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

LOT — Batch code

Use by (YYYY-MM-DD)

8°C / 2°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 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 A_1 and B to detect anti-A and anti-B. Group A_2 reagent red blood cells can be used to identify anti-A_1 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 A_1, A_2 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 A_1 and B) in Modified Alsever's Solution. The Rh phenotype of the group A_1, A_2, B and O reagent red blood cells is ccdee. The preservative solution has been specially formulated to preserve red cell integrity and antigenicity and 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 clotted specimens should be stored at 2°C - 8°C. Stored clotted 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.

	Reagent Red Blood Cells			
Blood Group	A_1	A_2	B	O
A_1	0	0	+	0
A_2	0	0	+	0
A_2 with anti-A_1	+	0	+	0
B	+	+	0	0
O	+	+	+	0
A_1B	0	0	0	0
A_2B 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.

A_1 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 patients' samples.

ALBAcyte® A_2 cells have been characterized using the Anti-A_1 lectin *Dolichos biflorus*. This lectin in its undiluted form has Anti-A specificity and requires appropriate dilution to react directly with A_1 and A_1B red blood cells yet fail to react with A_2 and A_2B red blood cells. At optimal dilution, Anti-A_1 lectin would be expected to react 2+-4+ with A_1 and A_1B red blood cells. It should be noted that some A_2 and A_2B cells may react weakly with Anti-A_1 if incubated too long. If ALBAcyte® A_2 cells are used as a negative control for Anti-A_1 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.
Prior to release, 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

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

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