REAGENT RED BLOOD CELLS
FOR DETECTION OF UNEXPECTED ANTIBODIES
ALBAcyte®
Antibody Screen (2-Cell)
For Tube Techniques
REF 2545U
- 2-3% Suspension
- No U.S. standard of potency
- Discard if markedly hemolyzed
- Preservatives:
  o Chloramphenicol (0.349 g/l)
  o Neomycin sulfate (0.103 g/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

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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 two 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, disodium and the preservatives, chloramphenicol and chlorohexidine. The preservative rh genotypes of these reagent red blood cells are R,P, and R,F. The full antigenic profile of the individual donations is shown on the enclosed antigen profiles. One or more of these reagent red blood 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 the notified expiry date.

CAUTION: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE WHEN TESTED IN ACCORDANCE WITH THE RECOMMENDED 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 testing is delayed, the specimen should be stored at refrigerated temperatures. Blood specimens exhibiting contamination should not be used.unted samples or those collected in EDTA should be tested within fourteen days from collection. Donor blood may be tested up to the expiry date of the donation.

TEST PROCEDURE
Test protocols for antibody screening should reflect the compatibility testing protocol.
Antibody controls should be included 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 potentiating reagent should be followed.

This reagent has been standardized for use by tube techniques. Users are advised to carefully confirm reagent suitability before using alternative techniques.

Materials provided
- ALBAcyte® Antibody Screen (2-Cell)

Additional materials required
- Autoanalyzer
- Potentiator (optional)
- Polyvalent Anti-Human Globulin/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
- Timer
- Agglutination viewer/Optical Aid

Tube Technique
Immediate Split
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 Anti-Human Globulin (AHG) to each test tube.
3. Add 1 drop of reagent red blood cell suspension to the appropriately labeled test tube.
4. Mix the contents of the test tube well and centrifuge*. 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.

Incubation
If a potentiator is used, refer to the reagents instructions for use.
Incubate at 37 °C ± 1 °C for 30 to 60 minutes or as recommended for the potentiator being used.

Add 2 drops of Anti-Human Globulin to each tube. Mix the contents of the test tube well and centrifuge*.
13. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.

Note: 038; (i) allow adequate spin time to sediment the red cells, add 1 drop of IgG sensitized reagent red cells to each negative test result.
14. Add two drops of Anti-Human Globulin reagent to each tube. Mix the contents of the test tube well and centrifuge*.
15. After centrifugation, gently shake the tube to dislodge the cell button 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 reagent in negative tests.

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

17. Any test which does not show a positive reaction should be considered invalid and repeated.

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

QUALITY CONTROL
Quality control of reagents is essential and should be performed in accordance with local or national regulatory standards.

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.

Negative reactions may be obtained if the patient sample contains antibodies at a concentration too low to be detected by the test method.

SUMMARY
Screening blood samples for unexpected blood group antibodies is an essential component of compatibility testing and donor selection testing protocols. Requirements for antibody screening of patient and donor samples differ according to blood bank practices. The 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 homozygous expression of a range of blood group antigens.

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 detected in these reagents.

Prior to release, each lot of ALBAcyte® Antibody Screen (2-Cell) is direct antigen tested by FDA recommended methods to confirm the presence or absence of the appropriate antigens.

TUBES
U.S. standard of potency.

BIBLIOGRAPHY

DATE OF ISSUE
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