LORNE LABORATORIES LTD.
GREAT BRITAIN

CE

CONTROL REAGENT
DIRECTIONS FOR USE

Inert AB Serum: For use as a reagent control or as a diluent.

SUMMARY

Inert AB serum is a serum derived from a pool of human serum, which is used as negative control for IAT tests, enzyme tests and as diluent.

INTENDED PURPOSE

This reagent is intended to be used as a diluent or as an inert control for blood group serology.

PRINCIPLE

A positive result obtained with Lorne Inert AB Serum in addition to those obtained with Lorne Blood Grouping Reagent indicates that the specimen is most likely reacting with components of the reagent anti-sera other than with the specific antibodies. A negative reaction with this control offers assurance that the positive results obtained with Lorne ABO blood grouping reagent are due to specific antigen-antibody interactions.

REAGENT

Lorne Inert AB Serum is prepared from pooled human serum. No potentiators or any other chemicals have been added to the reagent. 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 recommended techniques 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.

SPECIMEN COLLECTION

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 reagents are intended for *in vitro* diagnostic use only.
2. If reagent vial is cracked or leaking discard the contents.
3. Do not use 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, but is not supplied sterile. Once a vial has been opened the contents should remain viable up until the expiry date.
7. The plasma from which this reagent is manufactured is no longer delipidated, so it is normal for the reagent to have a turbid appearance.
8. 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.
9. 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.
10. 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 reagents and decontamination of a spillage site see **Safety Data Sheets**, available on request.

CONTROLS AND ADVICE

1. The antiglobulin tube technique can only be considered valid if all negative tests react positively with IgG sensitised red cells.
2. In **Recommended Techniques** one volume is approximately 50 µl when using the vial dropper provided.
3. 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.
4. The use of the reagent 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 reagent is in use.
5. The user must determine the suitability of the reagent for use in other techniques.

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED

- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- Volumetric pipettes.
- Test tube centrifuge.

RECOMMENDED TECHNIQUES

Lorne Inert AB Serum should be tested in parallel with Lorne Blood Grouping Reagents according to **Recommended Techniques** indicated in the pack insert of the reagent to be controlled.

INTERPRETATION OF TEST RESULTS

1. **Positive:** Agglutination of red cells with Inert AB Control Serum indicates that the results obtained with reagent may be invalid.
2. **Negative:** No agglutination of red cells with Inert AB Control Serum indicates absence of non-specific red cell agglutination.

LIMITATIONS

1. Lorne Inert AB Control Serum should be used only with Lorne Blood Grouping Reagents.
2. False positive or false negative results may 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 test reagents
   - Any deviation from the recommended technique

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The reagent has been characterised by the procedures mentioned in the **Recommended Techniques**.
2. Prior to release, each lot of Lorne Inert AB Serum is tested by the **Recommended Techniques** against a panel of antigen-positive red cells to ensure there is no reactivity.
3. The Quality Control of this reagent 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.
4. The presence of contaminating antibodies to antigens with an incidence of 1% or greater within the random population has been excluded either in tests employing the appropriate antigen-negative red cells or in tests employing the reagents previously absorbed to remove the interfering specificities.

5. Antibodies to Xg^a, Do^a, Yt^a, Co^b, Wr^a and Bg^a may not be excluded in routine specificity testing and detection will depend upon availability of appropriate test cell. This can also be said for Yt^b, M^g and V^w and other low frequency antigens which may not be excluded in routine specificity testing and detection will depend upon availability of appropriate test cells
6. The reagents comply 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 should be validated prior to use as specified in the article: Recommendations for evaluation, validation and implementation of new techniques for blood grouping, antibody screening and cross matching[2].

BIBLIOGRAPHY

1. Issitt, P D (1985) Applied Blood Group Serology, 3rd Edition. Montgomery Scientific, Miami, Chapter 3.
2. 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.
3. AABB Technical Manual, 16th edition, AABB 2008.

AVAILABLE REAGENT SIZES

	Vial Size	Catalogue Number	Tests per vial
Lorne Inert AB serum	10 ml	110010	200
	1000 ml	110000*	20,000

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

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

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