

BLOOD GROUPING REAGENT

Anti- \bar{c}

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

LOT

Batch code



Use by (YYYY-MM-DD)



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

IVD

In vitro diagnostic medical device



Consult instructions for use

www.alivedx.com



Manufacturer

REF

Product Code



Rx only

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 R₂R infants are likely to be more severely affected than are R₁r 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 μ L; 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.

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 \pm 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.

False positive test results are rarely seen with low-protein reagents. False positive agglutination may be due to a positive direct antiglobulin test (DAT), cold agglutinins, or abnormal serum proteins. If false positive results are suspected, or local regulations require, and a control test for spontaneous agglutination is desired, ALBACheck® - BGS Monoclonal Control (Z271U) or 6-10% albumin in saline may be substituted for the blood grouping reagent in the testing procedure. A negative result would serve as an appropriate control. If the monoclonal control test gives a positive reaction, a valid interpretation of the results obtained in red blood cell testing cannot be made without further investigation.

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.

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.

Care should be taken when testing red blood cells that have been treated with proteolytic enzymes, as these may produce false positive or false negative results.

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.

Comparator Study Results

During comparator studies (data on file at Alba Bioscience Limited), blood samples were tested with ALBAclone® Anti-c (Monoclonal) as follows*:

| Anti-c | | Comparator Reagent | | | One-sided 95% Exact lower confidence limit |
|-----------------------------|----------|--------------------|----------|-------|--|
| | | Positive | Negative | Total | |
| Trial Reagent | Positive | 177 | 0 | 177 | |
| | Negative | 0 | 23 | 23 | |
| | Total | 177 | 23 | 200 | |
| Positive Percent Agreement* | | | | 100 | 98.32 |
| Negative Percent Agreement* | | | | 100 | 87.79 |

* The data presented in this table was generated during field trials executed in support of the original US licensing of this reagent.

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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