PRINCIPLE OF THE TEST
Antigens on reagent red blood cells will react with the corresponding antibodies present in 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 four Group O donors and are available as 2.3% 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, inosine and the preservatives: neomycin sulfate and chloramphenicol.

The preservative Rh genotypes of these reagent red blood cells are rr, Rr, rr and Rr/Rr. The full antigenic profile of the individual donators is shown on the enclosed antigen profile. One or more of these red cells may have been held in frozen storage until required.

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

PRECAUTIONS
Store at 2-8 °C. Do not freeze.
Do not use if obviously discolored or hemolyzed.
Do not use beyond expiry date.

CAUTION: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS MATERIAL. FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE WHEN TESTED IN ACCORDANCE WITH THE 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 a standard collection technique with or without an anticoagulant. The specimen should be tested as soon as possible after collection. If storage is indicated, the specimen should be stored at refrigerated temperatures. Blood specimens exhibiting contamination should not be used. Stained specimens 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.

Tube Technique
Immediate Sp 1.
Label 1 test tube for each of the ALBAcyte® reagent red blood cells to be used to test the blood sample.
2.
Add 2 drops of the AHG reagent test tube.
3.
Add 1 drop of reagent red blood cell suspension to the test tube. Mix the contents of the tube well and centrifuge. (This step #3 and the following step #4 are optional).
4.
After centrifugation, gently shake the tube to dislodge the cell column from the bottom and immediately observe macroscopically for agglutination.

Incubation
If a potential reagent is used, refer to the reagents instructions for use.
5.
Incubate at 37 °C 1-2°C for 30 to 60 minutes or as recommended for the potentiator being used.
6.
Mix the contents of the test tube well and centrifuge. (This step and the following step #8 are optional).
7.
After centrifugation, gently shake the tube to dislodge the cell column from the bottom and immediately observe macroscopically for agglutination.

Indirect Antibiotin Test
Complete the indirect antiglobulin test by the procedure described below, or according to the instructions of the manufacturer of the Anti-Human Globulin test.

Test results should be read and interpreted immediately after incubation.

1.
Wash the test at least 3 times with a large excess of isotonic saline (e.g. 4 ml saline per 12 x 75 mm glass tube).

NOTE: 1) Allow adequate spin time to sediment the red cells, and (ii) make sure that most of the residual saline is removed at the end of each wash.

2.
Add two drops of Anti-Human Globulin reagent to each test tube.
3.
Mix the contents of the test tube well and centrifuge.

After centrifugation, gently shake the tube to dislodge the cell column from the bottom and immediately observe macroscopically for agglutination.

The use of weak IgG sensitized red blood cells is essential to confirm the activity of an Anti-Human Globulin in reagent tests.

14.
Add 1 drop of IgG sensitized reagent red cells to each negative Anti-Human Globulin test.

15.
Mix the contents of the test tube well and centrifuge.

16.
After centrifugation, gently shake the tube to dislodge the cell column from the bottom and immediately observe macroscopically for agglutination.

17.
The test is considered invalid if a positive reaction should be considered invalid and repeated.

Suggested duration of centrifugation is approximately 3000 rpm for 45 seconds or a time and speed appropriate for the centrifuge used that will allow the antibodies to be suspended in the supernatant layer.

STABILITY OF REACTION
Tests should be read and interpreted immediately after centrifugation. Delays may cause dissociation of antigen-antibody complexes resulting in weak positive or false negative reactions.

STABILITY OF REACTION
Tests 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 appropriate regulations.

PERFORMANCE LIMITATIONS
• The reaction characteristics of blood group antibody vary according to the test method and therefore no single technique will detect all blood group antibodies.

• Neutrophil 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. 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.

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

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

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

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

SPECIAL PERFOMANCE CHARACTERISTICS
The reagent red blood cells have been shown to have a negative direct antiglobulin test, indicating that no human IgG or C3 component contaminants are detected in the reagent red blood cells. Prior to release, each lot of ALBAcyte® Expanded Rh Negative Antibody Screen is tested by FDA recommended methods to confirm specificity.

No U.S. standard of potency.

BIBLIOGRAPHY

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CAUTION: THE ABSENCE OF ALL VIRUSES HAS NOT BEEN DETERMINED FOR THIS PRODUCT. IT CONTAINS 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 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 procedure for compatibility, allogeneic and donor testing protocols. Requirements for antibody screening of patient and donor samples differ and implementation of modern blood bank practices demands the use of a sensitive antibody screening procedure. In this respect the quality of reagent red cells is of paramount importance.

 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.