BLOOD GROUPING REAGENT
Anti-M
ALBAclone®
(Murine Monoclonal IgG)
For Tube Technique

INTENDED USE
This Anti-M reagent is for the in vitro detection and identification of the human M blood group antigen 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 blood 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 blood 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:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Product Code</th>
<th>Cell Line</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-M</td>
<td>Z171U</td>
<td>LM1</td>
</tr>
</tbody>
</table>

The formulation also contains bovine serum albumin, EPPS buffer and 0.1% (w/v) sodium azide.

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

STORAGE
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 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 a sink, flush with a large volume of water to prevent azide build-up.

This reagent is of animal origin, 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 which was used has been collected in a USDA approved facility.

Contains material of murine origin; therefore, handle appropriately as the absence of murine viruses has not been determined.

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.

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 stored in citrate anticoagulant may be tested until the expiry 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-M

Materials required but not provided
• Unbuffered isotonic saline
• Reagent red blood cells suitable for the control of Anti-M
• 10 x 75 mm or 12 x 75 mm glass test tubes
• Pipettes
• Centrifuge
• Timer
• Heating block/waterbath

PROCEDURE
NOTE: This reagent has been standardized 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 the reagent to reach 20-25 °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.
Cells modified by proteolytic enzymes must not be used, as M antigens may be destroyed.

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 blood. 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.

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

Gently re-suspend tube tests before reading. Excessive agitation may disrupt weak agglutination and produce false negative results.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

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

**BIBLIOGRAPHY**

2. AABB Standards Program Committee: Standards for Blood Banks and Transfusion Services, ed 30. AABB, 2016

**DATE OF ISSUE**

2017-02-28

---

**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. Modified 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.