REAGENT RED BLOOD CELLS
FOR USE IN IDENTIFICATION OF UNEXPECTED ANTIBODIES
ALB Acyte®
Antibody Identification Cells
REF Z471U
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)

INTERPRETATION OF LABELING SYMBOLS
Batch code
Use by (YYYY-MM-DD)
Storage temperature limitation (2-8 °C)
In vitro diagnostic medical device
www.quotientbd.com
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 usually necessary 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 selection of appropriate anti-rhelat 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 in 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 P1 PK systems. The preservative solution has been specially formulated to preserve red blood cell integrity and antigenicity and contains the following components - sodium citrate, dextrose, insulin, 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 character, 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 PREPARED WAS 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 collected as soon as possible after the patient arrives in the laboratory. If testing is delayed, the specimen should be stored at refrigerated temperatures. Extremes of temperature and hydration of samples exhibiting contamination should not be used. Extreme care should be taken if hemolyzed samples must be tested. Samples collected in EDTA should be tested within fourteen days from donation. Donor blood may be tested up to 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. Appropriate controls should be incorporated wherever 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 sera are tested with the reagent reagent system being used, it is necessary to determine if the test antibody is a polyvalent antibody. Testing performed using reagent red cells should not include the use of a reagent.

1. Weigh the required amount of red blood cells into a test tube.
2. Add 2 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 and immediately observe macroscopically for agglutination.

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 ALB Acyte® Reagent Red Blood Cells for Antibody Identification are tested by FDA recommended methods to confirm specificity.

The rate at which the antigen reactivity (e.g. agglutinability) is lost for the potentiator being used.

If a potentiator is used, the reagents instructions for use.

If an antibody is present in the serum/prasmas, it will agglutinate the appropriate labeled test tube.

The activity of an AHG reagent in negative tests.

Incubation rates are: 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.

PERFORMANCE LIMITATIONS
The reaction characteristics of group blood antibody groups 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.

Agglutination
No agglutination
Positive test result
Negative test result
QUALITY CONTROL
Quality control of reagents is essential and should be performed in accordance with local, state and federal regulations.

CAUTION: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS PREPARED WAS 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.

BIBLIOGRAPHY

Incubation (Z471U Native/Untreated cells)
If a potentiator is used, the reagents instructions for use.
1. Incubate at 37 °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 red blood 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.
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 red blood 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.
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 red blood 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.
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 red blood 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.
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 red blood 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.
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 red blood 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.
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 red blood 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.
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 red blood 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.
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.