ALBAclone®

Anti-D alpha

BLOOD GROUPING REAGENT
Monoclonal Direct Agglutinin
For Slide and Tube Techniques

REF **Z031**

2°C – 8°C

IVD

CE 0843

INTRODUCTION

First described in 1939, the RhD antigen is surpassed in importance only by the antigens of the ABO blood group system. Transfusion of RhD positive blood to a RhD negative recipient or failure to administer prophylactic anti-D to a RhD negative woman can result in the production of anti-D. Consequently, establishing the correct RhD group is fundamental to safe transfusion practice. Certain individuals exhibit a quantitative reduction in the expression of their RhD antigen and are categorised as weak D (D^u). Others display a qualitative variation in RhD antigen expression and are referred to as partial RhD. Weak D individuals may also be partial RhD.

The recent availability of potent, high quality IgM monoclonal anti-D reagents and a greater awareness of the clinical importance of partial RhD phenotypes, especially DVI, has resulted in a change to RhD testing policies in the UK.

UK Guidelines for RhD Grouping

The Guidelines for the Blood Transfusion Services in the United Kingdom and the British Committee for Standards in Haematology Blood Transfusion Task Force Guidelines for Compatibility Procedures in Blood Transfusion Laboratories recommend the following RhD grouping procedures:-

- For RhD grouping of **patients**, two different anti-D reagents should be used. Neither of these anti-D reagents should agglutinate DVI red cells by the method(s) recommended for use. Indirect antiglobulin tests for samples giving negative direct agglutination test results should not be used for RhD typing patient samples for the purpose of transfusion.
- For RhD grouping of **donors**, whilst it is neither essential nor possible to detect all weak D and partial RhD phenotypes, it is desirable that tests with two different anti-D reagents enable those donors who express weak or partial RhD antigen of clinical importance, eg DVI, to be classified as RhD Positive.

This monoclonal IgM anti-D will directly agglutinate red cells from most weak D and partial RhD except DVI and, therefore, is suitable for RhD grouping of patient samples.

INTERPRETATION OF LABEL SYMBOLS

LOT	Batch code
	Use by (YYYY-MM-DD)
2°C – 8°C	Storage temperature limitation (2°C– 8°C)
IVD	*In vitro* diagnostic medical device
www.quotientbd.com	Consult instructions for use
	Manufacturer
REF	Product Code

INTENDED PURPOSE

This Anti-D reagent is for the *in vitro* detection and identification of human RhD blood group status by direct agglutination.

REAGENT DESCRIPTION

The main component of this reagent is derived from the *in vitro* culture of the human/mouse heterohybridoma LDM1 which secretes IgM anti-D.
The formulation also contains EDTA and 1g/l sodium azide.
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.

STORAGE CONDITIONS

The reagent should be stored at 2°C - 8°C. Do not use if turbid. Do not dilute. The reagent is stable until the expiry date stated on the product label.

PRECAUTIONS FOR USE AND DISPOSAL

This reagent contains 0.1% sodium azide.
Sodium azide may react with lead and copper plumbing to form explosive compounds. If discarded into sink, flush with a large volume of water to prevent azide buildup.
Harmful to aquatic life with long lasting effects. Avoid release to the environment. Dispose of contents/container in accordance with local/regional/national/international regulations.

CAUTION: SOURCE MATERIAL FROM WHICH THIS PRODUCT IS DERIVED WAS FOUND NON-REACTIVE FOR HBsAg, ANTI-HIV 1/2 AND ANTI-HCV. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS DISEASE. APPROPRIATE CARE SHOULD BE TAKEN IN THE USE AND DISPOSAL OF THIS PRODUCT.
This reagent is for *in vitro* professional use only.

SPECIMEN COLLECTION AND PREPARATION

Specimens should be collected by aseptic technique with or without an anticoagulant. 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. Blood specimens exhibiting gross haemolysis or contamination should not be used. Clotted samples or those collected in EDTA should be tested within seven days from collection. Donor blood stored in citrate anticoagulant may be tested until the expiry date of the donation.

TEST PROCEDURES

General Information

This reagent has been standardised for use by the techniques described below and therefore its suitability for use in other techniques cannot be guaranteed.

ADDITIONAL MATERIALS AND REAGENTS REQUIRED

- PBS pH 7.0 ± 0.2
- LISS
- Reagent red cells for use in RhD grouping
- RhD Reagent Control - Product No Z271
- 12 x 75mm glass test tubes
- Glass slides
- Pipettes

- Optical aid
- Centrifuge

RECOMMENDED TECHNIQUES

Tube Technique - Immediate Spin

- Add 1 volume of blood grouping reagent to a test tube.
- Add 1 volume of red cells suspended to 2-3% in PBS pH 7.0 ± 0.2 or 1.5-2% in LISS.
- Mix the test well.
- Centrifuge at 1000g 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.

Tube Technique - LISS

- Add 1 volume of blood grouping reagent to a test tube.
- Add 1 volume of red cells suspended to 1.5 - 2% in LISS.
- Mix the test well and incubate for 15 minutes at 37°C.
- Centrifuge at 1000g 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 blood grouping reagent to an appropriately prepared area of a glass slide eg a wax pencil oval.
- Add 1 volume of red cells suspended to 30-45% in PBS pH 7.0 ± 0.2 or in group homologous plasma/serum.
- Mix well by rocking the slide for approximately 30 seconds and incubate the test for 5 minutes at room temperature with occasional mixing.
- Observe macroscopically for agglutination. This may be facilitated by reading over a diffuse light source.

INTERPRETATION OF RESULTS

Agglutination	=	positive test result
No agglutination	=	negative test result

QUALITY CONTROL

Quality control of reagents is essential and should be performed with each series of RhD groups and with single RhD groups. It is recommended that the following red cell samples are used to control the reactions of these reagents. Other red cell types may be suitable but should be selected with care.

O R_1r red cells should be used as a positive control
O rr red cells should be used as a negative control
A 'reagent control' is required for this anti-D

PERFORMANCE LIMITATIONS

The quantity of D antigen expressed by weak D individuals varies considerably. Whilst this anti-D reagent will directly agglutinate red cells from most weak D individuals, if it is considered important to test for weak D, a reagent specifically prepared for that purpose should be used.

Slide techniques are not recommended for the detection of weak D or partial RhD samples.

Certain tests performed on unwashed samples (e.g. cord) or samples stored and tested at 20°C or below, may exhibit false positive reactions due to the potentiators used in the formulation of this reagent. A reagent control (Product Code Z271) is available for use under these circumstances. If the control test gives a positive reaction, a valid interpretation of the results obtained in red cell testing cannot be made.

Driblocks and waterbaths promote better heat transfer and are recommended for 37°C tests, particularly where the incubation period is 30 minutes or less.

Some very weak D and/or partial RhD samples may not react with monoclonal anti-D reagents.

The expression of certain red cell antigens may diminish in strength during storage, particularly in EDTA and clotted samples. Better results will be obtained with fresh samples.

Tube tests should be read by a 'tip and roll' procedure. Excessive agitation may disrupt weak agglutination and produce false negative results.

Excessive centrifugation can lead to difficulty in resuspending the cell button, while inadequate centrifugation may result in agglutinates that are easily dispersed.

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

ALBAclone® Anti-D alpha meets the requirements of the Common Technical Specifications for products defined in Annex II, List A of Directive 98/79/EC on *in vitro* Diagnostic Medical Devices.

This monoclonal anti-D will directly agglutinate red cells from most weak D and partial RhD except DVI.

DATE OF ISSUE

2019-01-08

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