BLOOD GROUPING REAGENT

Anti-A

ALBAclone®

(Murine Monoclonal IgM)

For Slide and Tube Techniques

REF **Z001U**

- **FOR *IN VITRO* DIAGNOSTIC USE**
- **Meets FDA potency requirements**
- **Discard if turbid**
- **Preservative: 0.1% (w/v) 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)
REF	Product Code
2°C 8°C	Storage temperature limitation (2-8 °C)
IVD	*In vitro* diagnostic medical device
www.alivedx.com	Consult instructions for use
	Manufacturer
Rx only	Rx only

INTENDED USE

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

SUMMARY AND EXPLANATION

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 grouping of the patient's serum/plasma 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.

This Anti-A reagent will detect most significant subgroups of A, including A_1, A_2 and A_3.

PRINCIPLE OF THE TEST

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

REAGENT DESCRIPTION

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

Product Name	Product Code	Cell Line
Anti-A	Z001U	LA2

The formulation also contains bovine material, sodium chloride, EDTA and 0.1% (w/v) sodium azide. The reagent is colored with patent blue dye.

NOTE: The volume delivered by the reagent dropper bottle is approximately 40µL. Care should be taken to ensure that appropriate serum to cell ratios are maintained in all test systems.

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only
Products should be used by qualified personnel
Do not use beyond the expiration date
Do not use if turbid
Do not dilute
The format of the expiration date is expressed as YYYY-MM-DD (Year-Month-Day)

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.

This reagent is of animal origin (murine and bovine), therefore care must be taken during use and disposal as there is a potential infection risk.

CAUTION: SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED, WAS FOUND NEGATIVE FOR INFECTIOUS AGENTS WHEN TESTED IN ACCORDANCE WITH CURRENT FDA REQUIRED TESTS.

The bovine material used in the manufacture of this reagent was collected in a USDA approved facility.

Monoclonal antibodies exhibit a high degree of potency, avidity and specificity. When using such antibodies, great care should be taken to avoid cross contamination.

This product has components (dropper bulbs) containing dry natural rubber.

STORAGE

The reagent should be stored at 2-8 °C.

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.

Clotted samples or those collected in EDTA should be tested within fourteen days from collection. Donor blood may be tested until the expiration date of the donation.

Special care should be taken if hemolyzed samples must be tested. Grossly icteric or contaminated blood specimens should not be used.

MATERIALS

Material provided
- ALBAclone® Anti-A

Materials required but not provided
- Isotonic saline
- Reagent red blood cells suitable for the control of Anti-A
- 10 x 75 mm or 12 x 75 mm glass test tubes
- Pipets
- Optical aid (optional)
- Centrifuge
- Glass slides (optional)
- Timer
- Heating block/waterbath

PROCEDURES

General Information

NOTE: This reagent has been standardized for use by the techniques 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.

It is recommended to allow reagents to reach 20-24 °C prior to use.

When using supplemental testing equipment (i.e. centrifuge), follow the procedures that are contained in the operator's manual provided by the device manufacturer.

Tube Technique - Immediate Spin

1. Prepare a 2-4% suspension of red blood cells in isotonic saline solution (Reagent Red Blood Cells may be used

directly from the vial or according to the manufacturer's instructions).
2. Add 1 drop of blood grouping reagent to a glass test tube.
3. Add 1 drop of red blood cell suspension. Steps 2 and 3 may be performed in either order.
4. Mix the contents of the test tube and centrifuge.
   NOTE: 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 re-suspension of antigen-negative red blood cells.
5. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination. Negative reactions may be examined with an optical aid.
6. Record results.

Slide Technique

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

Refer to Performance Limitations section for additional guidance on the use of this product.

STABILITY OF REACTION

Test results should be read, interpreted and recorded immediately after centrifugation. Delays may cause dissociation of antigen-antibody complexes resulting in weak positive or false negative reactions.

INTERPRETATION OF RESULTS

Agglutination	=	positive test result
No agglutination	=	negative test result

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/plasma (reverse) grouping tests using known A_1 and B cells. Any discrepancy between cell and serum/plasma grouping must be investigated and resolved before the blood group is recorded. Refer to the AABB Technical Manual 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 each 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 and antibodies are not fully expressed at birth and, therefore, tests involving cord/neonatal red blood cells should be interpreted with particular care.

Slide techniques are not recommended for the detection of weakened antigen expression. If the detection of antigens exhibiting weakened or modified expression is required, negative slide tests should be confirmed by tube testing.

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 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.

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.

Suppressed or weak expression of blood group antigens may give rise to false negative reactions.

SPECIFIC PERFORMANCE CHARACTERISTICS

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

BIBLIOGRAPHY

1. Roback JD, Grossman BJ, Harris T, *et al*: AABB Technical Manual, 18th ed. AABB, 2014
2. AABB Standards Program Committee: Standards for Blood Banks and Transfusion Services, ed 30. AABB, 2016
3. Reid ME, Lomas-Francis C, Olsson ML: The Blood Group Antigen FactsBook, ed 3. Academic Press, 2012

DATE OF ISSUE

2025-06

Alba Bioscience Limited
James Hamilton Way
Penicuik
EH26 0BF
UK

U.S. License 1807

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@alivedx.com
Web: www.alivedx.com/us

 Z001UPI/07

ALBA