LORNE LABORATORIES LTD.

GREAT BRITAIN

CE 1434

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 appropriate Lorne reagents is recommended.

INTENDED PURPOSE

The Monoclonal D Negative Control reagent is intended to be used in parallel with Lorne's RhD and other appropriate (as indicated in the IFU's) blood grouping reagents when typing red cells from patients known or suspected of having auto-antibodies, serum protein abnormalities or a positive Direct Antiglobulin Test (DAT).

PRINCIPLE

A positive result obtained with Lorne Monoclonal D Negative Control in addition to those obtained with Lorne Monoclonal Anti-D and other appropriate Lorne 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 Lorne Anti-D reagents and some other Lorne reagents are due to specific antigen-antibody interactions (see **Limitations**).

REAGENT

Lorne Monoclonal D Negative Control is for the control of Lorne Monoclonal Anti-D and other appropriate Lorne reagents and is formulated with the same concentrations of phosphate buffer, sodium chloride, bovine albumin and macromolecular potentiators (1.5 g%) as Lorne Monoclonal Anti-D reagents with just the antibodies omitted. 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 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 37ºC and –25ºC 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, 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 (NaN_3). 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
9. Do not pool reagents in or between vials in any manner. Do not transfer reagent from a new vial to an opened vial. Do not transfer reagent from an open vial to any other container.
10. The bovine materials are obtained from sources for which origin information is available. The donor animals for bovine material have been inspected and certified disease free and are deemed to have low TSE (Transmissible Spongiform Encephalopathy) risk.
11. Once the vial content is used, discard the empty vial in a yellow burn bin.
12. Materials used to produce the reagent were tested at source and found to be negative for HIV 1+2 and HCV antibodies and HBsAg using approved microbiological tests.
13. No known tests can guarantee that products derived from human or 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

1. Manage waste according to local, state and national regulations. For more 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. Before use, let the reagent warm up to room temperature. As soon as the reagent has been used, put the reagent back in storage at 2-8ºC.
3. 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.
4. The use of the reagents and the interpretation of results must be carried out in a laboratory environment by properly trained and qualified personnel in accordance with the requirements of the country where the reagents are in use.
5. The reagent is used in a manual test procedure. It is the responsibility of the end user to determine the suitability of the device in other techniques and/or test systems.
6. Where applicable the use of calibrated or verified equipment is required.

REAGENTS AND MATERIALS REQUIRED

See the" Reagents and Materials required" section of the Lorne 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 shall be tested in parallel with the Lorne reagents as stipulated in the IFU of the appropriate Lorne reagent. Lorne Monoclonal D Negative Control reagent should be tested according to the **Recommended Techniques** indicated in the IFU of the appropriate Lorne reagent to be controlled.

INTERPRETATION OF TEST RESULTS

1. **Positive:** Agglutination of red cells with Negative Control indicates that the results obtained with appropriate Lorne reagents 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 appropriate Lorne reagents, hence the results obtained are valid.

LIMITATIONS

1. Lorne Negative Control for Monoclonal Anti-D Reagents should only be used as stipulated in the IFU of the appropriate Lorne reagent.
2. Lorne Negative Control for Monoclonal Anti-D Reagents is not suitable for use with enzyme treated cells or cells suspended in LISS.
3. In case of ambiguous results, it is recommended to wash red blood cells at least 2 times and retest with either test tube or gel card methods.
4. 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 the reagents was performed using red cells with phenotypes that were verified by a UK blood transfusion centre and had been washed 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].

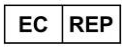
BIBLIOGRAPHY

1. Issitt, P D (1985) Applied Blood Group Serology, 3rd Edition. Montgomery Scientific, Miami Chapter 10.
2. AABB Technical Manual, 16th edition, AABB 2008.
3. Guidelines for the Blood Transfusion Service in the United Kingdom, 6th Edition 2002. The Stationary Office.
4. 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	Tests per vial
10 ml	650010	200

TABLE OF SYMBOLS

Symbol	Definition	Symbol	Definition
	Manufacturer		Catalogue number
	Temperature limitation		Use by YYYY-MM-DD
	In vitro diagnostic medical device		Consult instructions for use.
	Authorised Representative		Lot number
	CE symbol		

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