QUOTIENT

ALBAclone®
Anti-c
BLOOD GROUPING REAGENT
Monoclonal Direct Agglutinin

REF Z083

2°C – 8°C

IVD

CE 1434

INTRODUCTION
Since the description of the RhD antigen by Levine and Stetson in 1939, more than 40 other Rh antigen complexes have been identified. With the exception of C, c, E and e, and perhaps C^w, few of these antigens or their corresponding antibodies are encountered in routine testing. Rh antigens are controlled by a series of closely linked loci on chromosome 1, the genetic contribution from each parent being inherited as a haplotype e.g. Cde, cDE etc. Used separately, anti-Rh blood grouping reagents will indicate whether an individual expresses the corresponding antigen - an essential procedure in the determination of antibody specificity and selection of blood for transfusion of patients with Rh antibodies.

Testing red cell samples with anti-C, anti-D, anti-E, anti-c and anti-e will disclose the Rh phenotype from which the most probable genotype may be deduced. Knowing the probable paternal genotype can be of value in the management of RhD haemolytic disease of the foetus and newborn where R_2r infants are likely to be more severely affected than are R_1r infants. Probable genotype information can also be useful in establishing antibody specificity and in selecting blood for transfusion of patients with Rh antibodies.

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-c reagent is for the *in vitro* detection and identification of the human c blood group antigen by direct agglutination.

REAGENT DESCRIPTION
The main component of this reagent is derived from the *in vitro* culture of the IgM secreting human/mouse heterohybridoma H48.
The diluent formulation contains 5 g/L BSA and 0.1% (w/v) sodium azide in phosphate buffered saline.
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 Common Technical Specifications for products defined in Annex II, List A 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 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% (w/v) 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 build-up.
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 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 contamination should not be used. Extreme care should be taken if haemolysed samples must be tested. Clotted samples or those collected in EDTA should be tested within fourteen days from collection. Donor blood may be tested until the expiry date of the donation.

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

UK NEQAS exercises for blood group serology have demonstrated the importance of incorporating a reagent control in blood grouping tests where a potentiator is incorporated in the reagent formulation or is required to be added by the user. The reagent control should reflect the formulation of the reagent being used. For this reagent a satisfactory reagent control may be achieved by substituting inert AB serum, 8-10% BSA in saline or the patient's own serum for the blood grouping reagent in the procedure chosen for use.

ADDITIONAL MATERIALS AND REAGENTS REQUIRED
- PBS pH 7.0 ± 0.2
- LISS
- Reagent red cells suitable for the control of Anti-c
- 12 x 75mm glass test tubes
- Pipettes
- Centrifuge

RECOMMENDED TECHNIQUES
Tube Technique - 5 Minute Incubation / Spin
- Add 1 volume of blood grouping reagent to a 12 x 75 mm 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 and incubate at 37 °C ± 1 °C for 5 minutes.
- 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.

Tube Technique - 15 Minute Incubation / Spin

- Add 1 volume of blood grouping reagent to a 12 x 75 mm 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 and incubate at 37 °C ± 1 °C for 15 minutes.
- 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.

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 groups and with single groups. It is recommended that the following red cell samples are used to control the reactions of this reagent. Other red cell types may be suitable but should be selected with care.

O R_1R_2 red cells should be used as a positive control.
O R_1R_1 red cells should be used as a negative control.

PERFORMANCE LIMITATIONS

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

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.

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

It is important to use the recommended g force during centrifugation as 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.

The main component of this reagent is derived from the *in* vitro culture of the IgM secreting human/mouse heterohybridoma, H48. It should be noted that cell line H48 may show reduced or no reactivity with the c variant Rh:-26 It is possible that this antibody may show reduced or no reactivity with other rare variants of the c antigen.

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For further information or advice please contact your local distributor.

EC REP

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