QUOTIENT

BLOOD GROUPING REAGENT

Anti-M

ALBAclone®
(Murine Monoclonal)
For Tube Techniques

REF **Z171** CE

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

INTERPRETATION OF LABELLING SYMBOLS

LOT	Batch code
	Use by (YYYY-MM-DD)
2°C 8°C	Storage temperature limitation (2-8 °C)
IVD	*In vitro* diagnostic medical device
www.quotientbd.com	Consult instructions for use
	Manufacturer
REF	Product Code

INTENDED USE

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

SUMMARY AND EXPLANATION

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 cells carry 'N'-antigen on a minor red cell sialoglycoprotein, glycophorin B.

PRINCIPLE OF THE TEST

When used by the recommended technique, this reagent will cause the 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 IgG secreting mouse hybridoma:

Product Name	Product Code	Cell Line
Anti-M	Z171	LM1

The formulation also contains bovine serum albumin, EPPS buffer and 0.5% (w/v) sodium azide.

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

This reagent complies with the requirements 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 2-8 °C.

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

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 reagent contains 0.5% (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 build-up.

EUH032 — Contact with acids liberates very toxic gas.
H412 -- Harmful to aquatic life with long lasting effects.

P273- Avoid release to the environment.

P501- Dispose of contents/container in accordance with local/regional/national/international regulations.

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

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 seven days from collection. Donor blood stored in citrate anticoagulant may be tested until the expiration date of the donation.

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

MATERIALS

Material provided
- ALBAclone® Anti-M

Materials required but not provided
- Unbuffered Saline (9 g/L NaCl)
- Reagent red cells suitable for the control of Anti-M
- 10 x 75 mm or 12 x 75mm glass test tubes
- Pipettes
- Centrifuge
- Timer
- Heating block/waterbath (optional)

PROCEDURE

NOTE: This reagent has been standardised for use by the technique described below and therefore its suitability for use by 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 room temperature 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 - NIS 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.

1. Prepare a 2-3% suspension of washed red blood cells in unbuffered isotonic saline solution (9 g/L NaCl).
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 incubate at 18-24°C for 5 minutes.
5. Centrifuge the test tube.
   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.
6. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.
7. Record results.

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

QUALITY CONTROL

Quality control of reagents is essential and should be performed on the day of use.

M+N+ red blood cells should be used as a positive control
M-N+ red blood cells should be used as a negative control

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. Cells suspended in buffered medium e.g. Alsever's solution, should be washed and re-suspended 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.

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 re-suspending 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.

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

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 using recommended methods against a panel of antigen-positive and antigen-negative red blood cells to ensure suitable reactivity.

Comparator Study Results

During comparator studies (data on file at Alba Bioscience Limited), blood samples were tested with ALBAclone® Anti-M as follows:

Anti-M	Trial/Reference Reagent	Comparator Reagent		
		Positive	Negative	Total
Trial Reagent	Positive	177	0	177
	Negative	0	180	180
	Total	177	180	357
Positive Percent Agreement				100
Negative Percent Agreement				100
Overall Percentage Agreement				100

Precision Study Results

Precision and lot to lot studies were performed using multiple operators, days and runs to confirm repeatability and reproducibility of test results in the same run, day, and with the same operator and between runs, days, and operators. The study took account of variables such as days of the week, times of day, and supplementary reagents used in the testing.

There were no discordant results over 216 data points; all expected positive test outcomes generated unequivocal positive reactions and all expected negative test outcomes generated unequivocal negative reactions.

BIBLIOGRAPHY

1. British Committee for Standards in Haematology: Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, *Trans Med* 2013; 23: 3-35
2. National Blood Service: Guidelines for the Blood Transfusion Services in the United Kingdom, ed 8. TSO, 2013
3. Reid ME, Lomas-Francis C, Olsson ML: The Blood Group Antigen FactsBook, ed 3. Academic Press, 2012

DATE OF ISSUE

2023-12

For further information or advice please contact your local distributor.

EC REP

Emergo Europe B.V.
Westervoortedijk 60
6827 AT, Arnhem
The Netherlands

Alba Bioscience Limited
James Hamilton Way
Penicuik
EH26 0BF
UK

Tel No: +44 (0) 131 357 3333
Fax No: +44 (0) 131 445 7125
E-Mail: customer.serviceEU@quotientbd.com

Z171PI/09

INSTRUCTIONS FOR USE

Instructions for Use are available on Quotient website at www.quotientbd.com or can be requested from your Local Distributor, by providing the relevant Product Code stated on product labels and Instructions for Use supplied with the product.

ISTRUZIONI PER L'USO

Le istruzioni per l'uso son disponibili sul sito Web di Quotient, www.quotientbd.com, o possono essere richieste al proprio distributore locale fornendo il codice del prodotto indicato sulle etichette del prodotto e nelle istruzioni per l'uso fornite con il prodotto.

KULLANIM TALİMATLARI

Kullanım Talimatları Quotient web sitesi www.quotientbd.com adresinde bulunabilir veya ürün etiketinde veya ürünle birlikte verilen Kullanım Talimatlarında belirtilen ilgili Ürün Kodu sunularak Yerel Distribütörden talep edilebilir.