LORNE LABORATORIES LTD.

GREAT BRITAIN

CE 0843

BLOOD GROUPING REAGENTS

DIRECTIONS FOR USE

Monoclonal D 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, serum protein abnormalities or a positive Direct Antiglobulin Test (DAT), Lorne Monoclonal D Negative Control for Monoclonal Anti-D reagents is recommended.

PRINCIPLE

A positive result obtained with Lorne Monoclonal D Negative Control in addition to those obtained with Lorne Monoclonal Anti-D reagents indicates that the specimen is most likely reacting with components other than the Reagent 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 Monoclonal D 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

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. 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, 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.

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.

CONTROLS AND ADVICE

1. In the **Recommended Techniques** one volume is approximately 50µl when using the vial dropper provided.
2. The use of the reagents 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.
3. The user must determine the suitability of the reagent for use in other techniques.

REAGENTS AND MATERIALS REQUIRED

See the "Reagents and Materials required" section of the Monoclonal Anti-D reagent to be controlled.

RECOMMENDED TECHNIQUE

When typing red cells from patients known or suspected of having auto-antibodies, serum protein abnormalities or a positive Direct Antiglobulin Test (DAT), Lorne Negative Control for Anti-D reagents should be tested in parallel with the following Lorne Monoclonal Anti-D reagents:
Anti-D Clone 2 Monoclonal, catalogue # 710010
Anti-D Clone 1 Monoclonal, catalogue # 730010
Anti-D Duoclone Monoclonal, catalogue # 740010
Lorne Monoclonal D Negative Control reagent 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 red cells with Negative Control indicates that the results obtained with the Anti-D reagent may be invalid.
2. **Negative:** No agglutination of 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, hence the results obtained are valid.

LIMITATIONS

1. Lorne Negative Control for Monoclonal Anti-D Reagents should be used only with Lorne Monoclonal Anti-D reagents.
2. Lorne Negative Control for Monoclonal Anti-D Reagents is not suitable for use with enzyme treated cells or cells suspended in LISS.
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 or Isotonic saline 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*

***This size is For Further Manufacturing Use (FFMU) only and is therefore not CE marked.**

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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		