

MaxCLONE ANTI-D (IgM)

Blood Grouping Antibodies for Slide and Tube Tests

ORDERING INFORMATION

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

INTENDED USE :

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

INTRODUCTION

Monoclonal antibodies are derived from hybridoma cell lines, created by fusing mouse antibody producing B lymphocytes with mouse myeloma cells or are derived from a human B cell line through EBV transformation. Each hybridoma cell line produces homogenous antibodies of only one immunoglobulin class, which are identical in their chemical structure and immunological activity. Human red blood cells are classified as Rho (D) positive and Rho (D) negative depending upon the presence or absence of D (Rho) antigen on them. Approximately 85% of the Caucasian population are Rho (D) positive.

PRINCIPLE

Human red blood cell possessing D antigen will agglutinate in the presence of antibody directed towards the antigen. Agglutination of red blood cells with **MaxCLONE Anti-D (IgM)** reagent is a positive test result and indicates the presence of the D antigen. No agglutination with **MaxCLONE Anti-D (IgM)** reagent is a negative test result and indicates absence of D antigen.

REAGENT

MaxCLONE Anti-D (IgM) is a ready to use reagent, prepared from supernatants of cell cultures with antibody producing B lymphocytes obtained through EBV transformation. These antibodies are monoclonal antibodies of the same specificity having the capability of recognizing specific epitopes of the human red blood cell antigen D. 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 D	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

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.

SAMPLE 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-D (IgM)** reagent using the reagent dropper on a clean glass slide.
2. To the reagent drop, add a small drop of 25 µl whole blood.
3. Mix well the reagent and blood sample 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 the end of two minutes.

Tube Test

1. Prepare a 5% cell suspension of the red cells in isotonic saline.
2. Place one drop or 50µl **MaxCLONE Anti-D (IgM)** reagent into a labeled test tube.
3. Pipette 50µl of red cell suspension in to the test tube and mix well.
4. Centrifuge for one minute at 1000 RPM (125 g) or 20 seconds at 3400 RPM (1000 g).
5. Gently resuspend the cell button observing for agglutination macroscopically.

INTERPRETATION OF RESULTS

Slide and Tube Tests

- a) Agglutination with the **MaxCLONE Anti-D (IgM)** is a positive test result and indicates the presence of D antigen. Do not interpret peripheral drying or fibrin strands as agglutination.
- b) No agglutination with **MaxCLONE Anti-D (IgM)** is a negative test result and indicates the absence of D antigen.

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

- As under centrifugation and over centrifugation could lead to erroneous results, it is recommended that each laboratory calibrate its own equipment and the time required of achieving the results.
- It is strongly recommended that as a routine quality control measure with known D positive and D negative red cells be occasionally run, preferably on a daily basis to validate reagent performance.
- After usage, the reagents should be immediately recapped and replaced to 2-8°C storage.
- Cord Cells heavily sensitized with Anti-D (Rho) may give false negative result in immediate spin test.
- False positive reactions may occur if the test subject has cold agglutinins.

PERFORMANCE CHARACTERISTICS

The performance of **MaxCLONE** Anti-D (IgM) comply with the common technical specifications of in-vitro diagnostic medical devices under the recommended methods. The performance of **MaxCLONE** Anti-D (IgM) was evaluated on over 3035 samples (from donors, patients and neonates) drawn on the recommended anticoagulants. The evaluation demonstrated 100% specificity of reagent versus the expected results with common known Rhesus phenotypes.

NOTE

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

DISCLAIMER

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

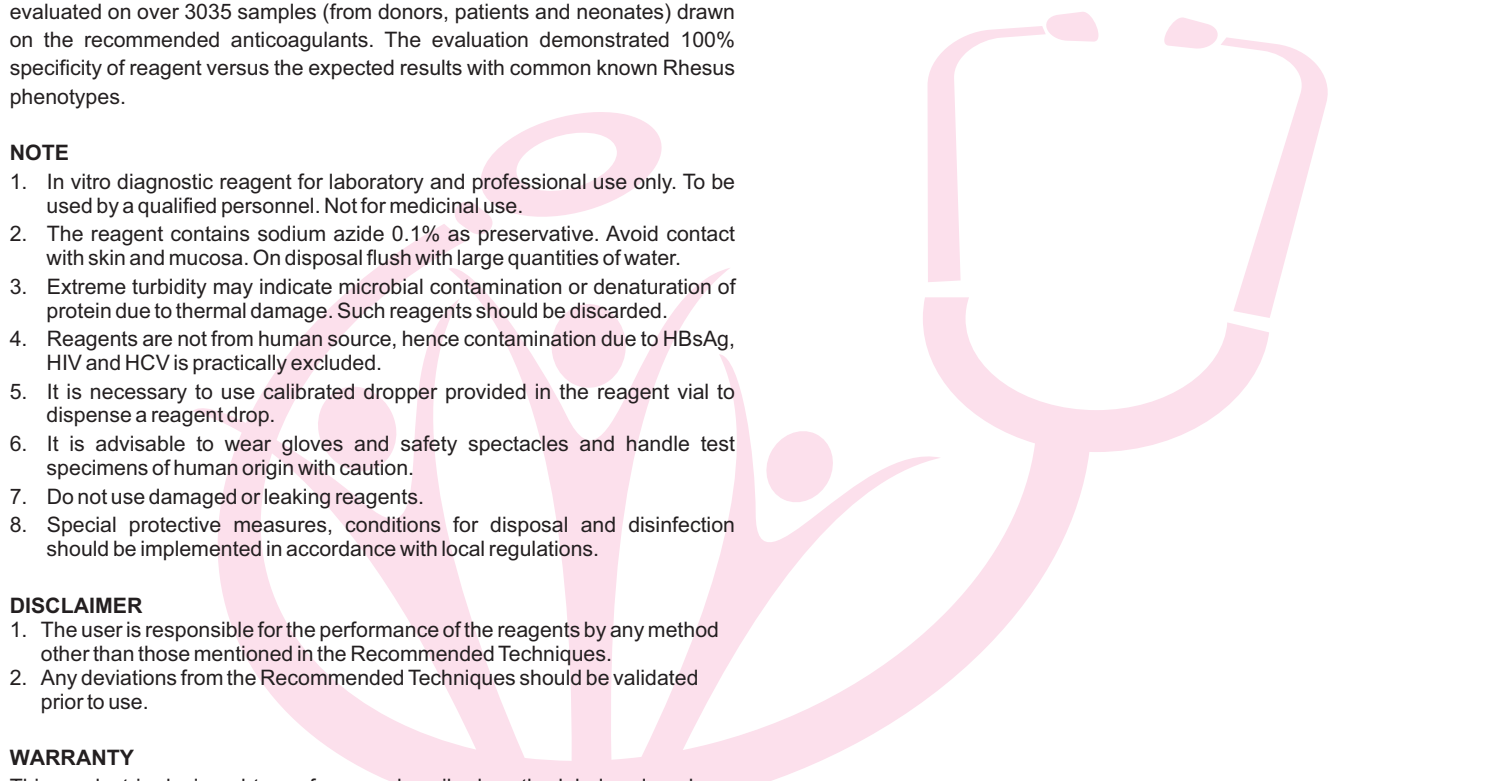
WARRANTY

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

- Kohler G., Milstein C., 1975 Continuous culture of fused cells secreting antibody of predefined specificity. Nature, 256, 495-497.
- Denise M. Harmening, 2005, Modern Blood Banking and Transfusion Practices, Fifth Edition, 108-110.
- Marian Petrides, MD; Laura cooling, MD; Gary Stack, MD, PhD; and lanne Maes, MD, 2011, Technical Manual, 17th Edition, 363-364.
- Indian Pharmacopoeia, 2010, Vol-1, 6th Edition, 248-250.
- Dacie and Lewis Practical Haematology by Barbara J Bain, Imelda Bates, Michael A Lattan, S. Mitchell Lewis, Eleventh Edition, 2011, Elsevier Limited.

- Human blood groups by Geoff Daniels, Second edition, 2002 by Blackwell Science Ltd.
- Guidance manual "Quality Control of ABO and Rh blood grouping reagents". 2012 Document ID No. NIB/BRL/GM/01.
- Guidance manual "Quality Control of ABO and Rh blood grouping", 2012 Document ID No. NIB/BRL/GM/02.
- 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		

Ver. : 06/01-26