BLOOD GROUPING REAGENT

Anti-B

ALBAclone®

(Murine Monoclonal IgM)

For Slide and Tube Techniques

This insert refers to product Z015U

- **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

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
	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. Ax, many laboratories also test with anti-A,B. Reverse or serum grouping of the patient's serum by testing with A_1 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-B reagent is for the *in vitro* detection and identification of the human B blood group antigen by direct agglutination.

PRINCIPLE OF THE TEST

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

REAGENT DESCRIPTION

The main component of this reagent is derived from the *in vitro* culture of the immunoglobulin secreting mouse hybridoma:-

Product Name	Product Code	Cell Line
Anti-B	Z015U	LB3

The formulation also contains sodium chloride, EDTA and 1g/l sodium azide. The reagent is colored yellow with tartrazine.
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% (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 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 fourteen days from collection. Donor blood stored in citrate anticoagulant 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 75mm or 12 x 75mm glass test tubes
- Glass slides
- Pipettes
- Optical aid
- Centrifuge
- Timer

RECOMMENDED TECHNIQUES

Tube Technique - Immediate Spin

- Add 1 volume of blood grouping reagent to a test tube.
- Add 1 volume of red blood cells suspended to 2-4% in isotonic saline.
- Mix the contents of the test tube well and centrifuge. Suggested centrifugation: 1000g 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 volume of blood grouping reagent to an appropriately prepared area of a glass slide e.g. a wax pencil oval.
- Add 1 volume 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 A_1 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 procedures used in resolution of 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 resuspend 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-B is tested by FDA recommended methods against a panel of antigen-positive and antigen-negative red blood cells to ensure suitable reactivity.

The acquired B phenotype is seen very occasionally in group A patients and is caused by deacetylation of the A antigen by bacterial enzymes, particularly those associated with intestinal infections. The Anti-B reagent derived from the cell line **LB3** does not recognise this 'pseudo B' antigen.

BIBLIOGRAPHY

1. Technical Manual. 15th ed. Bethesda, MD: American Association of Blood Banks, 2005.

2. Standards for Blood Banks and Transfusion Services. 24th ed. Bethesda, MD: American Association of Blood Banks, 2006.

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