








REAGENT RED BLOOD CELLS
FOR USE IN IDENTIFICATION OF UNEXPECTED ANTIBODIES
ALBAcyte®
Antibody Identification Cells
Antibody Identification Cells (papain-treated)
For Tube Techniques

- **2-3% Suspension**
- **No U.S. standard of potency**
- **Discard if markedly hemolyzed**
- **Preservatives:**
 - chloramphenicol (0.349 g/L)
 - 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 LABELING SYMBOLS

-  Batch code
-  Use by (YYYY-MM-DD)
-  Storage temperature limitation (2-8 °C)
-  *In vitro* diagnostic medical device
-  Consult instructions for use
-  Product code
-  Manufacturer

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

SUMMARY
 When antibody screening tests indicate the presence of an unexpected antibody in a serum or plasma sample and the tests performed at that time fail to permit resolution of antibody specificity, it is essential to further investigate the findings by testing with an antibody identification reagent red blood cell panel. Blood group antibodies are not of equal clinical importance and early identification of reaction characteristics and specificity is of considerable value in the provision of appropriate ante-natal care and selection of suitable blood for transfusion.

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.

REAGENT DESCRIPTION
 These reagent red blood cells were prepared from blood donated by ten Group O donors and are available as 2-3% suspensions of washed red blood cells in a preservative solution. Untreated red blood cells (Z471U), and papain treated red blood cells (Z472U). Papain treatment of cells destroys or depresses the antigens from MNS and Duffy systems and increases reactivity of antibodies directed against Rh, Kidd, Lewis and P1PK systems. The preservative solution has been specially formulated to preserve red blood 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). Although each panel has been specifically selected to permit maximal resolution of antibody specificity, the antigenic constitution of each batch will vary. Red blood cells which are considered to express a notably weak or strong P1 antigen will be denoted 'W' or 'S' in the accompanying antigenic profile sheet. 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.

SPECIMEN COLLECTION AND PREPARATION
 Specimens should be collected by a standard collection technique. 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. Extreme care should be taken if hemolyzed samples must be tested. 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
 Techniques used in the determination of antibody specificity should reflect the compatibility testing protocol used and should include those techniques by which the antibody was initially detected. Autologous 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 potentiating reagent should be followed. Testing performed using papain-treated cells should not include the use of a potentiator. 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 Identification Cells
 - ALBAcyte® Antibody Identification Cells (Papain-treated)

- Materials required but not provided**
- Isotonic saline
 - Potentiator (optional)
 - Polyspecific 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
 - Optical Aid

Tube Technique Immediate Spin

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 labeled test tube.
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.

Incubation (Z471U Native/Untreated cells)
 If a potentiator is used, refer to the reagents instructions for use.

1. Incubate at 37 °C±1 °C for 30 to 60 minutes or as recommended for the potentiator being used.
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.

Incubation (Z472U Papain treated cells)
 Testing performed using papain-treated cells should not include the use of a potentiator.

1. Standard recommended incubation times for papain-treated cell testing is 15 to 30 minutes at 37 °C±1 °C.
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.

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.

1. Wash the test at least 3 times with a large excess of isotonic saline (e.g. 4mL of saline per 12 (or 10) x 75 mm glass tube).
 NOTE:
 - (i) allow adequate spin time to sediment the red blood cells.
 - (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 tube.
3. Mix the contents of the test tube well and centrifuge.*
4. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.
5. The use of weak IgG sensitized red blood cells is essential to confirm the activity of an AHG reagent in negative tests.
6. Add 1 drop of IgG sensitized reagent red cells to each negative anti-human globulin test.
7. Mix the contents of the test tube well and centrifuge.*
8. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.
9. Any test which does not show a positive reaction should be considered invalid and repeated.

*Suggested centrifugation: 900-1000 g (approx. 3400 rpm) for 10 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive 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 of reagents is essential and should be performed in accordance with local, state and federal regulations.

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.
- Although these reagent red blood cells have been selected to permit differentiation of more than one antibody in the same serum, sera containing multiple antibodies may require additional testing with selected red blood cells.
- Negative 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 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 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 Identification are tested by FDA recommended methods to confirm specificity. No U.S. standard of potency.

BIBLIOGRAPHY

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2. Standards for Blood Banks and Transfusion Services. 28th ed. Bethesda, MD: American Association of Blood Banks, 2012.
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Z471U/Z472U/PI10

