REAGENT RED BLOOD CELLS

FOR USE IN IDENTIFICATION OF UNEXPECTED ANTIBODIES

ALBByc®

Antibody Identification (16-Cell)

For Tube Techniques

REF 2473U

- 2.3% Suspension
- 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 VACCINES HAS NOT BEEN DETERMINED. THIS PRODUCT HAS COMPONENTS (DROPPER BULBS) CONTAINING DRY NATURAL RUBBER.

INTERPRETATION OF LABEL SYMBOLS

LOT

Use by (YYYY-MM-DD)

Storage temperature limitation (2-8 °C)

In vitro diagnostic medical device

Product code

Consult instructions for use

Manufacturer

INTENDED PURPOSE

These reagent red blood cells are intended for the identification of unexpected red cell antibodies in blood samples.

SUMMARY

When antibody screening tests indicate the presence of an unexpected antibody in a serum or plasma sample and the tests performed at that time fail to permit resolution of antibody specificity, it is essential to further investigate the findings by testing with an antibody identification reagent red cell panel. Blood group antibodies are not of equal clinical importance and early identification of reaction characteristics and specificity is of considerable value in the provision of appropriate anti-natal care and selection of suitable blood for transfusion.

PRINCIPLE OF THE TEST

Antigens on reagent red blood cells will react with the corresponding antibodies present in the human serum or plasma. This will cause agglutination (clumping of red blood cells), either directly or after the addition of Anti-Human Globulin (AHG) reagents.

REAGENT DESCRIPTION

These reagent red blood cells were prepared from blood donated by sixteen Group O donors and are available as 2 mm glass test tubes containing dry natural rubber. This reagent is for in vitro diagnostic use only.

SPECIMEN COLLECTION AND PREPARATION

Specimens should be collected by a standard collection technique. The specimen should be tested as soon as possible after collection. If testing is delayed, the specimen should be stored at refrigerated temperatures. Blood specimens exhibiting contamination should not be used. Clotted samples or those collected in EDTA should be tested within fourteen days from collection. Donor blood may be tested up to the expiry date of the donation.

TEST PROCEDURE

Techniques used in the determination of antibody specificity should reflect the compatibility testing protocol used and should include those techniques by which the antibody was initially detected. Autologous controls should be incorporated where appropriate.

The procedure detailed below is intended as a guideline and it may be necessary to modify the procedure to comply with laboratory standard operating procedures.

If potentiation is used, the instructions for use supplied with the potentizing reagent should be followed.

This reagent has been standardized for use by tube techniques. Users are advised to carefully confirm reagent suitability before using alternative techniques.

Materials provided:

- ALBByc® Antibody Identification Cells (16-Cell)

Additional materials required:

- Isotonic saline
- Potentiator (optional)
- Polyspecific Anti-Human Globulin/Monspec® Anti-Human IgG
- IgG sensitized red blood cells
- 10 x 75 mm or 12 x 75 mm glass test tubes
- Pipettes
- Centrifuge
- Heating block/waterbath
- Timer
- Agglutination Viewer/Optical Aid

Tube Technique

Immediate Spin

1. Label 1 test tube for each of the ALBByc® reagent red blood cells to be used to test the blood sample.
2. Add 2 drops of serum or plasma to each test tube.
3. Add 1 drop of reagent red blood cell suspension to the appropriately labeled test tube. Steps #2 and #3 may be performed in any order.
4. Mix the contents of the test tube and centrifuge.
5. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe microscopically for agglutination.

Incubation

If a potentiator is used, refer to the reagents instructions for use.

1. Incubate at 37 °C for 30 to 60 minutes or as recommended for the potentiator being used.
2. Mix the contents of the test tube and centrifuge.
3. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe microscopically for agglutination.

Indirect Antiglobulin Test

Complete the indirect antiglobulin test by the procedure described below, or according to the instructions of the manufacturer of the Anti-Human Globulin (AHG) reagents.

1. Wash the test at least 3 times with a large excess of isotonic saline. Use a pipette tip, or 1 ml, of saline per 12 (or 10) x 75 mm glass tube.
2. Centrifuge at 1000 x g for 3 minutes.
3. Remove the supernatant.
4. Add 1 drop of IgG sensitized reagent red cells to each tube and incubate for 1 hour at room temperature.
5. Add 1 drop of 5% human serum to each tube.
6. Mix the contents of the test tube and centrifuge.
7. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe microscopically for agglutination.

Add 1 drop of IgG sensitized reagent red cells to each negative Anti-Human Globulin test.

8. Mix the contents of the test tube well and centrifuge.
9. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe microscopically for agglutination.

The use of weak IgG sensitized red blood cells is essential to confirm the activity of an AHG reagent in negative tests.

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.

INTERPRETATION OF RESULTS

Agglutination = positive test result
No agglutination = negative test result

QUALITY CONTROL

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

PERFORMANCE LIMITATIONS

- The reaction characteristics of blood group antibodies vary according to their specificity and therefore no single technique will detect all blood group antibodies.
- Although these reagent red blood cells have been selected to permit differentiation of more than one antibody in the same serum, sera containing multiple antibodies may require additional testing with selected red blood cells.
- Negative reactions may be obtained if the patient sample contains antibodies at a concentration too low to be detected by the test method.
- The reactivity of the product may decrease during the dating period and, therefore, should not be used after the expiration date.

SPECIFIC PERFORMANCE CHARACTERISTICS

- The reagent red blood cells have been shown to have a negative direct antiglobulin test, indicating that no human IgG or C3 complement components are detectable on the cell surface.
- Prior to release, each lot of ALBByc® Antibody Identification (16-Cell) is tested by FDA recommended methods to confirm the presence or absence of the appropriate antibodies.
- No U.S. standard of potency.

BIBLIOGRAPHY


DATE OF ISSUE

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US Distributor

Quotient

301 South State Street

S-204

Newtown

PA 18940

USA

Customer Service Tel: 1-888-228-1901

Product Technical Support Tel: 1-888-228-1900

Customer Service Fax: 1-888-694-5208

E-Mail:  quotient.service@quotient.com

Web: www.quotient.com

Alba Bioscience Limited

Edina’s Glen Road

Edinburgh EH7 7QT

Scotland, UK

U.S. License 1807

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