

LORNE LABORATORIES LTD.



GREAT BRITAIN

SEROLOGICAL ENHANCEMENT MEDIUM

DIRECTIONS FOR USE

LISS Ready for use: For Potentiating Serological Techniques.

SUMMARY

Reducing the ionic strength of a test system increases the rate of red blood cell antigen-antibody binding. Low and Messeter in 1974 showed that the use of a low ionic strength solution enhances the rate of antibody uptake in first stage of agglutination, allowing incubation times to be shortened.

PRINCIPLE

When used by the recommended techniques, the solution will reduce the ionicstrength of a test system, increase the rate of red blood cell antigen-antibody binding and permits a substantial reduction in incubation time and an increases in the test sensitivity with many antibody specificities (see Limitations).

REAGENT

Lorne LISS ready for use is a low ionic strength solution containing glycine, sodium chloride and phosphate buffer. The reagent is supplied at the optimal dilution, for use with all the recommended techniques stated below without the need for further dilution or addition. For lot reference number and expiry date see Vial Label.

STORAGE

Do not freeze. Reagent vials should be stored at 10 - 30°C on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity.

SAMPLE COLLECTION AND PREPARATION

Blood samples drawn with or without anticoagulant may be used for antigen typing. If testing is delayed then store specimens at 2-8°C. Specimens collected into ACD, CPD or CPDA-1 may be tested up to 35 days from the date of withdrawal. Other samples should be typed within 48 hours. All blood samples should be washed at least twice with PBS before being tested.

PRECAUTIONS

- The reagent is intended for *in vitro* diagnostic use only. If vial is cracked or leaking, discard the contents immediately. 2.
- 3. Do not use the reagent past the expiration date (see Vial Label).
- Do not use the reagent if a precipitate is present.
- Protective clothing should be worn when handling the reagent, such as disposable gloves and a laboratory coat.
- The reagent has been filtered through a 0.2 µm capsule to reduce the bio-burden. Once a vial has been opened the contents should remain viable up until the expiry date as long as there is no marked turbidity, which can indicate reagent deterioration or contamination. 6.
- 7. The reagent contains < 0.1% sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal flush away with large volumes of water.
- 8. Contact with LISS together with bleach causes accelerated corrosion of base metals such as copper and iron. This should be borne in mind when considering the use of bleach for decontaminating pluming or apparatus with metal parts, which have also been in contact with LISS

DISPOSAL OF REAGENT AND DEALING WITH SPILLAGES

For information on disposal of the reagent and decontamination of a spillage site see Material Safety Data Sheets, available on request.

CONTROLS AND ADVICE

- It is recommended Lorne Precise Weak Anti-D and appropriate red cells (ideally R₁r and rr) be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show the expected results.
- The antiglobulin technique can only be considered valid if all negative tests 2. react positively with IgG sensitised red cells
- The LISS solution, red cell suspensions and test sera should be at room 3 temperature prior to use to avoid encountering unwanted positive reactions due to "cold" antibodies.
- In the **Recommended Techniques** one drop is approximately 40 μ l when 4 using the vial dropper provided
- The use of the reagent and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagents are in use.
- The user must determine the suitability of the reagent for use in other techniques.

REAGENTS AND MATERIALS REQUIRED

- Anti-human globulin i.e. Lorne Polyspecific AHG Elite (Cat # 435010) or anti-IgG i.e. Lorne Monospecific Anti-IgG (Cat # 401010).
- Coombs cells washer.
- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- IgG sensitised red cells i.e. Lorne Coombs Control Cells (Cat # 970010).
- Lorne Precise Weak Anti-D (Cat # 209005).
- Phosphate Buffered Saline (PBS): NaCl 0.9%, pH 7.0 ± 0.2 at 22°C ± 1°C
- Positive (ideally $R_1 \boldsymbol{r})$ and negative (rr) control red cells.
- Volumetric pipettes.
- Water bath or dry heat incubator equilibrated to 37°C ± 2°C.

RECOMMENDED TECHNIQUE

- Wash test red cells at least twice in PBS and then wash once in Lorne LISS 1. "Ready For Use".
- Resuspend test red cells to 1.5-2.0% in LISS "Ready For Use".
- Equal volumes of LISS suspended red cells and serum should be mixed thoroughly for LISS procedures, e.g. 2 volumes of 1.5-2% cell suspension and 2 volumes of serum.

LIMITATIONS

- The suspension of red cells in LISS is associated with an accelerated deterioration in the expression of Fya, Fyb, s and S antigens and therefore red cells suspended in LISS should be discarded within 24 hours of their preparation.
- Adherence to 1:1 volumetric ratio of cell suspension to serum and thorough mixing is essential to the integrity of the low ionic test system.

 For optimum sensitivity, LISS IAT should be incubated for a minimum of 15
- 3.
- In order to avoid non-specific uptake of autologous complement red cells should be washed at least twice in NISS before they are finally washed and resuspended in LISS
- Not all antigen-antibody reactions are enhanced by LISS techniques.

SPECIFIC PERFORMANCE CHARACTERISTICS

- Prior to release, each lot of Lorne LISS "Ready For Use" has been shown to enhance many antigen-antibody reactions when used by the Recommended Techniques.
- The solution complies with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services.

DISCLAIMER

- The user is responsible for the performance of the reagent by any methods other than those mentioned in the Recommended Techniques.
- Any deviations from the **Recommended Techniques** should be validated prior to use¹⁰.

BIBLIOGRAPHY

- Low B., Messeter L. Antiglobulin test in low ionic strength salt solution for
- rapid antibody screening and crossmatching. Vox. Sang. 1974; **26**. 53-61. Moore C., Mollison P.L. Use of low ionic strength saline medium in manual tests for antibody detection. Transfusion 1976; **16**. 291-296. Wicker B., Wallas C.H. A comparison of low ionic strength saline medium
- 3. with routine methods for antibody detection. Transfusion 1976; 16. 469-
- Voak D., Downie D.M., Darnborough J., Haigh T.J., Fairham S.A. Low ionic strength media for rapid antibody detection: optimum conditions and quality
- control. Med. Lab. Sci. 1980; **37**. 107-118. Hiagh T.J., Fairham S.A. Advantages of low ionic strength saline (LISS) techniques in blood bank management. Med. Lab. Sci. 1980; **37**. 119-125. 5.
- Dynan P.K. Evaluation of commercially available low ionic strength salt 6 (LISS) solutions. Med. Lab. Sci. 1981; 38. 13-20.
- Voak D., Downie M., Haigh T.J., Cook N. Improved antiglobulin tests to detect difficult antibodies: detection of Anti-Kell by LISS. Med. Lab. Sci. 1982; **39**. 363-370.
- Phillips P.K., Bebbington C. The pH, conductivity and osmolality of low ionic strength solutions used within the U.K. for the antiglobulin test. Transfusion Medicine 1991; 1. 155-158. 8
- Guidelines for the Blood Transfusion Service in the United Kingdom. H.M.S.O. Current Edition.
- British Committee for Standards in Haematology, Blood Transfusion Task Force. Recommendations for evaluation, validation and implementation of new techniques for blood grouping, antibody screening and cross matching. Transfusion Medicine, 1995, **5**, 145-150.

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AVAILABLE REAGENT SIZES

| Vial Size | Catalogue Number | |
|-----------|------------------|--|
| 4x250 ml | 470250 | |
| 20x250 ml | 470020 | |
| 2500 ml | 470025 | |

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TABLE OF SYMBOLS

| LOT | Batch Number | IVD | <i>in-vitro</i> Diagnostic |
|-----|------------------------|------|-------------------------------|
| REF | Catalogue Reference | | Store At |
| | Expiry Date | \{\} | Manufacturer |
| i | Read Pack Insert | | |

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