SBio LISS

Low Ionic Salt Solution For Serological Applications

CE

REF	90250005
Pack	5 ml

+ 2°C + 8°C Store at 2-8°C	Manufacturer	IVD *In vitro* Diagnostic Medical Device	LOT Batch Number / Lot Number	Expiry date	EC REP Authorised Representative in the European Community
Consult Instructions for use	Date of Manufacture	REF Catalogue Number	This side up	Reagent Description of the reagent	Xn NaN_3 R22 S23-46-61 Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.

INTENDED USE

SBio LISS is helpful in detection of weak antibodies during cross match techniques, antibody screening and antibody identification.

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..

REAGENTS

SBio 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

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

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. 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. Do not freeze or expose the reagent to elevated temperature. 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.
5. It is necessary to use the dropper provided in the reagent vial to dispense a reagent drop.

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.

ADDITIONAL MATERIAL REQUIRED FOR SLIDE AND TUBE TESTS

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, optical aid.

TEST PROCEDURE

Bring reagents and samples 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 **SBio LISS**. A final wash with SBio 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 **SBio LISS.**
4. To an approximately labelled test tube add two drops of recipient serum.
5. Add two drops of **SBio 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.

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 1000RPM (125g) or for 20 seconds at 3400 rpm (100g).
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 **SBio LISS**.
   A final wash with **SBio 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 **SBio LISS**.
4. To an approximately labelled test tube add two drops of serum to be tested.
5. Add two drops of **SBio 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 1000RPM (125g) or for 20 seconds at 3400 rpm (100g)
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 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 **SBio LISS** reagent should be periodically evaluated with a known 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.
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.

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.

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.

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