

MaxCLONE ANTI-B (IgM)

Monoclonal Blood Grouping Antibodies for Slide and Tube Tests

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVANTIB-60	6 x 10 ml	Single Liquid Reagent

INTENDED USE :

MaxCLONE ANTI-B (IgM) reagent kit is intended for use of *in-vitro* determination of the presence or absence of B antigen on human red blood cells by the slide and tube test method.

INTRODUCTION

The ABO system is the most important among all blood groups in transfusion practice. The four groups are determined by the presence or absence of blood group antigen on the red cells and accordingly an individual's group is determined as A, B, AB or O (O denotes the absence of A or B antigens). In addition, it has been shown that corresponding antigens to A and B, occur naturally as antibodies Anti-A and Anti- B(agglutinins) in the plasma/serum of individual whose red cells lack the corresponding antigens. Group A individual have anti-B, Group-B individual have anti-A, Group O individual have both anti-A and anti-B and Group AB individual have no agglutination in the plasma/serum.

The ABO blood grouping reagents contain sera of monoclonal IgM antibodies derived from hybridoma cell lines, created by fusing mouse antibody producing B lymphocytes with mouse myeloma cells. Each hybridoma cell line produces homogeneous antibodies of only one immunoglobulin class, which are identical in their chemical structure and immunological activity.

ABO blood grouping reagents are of four types, namely Anti-A, Anti-B, Anti-A,B and Anti-D Blood Grouping Reagents. Anti-A Blood Grouping Reagent agglutinates human red corpuscles containing A antigens. It does not agglutinate human red corpuscles of groups O and B.

PRINCIPLE

Human red blood cells possessing B antigen will agglutinate in the presence of antibody directed towards the antigen. Agglutination of red blood cells with MaxCLONE Anti-B reagents is a positive test result and indicates the presence of the corresponding antigen.

Absence of agglutination of red blood cells with MaxCLONE Anti-B reagents is a negative test result and indicates the absence of the corresponding antigen.

REAGENTS

MaxCLONE Anti-B is ready to use reagents prepared from the supernatants of mouse hybridoma cell cultures. These antibodies of immunoglobulin class IgM are mixture of several monoclonal antibodies of the same specificity but having the capacity of recognising different epitopes of the human red blood cell antigens B. Each batch of reagent undergoes rigorous quality control at various stages of manufacture for its specificity, avidity and performance.

REAGENT STORAGE AND STABILITY

1. Store the reagent at 2-8°C . DO NOT FREEZE.
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label.

KIT CONTAINS

Name of Reagent	Antibody Type	Pack Size
Anti-B	IgM	6 x 10 ml

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution. When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Glass slides, Test tubes, Pasteur pipettes, Isotonic saline (0.9% NaCl Solution), Centrifuge, Timer, Mixing sticks, Sodium Hypochlorite (1%).

PRECAUTIONS AND WARNINGS

1. Test for In-vitro diagnostic use only and should be run by competent and trained person only.
2. Not for medicinal use.
3. Use clean and dry glass wares.
4. The reagent contains 0.1% sodium azide as a preservative. Avoid contact with skin & mucosa.
5. Extreme turbidity may indicate microbial contamination or denaturation of protein due to thermal damage. Such reagents should be discarded.
6. Always wear hand gloves while performing the test. Avoid re-using gloves or use of washed gloves.
7. Do not smoke, eat and drink in the testing area.
8. Do not use haemolysed specimen for testing.
9. Do not use the reagent beyond expiry date.
10. Do not pipette by mouth.
11. All the materials used in the assay and samples should be decontaminated in 1% sodium hypochlorite. They should be disposed of in accordance with established safely procedure.
12. Spills should be decontaminated promptly with sodium hypochlorite or any other suitable disinfectant.
13. Wash hands thoroughly with soap or any suitable detergent, after the use of kit. Consult a physician immediately in case of accident or contact with eyes.

SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient is required prior to sample collection by approved techniques. Samples should be stored at 2-8°C if not tested immediately. Do not use haemolysed samples. Anticoagulated blood using various anticoagulants should be tested within the below mentioned time period:

EDTA or HEPARIN	:	2 days
Sodium citrate or sodium oxalate	:	14 days
ACD or CPD	:	28 days

TEST PROCEDURE

Bring reagents and samples to room temperature before testing.

SLIDE TEST

1. Place one drop or 50µl MaxCLONE Anti-B reagents using the reagent dropper separately on a clean glass slide.
2. To each reagent drop, **add one small drop or 25 µl of whole blood.**
3. Mix well with a mixing stick uniformly over an area of approximately 2.5 cm².
4. Rock the slide gently, back and forth.
5. Observe for agglutination macroscopically at two minutes.

TUBE TEST

1. Prepare a 5% suspension of the red cells to be tested in isotonic saline.
2. Place one drop or 50µl of MaxCLONE Anti-B reagents using the reagent dropper into corresponding labeled test tubes.
3. Pipette into each of test tubes, one drop or 50 µl red cell suspension and mix well.
4. Centrifuge for one minute at 1000 RPM(125 g) or 20 sec. at 3400 RPM(1000 g)
5. Gently resuspend the cell button, observing for agglutination macroscopically.

INTERPRETATION OF RESULTS

Slide and tube tests

Agglutination is a positive test result and indicates the presence of B antigen. No agglutination is a negative test result and indicates the absence of B antigen. Avidity: It is defined as the reactivity time (In seconds) taken by the antibodies to show the agglutination.

Intensity: It shows the strength of the reaction (clumping).

Grades	Description
4+	1 big clump
3+	2 or 3 clumps
2+	many small clumps with clear supernatant
1+	many small clumps with turbid supernatant
W	granular suspension
Zero or -ve	smooth suspension
H	partial or complete hemolysis (positive reaction)

REMARKS

1. **MaxCLONE** Anti-B reagents do not show a reaction with crypt antigens (T, Tn, Tk activated cells).
2. In the tube test procedure, it is recommended that tubes with negative reactions should be recentrifuged and results read again after 5 minutes so that weak antigens are not overlooked.
3. As under centrifugation or over centrifugation could lead to erroneous results, it is recommended that each laboratory calibrate its own equipment and determine the time required for achieving the desired results.
4. Results of forward grouping obtained by using **MaxCLONE** Anti-B, reagents should always be reconfirmed by performing reverse grouping with known red cells.
5. It is strongly recommended that red cells with known ABO characteristics should be occasionally run, preferably on a daily basis so as to control reagent performance and validate the test results.
6. After usage the reagents should be immediately recapped and replaced to 2-8°C storage.
7. The label minimum titre claim is based on, B group cells for **MaxCLONE** Anti-B reagent. This is based on titration procedure as recommended by the manufacturer. Any deviation in test procedure could result in variable results.

PERFORMANCE CHARACTERISTICS

1. The reagents have been characterized by all the procedures mentioned in the Recommended Techniques.
2. Prior to release, each lot tested by the Recommended Techniques against a panel of antigen-positive red cells to ensure suitable reactivity.
3. Specificity of source monoclonal antibodies is demonstrated using a panel of antigen-negative cells.
4. The potency of the reagents has been tested against the minimum potency reference standards obtained from National Institute of Biological Standards and Controls (NIBSC).
5. The Quality Control of the reagents was performed using red cells that had been washed at least twice with PBS or Isotonic saline prior to use

NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. To be used by a qualified personnel. Not for medicinal use.
2. The reagent contains sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
3. Extreme turbidity may indicate microbial contamination or denaturation of protein due to thermal damage. Such reagents should be discarded.
4. Reagents are not from human source, hence contamination due to HBsAg, HIV and HCV is practically excluded.
5. It is necessary to use calibrated dropper provided in the reagent vial to dispense a reagent drop.
6. It is advisable to wear gloves and safety spectacles and handle test specimens of human origin with caution.
7. Do not use damaged or leaking reagents.
8. Special protective measures, conditions for disposal and disinfection should be implemented in accordance with local regulations.

DISCLAIMER

1. The user is responsible for the performance of the reagents by any method other than those mentioned in the Recommended Techniques.
2. Any deviations from the Recommended Techniques should be validated prior to use.














WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

REFERENCE

1. Kohler G., Milstein C., 1975 Continuous culture of fused cells secreting antibody of predefined specificity. *Nature*, 256, 495-497.
2. Denise M. Harmening, 2005, *Modern Blood Banking and Transfusion Practices*, Fifth Edition, 108-110.
3. Marian Petrides, MD; Laura cooling, MD; Gary Stack, MD, PhD; and lanne Maes, MD, 2011, *Technical Manual*, 17th Edition, 363-364.
4. *Indian Pharmacopoeia*, 2010, Vol-1, 6th Edition, 248-250.
5. *Dacie and Lewis Practical Haematology* by Barbara J Bain, Imelda Bates, Michael A Lattan, S. Mitchell Lewis, Eleventh Edition, 2011, Elsevier Limited.
6. *Human blood groups* by Geoff Daniels, Second edition, 2002 by Blackwell Science Ltd.
7. Guidance manual "Quality Control of ABO and Rh blood grouping reagents". 2012 Document ID No. NIB/BRL/GM/01.
8. Guidance manual "Quality Control of ABO and Rh blood grouping", 2012 Document ID No. NIB/BRL/GM/02.
9. *Transfusion medicine technical manual*, 2nd edition 2003 Edited by Dr. R.K. Saran. QAOI-701.84

Symbols Used on Pack

 REF	Catalogue Number		Warning/Caution
 LOT	Batch No.		In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		



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