QUOTIENT

ALBAcyte®
O rr Cells
REAGENT RED CELLS

REF Z421

CE 1434

INTERPRETATION OF LABEL SYMBOLS

LOT	Batch code
	Use by (YYYY-MM-DD)
2°C 8°C	Storage temperature limitation (2°C– 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 control of serological tests.

INTRODUCTION

First described in 1939, the RhD antigen is surpassed in importance only by the antigens of the ABO blood group system. Transfusion of RhD positive blood to an RhD negative recipient, or failure to administer prophylactic anti-D to an RhD negative woman, can result in the production of anti-D. Consequently, particular care should be taken to establish the correct RhD group and the appropriate control of RhD blood grouping tests is clearly fundamental to safe transfusion practice. Red cells of presumptive Rh genotypes R_1r and rr should be used to demonstrate appropriate reactivity of anti-D blood grouping reagents with each batch of tests and with single tests.

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 O rr. 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.

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.

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.

TEST PROCEDURES

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

PERFORMANCE LIMITATIONS

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.

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) Z421 was tested against random plasma samples and ABO and Rh typing antisera. The performance of Z421 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.

DATE OF ISSUE

2023-08

For further information or advice please contact your local distributor.

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Instructions for Use are available on Quotient website at www.quotientbd.com or can be requested from your Local Distributor, by providing the relevant Product Code stated on product labels and Instructions for Use supplied with the product

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