

BLOOD GROUPING REAGENT

Anti-A,B

ALBAclone®

(Murine Monoclonal IgM)

For Slide and Tube Techniques

REF Z023U

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

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

INTERPRETATION OF LABELING SYMBOLS



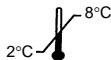
Batch code



Use by (YYYY-MM-DD)



Product Code



Storage temperature limitation (2- 8 °C)



In vitro diagnostic medical device



Consult instructions for use



Harmful



Manufacturer

SUMMARY

ABO blood grouping is generally performed by testing red blood cells with Anti-A and Anti-B. In order to generate confirmatory blood group information and exclude misgrouping of weak A variants as group O, e.g. A_x, many laboratories also

test with Anti-A.B. Reverse or serum grouping of the patient's serum by testing with A₁ red blood cells and B red blood cells should be performed to provide a further check of the accuracy of observed ABO blood grouping results. Monoclonal antibodies exhibit a high degree of potency, avidity and specificity. When using such antibodies, great care should be taken to avoid cross contamination.

INTENDED USE

This Anti-A,B reagent is for the *in vitro* detection and identification of human ABO blood groups by direct agglutination.

PRINCIPLE OF THE TEST

When used by the recommended technique, this reagent will cause agglutination (clumping) of red blood cells carrying A and/or B antigens. Lack of agglutination demonstrates the absence of A and B antigens.

REAGENT DESCRIPTION

The main components of this reagent are derived from the *in vitro* culture of the IgM immunoglobulin secreting mouse hybridomas:-

Product Name	Product Code	Cell Line
Anti-A,B	Z023U	LA2, LB3, ES15

The formulation also contains sodium chloride, EDTA and 0.1% (w/v) sodium azide. 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. As this reagent is of animal origin care must be taken during use and disposal as there is a potential infection risk. 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

ADDITIONAL MATERIALS AND REAGENTS REQUIRED

- Isotonic saline
- Reagent red blood cells for use in ABO grouping
- 10 x 75 mm or 12 x 75 mm glass test tubes
- Glass slides
- Pipettes
- Optical aid
- Centrifuge
- Timer

RECOMMENDED TECHNIQUES

Tube Technique - Immediate 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 centrifuge. Suggested centrifugation: 900-1000 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 resuspension 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.

Slide Technique

- Add 1 drop of blood grouping reagent to an appropriately prepared area of a glass slide e.g. a wax pencil oval.
- Add 1 drop of red blood cells suspended to 30-45% in group homologous plasma/serum.
- Mix well by rocking the slide for approximately 30 seconds and incubate the test for 5 minutes at 18 – 24 °C with occasional mixing.
- After incubation, immediately observe macroscopically for agglutination. This may be facilitated by reading over a diffuse light source.

INTERPRETATION OF RESULTS

The reaction patterns of the most common ABO phenotypes are shown below.

Anti-A	Anti-B	Anti-A,B	Blood Group
-	-	-	O
+	-	+	A
-	+	+	B
+	+	+	AB

All red blood cell (forward) grouping tests, except those on red blood cells of infants, should be confirmed by serum (reverse) grouping tests using known A₁ and B cells. Any discrepancy between cell and serum grouping must be investigated and resolved before the blood group is recorded. Refer to the AABB Technical Manual⁽¹⁾ for possible causes and procedures to use in resolution of ABO grouping discrepancies.

QUALITY CONTROL

Quality control of reagents is essential and should be performed on the day of use and in accordance with local, state and federal regulations. For ABO blood grouping reagents, appropriate antigen positive and negative red blood cells should be used.

PERFORMANCE LIMITATIONS

ABO antigens are not fully expressed at birth and, therefore, tests involving cord/neonatal red blood cells should be interpreted with particular care.

All negative slide tests should be confirmed by tube testing to confirm absence of weak subgroups.

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.

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.

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

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

This Anti-A,B reagent will detect most weak subgroups of A, especially A_x.

It should be noted that the LB3 cell line, from which the ALBAclone[®] Anti-A,B reagent is derived, does not detect the following alleles:

1. The Bx06 allele demonstrates an extremely rare molecular change (900G>C) and has been demonstrated only twice to date. Bx06 has received the provisional name ABO*BW.31 in the new ISBT allele terminology⁽³⁾.
2. A novel B allele with all B specific mutations except 703G>A but also with the addition of 646T>A which is associated with the A_x phenotype when it occurs in A subgroup alleles. This allele has not been described before and has yet to be assigned a name using ISBT allele terminology.

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. Described on the dbRBC database as Bx06 by the Shanghai Blood Center. Given the provisional name ABO*BW.31 in the new ISBT allele terminology.

DATE OF ISSUE

8th October 2013

US Distributor

Quotient
301 South State Street
S-204
Newtown
PA 18940
USA

Customer Service Tel: 1-888-284-1901
Product Technical Support Tel: 1-888-228-1990
Customer Service Fax: 1-888-694-5208
E-Mail: customer.serviceUS@quotientbd.com
Web: www.quotientbd.com



Alba Bioscience Limited
Ellen's Glen Road
Edinburgh
Scotland, UK
EH17 7QT

US License 1807

Tel: +44 (0) 131 658 5700
Fax: +44 (0) 131 672 3026
E-Mail: customer.serviceEU@quotientbd.com

© Alba Bioscience Limited 2013

Z023UQPI/05

