



INSTRUCTION FOR USE

English Version

Product Name :
indosera LISS

INDOSERA™

LISS

LOW IONIC SALT SOLUTION FOR SEROLOGICAL APPLICATIONS

SUMMARY

The antigen-antibody interaction in blood group serology is dependant on antigen density, concentration of antibody, pH, ionic concentration of reaction medium and temperature. Reducing the ionic concentration of the reaction medium especially enhances the uptake of weak antibodies by the red blood cell antigens. Usage of low ionic salt solution is helpful in detection of weak antibodies during cross match techniques, antibody screening and antibody identification.

REAGENT

INDOSERA™ LISS is a buffered low ionic salt solution of appropriate sodium chloride molarity useful in serological applications such as antibody detection and cross match techniques.

REAGENT STORAGE AND STABILITY

Store the reagent at 2-8°C. DO NOT FREEZE. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label.

PRINCIPLE

In blood group serology the ionic concentration of reaction medium is largely dependant on the concentration of sodium and chloride ion contributed by isotonic saline. When optimum concentration of antibody is present, antigen-antibody interaction occurs even though the sodium and chloride ions are present in sufficient quantity. But when weak antibodies are present, sodium and chloride ions may interfere with binding of antibody to the antigens present on the red blood cell membrane. By lowering the ionic concentration of salt, the ionic strength is reduced which increases the rate of antibody uptake by red blood cells.

NOTE

(1) In vitro diagnostic reagent for laboratory and professional use only. (2) The reagent contains 0.1% sodium azide as a preservative. Avoid contamination with skin and mucosa. On disposal flush with large quantity of water. (3) Do not freeze or expose the reagent to elevated temperatures. After usage immediately replace the reagent vial back to 2-8°C. (4) Marked turbidity may indicate reagent deterioration or contamination, such reagent should not be used. Do not use the reagent beyond expiry date.

SAMPLE COLLECTION AND STORAGE

No special preparation of the patient is required prior to sample collection by approved techniques. Sample 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 samples.

ADDITIONAL MATERIAL REQUIRED

Test tubes (12x75 mm), Pasteur pipettes, laboratory centrifuge, incubator (37°C), isotonic saline/ isotonic buffered saline, donor red blood cells and recipient serum for cross match, reagent red blood cells for antibody detection, Anti-human Globulin reagent for cross match and antibody detection (**INDOSERA™ AHG** Cat. No.6211070310), optical aid.

PROCEDURE

Bring all the reagents to room temperature before testing.

INDIRECT ANTIGLOBULIN TEST FOR CROSS MATCH

Initial phase

1. Wash donor red blood cells three times in isotonic saline. Decant the supernatant completely after last wash.
2. Finally wash the donor blood red cells with **INDOSERA™ LISS**. A final wash with **INDOSERA™ LISS** is recommended to reduce the effect of residual isotonic saline on the final ionic concentration of the test medium.
3. Prepare a 2-3% donor red blood cells suspension in **INDOSERA™ LISS**.
4. To an approximately labelled test tube add two drops of recipient serum.
5. Add two drops of **INDOSERA™ LISS** suspended donor red blood cells
6. Centrifuge for one minute at 1000 rpm (125g) or for 20 seconds at 3400 rpm (1000g).
7. First observe for haemolysis. Resuspend the cell button and observe for agglutination macroscopically.





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Incubation phase

1. Incubate the tube containing the mixture of donor red blood cells and recipient serum at 37°C for 10 minutes.
2. Centrifuge for one minute at 1000 rpm (125g) or for 20 seconds at 3400 rpm (1000g).
3. First observe for haemolysis. Resuspend the cell button and observe for agglutination macroscopically.
4. Proceed to the antiglobulin phase.

Antiglobulin phase

1. Wash the mixture of donor red blood cells and recipient serum thoroughly with isotonic saline minimum for three times. Decant completely after the last wash.
2. Place two drops of Anti-human globulin reagent into the test tube and mix well.
3. Centrifuge for one minute at 1000 rpm (125g) or for 20 seconds at 3400 rpm (1000g).
4. Very gently, resuspend the cell button and observe for agglutination macroscopically.

FOR ANTIBODY DETECTION

Initial phase

1. Wash red blood cells three times in isotonic saline. Decant the supernatant completely after last wash.
2. Finally wash the reagent red blood cells with **INDOSERA™ LISS**. A final wash with **INDOSERA™ LISS** is recommended to reduce the effect of residual isotonic saline on the final ionic concentration of the test medium.
3. Prepare a 2-3% reagent red blood cell suspension in **INDOSERA™ LISS**.
4. To an approximately labelled test tube add two drops of serum to be tested.
5. Add two drops of **INDOSERA™ LISS** suspended reagent red blood cells.
6. Centrifuge for one minute at 1000 rpm (125g) or for 20 seconds at 3400 rpm (1000g).
7. First observe for haemolysis. Resuspend the cell button and observe for agglutination macroscopically.

Incubation Phase

1. Incubate the tube containing the mixture of donor red blood cells and recipient serum at 37°C for 10 minutes.
2. Centrifuge for one minute at 1000 rpm (125g) or for 20 seconds at 3400 rpm (1000g).
2. First observe for haemolysis. Resuspend the cell button and observe for agglutination macroscopically
3. Proceed to the antiglobulin phase.

Antiglobulin phase

1. Wash the mixture of reagent red blood cells and serum thoroughly with isotonic saline minimum for three times. Decant completely after the last wash.
2. Place two drops of Anti-human Globulin reagent into the test tube and mix well.
3. Centrifuge for one minute at 1000 rpm (125g) or for 20 seconds at 3400 rpm (1000g).
4. Very gently, resuspend the cell button and observe for agglutination macroscopically

INTERPRETATION OF RESULTS

Crossmatch

In all phases of the compatibility test, if no agglutination or haemolysis is observed then the patient and donor may be considered to be compatible. If haemolysis or agglutination at any point till the completion of the antiglobulin phase is observed, the patient and donor are considered to be incompatible.

Antibody detection

Agglutination or haemolysis indicates that the antibody has reacted with the corresponding red blood cell antigen. No agglutination or haemolysis indicates the absence of corresponding antibody.

REMARKS

1. As under centrifugation or over centrifugation 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. Erroneous results may also occur due to improper red blood cell concentration, improper incubation time or temperature while performing the test.
3. The ionic strength of the test system is dependant on the amount of serum used. Alteration of the ionic strength of **INDOSERA™ LISS** procedure by addition of excess human serum will increase the ionic strength and decrease the sensitivity of the test system.
4. The performance of **INDOSERA™ LISS** reagent should be periodically evaluated with a known **INDOSERA™ LISS** enhanced antibody and the corresponding antigen for positive result and red cell lacking the corresponding antigen for negative result.
5. To all negative test results after the antiglobulin test phase, one drop of Coombs control cells should be added. If Coombs control cells do not agglutinate then the test must be repeated.





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6. Low ionic strength media have been used to enhance many antigen-antibody reactions. However not all antibodies are reactive in a **LISS** test system. Some weakly reactive IgM antibodies of ABO system may not be detected in the system employing low ionic strength media.

PERFORMANCE & CHARACTERISTICS

The performance of **INDOSERA™ LISS** products has been evaluated with comparative products. A total of 50 samples were tested using the reference reagent kit. Based on the study results, the product has a good correlation with the reference reagent. In the tests that have been carried out, there are no results that show False Negative or False Positive. This shows that the **INDOSERA™ LISS** product has 100% sensitivity to the comparison reference reagent.

WARRANTY

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

BIBLIOGRAPHY

1. Blood Transfusion in Clinical Medicine, PL Mollison, CP Engelfriet, Marcela Contreras, 9th Edition, 1994, Blackwell Science Publications.
2. AABB Technical Manual, 13th Edition, 1999.
3. Data on file: PT Tulip Diagnostics Indonesia.

KUNCI SIMBOL

	Batasan Suhu		Produsen		Nomor Batch/ Nomor Lot
	Digunakan oleh		Konsultasikan Petunjuk untuk digunakan		Sisi atas ini
	Tanggal Produksi		Nomor Katalog		Perangkat Medis Diagnostik <i>in vitro</i>

Diproduksi oleh:



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