QUOTIENT

ALBAcyte®
A_2 Cells
REAGENT RED CELLS

REF Z406 CE 1434

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
These reagent red cells are for the ABO reverse grouping of patient or donor serum/plasma and may be used for the control of serological tests.

INTRODUCTION
ABO blood grouping is generally performed by testing red cells with anti-A and anti-B (many laboratories also test with anti-A,B). A_1, A_2, B and O cells should be used to control each batch of tests. Confirmation of the red cell group can be provided by simultaneously performing a reverse or serum group i.e. testing the donor or recipients serum/plasma with reagent red blood cells of groups A1 and B to detect anti-A and anti-B. Group A2 reagent red blood cells can be used to identify anti-A1 in the serum of group A people. Group O cells can be used to identify agglutination due to non-ABO agglutinins.

REAGENT DESCRIPTION
These reagent red cells are presented as a 2-3% suspension of washed red cells in Modified Alsever's Solution. The cells are group A_2. 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).

The volume delivered by the reagent dropper bottle 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.

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.

These reagent red cells may be used directly from the vial or may be washed and resuspended before use to 2-3% in PBS or 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 for long term storage in another container is not recommended.

Furthermore, when the user changes the reagent in any way, e.g. the preparation of LISS 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

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

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 2-8 °C for a maximum of 48 hours. Blood specimens exhibiting gross haemolysis or contamination should not be used.

TEST PROCEDURES
No specific test procedures are recommended. Users are advised to carefully validate procedures and confirm reagent suitability before use.

PERFORMANCE LIMITATIONS
The presence of irregular antibodies in the serum/plasma of a patient/donor may cause unexpected agglutination of these reagent red cells.

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.

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.

A_2 cells have been characterised using the Anti-A_1 lectin *Dolichos biflorus*. This lectin in its undiluted form has Anti-A specificity and requires appropriate dilution to react directly with A_1 and A_1B red blood cells yet fail to react with A_2 and A_2B red blood cells. A small number of red blood cells may give strong reactions with Anti-A and weak reactions with Anti-A_1. The status of these red blood cells may be regarded as A_{int} a subgroup with phenotype characteristics in between A_1 and A_2. It should be noted that some A_2 and A_2B cells may react weakly with Anti-A_1 if incubated too long. Anti-A_1 lectin would be expected to react 2+-4+ with A_1 and A_1B red blood cells.

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.

In performance evaluation studies (data on file at Alba Bioscience Limited); Z406 was tested against random plasma samples and ABO antisera. The performance of Z406 is summarised as positive and negative percentage agreement .

Positive percentage agreement was 100% and negative percentage agreement was 100%.

The test outcomes were 100% in concordance with the expected test outcome based on the antibody contained in the plasma or reagent.

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For further information or advice please contact your local distributor.

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 Z406PI/09

INSTRUCTIONS FOR USE
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