BLOOD GROUPING REAGENT

Anti-c̄

ALBAclone®

REF Z083U

(Human/Murine Monoclonal IgM)
For Tube Technique

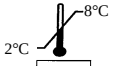
- **Meets FDA potency requirements**
- **Discard if turbid**
- **Preservative: 0.1% sodium azide**

CAUTION: THE ABSENCE OF ALL VIRUSES HAS NOT BEEN DETERMINED. THIS PRODUCT HAS COMPONENTS (DROPPER BULBS) CONTAINING DRY NATURAL RUBBER.

INTERPRETATION OF LABELING SYMBOLS

Batch code


Use by (YYYY-MM-DD)



Storage temperature limitation (2°C– 8°C)

In vitro diagnostic medical device


Consult instructions for use


Harmful


Manufacturer

Product Code

SUMMARY
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 blood 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 hemolytic disease of the fetus 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.

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

PRINCIPLE OF THE TEST
When used as recommended, this reagent will cause agglutination (clumping) of red blood cells carrying the c antigen. Lack of agglutination demonstrates the absence of the c antigen.

REAGENT DESCRIPTION
The main component of this reagent is derived from the *in vitro* culture of the IgM secreting human/mouse heterohybridoma H48.
The formulation contains 20 g/L BSA and 0.1% (w/v) sodium azide in PBS.
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.

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 be toxic if ingested and 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.
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 product has components (dropper bulbs) containing dry natural rubber. This reagent is for *in vitro* diagnostic 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 hemolyzed 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
General Information
This reagent has been standardized for use by the technique described below and therefore its suitability for use in other techniques cannot be guaranteed. When a test is required to be incubated for a specific time period, a timer should be used.

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ADDITIONAL MATERIALS AND REAGENTS REQUIRED
. Isotonic saline
. Reagent red blood cells suitable for the control of Anti-c
. 10 x 75 mm or 12 x 75 mm glass test tubes
. Pipettes
. Centrifuge
. Heating block / waterbath
. Timer

RECOMMENDED TECHNIQUES
Tube Technique – 5-15 Minute Incubation / Spin
. Add 1 drop of blood grouping reagent to a test tube.
. Add 1 drop of red blood cells suspended to 2-4% in isotonic saline. Reagent red cells may be tested as provided (preservative suspended).
. Mix the contents of the test tube well and incubate at 37 °C ± 1 °C for 5-15 minutes.
. Centrifuge the test tube.
Suggested centrifugation: 1000 g (approx. 3400 rpm) for 10 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive red blood cells, yet allows easy re-suspension of antigen-negative red blood cells.
. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately 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 on each day of use and in accordance with local, state and federal regulations. We suggest that the following red blood cell samples are used to control the reactions of this reagent.

c+C+ red blood cells should be used as a positive control.
c-C+ red blood 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 blood cell antigens may diminish in strength during storage, particularly in EDTA and clotted samples. Better results will be obtained with fresh samples.

Direct antiglobulin test positive samples may exhibit false positive reactions due to the potentiators used in the formulation of this reagent. A satisfactory reagent control may be achieved by substituting 6-10% BSA in saline for the blood grouping reagent in the procedure chosen for use. If the control test gives a positive reaction, a valid interpretation of the results obtained in red blood cell testing cannot be made.

Gently re-suspend tube tests before reading. 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.

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.

SPECIFIC PERFORMANCE CHARACTERISTICS

Prior to release, each lot of ALBAclone® Anti-c is tested by FDA recommended methods against a panel of antigen-positive and antigen-negative red blood cells to ensure suitable reactivity.

BIBLIOGRAPHY

1. Technical Manual. 17th ed. Bethesda, MD: American Association of Blood Banks, 2011.
2. Standards for Blood Banks and Transfusion Services. 28th ed. Bethesda, MD: American Association of Blood Banks, 2012.
3. Involvement of Gly96 in the Formation of the Rh26 Epitope, Faas *et al.,* Transfusion, 37; 1123-1130, 1997.

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