

LORNE LABORATORIES LTD.



GREAT BRITAIN

RED BLOOD CELL PRESERVATION SOLUTION

DIRECTIONS FOR USE

Preservacell: For Preservation Of Red Blood Cells.

SUMMARY

Red cell suspensions can have their shelf life extended by being prepared in a suspending medium shown to extend their viability. Such preservative solutions work by providing the metabolic requirements of the red cells whilst preventing infection and maintaining antigenic expression.

INTENDED PURPOSE

This solution is intended to be used as an anticoagulant and preservative for red blood cells when used in accordance with the recommended techniques stated in this IFU. Red blood cell suspensions prepared with this solution are suitable to be used in immuno-haematological tests.

PRINCIPLE

When used by the recommended technique, the reagent will extend the shelf life of red cells by up to 28 days (See Limitations).

REAGENT

Lorne Preservacell is a citrate / phosphate buffered solution containing glucose, sodium chloride, calcium chloride and purine bases, with Chloramphenicol, Gentamycin Sulphate and Neomycin Sulphate as antibiotics. The reagents do 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 s supplied at optimal dilution for use with all 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 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.

SAMPLE COLLECTION AND PREPARATION

Specimens should be drawn into EDTA or citrate using an aseptic phlebotomy technique. The cells should be as fresh as possible when treated, preferably within 12 hours of collection.

PRECAUTIONS

- The reagent is intended for in vitro diagnostic use only.
- 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.

 Protective clothing should be worn when handling the reagent, such as 5. disposable gloves and a laboratory coat.
- The reagent has been filtered through a 0.2 µm capsule to reduce the bioburden, 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.

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.

REAGENTS AND MATERIALS REQUIRED

- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- PBS solution (pH 6.8-7.2) or Isotonic saline solution (pH 6.5-7.5).
- Test tube centrifuge.
- Volumetric pipettes.

RECOMMENDED TECHNIQUE

- Wash cells at least twice in PBS or Isotonic saline and then wash once in 1. Lorne Preservacell.
- Resuspend red cells to desired concentration in Lorne Preservacell.
- In the space provided on the vial label, record details of cell identification and expiry date.

STABILITY OF CELL SUSPENSIONS

- Following the resuspension of test red cells in Lorne Preservacell the suspensions should remain stable for up to 28 days if stored in a fridge at
- Discard if visible haemolysis occurs.

LIMITATIONS

- Deterioration of red cells suspended in Lorne Preservacell may occur if the saline used for washing is contaminated with microorganisms.
- False positive results may occur if the test serum contains antibodies to components of Lorne Preservacell.
- Cells stored in Lorne Preservacell and then resuspended in LISS, may demonstrate accelerated deterioration of protease-labile antigens such as S, s, Fy^a and Fy^b.

SPECIFIC PERFORMANCE CHARACTERISTICS

- Prior to release, each batch of Lorne Preservacell is tested by the **Recommended Techniques** and found to show no non-specific reactions with normal red cells.
- Lorne Preservacell has been quality controlled to be within the following
 - pH 7.0-7.2 at 22°C ± 1°C.
 - Conductivity: 12.0-12.7 mS/cm at 22 °C ± 1°C
 - Osmolality: 285-305 mOsm/Kg
- The formulation does not interfere with complement-mediated haemolysis.
- The reagent 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 method other than those mentioned in the Recommended Technique
- Any deviations from the Recommended Technique should be validated prior to use1.

BIBLIOGRAPHY

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 |
|-----------|------------------|
| 500 ml | 980500 |



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



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

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