



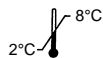
Consult instructions for use



Manufacturer

# ALBAcyte® REAGENT RED CELLS FOR ANTIBODY SCREENING

REF Z451



IVD

CE  
0843

## INTRODUCTION

Screening plasma/serum 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.

## INTERPRETATION OF LABEL SYMBOLS

LOT

Batch code



Use by (YYYY-MM-DD)

REF

Product code



Storage temperature limitation (2– 8°C)

IVD

In vitro diagnostic medical device

## INTENDED PURPOSE

The reagent red cells are intended for the detection of irregular red cell antibodies in patient and donor blood samples.

## REAGENT DESCRIPTION

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

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 (0.103 g/L) and chloramphenicol (0.349 g/L).

The presumptive Rh genotypes of these reagent red cells is R<sub>1</sub>R<sub>1</sub>, R<sub>2</sub>R<sub>2</sub> and rr. The R<sub>1</sub>R<sub>1</sub> sample may be C<sup>w</sup> positive, i.e. R<sub>1</sub><sup>w</sup>R<sub>1</sub>. 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.

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 - 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 a standard collection technique. The specimen should be tested as soon as possible after collection. If testing is delayed, the specimen should be stored at refrigerated temperatures. Blood specimens exhibiting gross haemolysis or contamination should not be used.

## TEST PROCEDURES

The recommended protocol for antibody screening includes direct agglutination and indirect antiglobulin tests at 37 °C.

Test protocols for antibody screening should reflect the compatibility testing protocol.

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.

Antibody screening of patient samples should be performed with fresh plasma/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.

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.

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For further information or advice please contact your local distributor.



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