**ADDITIONAL MATERIAL REQUIRED FOR SLIDE AND TUBE TESTS**

Glass slides (60 x 85 mm), Test tubes (12 x 75 mm), Test tube rack, Pasteur pipettes, Isotonic saline, Centrifuge, Timer, Mixing sticks, Anti Human Globulin (Coombs) reagent.

**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 dropper drop a drop of whole blood (Approximately 25µl)
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 three 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 into 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**

- 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.
- No agglutination with **MaxCLONE Anti-D (IgM)** is a negative test result and indicates the absence of D antigen.

**REMARKS**

1. 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.
2. 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.
3. After usage, the reagents should be immediately recapped and replaced to 2-8°C storage.
4. Cord Cells heavily sensitized with Anti-D (Rho) may give false negative result in immediate spin test.
5. 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 re-commended 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.

**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.

**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 advisable to wear gloves and safety spectacles and handle test specimens of human origin with caution.
6. Do not use damaged or leaking reagents.
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.

**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

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**MaxCLONE ANTI-D (IgM) Monoclonal**

**Blood Grouping Antibodies for Slide Tube Tests**

**SUMMARY**

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 homogeneous 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.

**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. Once opened the shelf life of the reagent vial is as described on the reagent vial label provided it is not contaminated.

**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.

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**Website : www.aveconhealthcare.com**

**CIN NO : U24230HP2006PTC030275**

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**O Six Sigma MaxCLONE ANTI-D (IgM) Monoclonal**

**for advanced diagnostic solutions you can count on AVECON**