LORNE LABORATORIES LTD.

GREAT BRITAIN

BLOOD GROUPING REAGENTS

DIRECTIONS FOR USE

Negative Control: For The Control Of Monoclonal Anti-D Reagents.

SUMMARY

False positive reactions rarely occur with monoclonal blood grouping reagents due to their low protein content. However, if a reagent control is required, e.g. when typing red cells from patients suspected of having auto-antibodies or serum protein abnormalities, Lorne Negative Control for Monoclonal Anti-D reagents is advised.

PRINCIPLE

A positive result obtained with Lorne Negative Control in addition to those obtained with Lorne Monoclonal IgM Anti-D reagents indicates that the specimen is most likely reacting with components of the reagent diluent other than the antibodies. A negative reaction with this control offers assurance that the positive results obtained with Anti-D reagent are due to specific antigen-antibody interactions (see **Limitations**).

REAGENT

Lorne Negative Control is for the control of Monoclonal Anti-D reagents and is formulated with the same concentrations of phosphate buffer, sodium chloride, bovine albumin and macromolecular potentiators as Lorne Monoclonal Anti-D reagents with just the antibodies omitted. 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**.

STORAGE

Do not freeze. Reagent vials should be stored at 2 - 8ºC 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 2-8ºC. 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. 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. 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

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

- Automatic plate reader.
- Applicator sticks.
- DiaMed ID-Cards (neutral).
- DiaMed ID-Centrifuge.
- DiaMled ID-Diluent e.g. ID-CellStab.
- Glass microscope slides.
- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- Phosphate Buffered Saline (PBS): NaCl 0.9%, pH 7.0 ± 0.2 at 22ºC ± 1ºC
- Positive (ideally R_1r) and negative (rr) control red cells.
- Plate shaker.
- Test tube centrifuge.
- Validated “U” well microplates.
- Volumetric pipettes.

RECOMMENDED TECHNIQUE

Lorne Negative Control should be tested in parallel with Lorne Monoclonal IgM Anti-D reagents designed for use in slide, rapid tube, microtitre plates and Diamed ID-Card tests. Lorne Negative Control Serum should be tested according to the **Recommended Techniques** indicated in the pack insert of the Monoclonal Anti-D reagent to be controlled.

INTERPRETATION OF TEST RESULTS

1. **Positive:** Agglutination of test red cells with Negative Control indicates that the results obtained with the Anti-D reagent may be invalid.
2. **Negative:** No agglutination of test red cells with Negative Control indicates that the red cells are not spontaneously agglutinating in the presence of the diluent used to prepare Lorne Anti-D reagents.

LIMITATIONS

1. Lorne Negative Control for Monoclonal Anti-D Reagents should be used only with Lorne Monoclonal IgM Anti-D reagents.
2. Lorne Negative Control for Monoclonal Anti-D Reagents is not suitable for use with enzyme treated cells, cells suspended in LISS or for use in indirect antiglobulin (IAT) techniques.
3. 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

SPECIFIC PERFORMANCE CHARACTERISTICS

1. Prior to release, each batch of Lorne Negative Control for Monoclonal Anti-D reagents is tested by **Recommended Techniques** and found to show no non-specific reactions with normal red cells.
2. The Quality Control of this reagent was performed using red cells that had been washed twice with PBS prior to use.
3. The reagent complies with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services.

DISCLAIMER

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].

BIBLIOGRAPHY

1. Walker RH. Technical Manual. 11th Edition. American Association of Blood Banks, Bethesda, MD 1993; Chapter 11
2. Standards for Blood Banks and Transfusion Services, 8th ed. Washington DC; American Association of Blood Banks 1984; 25.
3. Issitt, P D (1985) Applied Blood Group Serology, 3rd Edition. Montgomery Scientific, Miami Chapter 10
4. Guidelines for the Blood Transfusion Service in the United Kingdom. H.M.S.O. Current Edition.
5. 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
10 ml	650010
1000 ml	650000

Lorne Laboratories Limited
Unit 1 Danehill
Cutbush Park Industrial Estate
Lower Earley, Reading,
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England
Tel: +44 (0) 118 921 2264
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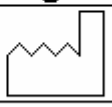
TABLE OF SYMBOLS

LOT	Batch Number	IVD	*In-vitro* Diagnostic
REF	Catalogue Reference		Store At
	Expiry Date		Manufacturer
	Read Pack Insert		