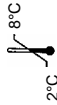




ALBACYTE®
REAGENT RED CELLS FOR REVERSE GROUPING

A₁ Cells






This insert refers to product Z401



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). A₁, A₂, B and O cells should be used to control each batch of tests and single tests. Confirmation of the red cell group is normally provided by simultaneously performing a reverse or serum group ie testing the donor or recipients serum/plasma with reagent red cells of groups A₁ and B.

INTERPRETATION OF LABEL SYMBOLS

-  Batch code
-  Use by (YYYY-MM-DD)
-  Storage temperature limitation (2°C– 8°C)
-  *In vitro* diagnostic medical device
-  Consult instructions for use

INTENDED PURPOSE

These reagent red cells are for the ABO reverse grouping of patient or donor serum/plasma.

REAGENT DESCRIPTION

These reagent red cells are presented as a 2-3% suspension of pooled washed red cells in Modified Alsever's Solution. The Rh phenotype of the A₁ red cells is ccdee. 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). 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 to another container is not recommended. Furthermore, when the user changes the reagent in any way, eg 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.

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°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

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.

For samples showing discrepant results, the patient's serum/plasma should be retested with their own red cells (autotest) and with group O red cells at room temperature.

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.

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For further information or advice please contact your local distributor.

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