

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.

INTENDED PURPOSE

LISS Ready for use solution is a low ionic strength saline that is intended for use in blood grouping for cross matching and antibody screening procedures when used in accordance with the recommended techniques stated in this IFU.

PRINCIPLE

When used by the recommended techniques, the solution will reduce the ionic strength of a test system, increase the rate of red blood cell antigen-antibody binding and permits a substantial reduction in incubation time and an increase 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 does not contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the user. 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

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. This reagent has undergone transportation stability studies at 37°C and -25°C as described in document BS EN ISO 23640:2015.

SAMPLE COLLECTION AND PREPARATION

Blood samples can be collected into EDTA anticoagulants or as a clotted sample. The samples should be tested as soon as possible following collection. If a delay in testing should occur, store the samples at 2-8°C. Samples displaying gross haemolysis or microbial contamination should not be used for testing. Blood samples showing evidence of lysis may give unreliable results.

PRECAUTIONS

1. The reagent is intended for *in vitro* diagnostic use only.
2. If vial is cracked or leaking, discard the contents immediately.
3. Do not use the reagent past the expiration date (see **Vial Label**).
4. Do not use the reagent if a precipitate is present.
5. Protective clothing should be worn when handling the reagent, such as disposable gloves and a laboratory coat.
6. The reagent has been filtered through a 0.2 µm capsule to reduce the bio-burden, but is not supplied sterile. 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.
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 plumbing 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

1. IgG sensitised red cells e.g. Lorne Coombs Control Cells (as positive control) and non-sensitized red cell (negative control) shall be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show the expected results.
2. The antiglobulin technique can only be considered valid if all negative tests react positively with IgG sensitised red cells
3. The LISS solution, red cell suspensions and test sera should be at room temperature prior to use to avoid encountering unwanted positive reactions due to "cold" antibodies.
4. In the **Recommended Techniques** one drop is approximately 50 µl when using the vial dropper provided

5. 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.
6. The end user must determine the suitability of the reagent for use in other techniques.

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED

- Anti-human globulin i.e. Lorne AHG Elite (Cat # 435010 or 415010) or anti-human IgG i.e. Lorne Anti-Human IgG (Cat # 401010 or 402010).
- Coombs cells washer.
- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- IgG sensitised red cells e.g. Lorne Coombs Control Cells (Cat # 970010).
- Lorne Precise Weak Anti-D (Cat # 209005).
- PBS solution (pH 6.8-7.2) or Isotonic saline solution (pH 6.5-7.5).
- Positive (ideally R_{1r}) and negative (rr) control red cells.
- Volumetric pipettes.
- Water bath or dry heat incubator equilibrated to 37°C ± 2°C.

RECOMMENDED TECHNIQUE

1. Wash red cells at least twice in PBS or Isotonic saline and then wash once in Lorne LISS "Ready For Use".
2. Resuspend red cells to 1.5-2.0% in LISS "Ready For Use".
3. 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

1. The suspension of red cells in LISS is associated with an accelerated deterioration in the expression of Fy^a, Fy^b, s and S antigens and therefore red cells suspended in LISS should be discarded within 24 hours of their preparation.
2. 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.
3. For optimum sensitivity, LISS IAT should be incubated for a minimum of 15 minutes at 37°C.
4. In order to avoid non-specific uptake of autologous complement red cells should be washed at least twice in LISS before they are finally washed and resuspended in LISS.
5. Not all antigen-antibody reactions are enhanced by LISS techniques.

SPECIFIC PERFORMANCE CHARACTERISTICS

1. 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**.
2. The solution complies with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services.

DISCLAIMER

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

BIBLIOGRAPHY






1. Low B., Messeter L. Antiglobulin test in low ionic strength salt solution for rapid antibody screening and crossmatching. *Vox. Sang.* 1974; **26**: 53-61.
2. Moore C., Mollison P.L. Use of low ionic strength saline medium in manual tests for antibody detection. *Transfusion* 1976; **16**: 291-296.
3. Wicker B., Wallas C.H. A comparison of low ionic strength saline medium with routine methods for antibody detection. *Transfusion* 1976; **16**: 469-472.
4. 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.
5. Haigh T.J., Fairham S.A. Advantages of low ionic strength saline (LISS) techniques in blood bank management. *Med. Lab. Sci.* 1980; **37**: 119-125.
6. Dynan P.K. Evaluation of commercially available low ionic strength salt (LISS) solutions. *Med. Lab. Sci.* 1981; **38**: 13-20.
7. 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.
8. 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.
9. Guidelines for the Blood Transfusion Service in the United Kingdom, 6th Edition 2002. The Stationary Office.
10. 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.

AVAILABLE REAGENT SIZES

Vial Size	Catalogue Number
4x250 ml	470250
20x250 ml	470020

TABLE OF SYMBOLS

Symbol	Definition	Symbol	Definition
	Manufacturer	REF	Catalogue number
	Temperature limitation		Use by YYYY-MM-DD
IVD	In vitro diagnostic medical device		Consult instructions for use.
EC REP	Authorised Representative	LOT	Lot number
	CE symbol with verification by a Notified Body		



Lorne Laboratories Limited
 Unit 1 Cutbush Park Industrial Estate
 Danehill
 Lower Earley
 Berkshire, RG6 4UT
 United Kingdom
 Tel: +44 (0) 118 921 2264
 Fax: +44 (0) 118 986 4518
 E-mail: info@lornelabs.com

EC REP Advena Ltd. Tower Business Centre, 2nd Flr.,
 Tower Street, Swatar, BKR 4013, Malta