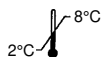




ALBAclone® Anti-B

BLOOD GROUPING REAGENT
Mouse Monoclonal / Direct Agglutinin

REF Z011



IVD

CE
1434

INTRODUCTION

ABO blood grouping is generally performed by testing red 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, eg Ax, many laboratories also test with anti-A,B. Reverse or serum grouping of the patient's serum by testing with A₁ cells and B cells (A₂ cells may be additionally included) 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.

INTERPRETATION OF LABEL 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



Manufacturer



Product Code

INTENDED PURPOSE

The Anti-B reagent is for the *in vitro* detection and identification of the B antigen on human red blood cells by direct agglutination.

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	Z011	LB2

The formulation also contains sodium chloride and EDTA and 1g/l sodium azide. The reagent is coloured 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.

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°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% 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.

As this reagent is of animal origin care must be taken during use and disposal as there is a potential infection risk. This reagent is for *in vitro* professional 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 seven days from collection. Donor blood stored in citrate anticoagulant may be tested until the expiry date of the donation.

TEST PROCEDURES

General Information

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

ADDITIONAL MATERIALS AND REAGENTS REQUIRED

- PBS pH 7.0 ± 0.2
- LISS
- Reagent red cells for use in ABO grouping
- 12 x 75mm glass test tubes
- Glass slides
- Pipettes
- Optical aid
- Centrifuge

RECOMMENDED TECHNIQUES

Tube Technique - Immediate Spin

- Add 1 volume of blood grouping reagent to a 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.
- Centrifuge immediately at 1000g 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 - LIS

- Add 1 volume of blood grouping reagent to a test tube.
- Add 1 volume of red cells suspended to 1.5 - 2% in LISS.
- Mix the test well and incubate for 15-20 minutes at approximately 20°C.
- Centrifuge at 1000g 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.

Slide Technique

- Add 1 volume of blood grouping reagent to an appropriately prepared area of a glass slide eg a wax pencil oval.

- Add 1 volume of red cells suspended to 30-45% in PBS pH 7.0 ± 0.2 or in group homologous plasma/serum.
- Mix well by rocking the slide for approximately 30 seconds and incubate the test for 5 minutes at room temperature with occasional mixing.
- 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 cell (forward) grouping tests, except those on cells of infant blood, should be confirmed by serum (reverse) grouping tests using known A₁ and B cells.

QUALITY CONTROL

Quality control of reagents is essential and should be performed at the start of each day's testing, with each series of groups performed and with single tests, eg an emergency compatibility test ie:

Anti-A)
Anti-B) should be tested with A₁, A₂, B and O cells
Anti-A,B)

PERFORMANCE LIMITATIONS

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

Slide tests are not recommended for detection of weak subgroups. All slide tests should be confirmed by tube grouping.

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.

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.

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

ALBAclone® Anti-B reagent meets the requirements of the Common Technical Specifications for products defined in Annex II, List A of Directive 98/79/EC on *in vitro* Diagnostic Medical Devices.

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 **LB2** does not recognise this 'pseudo B' antigen.

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For further information or advice please contact your local distributor.



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INSTRUCTIONS FOR USE

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ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

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