**PRINCIPLE OF THE TEST**

Antigens on recombinant red blood cells will react with the corresponding antibodies present in human serum or plasma. This will cause agglutination (clumping) of the 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 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 (0.103 g/L) and chloramphenicol (0.349 g/L). The preservative effectively inactivates the reagent red blood cells is R1, R2, and R3. The R1 sample may be C-positive, i.e. R1. 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 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.

**SPECIMENT COLLECTION AND PREPARATION**

Specimens should be collected by a standard collection technique. The specimen should be allowed to stand at room temperature for at least 30 minutes before use. Clotted 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 procedures for antibody screening should reflect the compatibility testing protocol.

**Antibody 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 potentials are used, the instructions for use supplied with the reagent red blood cells should be followed. This reagent has been standardized for use by tube testing techniques. Users are advised to certify confirm reagent suitability before using alternative test procedures.

**Materials provided**

- ALBAcyte® Antibody Screening Cells
- Additional materials required
  - Isoosmolar saline
  - Potentiator (optional)
  - Polymeric Anti-Human Globulin / Monospecific Anti-Human IgG
  - IgG sensitized red blood cells
  - 10 x 75 mm or 12 x 75 mm glass test tubes
  - Pipette
  - Centrifuge
  - Heating block/waterbath
  - Timer
  - Optical Aid

**Tube Technique**

**Immediate Spin**

- **Label 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 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.**

**Incubation**

If a potentiation is used, refer to the reagents instructions for use.

- **Incubate at 37°C 1 to 2 hours or 30 to 60 minutes or 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.**

**Indirect Antiglobulin Test**

After reading the incubation tube test, complete the indirect antiglobulin test by the procedure described below, or according to the instructions of the manufacturer of the anti-human globulin reagent.

- **Wash the test at least 3 times with a large excess of isotonic saline (e.g. 4 L) of saline per 12 (or 10 x 75 mm glass tube).**
- **NOTE:** (i) allow adequate spin time to sediment the red cells.
- **After washing, remove the residual 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.**

**SPECIMENT COLLECTION AND PREPARATION**

The use of IgG sensitized red blood cells is essential to confirm the activity of an ABO reagent in negative tests.

- **Add 3 drops of each of 2 red cells to each negative anti-human globulin test.**
- **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.**

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

**Suggested centrifugation = 1000 RPM, 5 minutes or 10 seconds** and the speed appropriate for the centrifuge used that produces the strongest reaction in the test tube with anti-human globulin red blood cells, yet allows easy re-suspension of antigen-negative red blood cells.

**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 reagents is essential and should be performed in accordance with local, state and federal regulations.

**PERFORMANCE LIMITATIONS**

The intended use of the reagent is the detection of unexpected red blood cell antibodies in blood samples. The method is not designed to detect all low-incidence antibodies. 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 reaction temperature, improper storage of materials, omission of test reagents and certain disease states.

**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 Antibody Screening is tested by FDA recommended methods to confirm specificity. No U.S. standard of potency.

**BIBLIOGRAPHY**