PETUNJUK PENGGUNAAN
Bahasa Indonesia

INDOSERA™

ANTI-D (Rho) (IgM)
MONOCLONAL BLOOD TYPING ANTIBODIES FOR SLIDE AND TUBE TESTS

SUMMARY
Monoclonal antibodies are derived from hybridome 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 hybridome 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 recognized by performing the anti-globulin 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
INDOSERA™ Anti-D (Rho) (IgM) is a ready to use reagent, prepared from supernatant 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 recognizing different epitopes of the human red blood cell antigen D (Rho).
INDOSERA™ Anti-D (Rho) (IgM) does not detect all weak and partial D's. For the confirmation of negative reactions with INDOSERA™ Anti-D (Rho) (IgM) further testing with an incomplete Anti-D (Rho) of IgG class or INDOSERA™ 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^{0}C. DO NOT FREEZE.
2. The shelf life for sealed product is 24 months or as per mentioned in the label expiry date.
3. The shelf life for opened products, as long as no contamination indicated is same as per mentioned in the label expiry date.

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 INDOSERA™ Anti-D (Rho) (IgM) reagent is a positive test result & 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) of IgG class, as described later.

PRECAUTIONS
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. MSDS available on request.
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. For optimal results, freshly collected venous whole blood sample should be used. Anticoagulants like EDTA, CPD-A and Citrate can be used.

ADDITIONAL MATERIAL REQUIRED FOR SLIDE AND TUBE TESTS
Slides (60 x 85 mm), Test tubes (12 x 75 mm), Micropipettes, Isotonic saline (0.9% NaCl), Centrifuge, Timer, Mixing sticks, INDOSERA™ Anti-D (Rho)(IgG) or INDOSERA™ Anti-D (Rho)(IgM + IgG) and INDOSERA™ Anti-Human Globulin (Coombs) reagent.

TEST PROCEDURE
Bring reagent and samples to room temperature before testing.

Slide Test
1. Place one drop of INDOSERA™ Anti-D (Rho) (IgM) reagent on a clean 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.

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Immediate Spin Tube Test
1. Prepare a 5% suspension of red cells to be tested in isotonic saline.
2. Place one drop of INDOSERA™ 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 125 g or 20 seconds at 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 any incomplete Anti-D (IgG) containing reagent.
3. Add to the test tube 50µl of the 5% cell suspension and mix well. Incubate at 37°C for 15 minutes.
4. Wash the contents of the tube thoroughly, atleast three times, with isotonic saline and decant completely after the last wash.
5. Add 100µl of INDOSERA™ 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 INDOSERA™ Anti-D (Rho) may give a false negative immediate spin test result.
c) 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.

D^{u} Test Procedure
(a) Agglutination with reagent indicates the presence of D^{u} antigen (weak / partial D's). (b) No agglutination with reagent indicates the absence of D^{u} antigen (Absence of weak / partial D's). Negative reactions obtained in D^{u} test must be validated:- add 50µl of coomb's control cells to the reaction mixture. A positive reaction confirms the activity of the coomb's reagent and validates the negative reaction before the addition of the coomb's control cells. (c) 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. (d) Red cells demonstrating a positive direct antiglobulin test cannot be accurately tested for D^{u} antigen (Presence of weak / partial D's).

PERFORMANCE CHARACTERISTICS
The Performance of INDOSERA™ Anti-D (Rho) (IgM) has been tested at an accredited institution, performed in accordance with the general technical specifications with the recommended methods by comparative studies with appropriate comparative instruments. The performance of INDOSERA™ Anti-D (Rho) (IgM) has been evaluated using 200 recommended samples. The evaluation showed 100% sensitivity and specificity of each reagent whose results were compared with the corresponding comparator instrument.

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. After usage, the reagents should be immediately recapped and replaced to 2-8°C storage.

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.Human Blood Groups, by Geoff Daniels, 2nd Ed., Blackwell Science, Oxford 1995.
3.HMSO, Guidelines for Blood Transfusion Services., 2nd Ed., 1994.
4.Data on file: PT Tulip Diagnostics Indonesia

8°C / 2°C Simpan pada suhu 2-8°C	Hanya digunakan oleh Profesional	IVD Perangkat Medis Diagnostik *in vitro*
Digunakan sebelum (hari terakhir bulan yang disebutkan)	Konsultasikan Petunjuk untuk digunakan	LOT Nomor Batch/ Nomor Lot
Tanggal Produksi	REF Nomor Katalog	Sisi atas ini

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