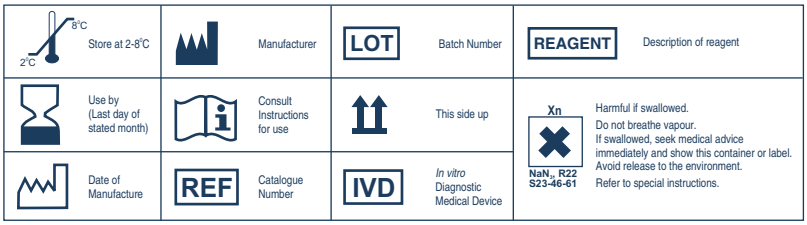
SBio Anti-D (Rho) (IgM)

Monoclonal Blood Typing Antibodies for Slide and Tube Tests

REF	90150610	90150010
Pack	6 x 10 ml	10 ml



INTENDED USE

SBio Anti-D reagent is used for the in vitro detection and identification of human RH D blood group antigens by direct agglutination through slide or tube test method.

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 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 or 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. The D^{u} phenotype is a variant of D (Rho) antigen and is recognised by performing the antiglobulin test.

About 60% of the D^{u}s, now classified as weak or partial D's, may react with Anti-D (Rho) (IgM) in slide tests and about 90% may be detected by the tube technique.

REAGENT

SBio Anti-D (Rho)(IgM) is a ready to use reagent, prepared from supernatants of cell cultures with antibody producing B lymphocytes obtained through EBV transformation and is a blend of Agglutinating sera of immunoglobulin class IgM (Clone P3x61+NaTH119), having the capability of recognising different epitopes of the human red blood cell antigen D (Rho).

SBio Anti-D (Rho)(IgM) does not detect all weak and partial D's. For the confirmation of negative reactions with SBio Anti-D (Rho)(IgM) further testing with an incomplete Anti-D (Rho) (IgG) or SBio Anti-D (Rho)(IgM + IgG) is strongly recommended to confirm the presence or absence of weak/partial D's.

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 cells possessing the D (Rho) antigen will agglutinate in the presence of agglutinating sera directed towards the antigen. Agglutination of red blood cells with SBio Anti-D (Rho)(IgM) reagent is a positive test result and indicates the presence of D (Rho) antigen. No agglutination with the reagent is a negative test result and indicates the absence of D (Rho) antigen. All negative test results should be further tested for D^{u} (Presence of weak / partial D's) by performing the D^{u} test procedure using incomplete Anti-D (Rho)(IgG), as described later.

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 the 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.

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. For optimal results, freshly collected sample should be used. Anticoagulants like EDTA,CPD-A and Citrate can be used. Do not use haemolysed sample.

ADDITIONAL MATERIAL REQUIRED FOR SLIDE AND TUBE TESTS

Glass slides (60 x 85 mm), Test tubes (12 x 75 mm), Pasteur pipettes, Isotonic saline, Centrifuge, Timer, Mixing sticks, Anti-D (Rho) (IgG) or Anti-D (Rho) (IgM + IgG) and SBio Anti-Human Globulin (Coombs) reagent.

TEST PROCEDURE

Bring reagent and samples to room temperature before testing.

Slide Test

1. Place one drop of SBio Anti-D (Rho)(IgM) reagent on a clean glass slide.
2. Pipette 50µl of whole blood on the slide.
3. Mix well with a mixing stick uniformly over an area of approximately 2.5 cm^{2}.
4. Rock the slide gently, back and forth.
5. Observe for agglutination macroscopically at the end of two minutes.

Immediate Spin Tube Test

1. Prepare a 5% suspension of red cells to be tested in isotonic saline.
2. Place one drop of SBio Anti-D (Rho) (IgM) reagent into a labeled test tube.
3. Pipette into the test tube 50µl of 5% cell suspension 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.

D^{u} TEST PROCEDURE

1. Prepare a 5% suspension of the red cells to be tested in isotonic saline.
2. Place one drop of SBio Anti-D (Rho)(IgM+IgG) reagent into a labeled test tube.
3. Add to the test tube 50µl of the 5% cell suspension and mix well. Incubate at 37^{0}C for 15 minutes.
4. Wash the contents of the tube thoroughly, at least three times, with isotonic saline and decant completely after the last wash.
5. Add 100µl of SBio Anti Human Globulin reagent and mix well.
6. Centrifuge for 1 minute at 1000 RPM (125 g) or 20 seconds at 3400 RPM (1000 g).
7. Very gently, resuspend the cell button and observe for agglutination macroscopically.

INTERPRETATION OF RESULTS

Slide and Tube Tests

a) Agglutination is a positive test result and indicates the presence of D (Rho) antigen. Do not interpret peripheral drying or fibrin strands as agglutination. No agglutination is a negative test result and indicates the absence of D (Rho) antigen.

b) Cord cells heavily sensitized with SBio Anti-D (Rho) may give a false negative immediate spin test result.

D^{u} Test Procedure

(a) Agglutination indicates the presence of D^{u} antigen (Presence of weak / partial D's). No agglutination indicates the absence of D^{u} antigen (Absence of weak / partial D's). (b) Mixed field agglutination in the D^{u} test on red cells from a recently delivered woman may indicate a mixture of maternal Rho (D) negative and fetal Rho (D) positive blood. (c) Red cells demonstrating a positive direct antiglobulin test cannot be accurately tested for D^{u} antigen (Presence of weak / partial D's).

REMARKS

1. As undercentrifugation and overcentrifugation could lead to erroneous results, it is recommended that each laboratory calibrate its own equipment and the time required for achieving the desired results.
2. It is strongly recommended that as a routine quality control measure known as Rho (D) positive and Rho (D) negative red cells be occasionally run, preferably on a daily basis so as to control reagent performance and validation of test results.
3. After usage, the reagents should be immediately recapped and replaced to 2-8^{0}C storage.

PERFORMANCE CHARACTERISTICS

The performance of SBio Anti-D (Rho)(IgM) comply with the common technical specifications of in-vitro diagnostic medical devices under the recommended methods.

The performance of SBio Anti-D (Rho)(IgM) was evaluated on over 3275 samples (from donors, patients and neonates) drawn on the recommended anticoagulants. The process, techniques and protocols used were as defined in the package insert. The evaluation demonstrated 100% specificity. The sensitivity of reagent by slide test is 98.77% and by tube test it is 99.37% 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.

BIBLIOGRAPHY

(1) Kohler C. & Milstein C. (1975), Continuous cultures of fused cells secreting antibody of predefined specificity., Nature, 256, 495-497. (2) Lee H.H., Rouger P., Germain C., Muller A & Salmon C. (1983). The production and standardisation of monoclonal antibodies as AB blood group typing reagents. Symposium of International Association of Biological Standardisation on Monoclonal antibodies. (3) Human Blood Groups by Geoff Daniels, 1st Ed., Blackwell Science, Oxford 1995. (4) HMSO, Guidelines for Blood Transfusion Services., 2nd Ed., 1994.

Manufactured by:

TULIP DIAGNOSTICS (P) LTD.

Plot Nos. 92/96, Phase II C, Verna Industrial Estate,
Verna, Goa - 403 722, INDIA.
Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh,
Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.
Website: www.tulipgroup.com Email: sales@tulipgroup.com

0522/VER-04

Manufactured for:

Singapore Biosciences PTE Ltd.
11 Yishun Street 51, #04-23,The Criterion,
Singapore 767971