



ALBAcyte[®] RhD Negative CAT Reagent Red Cells for ANTIBODY SCREENING

REF Z466

INTERPRETATION OF LABEL SYMBOLS

	Batch code
	Use by (YYYY-MM-DD)
	Storage temperature limitation (2-8 °C)
	<i>In vitro</i> diagnostic medical device
	Product code
	Consult instructions for use
	Manufacturer

INTENDED PURPOSE

The reagent red cells are intended for the detection of irregular red cell antibodies in blood samples from patients who have received prophylactic anti-D.

INTRODUCTION

Screening patient samples for irregular blood group antibodies is an essential component of compatibility, ante-natal and donor testing protocols. Requirements for antibody screening of patient and donor samples differ and it is acknowledged that implementation of modern blood bank practices demands the use of a sensitive antibody screening procedure. In this respect the quality of reagent red cells is of paramount importance.

For antibody screening of patient samples, reagent red cells should not be pooled and should display homozygous expression of a range of blood group antigens.

REAGENT DESCRIPTION

These reagent red cells were prepared from blood donated by three Group O donors and are available as a suspension of washed red cells in a preservative solution ready for use in Column Agglutination Technology (CAT) test systems. The preservative solution contains antibiotics and has been specially formulated to preserve red cell integrity and antigenicity.

The presumptive Rh genotypes of these reagent red cells is r'r, r'r and rr. The full antigenic profile of the individual donations is shown on the enclosed antigen profile. One or more of these red cells may have been held in frozen storage until required.

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.**

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

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

General Information

CAT and LIS 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.

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

For use on the Ortho BioVue system the vial must be aligned such that the barcode printed on the left edge of the vial label (below the red dot) may be read by the system.

For use on the BioRad system the vial must be aligned such that the barcode printed on the right edge of the vial label (below the green dot) may be read by the system.

If the incorrect barcode is scanned due to mis-positioning of the vial, the information will not be recognised.

Materials provided

- ALBAcyte[®] RhD Negative CAT Reagent Red Blood Cells for Antibody Screening (Ref: Z466)

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.

The reactivity of the product may decrease during the dating period and, therefore, the product 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.

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

Unwanted positive reactions may occur as a result of red cell donations used in the manufacture of this product, which are untested for HLA Class I (B_g) antigens or associated antigens.

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.

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For further information or advice please contact your local distributor.



Alba Bioscience Limited
Ellen's Glen Road
Edinburgh
Scotland, UK
EH17 7QT



Tel No: +44 (0) 131 658 5700
Fax No: +44 (0) 131 672 3026

E-Mail: customer.serviceEU@quotientbd.com

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INSTRUCTIONS FOR USE

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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