LORNE LABORATORIES LTD.

GREAT BRITAIN

RH CONTROL

DIRECTIONS FOR USE

Rh-Hr Control Serum: For Control Of Human Rh Blood Grouping Reagents.

SUMMARY

When cell suspensions from people with serum protein abnormalities or strongly positive direct antiglobulin tests are tested against Lorne IgG Rh Blood Grouping Reagents they may produce false positive reactions. This is due to the fact that these reagents are formulated with potentiators and contain high protein levels to enable the IgG antibodies to react in direct agglutination tests. The use of Rh-Hr Control Serum enables such false positive results to be recognised. A positive result with Rh-Hr Control Serum invalidates the results obtained with these Rh Grouping Reagents.

PRINCIPLE

A positive result obtained with Rh-Hr Control Serum in addition to those obtained with Lorne IgG Rh Grouping Reagents indicates that the specimen is most likely reacting with components of the reagent antisera other than the antibodies. A negative reaction with this control offers assurance that the positive results obtained with Rh grouping sera are due to specific antigen-antibody interactions (see **Limitations**).

REAGENT

Lorne Rh-Hr Control Serum is formulated with the same levels of potentiators and protein as Lorne Human Rh Grouping Reagents with the blood group 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. Reagent will remain stable for up to 7 days when subjected to temperatures not exceeding 30ºC.

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. EDTA and citrate samples should be typed within 48 hours. Samples collected into ACD, CPD or CPDA-1 may be tested up to 35 days from the date of withdrawal. All blood samples should be washed at least twice with PBS before being tested.

PRECAUTIONS

1. The reagent is intended for *in vitro* diagnostic use only.
2. If a reagent 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 reagents, 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 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 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

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

- Applicator sticks.
- Glass microscope slides.
- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- Lighted Rh viewbox.
- Phosphate Buffered Saline (PBS): NaCl 0.9%, pH 7.0 ± 0.2 at 22ºC ± 1ºC.
- Test tube centrifuge.
- Volumetric pipettes.
- Water bath or dry heat incubator equilibrated to 37ºC ± 2ºC.

RECOMMENDED TECHNIQUE

Lorne Rh-Hr Control Serum should be tested in parallel with Lorne IgG Rh Blood Grouping Reagents designed for use in slide and rapid tube tests. Lorne Rh-Hr Control Serum should be tested according to the **Recommended Techniques** indicated in the pack insert of the Rh reagent to be controlled.

INTERPRETATION OF TEST RESULTS

1. **Positive:** Agglutination of test red cells with Rh-Hr Control Serum indicates that the results obtained with the Lorne Human Rh Blood Grouping Reagent may be invalid. Test red cells producing these results should be retested using well-washed red cells or retested with a Monoclonal Rh Blood Grouping Reagent.
2. **Negative:** No agglutination of test red cells with Rh-Hr Control Serum indicates that the test red cells are not spontaneously agglutinating in the presence of the diluent used to prepare Lorne Human Rh Blood Grouping Reagents.

LIMITATIONS

1. Lorne Rh-Hr Control Serum should be used only with Lorne Human Rh Blood Grouping Reagents for tube, DiaMed-ID, Ortho BioVue and slide techniques.
2. Rh testing of infant red cells so heavily coated with antibody that all antigen sites are occupied may yield false negative results[1].
3. False positive or false negative results may also occur due to:
   - ontamination of test materials
   - Improper storage, cell concentration, incubation time or temperature
   - Improper or excessive centrifugation
   - Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS

1. Prior to release, each lot of Lorne Rh-Hr Control Serumis tested by the **Recommended Techniques** and found to show no non-specific reactions with normal red cells.
2. The Quality Control of the 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 Techniques**.
2. Any deviations from the **Recommended Techniques** should be validated prior to use[7].

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. Reid ME, Ellisor SS, Frank BA. Another potential source of error in Rh-Hr typing. Transfusion 1975; **115**: 485.
4. Issitt, P D (1985) Applied Blood Group Serology, 3rd Edition. Montgomery Scientific, Miami Chapter 10
5. Garraty G, Postoway N, Nance SJ. Spontaneous agglutination of red cells with a positive direct antiglobulin test in various media. Transfusion 1984; **24:** 214-217
6. Guidelines for the Blood Transfusion Service in the United Kingdom. H.M.S.O. Current Edition.
7. 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	200010
1000 ml	200000

For the availability of other sizes, please contact:

Lorne Laboratories Limited
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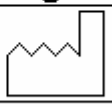
TABLE OF SYMBOLS

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