LORNE LABORATORIES LTD.

GREAT BRITAIN

LECTIN BLOOD GROUPING REAGENTS

DIRECTIONS FOR USE

Anti-A_1 Lectin: For Tube Technique.

SUMMARY

A_1 antigen is a subgroup of A and was discovered in 1910. Anti-A_1 is usually non-reactive at 37ºC, however examples reactive at 37ºC and predominately IgM can cause *in vivo* red blood cell destruction. About 78%[3] of group A people are A_1 and 22%[3] are A_2, similar proportions apply among AB people.

INTENDED PURPOSE

This reagent is a blood grouping reagent intended to be used to qualitatively determine the presence or absence of the A_1 antigen (ABO4) 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 *Dolichos biflorus* seed origin that will cause agglutination (clumping) of red cells that carry the A_1 antigen, after centrifugation. No agglutination (no clumping) generally indicates the absence of the A_1 antigen (see **Limitations**).

REAGENT

Lorne Anti-A_1 Lectin blood grouping reagent is prepared from an extract of *Dolichos biflorus* 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 positive control (ideally group A_1B cells) and a negative control (group A_2 cells) shall be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
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. In the **Recommended Techniques** one volume is approximately 50µl when using the vial dropper provided.
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. 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).
- PBS solution (pH 6.8–7.2) or Isotonic saline solution (pH 6.5–7.5).
- Positive (group A_1B) and negative (group A_2) control red cells.
- Test tube centrifuge.
- Volumetric pipettes.

RECOMMENDED TECHNIQUES

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-A_1 reagent and 1 volume red cell suspension.
3. Mix thoroughly and then centrifuge all the tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
4. Gently resuspend red cell button and read macroscopically for agglutination

INTERPRETATION OF TEST RESULTS

1. **Positive:** Agglutination of red cells constitutes a positive test result and within the accepted limitations of the test procedure, indicates the presence of A_1 antigen on the red cell.
2. **Negative:** No agglutination of red cells constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of A_1 antigen on the red cells.
3. **Discrepancies:** If the results obtained with reverse group don't correlate with forward group, further investigation is required.

STABILITY OF THE REACTIONS

1. Tube tests must be read immediately after centrifugation. Delays may cause 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. Anti-A_1 may react with Tn-polyagglutinable or Cad-positive cells
2. Cord blood and specimens from infants cannot be accurately typed using Anti-A_1 Lectin since the A_1 antigen is not fully developed on red blood cells until the age of six months.
3. Individuals older than six months should have their ABO blood-grouping results confirmed by testing their serum or plasma against known group A_1 and B cells before their ABO blood group can be confirmed.
4. Stored blood may give weaker reactions than fresh blood.
5. 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. The tests complied with the test requirements as stated in the current version/issue of the "Guidelines for the Blood Transfusion Services in the United Kingdom".
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.

DISCLAIMER

1. The end 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[6].

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, page 146.
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.

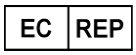
AVAILABLE REAGENT SIZES

	Vial Size	Catalogue Number	Tests per vial
Anti-A1 Lectin	5 ml	116005	100

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		

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



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