It is well established that reducing the ionic strength of a test system increases the rate of antigen-antibody binding in indirect antiglobulin tests. The sensitivity of indirect antiglobulin techniques can also be increased by the use of polyethylene glycol (PEG) as a potentiating medium.

When added to a solution of immuno-reactants, high molecular weight polymers displace other molecules, thereby increasing the amount of contact between antigen and antibody. When PEG is dissolved in a low ionic strength solution, the enhancement properties of both are combined and a smaller volume can be added to each test than if PEG is dissolved in normal ionic strength saline.

Lorne PEG-ADD is a low ionic strength solution contains glycerine, a phosphate buffer and polyethylene glycol. The reagent is supplied at 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.

Reagent vials should be stored at 2 - 8°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.

Blood samples can be collected into EDTA, citrate, CPDA 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. It is preferable (but not essential) to wash all blood samples with PBS or Isotonic saline before being tested.

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 bioburden. 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. No known tests can guarantee products derived from animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

For information on disposal of the reagent and the interpretation of results must be carried out by any method other than those mentioned in the Guidelines for the UK Blood Transfusion Services.

1. Red cells that have a positive DAT due to a coating of IgG cannot be typed by the indirect antiglobulin technique.
2. Lorne PEG-ADD should not be used as a red cell suspending medium.
3. Not all antigen-antibody reactions are enhanced by the use of Lorne PEG-ADD in the indirect antiglobulin technique.
4. Red cells tend to aggregate in the presence of linear polymers therefore Lorne PEG-ADD may only be used in the indirect antiglobulin test.
5. IgM antibodies may not be detected by the indirect antiglobulin technique.
6. False positive or false negative results may also occur due to:
   - Contamination of test materials
   - Improper cell concentration
   - Improper incubation time or temperature
   - Improper or excessive centrifugation
   - Improper storage of test materials or omission of reagent
   - Deviation from the recommended techniques

For prior release, each lot of Lorne PEG-ADD has been shown to enhance many antigen-antibody reactions when used by the Recommended Technique.

1. The user is responsible for the performance of the reagent by any method other than those mentioned in the Recommended Technique.
2. Any deviations from the Recommended Technique should be validated prior to use.

5. R.S.Shirey, J.S.Boyd and P.M.Ness, Polyethylene glycol versus low-ionic-strength solution in pretransfusion testing: a blinded comparison study, Transfusion 1994-Vol.34, No.5


AVAILABLE REAGENT SIZES

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<tr>
<td>1000 ml</td>
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*This size is For Further Manufacturing Use (FFMU) only and is therefore not CE marked.

For the availability of other sizes, please contact:

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

TABLE OF SYMBOLS

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