

BLOOD GROUPING REAGENT

Anti-M

ALBAclone®

(Murine Monoclonal IgG)

For Tube Technique

This insert refers to product Z171U

- 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.

SUMMARY

The MN status of red blood cells is defined by the amino acid sequence of the major red cell sialoglycoprotein, glycophorin A. Anti-M and anti-N react with their respective antigens on glycophorin A, causing agglutination of the red cells and classifying these cells into three distinct phenotypes: M+N-, M+N+ and M-N+. Additionally, irrespective of the MN status of their major glycoprotein, almost all human red blood cells carry the 'N'-antigen on a minor red cell sialoglycoprotein, glycophorin B.

INTENDED USE

The Anti-M reagent is for the *in vitro* detection and identification of human M positive red blood cells 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 M antigen. Lack of agglutination demonstrates the absence of the M antigen.

REAGENT DESCRIPTION

The main component of this reagent is derived from the *in vitro* culture of the immunoglobulin secreting mouse hybridoma LM1. The formulation consists of culture supernatant in EPPS buffer, pH8.5 and also contains 1g/l sodium azide.

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

General Information

This reagent has been standardised 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

- Unbuffered isotonic saline
- Reagent red blood cells suitable for the control of Anti-M
- 10 x 75mm or 12 x 75mm glass test tubes
- Pipettes
- Centrifuge
- Incubator
- Timer

RECOMMENDED TECHNIQUE

Tube Technique - 5 Minute Incubation / Spin

All red blood cells to be tested with this reagent should be washed at least once and resuspended in **unbuffered** isotonic saline. This includes red blood cells used for quality control.

- Add 1 volume of blood grouping reagent to a test tube.
- Add 1 volume of red blood cells suspended to 2-4% in **unbuffered isotonic saline (9g/L NaCl)**.
- Mix the contents of the test tube well and incubate at 20° - 25°C for 5 minutes.
- Centrifuge the test tube.
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.

INTERPRETATION OF RESULTS

Agglutination = positive test result
No agglutination = negative test result

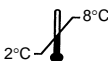
INTERPRETATION OF LABELING SYMBOLS



Batch code



Use by (YYYY-MM-DD)



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



In vitro diagnostic medical device



Consult instructions for use



Harmful



Manufacturer

QUALITY CONTROL

Quality control of reagents is essential and should be performed with each series of groups, single groups 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.

- MN red blood cells should be used as a positive control
- NN red blood cells should be used as a negative control

PERFORMANCE LIMITATIONS

As this reagent reacts optimally at pH 8.5 and is extremely sensitive to pH, test red blood cells should be suspended in unbuffered medium. All red blood cells suspended in buffered medium e.g. Alsever's solution, should be washed at least once and resuspended in unbuffered saline prior to use.

Incubation at temperatures above that recommended may result in weaker reactions.

Cells modified by proteolytic enzymes must not be used, as M antigens may be destroyed.

Do not use any optical aid to examine the tests 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-M is tested by FDA recommended methods against a panel of antigen-positive and antigen-negative red blood cells to ensure suitable reactivity.

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.

DATE OF ISSUE

April 2009

US Distributor

Quotient Biodiagnostics Inc.
41 University Drive
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.service@quotientbiodiagnostics.com
Web: www.quotientbiodiagnostics.com

Manufacturer:

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

US License 1807

Tel: +44 (0) 131 536 5907
Fax: +44 (0) 131 536 5897
E-Mail: customer.services@albabioscience.co.uk

© Alba Bioscience Limited 2009

Z171UQPI/01

