REAGENT RED BLOOD CELLS
FOR USE IN IDENTIFICATION OF UNEXPECTED ANTIBODIES
ALBAcyte®
Antibody Identification (16-Cell)
For Tube Techniques
REF Z473U

- **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 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

Rx only

INTENDED PURPOSE
These 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 (AHG) reagents.

REAGENT DESCRIPTION
These reagent red blood cells were prepared from blood donated by sixteen 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 blood cell integrity and antigenicity and contains the following components – trisodium citrate, citric acid, dextrose, inosine and the preservatives neomycin sulfate and chloramphenicol.
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. 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.
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 (16-Cell)

Additional materials required
- 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
- Agglutination Viewer/Optical Aid

Tube Technique
Immediate Spin
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 serum or plasma to each test tube.
3. Add 1 drop of reagent red blood cell suspension to the appropriately labeled test tube. Steps #2 and #3 may be performed in any order.
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
If a potentiator is used, refer to the reagents instructions for use.
6. Incubate at 37 °C ± 1 °C for 30 to 60 minutes or as recommended for the potentiator being used.
7. Mix the contents of the test tube well and centrifuge*. (This step #7 and the following step #8 are optional).
8. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.

Indirect Antiglobulin 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.
9. Wash the test at least 3 times with a large excess of isotonic saline (e.g. 4 mL of saline per 12 (or 10) x 75 mm glass tube).
10. NOTE: (i) allow adequate spin time to sediment the red blood cells, and (ii) make sure that most of the residual saline is removed at the end of each wash.
11. Add two drops of Anti-Human Globulin reagent to each tube.
12. 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.

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

*Suggested centrifugation: 900-1000g (approximately 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® Antibody Identification (16-Cell) is tested by FDA recommended methods to confirm the presence or absence of the appropriate antigens.
No U.S. standard of potency.

BIBLIOGRAPHY
1. Technical Manual. 18th ed. Bethesda, MD: American Association of Blood Banks, 2014.
2. Standards for Blood Banks and Transfusion Services. 29th ed. Bethesda, MD: American Association of Blood Banks, 2014.

DATE OF ISSUE
2025-04


Alba Bioscience Limited
James Hamilton Way
Penicuik
EH26 0BF
UK

U.S. License 1807

Customer Service Tel: 1-888-284-1901
Product Technical Support Tel: 1-888-228-1990
Customer Service Fax: 1-888-694-5208
E-Mail: customer.serviceUS@alivedx.com
Web: www.alivedx.com/us

 Z473UPI/05

ALBA