REAGENT RED BLOOD CELLS
FOR DETECTION OF UNEXPECTED ANTIBODIES
ALBaCyte® Antibody Screening Cells
For Tube Techniques

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

**PRINCIPLE OF THE TEST**
Agglutination 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.

**REAGENT DESCRIPTION**
These reagent red blood cells were prepared from blood donated by three group O donors and are available as 2-3% suspensions of 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 - Triton X-100, citric acid, dextrose, and the preservatives, neomycin sulfate (0.103 g/L) and chloramphenicol (0.349 g/L). The presumptive Rh genotypes of these reagent red blood cells is R₃, R₃⁺, R₇, and M. The R₇ group may be C⁺ positive, i.e. R₃⁺. The full antigenic profile of the individual donors 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 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 heme-filled.
Do not use beyond the expiry date.

**SPECIMEN COLLECTION AND PREPARATION**
Specimens should be collected by a standard collection technique. The specimen should be tested as soon as possible after collection testing is delayed, the specimen should be stored at refrigerated temperatures. Blood specimen extraction should not be used. Cigarette samples, or those collected in EDTA, should be tested within fourteen days from donation. Donor blood may be tested until the expiry date of the donation.

**TEST PROCEDURE**
Test protocols for antibody screening should reflect the compatibility testing protocol. Anti-D controls should be incorporated in the test. The procedure described below is intended as a guideline and it may be necessary to modify the procedure to comply with laboratory standard operating procedures. If platelets are used, the instructions for use provided with the platelet 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 Screening Cells
- Additional materials required
  - Isotonic saline
  - Potassium citrate
  - Polyspecific Anti-Human Globulin / Monospecific Anti-Human IgG
  - IgG sensitized negative red blood cells
  - 10 x 75 mm or 12 x 75 mm glass test tube
  - Pipettes
  - Centrifuge
  - Heading block /waterbath
  - Timer
  - Optical Aid

**Tube Technique**
Immediate Spin
- 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 labeled test tube.
- Mix contents of the test tube well and centrifuge.*
- After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.

**Indirect Antiblood Test**
After reading the incubation tube test, complete the indirect antiglobulin test using the procedure described below, or according to the instructions of the manufacturer of the anti-human globulin reagent.
- Wash the test with at least 3 times with a large excess of isotonic saline (e.g., 3 x saline per 12 (10 x 75 mm glass tube). NOTE: (i) allow adequate spin time to sediment the red cells.
- Mix the contents of the test tube well with saline and keep at 8°C for 30 minutes to an hour. If the saline is removed at the end of each wash.
- Add two drops of anti-human globulin reagent to each tube.
- Mix the contents of the test tube well and centrifuge.*
- 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 AHG reagent in negative tests.

- Add 1 drop of reagent red blood cells to each negative anti-human globulin test.
- Mix contents of the test tube well and centrifuge.
- After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.

**STABILITY OF REACTION**
Test results should be read and interpreted immediately after centrifugation. Decays may cause dissociation of antigen-antibody complexes resulting in weak positive or false negative reactions. Due to dosage effects, weak antibodies may not be detected by reagent red blood cells showing heterogeneous expression of specific antigens.

**INTERPRETATION OF RESULTS**
Agglutination = positive test result
No agglutination = negative test result

**QUALITY CONTROL**
Quality control for reagents is essential and should be performed in accordance with local, state and federal regulations.

**PERFORMANCE LIMITATIONS**
The performance of the reagent red blood cells 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 serum contains antibodies at a concentration too low to be detected by the test method.

**SPECIFIC PERFORMANCE CHARACTERISTICS**
The reagent red blood cells have been shown to have a 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 Antibody Screening is tested to FDA recommended methods to confirm specificity.

**INTENDED USE**
This test is intended for use by tube techniques.

**CAUTION**
The absence of all viruses has not been determined. This product contains components (dropper bulbs) containing dry natural rubber.

**INTERPRETATION OF LABEL SYMBOLS**

**Lot code**  
Batch code  
Storage temperature limitation  
IVD  
In vitro diagnostic medical device  
Consult instructions for use  
Manufacturer  
Product Code  
Use by (YYYY-MM-DD)  
By (YYYY-MM-DD)

**SUMMARY**
Screwing blood samples for unexpected group antibodies is an essential component of compatibility, anti-natal and donor testing protocols. Requirements for antibody screening of patient and donor samples differ and it is acknowledged that implementation of modern blood group base 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 hemagglutination expression of a range of blood group antigens.

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**Induction**
If a potentiator is used, refer to the reagents instructions for use.
- Incubate at 37°C x 1 h or 30 to 60 minutes as recommended for the potentiator being used.
- Mix the contents of the test tube well and centrifuge.*
- After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.

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