



INDOSERA™

ANTI-HUMAN GLOBULIN REAGENT FOR DIRECT AND INDIRECT ANTI-GLOBULIN TESTS

SUMMARY

Generally antibodies involved in transfusion reactions are of two types, namely the complete and the incomplete, whereas the complete antibodies agglutinate red cells in saline medium, the incomplete type of antibody sensitizes red cells without agglutination. Usually IgM class of antibodies and IgG₁ and IgG₂ type of IgG antibodies fix complement. Cell lysis, *in vivo*, is mediated through the complement system and the complement component C_{3b} is further acted upon to produce C_{3d}.

In the direct antiglobulin tests, Anti-Human Globulin Reagent is used to detect antibodies adsorbed to the red blood cells *in vivo*.

In the indirect antiglobulin tests, Anti-Human Globulin Reagent is used to detect antibodies adsorbed to the red blood cells *in vitro*.

Anti-Human Globulin Reagent is useful for compatibility testing, antibody detection, antibody identification, umbilical cord red blood testing and detection of the D^v variant of the human red blood cell antigen D (Rho).

REAGENT

INDOSERA™ Anti-Human Globulin is a balanced ready to use blend of highly purified immunoglobulins. It contains Agglutinating sera for Human IgG and Agglutinating sera reactive with human complement components C_{3d}. The agglutinating sera which are specific for human complement components are of IgM class and they impart the necessary sensitivity to the reagent.

Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, avidity and titre.

REAGENT STORAGE AND STABILITY

(a) Store the reagent at 2-8°C. DO NOT FREEZE.

(b) 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

Normal human red blood cells, in presence of antibody directed towards the antigen they possess, may fail to agglutinate and become sensitized. This may be due to the particular nature of the antigen and agglutinating sera involved. INDOSERA™ Anti human globulin reagent would react with red cells sensitized with gamma globulins or components of human complement involved and cause agglutination of the red blood cells.

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. 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 STORAGE

No special preparation of the patient is required prior to sample collection by approved techniques. Do not use haemolysed samples.

For Direct Antiglobulin Test: Blood drawn into EDTA is preferred but oxalated, citrated or clotted whole blood may be used. The blood sample should be tested as soon as possible after collection and should not be stored.

For Indirect Antiglobulin Test: Serum, not more than 48 hours old, should be used. Donor units may be tested upto the end of their dating.





INSTRUCTION FOR USE

English Version

Product Name :
Indosera Bovine Serum Albumin

7. First observe for haemolysis. Resuspend the cell button and observe for agglutination macroscopically.
8. Proceed to incubation phase.

INCUBATION PHASE

1. Incubate the saline tube at room temperature and the albumin tube at 37°C for 15 minutes.
2. First observe for haemolysis. Resuspend the cell button and observe for agglutination macroscopically.
3. Proceed to the antiglobulin phase.

ANTIGLOBULIN PHASE

1. Only the albumin tubes (A) are tested in the antiglobulin phase.
2. Wash the mixture of red blood cells and serum thoroughly with isotonic saline for a minimum of three times. Decant completely after the last wash.
3. Place two drops of **INDOSERA™** Anti-Human Globulin Reagent into the test tube containing the sedimented cells and mix well.
4. Centrifuge for one minute at 1000 RPM (125 g) or 20 seconds at 3400 RPM (1000 g).
5. Very gently, resuspend the cells and observe for agglutination macroscopically.

Antibody Titration Test

1. (a) Prepare a 5% suspension of red blood cells with specific antigen reacting with antibody to be titrated, in **INDOSERA™** Bovine Serum Albumin Reagent.
(b) Also prepare a 5% suspension of patient's red cells in **INDOSERA™** Bovine Serum Albumin Reagent.
2. Label ten test tubes (1 to 10) and make progressive dilutions of the patient serum as indicated below:
 - i) Pipette 0.1 ml of AB Neutral serum into each test tube except the first tube.
 - ii) Pipette 0.1 ml of the patient serum into first two tubes only.
 - iii) After mixing the contents of the second tube thoroughly, transfer 0.1 ml of the mixture to the third tube. Continue the serial dilution by transfer upto tube No. Ten, Discard 0.1 ml of the mixture from the last tube.
3. To tubes No. One thru' to Nine, add one drop of Albumin suspended selected red blood cells, (as prepared in point No. 1 (a) above) and mix well.
4. To tube No. Ten add one drop of patient red cells suspended in albumin (as prepared in point No. 1(b) above) and mix well.
5. Incubate all the tubes at 37°C for a minimum of 15 minutes.
6. Centrifuge all the tubes for one minute at 1000 RPM or 20 seconds at 3400 RPM (1000 g).
7. Very gently, resuspend the cell buttons and observe for agglutination macroscopically.
8. Antiglobulin test should be performed on all tubes, which do not show a very strong agglutination.

INTERPRETATION OF RESULTS

Compatibility Test

In all phases of the compatibility test, if no agglutination or haemolysis is observed then the patient and the donor may be considered compatible.

If haemolysis or agglutination at any point till the completion of the antiglobulin phase is observed the patient and donor are considered incompatible.

Antibody Titration Test

The end point of the titration is the reciprocal of the dilution in the last tube showing agglutination.

PERFORMANCE CHARACTERISTICS

The performance of **INDOSERA™** BSA comply with the common technical specifications of in-vitro diagnostic medical devices under the recommended methods. The performance of **INDOSERA™** BSA products has been evaluated using a comparative test method. **INDOSERA™** BSA products confirmed to has 100% sensitivity compared to the comparative reagent.

REMARKS

1. If plasma is used in the indirect antiglobulin test, the complement dependent antibodies may not be detected due to the absence of calcium.
2. To all negative test results, after the antiglobulin test phase, one drop of Coombs control cells should be added. If the Coombs control cells do not agglutinate, then the compatibility test must be repeated.
3. Red blood cells showing a positive direct antiglobulin test should not be used for the indirect antiglobulin test.
4. Bovine Serum Albumin will not bring about agglutination of red cells by all IgG blood grouping typing antibodies.
5. As undercentrifugation or overcentrifugation can lead to erroneous results, it is recommended that each laboratory calibrate its own equipments and the time required for achieving the desired results.
6. After usage the reagent should be immediately recapped and replaced at 2-8°C storage.

WARRANTY

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





INSTRUCTION FOR USE

English Version

Product Name :
indosera Bovine Serum Albumin

BIBLIOGRAPHY

1. 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.
2. Human Blood Groups by Geoff Daniels, First Edition, Blackwell Science Oxford 1995.
3. HMSO, Guidelines for the Blood Transfusion Services, Second Edition, 1994.
4. Data on file: PT Tulip Diagnostics Indonesia.

SYMBOL KEYS

	Temperature Limitation		Manufacturer		Batch Number/ Lot Number	 Professional Use only
	Use by		Consult Instructions for use		This side up	
	Date of Manufacture		Catalogue Number		In vitro Diagnostic Medical Device	

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