A.
Mix the contents of the test tube well and centrifuge.

REAGENT RED BLOOD CELLS
For ABO Reverse Grouping
ALBAcyte® A1 Cells
ALBAcyte® A2 Cells
ALBAcyte® B Cells
ALBAcyte® Orr Cells
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

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, B, and O) in Modified Alsever’s Solution. The Rh phenotype of the group A-, A+, 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 (0.103%) and chloramphenicol (0.349%). 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 visibly 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.

SPCIFICATION 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 citrated specimens should be stored at 2°C - 8°C. Stored citrated 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
Advisal 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: 1000 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 dissolve 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:

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.

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 discordant results, the patient’s serum/plasma should be tested with their own red blood cells (auto) and with group O reagent red blood cells at room temperature.

The reactivity of the patient’s red blood cells may decrease during the dialysis 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 patient characteristics that are neither controlled nor predictable by the manufacturer.

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

A, 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.

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

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