QUOTIENT

ALBAcyte®
IgG Sensitised Cells
REAGENT RED CELLS

REF Z441

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
	Consult instructions for use
	Manufacturer

INTENDED PURPOSE

These reagent red cells are for the control of the anti-human globulin test.

INTRODUCTION

1. Confirmation of the validity of the antiglobulin test:
To confirm that anti-human globulin tests have been conducted correctly, reagent red cells sensitised with IgG antibody should be added to all negative tests.

Reagent red cells for use in control of the antiglobulin test should be weakly sensitised so that they will exhibit a weakened reaction (negative or grade 1 reaction score), where the anti-human globulin reagent has been neutralised by residual IgG antibody. Strongly sensitised red cells may still react with partially neutralised anti-human globulin reagents.

2. Control of the Direct Antiglobulin Test in BioVue CAT:
When IgG sensitised red blood cells are added to a column containing Anti-IgG the resultant agglutination indicates both the presence and the activity of the anti-human globulin.

REAGENT DESCRIPTION

These reagent red cells were prepared from at least 4 group O R_1r blood donors, sensitised using an IgG antibody of anti-D specificity. The product is available as a 3-5% suspension of washed red cells suspended in Modified Alsever's 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).
Transfer of these reagent red cells to another container is not recommended.
The volume delivered by the reagent dropper bottle is approximately 40 µL; 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.

TEST PROCEDURES

1. Confirmation of the validity of the antiglobulin test:
These reagent red cells have been standardised for use in controlling both tube and slide anti-human globulin tests, described below, where 2 volumes of anti-human globulin reagent are used.

Their suitability for use in other techniques cannot be guaranteed. Users are advised to carefully confirm reagent suitability before using alternative techniques.

Tube Technique

- Add 1 volume of reagent red cells to each negative test.
- Mix well and incubate for 1 minute at 20 °C.
- Centrifuge at 1000 g for 10 seconds or at a suitable alternative g force and time.
- Gently shake the tube to dislodge the cell button from the bottom and observe macroscopically for agglutination.

Slide Technique

- Add 1 volume of reagent red cells to each negative test.
- Mix for 1 minute and leave at 20 °C for a further 4 minutes mixing occasionally.
- Mix and observe macroscopically for agglutination.

2. Control of the Direct Antiglobulin Test in BioVue CAT:

Ortho BioVue® Cassette (CAT) Technique

Suitable for use on:
- Anti-IgG/Anti-C3b –C3d/Control Ortho BioVue® Cassette
- Anti-IgG –C3d Polyspecific Ortho BioVue® Cassette
- Anti-IgG Ortho BioVue® Cassette

Manual method:
- Add 10 µL of 3 to 5% suspension of IgG Sensitised red blood cells to the appropriate reaction chamber(s) of the cassette.
- Centrifuge the cassette using the Ortho BioVue® System centrifuge.
- Read the reaction from front and back of the individual columns for agglutination.

When using automated instruments, follow the procedures that are contained in the operator's manual provided by the device manufacturer.

INTERPRETATION OF RESULTS

Agglutination	=	positive test result
No agglutination	=	negative test result

PERFORMANCE LIMITATIONS

Some loss of sensitisation 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.
It should be noted that slide techniques are less sensitive than tube or column agglutination methods.
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

These reagent red cells have been shown to have a positive direct antiglobulin test, indicating that human IgG is detectable on the cell surface.

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For further information or advice please contact your local distributor.

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