

REAGENT RED BLOOD CELLS

For ABO Reverse Grouping

ALBACYTE® A1 Cells REF Z401U
ALBACYTE® A2 Cells REF Z406U
ALBACYTE® B Cells REF Z411U
ALBACYTE® Orr Cells REF Z421U

2-3% Suspension

For Tube Techniques

No U.S. standard of potency

Discard if markedly hemolyzed

Preservatives: chloramphenicol (0.349g/L)
 neomycin sulfate (0.103g/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



Product code



Consult instructions for use



Manufacturer

INTENDED PURPOSE

These reagent red blood cells are for the ABO reverse grouping of patient or donor serum/plasma.

SUMMARY

ABO blood grouping is generally performed by testing red cells with anti-A and anti-B (many laboratories also test with anti-A,B). Confirmation of the red cell group can be provided by simultaneously performing a reverse or serum group i.e., testing the donor or recipient's serum/plasma with reagent red blood cells of groups A₁ and B to detect anti-A and anti-B. Group A₁ reagent red blood cells can be used to identify anti-A in the serum of group A people. Group O cells can be used to identify agglutination due to non-ABO agglutinins.

PRINCIPLE OF THE TEST

When mixed with human serum/plasma, group A₁, A₂ and B reagent red blood cells will be agglutinated (clumping of red blood cells) if the corresponding antibody is present. Agglutination of group O reagent red blood cells shows the presence of a cold-reactive antibody other than anti-A and anti-B. This can indicate that the reactions with group A and B reagent red blood cells may not be due to the presence of anti-A or anti-B.

REAGENT DESCRIPTION

These reagent red blood cells are presented as a 2-3% suspension of washed red blood cells (pooled red blood cells for groups A₁ and B) in Modified Alsever's Solution. The RBC phenotype of the group A₁, A₂, B and O reagent red blood cells is confirmed by serological methods. The product contains the following components - trisodium citrate, citric acid, dextrose inosine, and the preservatives, neomycin sulfate (0.103g/L) and chloramphenicol (0.349g/L). The volume delivered by the reagent dropper bottle is approximately 40µL. Bearing this in mind, care should be taken to ensure that appropriate serum: cell ratios are maintained in all test systems.

PRECAUTIONS

Store at 2°C - 8°C.

Do not freeze.

Do not use if obviously discolored or hemolyzed.

Do not use beyond the notified expiry date.

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.

This product has components (dropper bulbs) containing dry natural rubber. This reagent is for *in vitro* diagnostic use only.

SPECIMEN COLLECTION AND PREPARATION

Specimens should be collected by aseptic technique with or without an anticoagulant. The specimen should be tested as soon as possible after collection. If testing is delayed, EDTA and diluted specimens should be stored at 2°C - 8°C. Stored diluted or EDTA samples can be tested, however, antibody reactivity may decrease over time. Blood specimens exhibiting gross hemolysis or contamination should not be used.

TEST PROCEDURE

Materials provided

- ALBACYTE® reagent red blood cells

Additional materials required

- Isotonic saline
- 10 x 75mm or 12 x 75mm glass test tubes
- Pipettes
- Centrifuge
- Timer
- Agglutination viewer

Tube Technique

- Label 1 test tube for each of the ALBACYTE® reagent red blood cells to be tested.
- Add 2 drops of serum or plasma to each test tube.
- Add 1 drop of reagent red blood cell suspension to the appropriately labelled test tube.
- Mix the contents of the test tube well and centrifuge.*
- Suggested centrifugation: 1000g for 10 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive red blood cells, yet allows easy resuspension of antigen-negative red blood cells.
- After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.
- * Incubation for 5-45 minutes at room temperature may be necessary to detect weakly reactive ABO antibodies.

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

The expected reaction patterns for serum grouping are shown below.

Blood Group	Reagent Red Blood Cells			
	A ₁	A ₂	B	O
A ₁	0	0	+	0
A ₂	+	0	+	0
A ₂ with anti-A ₁	+	0	+	0
B	+	+	0	0
O	+	+	+	0
A,B	0	0	0	0
A,B with anti-A ₁	+	0	0	0

QUALITY CONTROL

Quality control of reagents is essential and should be performed on the day of use and in accordance with local, state and federal regulations. For ABO reagent red blood cells, appropriate ABO antibodies should be used.

PERFORMANCE LIMITATIONS

The presence of unexpected antibodies in the serum/plasma of a patient/donor may cause unexpected agglutination of these reagent red blood cells.

ALBACYTE® group O reagent red blood cells **do not meet the FDA requirements** for reagent red blood cells intended for antibody screening of unexpected antibodies.

Negative reactions may be obtained with one or more reagent red blood cells if the patient sample contains antibodies at a concentration too low to be detected by the test method.

For samples showing discrepant results, the patient's serum/plasma should be retested with their own red blood cells (autotest) and with group O reagent red blood cells at room temperature.

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 (e.g. agglutinability) is lost is partially dependent upon individual donor characteristics that are neither controlled nor predicted by the manufacturer.

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

A₁ and B pooled red blood cells are not recommended for pre-transfusion tests performed in lieu of a major crossmatch, to detect unexpected antibodies in patient's samples.

ALBACYTE® A₂ cells have been characterized using the Anti-A₁ lectin *Dalichos biflorus*. This lectin in its undiluted form has Anti-A specificity and requires appropriate dilution to react directly with A₁ and A₁B red blood cells yet fail to react with A₂ and A₂B red blood cells. At optimal dilution, Anti-A₁ lectin would be expected to react 2⁺-4⁺ with A₁ and A₁B red blood cells. It should be noted that some A₂ and A₂B cells may react weakly with Anti-A₁ if incubated too long. If ALBACYTE® A₂ cells are used as a negative control for Anti-A₁ lectin, strict adherence to the package insert is necessary to avoid extended incubation which may cause unexpected weak reactivity.

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.

SERUM GROUPING: each lot of ALBACYTE® Reagent Red Blood Cells for ABO SERUM GROUPING are tested by FDA recommended methods to confirm specificity.
 No U.S. standard of potency.

BIBLIOGRAPHY

- Technical Manual, 16th ed, Bethesda, MD: American Association of Blood Banks, 2008.
- Standards for Blood Banks and Transfusion Services, 27th ed, Bethesda, MD: American Association of Blood Banks, 2011.

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