QUOTIENT

ALBAcyte®
REAGENT RED CELLS
FOR ANTIBODY IDENTIFICATION

REF Z471 and Z472

CE
1434

ALBAcyte® Antibody Identification Cells
REF **Z471**

ALBAcyte® Antibody Identification Cells (Papain treated)
REF **Z472**

INTERPRETATION OF LABEL SYMBOLS

LOT	Batch code
	Use by (YYYY-MM-DD)
2°C – 8°C	Storage temperature limitation (2-8 °C)
IVD	*In vitro* diagnostic medical device
REF	Product code
www.quotientbd.com	Consult instructions for use
	Manufacturer

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

INTRODUCTION
When antibody screening tests indicate the presence of an irregular antibody in a serum 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 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.

REAGENT DESCRIPTION
These reagent red cells were prepared from blood donated by 10 Group O donors and are available as 2-3% suspensions of washed red cells, or papain treated red cells, in a preservative solution.

Papain treatment of cells destroys or depresses the antigens from MNS and Duffy systems and increases reactivity of antibodies directed against Rhesus, Kidd, Lewis and P systems.

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, neomycin sulphate (0.103g/l) and chloramphenicol (0.349g/l).

Although each panel has been specifically selected to permit maximal resolution of antibody specificity, the antigenic constitution of each batch will vary. Red cells which are considered to express a notably weak or strong P_1 antigen will be denoted 'W' or 'S' in the accompanying antigenic profile sheet. One or more of these red cells may have been held in frozen storage until required.

These reagent red cells may be used directly from the vial or may be washed and resuspended, before use, to approx. 1.5-2% in LISS. Reagent red cells treated in this way must be discarded within 24 hours of preparation. Transfer of these reagent red cells to another container is not recommended.

Furthermore, when the user changes the reagent in any way, eg the preparation of LISS red cell suspensions, the user is responsible for assuring the strength of red cell suspension, the quality of PBS or LISS used and the generation and storage of relevant documentation.

The volume delivered by these dropper bottles is approximately 40µl; bearing this in mind, care should be taken to ensure that appropriate serum: cell ratios are maintained in all test systems.

This reagent complies with the requirements of Directive 98/79/EC on *in vitro* Diagnostic Medical Devices and the recommendations contained in the Guidelines for Blood Transfusion Services in the United Kingdom.

STORAGE CONDITIONS
The reagent should be stored at 2°C - 8°C. Do not freeze. Do not use if obviously discoloured or haemolysed. Do not use beyond the notified expiry date.

PRECAUTIONS FOR USE AND DISPOSAL
Source material from which this product is derived was found non reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV.

No known test method can offer assurances that products derived from human blood will not transmit infectious disease, therefore appropriate care should be taken in the use and disposal of this product.

Chloramphenicol is classified as a carcinogen and neomycin sulphate is classified as an irritant.

This reagent is for *in vitro* professional use only.

SPECIMEN COLLECTION AND PREPARATION
Specimens should be collected by aseptic technique. The specimen should be tested as soon as possible after collection. If testing is delayed, the specimen should be stored at 2°C-8°C for a maximum of 48 hours. Blood specimens exhibiting gross haemolysis or contamination should not be used.

TEST PROCEDURES
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.

LISS test procedures offer the potential for increased test sensitivity with decreased incubation time and are therefore well suited to emergency and routine blood bank situations.
Glass tubes are recommended and autocontrols should be incorporated where appropriate.

Tests to determine antibody specificity are best performed with fresh serum to ensure adequate levels of complement and calcium ions are present for optimal reactivity.

This reagent has been standardised for use by tube techniques, therefore its suitability for use in other techniques cannot be guaranteed. Users are advised to carefully confirm reagent suitability before using alternative techniques.

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.

Some loss of antigenic expression may occur during the stated shelf life. Since this loss is partly determined by characteristics of individual blood donations or donors which cannot be predicted or controlled, the recommended conditions of storage and use must be rigidly applied.

Although these reagent red 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 cells.

Antibodies specific for low incidence antigens not present on the test cells will not be detected.

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 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.

DATE OF ISSUE

2023-07

For further information or advice please contact your local distributor.

EC REP

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