

# 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<sub>h</sub> (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				
0	$A_2$	В	$A_2B$	$A_1$	A₁B

#### **PRINCIPLE**

The reagent will cause agglutination (clumping) of red cells, that carry the H antigen, after centrifugation. No agglutination 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 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 - 8°C 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**

- The reagent is intended for in vitro diagnostic use only.
- If a reagent vial is cracked or leaking, discard the contents immediately.
- Do not use the reagent past the expiration date (see Vial Label).
- Do not use the reagent if a precipitate is present.
- Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
- 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 6 indicate reagent deterioration or contamination.
- 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.
- 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**

- It is recommended known A2 and A1 control red cells 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 50ul when using the vial dropper provided.
- 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.
- User must determine suitability of the reagent for use in other techniques.

## REAGENTS AND MATERIALS REQUIRED

- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- Known group A<sub>2</sub> and A<sub>1</sub> 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

### **Tube Technique**

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

## INTERPRETATION OF TEST RESULTS

- 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.
- 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

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

#### **LIMITATIONS**

- Lorne Anti-H Lectin may react with red cells that are Tn-polyagglutinable or Cad-positive.
- Stored blood may give weaker reactions than fresh blood.
- 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

- The reagent has been characterised by all the procedures mentioned in the Recommended Technique.
- Prior to release, each lot of Lorne Anti-H Lectin reagent is tested by the 2 Recommended Technique against a panel of antigen-positive red cells to ensure suitable reactivity.
- Lorne Anti-H has been formulated to be non-reactive with most A<sub>1</sub> and A<sub>1</sub>B red cells and reactive with A2 red cells.
- The Quality Control of the reagent was performed using red cells that had been washed twice 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**

- The user is responsible for the performance of the reagent by any method other than those mentioned in the Recommended Technique.
- Any deviations from the Recommended Technique should be validated prior to use6.

### **BIBLIOGRAPHY**

- Widman FK. Technical Manual, 9th Edition. American Association of Blood Banks, Arlington, VA, 1985; Chapter 8
- Race RR, Sanger R. Blood Groups in Man, 6<sup>th</sup> Edition. Blackwell Scientific, Oxford 1975; Chapter 2 Mollison PL. Blood Transfusion in Clinical Medicine, 8<sup>th</sup> Edition. Blackwell
- 3. Scientific, Oxford 1987; Chapter 7
  Issitt PD. Applied Blood Group Serology, 3<sup>rd</sup> Edition. Montgomery Scientific,
- 4 Miami 1985; Chapter 6
- Guidelines for the Blood Transfusion Service in the United Kingdom. H.M.S.O. Current Edition.
- 6 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.

Document reference number: CEPI115 Document issue number: 6/07/2018 Page 1 of 2

## **AVAILABLE REAGENT SIZES**

Vial Size	Catalogue Number	
2 ml	115002	
1000 ml	115000*	

 ${}^{\star}\text{This}$  size is For Further Manufacturing Use (FFMU) only and is therefore not CE marked.

For the availability of other sizes, please contact:

**Lorne Laboratories Limited**Unit 1 Cutbush Park Industrial Estate Unit 1 Cutbush Park Industria Danehill Lower Earley, Reading, Berkshire, RG6 4UT United Kingdom Tel: +44 (0) 118 921 2264 Fax: +44 (0) 118 986 4518 E-mail: info@lornelabs.com

## **TABLE OF SYMBOLS**

LOT	Batch Number	IVD	<i>in-vitro</i> Diagnostic
REF	Catalogue Reference		Store At
	Expiry Date		Manufacturer
<b>∃i</b>	Read Pack Insert		