ANTI-A1 Lectin

BHAT Bio Scan®

For Professional Use

DIFFERENTIAL GROUPING OF HUMAN RED BLOOD CELLS

IVD

Read the pack Insert before use provided along with the kit

REF A1

INTENDED USE : Anti-A1Lectin db is for in vitro recognition of human red cell sub grouping to differentiate 'A1' subgroup from other weaker subgroups of 'A' Red Blood cells like A2,Ax,Aem,Ael or A2B,AxB etc.

INTRODUCTION : The human erythrocyte has some 100 known blood group determinants that comprise 15 genetically distinct blood group systems. Of these, only two, the ABO blood group system and the Rhesus (Rh) blood group system have major clinical importance. According to the ABO blood group system human red blood cells are classified into four groups A,B,AB and O depending upon the presence or absence of specific inheritable blood group antigens on the erythrocytes. In the Rh system of blood typing human red blood cells are classified into two types based on the presence or absence of Rh factor (D-antigen). The term Rh positive is used to denote the presence of D-antigen on the red cells. Anti-A1 Lectin db is intended for Human Red Blood cell subgrouping, to differentiate 'A'subgroup from other weaker subgroups of 'A' Red Blood Cells like A2,Ax,Aem,Ael or A2B,AxB etc. These antibodies are standardized for their potency, Specificity, and Avidity.

PRINCIPLE: Anti-A1 Lectin db reacts with A1 antigen and causes agglutination of A1 human red blood cells selectively and specifically. Anti-A1 Lectin db only agglutinates with A1 and A1B human red blood cells (RBCs). Anti-A1 Lectin db will not react with other subgroups 'A' (like A2,Ax,Aem,Aet or A2B,AxB etc.,)

STORAGE AND STABILITY : Store the reagents at 2-8° C. Do not use the reagent beyond the expiry date mentioned on it. Before performing the test bring all the reagents to room temperature. Replace the reagents to 2-8° C soon after performing the test. DO NOT FREEZE THE REAGENTS.

1.The unopened kit is stable for 2 years from the date of manufacturing as indicated on the package.

2.The opened kit is stable for 6 months from the date of opening.

3. Repeated freeze thaw of reagents from 2-8°C to room temperature several times will reduce the stability of the kit.

PACK SIZE : Available in packs of 2ml, 5ml,and 10ml.

Titre : 1:256

AVIDITY : 2-7 Seconds

CONTENTS OF THE KIT : Anti-A1 Lectin 2ml/5ml/10ml.

MATERIALS REQUIRED BUT NOT PROVIDED :

1. Slide or Tube 2. Lancet 3. Applicator sticks 4.Isotonic saline

AUXILLARY REAGENT NOT PROVIDED Normal saline

SPECIMEN: Whole blood with or without an anticoagulant. In case of delay in testing, the specimen o with an anticoagulant should be stored at 2-8 °C.

PRECAUTIONS:

1. For in vitro diagnostic use only.
2.Bring all reagents and specimens to Room temperature, prior to testing.
3. Avoid using hemolyzed sample.
4. Microbial contamination should be avoided.
5. All human serum and plasma samples should be considered potentially infectious. It is recommended that all specimens of human origin should be handled as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control / National Institute of Health manual “Bio-safety in Microbiological and Biomedical Laboratories”, 1984.
6. Never pipette by mouth.
7. Do not smoke, eat or drink in areas in which specimens or kit reagents are handled.
8. Wear disposable gloves while handling specimens and kit reagents. Afterwards wash hands carefully.
9. Avoid splashing or forming aerosols.
10. Discard all materials and specimens as if capable of transmitting infection. The preferred method of disposal is autoclaving for a minimum of one hour at 121 °C. Liquid waste containing acid may be mixed with sodium hypochlorite in volumes such that the final mixture contains 50-500mg/l available chlorine. Allow 30 minutes for decontamination to be completed.

NOTE:

1.The source material (tissue culture supernatant) used to produce this reagent has been tested and found to be negative for HIV and HCV antibodies and HBsAg in Micro biological test required. No known regime of testing can completely guarantee that any product derived from human blood is incapable of transmitting infections.
2.Liquid waste containing acid must be neutralized with a proportional amount of base prior to the addition of sodium hypochlorite. Spills should be wiped thoroughly using either an iodophor disinfectant or sodium hypochlorite solution. Materials used to wipe up spills should be added to bio hazardous waste matter for proper disposal.
3. Deterioration is indicated by a significant decrease by weak agglutination.
4. Do not use reagents after the expiration date printed on the label.
5. When removing reagents from the bottles, use aseptic technique to avoid contamination.
6. Mix the reagent bottle gently before use.
7. Do not use clotted blood sample for testing.
8. Ensure reused glass slide is disinfected, washed thoroughly and rinsed free of detergents.

TEST PROCEDURE :

A. Slide test :

1. Place one drop of differential blood grouping reagent Anti-A1 Lectin db on a glass slide.
2. To the reagent drop, add one drop of whole blood or 10% saline suspension.
3. Rock the slide gently back and forth.
4. Observe for agglutination at the end of two minutes. Peripheral drying should not be misinterpreted as a positive result.

B. TUBE TEST:

1. Place one drop of differential blood grouping reagent Anti-A1 Lectin db into labeled tubes (“2x3/8”) such as test (T)
2. Add one drop of above cell suspension to both the tubes labeled as Test (T) and Control (C) and mix well.
3. Centrifuge for one minute at 1000rpm or allow the tubes to stand at room temperature for 15-60 minutes.
4. Gently dislodge the cell button and observe for agglutination either microscopically or macroscopically.

INTERPRETATION OF RESULTS:

Agglutination of red blood cells within two minutes indicates the presence of A1 antigen on human red blood cells. Absence of agglutination indicates the absence of A1 antigens on the human red blood cells. No interpretation should be made if the agglutination appears in negative control with either slide test or tube test.

TROUBLE SHOOTING:

Cause / Error	Remedy
1. Contaminated Blood specimen or reagents	Make sure that there is no contamination of blood specimen or reagent. Use clean side or tube for testing Do not read the result after 2 minutes
2. Drying in slide test	Do not read the result after 2 minutes
3. Clotting of blood	Test the sample immediately if anticoagulant is not added to the sample

FALSE NEGATIVE	
Cause / Error	**Remedy**
1. Contaminated Blood specimen or reagents	Make sure that there is no contamination of blood specimen or reagent. Use clean side or tube for testing Do not read the result after 2 minutes

WEAKLY / DELAYED REACTION	
Cause / Error	**Remedy**
1. Prolonged storage of red blood cells	Store the blood sample with anticoagulant at 2-8°C for less than 30 days
2. Expired reagent	Check the expiry date on the reagent bottle

LIMITATIONS OF THE TEST :

1. It is recommended that with every set of tests, positive and negative controls should be included. The result of positive and negative controls should be read before reading the test results. The satisfactory result of positive and negative control indicates that the reagents are working well.
2. Factors other than reagents, which might affect the performance of the test, include cleanliness of glassware, meticulous follow up of the procedure and rouleaux formation.
3. Blood obtained by finger prick may be tested directly by the slide method, but to avoid clotting, blood should be immediately mixed with the reagent.
4. Contaminated blood specimen or reagents may interfere with test results. Peripheral drying in slide test should not be misinterpreted as agglutination.

PRESENTATION:

1. The blood drop on the slide should not be allowed to dry, partial drying of the blood could be misinterpreted as agglutination.
2. Centrifugation should be perfect. Over centrifugation or under-centrifugation may result in false negative interpretation.
3. Dislodgement of sedimented red cells in tube test should be done as gently as possible, rough dislodgement may disrupt small or weak agglutinates and hence may lead to false negative interpretation.
4. The entire procedure should be carried out at room temperature. Warm or cold antibodies in the tested blood can cause agglutination and may lead to wrong interpretation.
5. Hemolysed blood samples should not be used.
6. Improper A1 lectin db concentration as well as that A1 antigen may cause delayed agglutination.

REFERENCE :

1. Race, R.R & Sanger. R. (1975) Blood groups in man, Sixth edition, Blackwell publications.p.813.
2. Technicals manual of the American Association of Blood Banks (1981) Eight edition.p.124.
3. Molison.p.l. (1977) Blood Transfusion in clinical Medicine, Sixth edition.p.292.

NOTE:: Even after the best effort is made to supply the product as per the sample submitted but due to continuous R & D, the company reserves the right to improve/change any specifications/components without prior information/notice to the buyer

LIMITED EXPRESSED WARRANTY OF MANUFACTURER

The manufacturer limits the warranty to this test kit, as much as that the test kit will function as an in vitro diagnostic assay within the Nature of Sample, Procedure limitations and specifications as described in the product instruction manual, when used strictly in accordance with the instructions contained. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

BS ISO-15223-1:2012(E) MEDICAL DEVICES SYMBOL					
2℃ 8℃	Temperature Limitation	2001-06	Date of Manufacture	IVD	In vitro Diagnostic Device
LOT	Batch Code		Company name & address		Consult Instructions For Use
	Use by	Company	Company Name	EC REP	Authorised Representative in European Community
	Do Not Reuse	Σ	Sufficient for		KEEP AWAY FROM SUNLIGHT
	KEEP DRY	NON STERILE	NON-STERILE	CONTROL −	NEGATIVE CONTROL
CONTROL +	POSITIVE CONTROL				

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