QUOTIENT

ALBAcyte®
IgG Sensitised Cells
REAGENT RED CELLS

REF Z441 CE

1434

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
www.quotientbd.com	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).

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.

Transfer of these reagent red cells to another container is not recommended.

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 IgG Sensitised red blood 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 IgG Sensitised red blood 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.

In performance evaluation studies (data on file at Alba Bioscience Limited); Z441 was tested against random plasma samples.

The performance of Z441 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 results obtained.

DATE OF ISSUE

2020-01-30

For further information or advice please contact your local distributor.

EC REP

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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.

GEBRAUCHSANWEISUNG
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FEUILLET TECHNIQUE
Le feuillet technique est disponible sur le site Web de Quotient à l'adresse www.quotientbd.com. Vous pouvez également le demander à votre distributeur local en renseignant le code produit concerné, qui est mentionné sur l'étiquette du produit et dans le feuillet technique fourni avec ce dernier.

ISTRUZIONI PER L'USO
Le istruzioni per l'uso son disponibili sul sito Web di Quotient, www.quotientbd.com, o possono essere richieste al proprio distributore locale fornendo il codice del prodotto indicato sulle etichette del prodotto e nelle istruzioni per l'uso fornite con il prodotto.

 Z441PI/08

The linear barcode is provided below for scanning purposes.
Please note the barcode below is lot specific (lot number is displayed immediately under the barcode) - this IFU should be retained with the product vial with which it was supplied.

Nachstehend wird der lineare Barcode zum Scannen angegeben.
Beachten Sie bitte, dass der nachstehende Barcode losspezifisch ist (die Losnummer wird direkt unterhalb des Barcodes angezeigt) – diese Gebrauchsanweisung sollte zusammen mit dem Produktfläschchen aufbewahrt werden, mit dem sie geliefert wurde.

Le code à barres linéaire est fourni ci-dessous à des fins de lecture.
Veuillez noter que le code à barres ci-dessous est spécifique au lot (le numéro de lot s'affiche immédiatement sous le code à barres) - cette notice d'utilisation doit être conservée avec le flacon de produit avec lequel elle a été fournie.

Di seguito è riportato il codice a barre lineare per la scansione.
Tenere presente che il codice a barre sottostante è specifico per il lotto (il numero di lotto è riportato sotto il codice a barre) - queste IFU devono essere conservate con il flaconcino di prodotto con cui sono state fornite.