LORNE LABORATORIES LTD.
GREAT BRITAIN

LECTIN BLOOD GROUPING REAGENTS
DIRECTIONS FOR USE

Anti-H Lectin: For Tube Techniques.

SUMMARY

The H antigen is part of the Hh system and is found on all red cells except those of O_h (hh) Bombay phenotype, which is extremely rare.

Anti-H	Phenotype	Prevalence %
+	**H+**	99.9%
0	**H-**	Very rare

H is the precursor of A and B and so group A and B people have less H than O people. The order of reactivity of Anti-H with red cells of various ABO groups is:

Strong ———					Very weak
O	A_2	B	A_2B	A_1	A_1B

INTENDED PURPOSE

This reagent is a blood grouping reagent intended to be used to qualitatively determine the presence or absence of the H antigen (H1) on the red cells of blood donors or patients requiring a blood transfusion when tested in accordance with the recommended techniques stated in this IFU.

PRINCIPLE

The reagent contains glycoproteins of *Ulex europaeus* seed origin that will cause agglutination (clumping) of red cells that carry the H antigen, after centrifugation. No agglutination (no clumping) generally indicates the absence of the H antigen (see **Limitations**).

REAGENT

Lorne Anti-H Lectin blood grouping reagent is prepared from an extract of *Ulex europaeus* seeds, diluted with a sodium chloride solution containing bovine albumin. 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 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 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 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 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. 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.

CONTROLS AND ADVICE

1. A_2 and A_1 control red cells shall be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. In the **Tube Technique** one volume is approximately 50µl 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. Use of the reagent and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with requirements of the country where the reagent is in use.
5. End user must determine 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).
- Known group A_2 and A_1 control red cells.
- PBS solution (pH 6.8–7.2) or Isotonic saline solution (pH 6.5–7.5).
- Test tube centrifuge.
- Volumetric pipettes.

RECOMMENDED TECHNIQUE

A. Tube Technique

1. Prepare a 2-3% suspension of red cells in PBS or Isotonic saline.
2. Place in a labelled test tube: 1 volume Lorne Anti-H reagent and 1 volume red cell suspension.
3. Mix thoroughly and incubate at room temperature for 5 minutes.
4. Centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
5. Gently resuspend red cell button and read macroscopically for agglutination

INTERPRETATION OF TEST RESULTS

1. **Positive:** Agglutination of the red cells constitutes a positive test result and within accepted limitations of test procedure, indicates the presence of the H antigen on the red cells.
2. **Negative:** No agglutination of the red cells constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of the H antigen on the red cells.

STABILITY OF THE REACTIONS

1. Tests should be read immediately after centrifugation. Delays may result in dissociation of antigen-antibody complexes leading to false negative, or weak positive reactions.
2. Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.

LIMITATIONS

1. Lorne Anti-H Lectin may react with red cells that are Tn-polyagglutinable or Cad-positive.
2. Stored blood may give weaker reactions than fresh blood.
3. False positive or false negative results may also occur due to:
   - Contamination 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 reagent was tested using the recommended test methods listed in this IFU.
2. Lorne Anti-H has been formulated to be non-reactive with most A_1 and A_1B red cells and reactive with A_2 red cells.
3. 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.
4. The reagent complies with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services.

DISCLAIMER

1. The end 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. AABB Technical Manual, 16th edition, AABB 2008.
2. Marion E.Reid & Christine Lomas-Francis, Blood Group Antigens & Antibodies, SBB Books, New York 2007.
3. Issitt PD. Applied Blood Group Serology, 3rd Edition. Montgomery Scientific, Miami 1985; Chapter 6.

4. Guidelines for the Blood Transfusion Service in the United Kingdom, 6th Edition 2002. The Stationary Office.
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	Tests per vial
2 ml	115002	40

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 with verification by a Notified Body		

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