REAGENT RED BLOOD CELLS
FOR DETECTION OF UNEXPECTED ANTIBODIES
ALBAcyte®

Expanded Rh Negative
Antibody Screen
For Tube Techniques

CAUTION: THE ABSENCE OF ALL VIRUSES HAS NOT BEEN DETERMINED. THIS PRODUCT CONTAINS DROPPER BULBS CONTAINING DRY NATURAL RUBBER.

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

SUMMARY
Screening blood samples for unexpected blood group antibodies is an essential component of compatibility, anti-red cell and donor testing protocols. Requirements for antibody screening of patient and donor samples and appropriate implementation of modern blood bank practices demands the use of a sensitive antibody screening procedure. In this respect the quality of reagent red blood cells is of paramount importance.

For antibody screening of patient samples, reagent red blood cells should not be pooled and should display homogenous expression of a range of blood group antigens.

PRINCIPLE OF THE TEST
Antigens on reagent red blood cells will react with the corresponding antibodies present in the human serum or plasma. This causes 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 four Group O donors and are available as 2.5% suspensions of washed red blood cells in a preservative solution.

The preservative solution has been specially formulated to preserve red cell integrity and antigenicity and contains the following components – trisodium citrate, citric acid, dextrose, and the preservatives, neomycin sulfate and chloramphenicol.

The preservative RH preparations of these reagent red blood cells are Rr, R\(r^+\), and R\(r^+\)/R\(r^+\).

The full antigenic profile of the individual donations is shown on the enclosed antigen profile. One or more of these red blood cells may have been held in frozen storage until required.

The volume delivered by the disposable dropper bulb is approximately 40 µL; bearing this in mind, care should be taken to ensure that appropriate serum red cell ratios are maintained in all test systems.

PRECAUTIONS
Store at 2-8 °C.
Do not freeze.
Do not use if discolored or hemolysed.
Do not use beyond the expiration 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 TESTED IN ACCORDANCE WITH CURRENT FDA REQUIRED TESTS.

SPECIMEN COLLECTION AND PREPARATION
Specimens should be collected by a standard collection technique with or without an anticoagulant. 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 coagulation should not be used. Cord blood samples or those collected in EDTA should be tested within fourteen days from collection. Donor blood may be tested until the expiry date of the donation.

TEST PROCEDURE
Test protocols for antibody screening should reflect the compatibility testing requirements for blood transfusion.

Autoagglutination 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 potentiators are used, the instructions for use supplied with the potentiator being used should be followed. The reagent has been standardized for use by tube techniques. Users are advised to carefully confirm reagent suitability before using alternative techniques.

Materials provided
- ALBAcyte® Expanded Rh Negative Antibody Screen
- Potentiator (optional)
- Polyospecific Anti-Human Globulin in a Monospecific 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
- Agglutination viewer/Optical Aid

Tube Technique
ImmediateSpin
1. Label 1 test tube for each of the ALBAcyte® reagent red blood cells to be tested.
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 labelled test tube. Steps #2 and #3 may be performed in any order.
4. Mix the contents of the test tube well and centrifuge.
5. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.

Indirect Antiglobulin Test
Complete the indirect antiglobulin test by the procedure described below, or as modified to meet the specific requirements of the Anti-Human Globulin reagent.

1. Wash the test at least 3 times with a large excess of isotonic saline (e.g. 4 mL of saline per 12 or 10 x 75 mm glass tube). Place the washed cells into a test tube.
2. ADD 0.1 mL of an appropriate saline to the tube to cover the test cells. Add 0.05 mL of an appropriate saline to the anti-human globulin reagent.

3. Mix the contents of the tube and centrifuge.
4. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.

The use of an indirect antiglobulin test is essential to confirm the activity of an Anti-Human Globulin reagent in negative tests.

1. Add 2 drops of IgG sensitized reagent red blood cells to each negative Anti-Human Globulin test.
2. Mix the contents of the test tube well and centrifuge.
3. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.

If the test cell does not show a positive reaction, it should be considered invalid and repeated.

SPECIFIC PERFORMANCE CHARACTERISTICS
The reagent red cells have been shown to have a negative direct antiglobulin test, macroscopic for IgM or C3 complement components are detectable on the cell surface.

Performance limitations
The ALBAcyte® Expanded Rh Negative Antibody Screen is listed by FDA recommended methods to confirm specificity.

No US standard of potency.

BIBLIOGRAPHY


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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.

Antibodies may be detected if the patient sample contains antibodies at a concentration too low to be detected by the test the reagent has been standardized for use. 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 poorly characterized and is dependent on the storage characteristics that are neither controlled nor predicted by the manufacturer.

Due to dosage effects, weak antibodies may not be detected by reagent red blood cells showing heterozygous expression of specific antigens.

Antibodies specific for low incidence antigens not present on the test cells will not be detected.

In very rare cases HLA related antigens on the reagent red blood cells may cause unwanted positive reactions.

False positive or false negative results can occur due to contamination of test materials, improper reagent temperatures/improper storage of materials, omission of test reagents and improper handling of test systems in all test systems.

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