

STABILITY OF REACTION

Test results should be read, interpreted and recorded immediately after centrifugation. Delays may cause dissociation of complement/anti-complement complexes resulting in weak positive or false negative reactions.

INTERPRETATION OF RESULTS

Agglutination: Active anti-C3 is present in the test.

No agglutination: Active anti-C3 is not present or has been neutralized. Therefore, the antiglobulin test performed is not valid, or complete, or partial neutralization of the anti-C3 component of the AHG has occurred.

When checking for neutralization, any test which does not show a positive reaction should be considered invalid and repeated.

QUALITY CONTROL

Quality control of reagents is essential and should be performed on the day of use in accordance with local, state and federal regulations.

This is a quality control reagent and its' satisfactory performance when used by the recommended techniques represents an adequate level of control.

PERFORMANCE LIMITATIONS

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

The reactivity of the product may decrease during storage and therefore should not be used after the expiration date.

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

ALBAcyte® C3 Coated Red Blood Cells are coated with C3b (C3c/C3d) and should react with AHG reagents containing anti-C3b or anti-C3d. However, some reagents containing anti-C3d may give weaker or even no agglutination if the epitope against which they are directed is not exposed on C3b coated red cells. Users should ensure that the anti-C3 reagent they use will react with C3b as well as C3d coated red blood cells.

SPECIFIC PERFORMANCE CHARACTERISTICS

ALBAcyte® C3 Coated Red Blood Cells have been shown to have a positive direct antiglobulin test with monospecific anti-C3 and polyspecific AHG reagents containing anti-C3, and a negative antiglobulin test with monospecific anti-IgG. This demonstrates that only C3 is detectable on the cell surface.

Prior to release, each lot of ALBAcyte® C3 Coated Red Blood Cells is tested to ensure the product performance specification is achieved.

BIBLIOGRAPHY

1. FDA Draft Docket, Docket No: 84S-0182, March 1992, "Recommended Methods for Evaluation Potency, Specificity, and Reactivity of Anti-Human Globulin".

2. FDA 42 CFR 493.1256 Standard: Control Procedures.

3. AABB Standards Program Committee. Standards for Blood Banks and Transfusion Services. 29th ed. 2014.

4. Roback JD, Grossman BJ, Harris T, *et al* AABB Technical Manual. 18th ed. AABB 2014.

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