LISS
Low Ionic Strength Additive Solution

INTENDED USE
American Red Cross (Red Cross) LISS is intended for use as a potentiator in antibody detection, antibody identification and compatibility testing.

SUMMARY AND EXPLANATION
Low ionic strength solutions (LISS) have a lower ionic strength than normal saline, which increases the rate of binding of antibody to red blood cells. \(^{(1,2,3)}\)

PRINCIPLE OF PROCEDURE
The principle of the test is the antiglobulin technique which is based on antigen-antibody mediated agglutination. Red Cross LISS is added directly to antibody screens, antibody identification panels and crossmatches to reduce the ionic strength of the testing environment.

REAGENT
This reagent is a low-ionic strength solution containing glycine and bovine albumin. Red Cross LISS is designed to be added directly to a serologic test system. The reagent contains 0.1% (w/v) sodium azide as a preservative. All cattle used for source bovine blood are from USDA-licensed facilities. Cattle receive health inspections and were apparently free from infectious and contagious disease. All donor animals are sourced in the U.S.

CAUTION
This product is for in vitro diagnostic use only.

WARNING: Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. If discarded into sinks, flush with a large volume of water to prevent azide build-up.

STORAGE
This reagent should be stored at 1-8°C when not in use. Do not freeze. Do not use if turbid. Do not dilute.

Do not use beyond expiration date. The format for the expiration date is expressed as YYYY-MM-DD (year-month-day).

SPECIMEN COLLECTION AND PREPARATION
Specimens (plasma, serum or eluate) should be collected/prepared by standard techniques. Specimens should be tested as soon as possible after collection/preparation. If testing is delayed, specimens should be stored at 1-8°C.

MATERIALS
Materials provided: Red Cross LISS
Materials required but not provided:
1. Test tubes, 10 X 75 mm or 12 X 75 mm
2. Test tube racks
3. Pipettes
4. Calibrated serologic centrifuge
5. Isotonic saline or phosphate buffered saline (pH 6.0-7.5)
6. Heat block / water bath at 36-38°C
7. Patient, donor and/or reagent red blood cells
8. Anti-Human Globulin Reagent, containing Anti-IgG
9. Antiglobulin control cells (IgG-sensitized red blood cells)
10. Timer
11. Optical aid(s) [optional]

PROCEDURE
1. Prepare a 2.4% suspension of red blood cells washed at least once with isotonic saline or phosphate buffered saline.

   NOTE: Reagent red blood cells may be used directly from the vial or in accordance with the manufacturer’s instructions.

2. Add 2 drops of serum/plasma/eluate to be tested to an appropriately labeled test tube(s).

3. Add 1 drop of the previously prepared or reagent 2-4% red blood cell suspension.

   NOTE: Immediate spin may be performed prior to the addition of Red Cross LISS and the 36-38°C incubation.

4. Add 2 drops of Red Cross LISS.

5. Mix well.

6. Incubate at 36-38°C for 15-30 minutes.

7. Centrifuge tube for 15 seconds at 3400 rpm (900-1000 rcf*) or 1 minute at 1000 rpm (100-120 rcf*) or equivalent, as indicated by equipment calibration.

8. Following centrifugation, examine the supernatant for hemolysis. Resuspend the red blood cells by gentle agitation. Examine macroscopically for agglutination.

9. All tests should be read immediately and results recorded without delay.

10. Wash the tests 3-4 times with isotonic saline or phosphate buffered saline.

11. Add Anti-Human Globulin containing anti-IgG according to the manufacturer’s directions. (Anti-IgG or polyspecific Anti-Human Globulin may be used in the test system.)

12. Mix well and centrifuge for 15 seconds at 3400 rpm (900-1000 rcf*) or 1 minute at 1000 rpm (100-120 rcf*) or equivalent, as indicated by equipment calibration.

13. Resuspend the red blood cells by gentle agitation. Examine for agglutination (optical aids may be used).

14. All tests should be read immediately and results recorded without delay.

15. Add antiglobulin control cells to all negative tests and centrifuge as above. Agglutination of the antiglobulin control cells confirms the presence of active anti-IgG. No agglutination of the antiglobulin control cells may indicate that the antiglobulin reagent has been neutralized or omitted and that tests should be repeated.

\(^{*}\text{rcf}=0.00001118 \times \text{radius (cm)} \times (\text{rpm})^2\)

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STABILITY OF REACTION

Delays in reading antiglobulin tests may result in the disassociation of antigen-antibody complexes leading to false negative or weak positive results.

QUALITY CONTROL

All negative antiglobulin tests should be tested with antiglobulin control cells (IgG-sensitized cells). Agglutination after the addition of IgG-sensitized red blood cells ensures that the antiglobulin reagent was added, reactive and that washing was complete. A positive result indicates the presence of active anti-human globulin (anti-IgG) and complete removal of proteins. A negative result should be considered invalid and the test repeated.

INTERPRETATION OF RESULTS

Positive result: Agglutination and/or hemolysis of the red blood cells.

Negative result: No agglutination and/or hemolysis of the red blood cells.

LIMITATIONS

All serological tests have limitations. To maximize success in obtaining valid results, follow the directions carefully. Deviation from manufacturers’ instructions without appropriate validation and controls may produce erroneous results.

Following centrifugation, all tests should be read immediately and the results recorded without delay.

The ionic strength of the test system is dependent upon the amount of serum used. Increasing the amount of serum may increase the ionic strength of the testing environment and may result in reduced test sensitivity.

False positive or false negative results may occur due to the contamination of the test materials, improper washing, improper incubation times and temperatures and omission of testing reagents.

The pH of the saline used for washing may affect the stability of the reaction. It is recommended that the pH be 6.0-7.5.

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance of this reagent is predicated on the use of appropriate materials and methods.

Equilibrate all materials to room temperature for optimal test performance.

To assure optimal test performance, each lot is qualified serologically with known antibodies and inert samples. Additionally, pH, osmolality and total protein are measured/standardized to maintain lot to lot consistency.

Non-concordance may be observed with similar reagents and/or alternate methodologies.

For technical questions, contact the American Red Cross Diagnostic Manufacturing Division at 1-800-882-3737.

BIBLIOGRAPHY