ANTI-AB (IgM)

MONOCLONAL

BHAT Bio Scan®

For Professional Use

Blood grouping antibodies for Slide and Tube test

IVD

Read the pack Insert before use provided along with the kit

REF A-ABm

INTENDED USE : Anti-AB (Monoclonal-IgM) is intended to use as a reagent for the detection of the 'AB' antigen present on human red blood cell.

INTRODUCTION : The human erythrocyte (RBC) 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 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 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-AB is IgM class of monoclonal antibodies directed against human red blood cell antigen A&B. The antibodies are standardized for their potency, specificity and avidity.

PRINCIPLE : Human red blood cells possessing AB antigen will agglutinate when mixed with Anti-AB antibody, directed towards AB antigen. Agglutination of red blood cells with Anti-AB is a positive test reaction and indicates the presence of AB antigens on the RBCs. Absence of agglutination of red blood cells with Anti-AB is a negative test result and it indicates the absence of AB antigen on the RBCs.

STORAGE AND STABILITY :

Storage: 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

Stability :

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-A B (IgM) (Monoclonal) 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

PRECAUTIONS:

1. For in vitro diagnostic use only.
2.Bring all reagents and specimens to Room temperature, prior to testing.
3. Avoid using hemolysed 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 blood grouping reagent Anti-AB on a glass slide.
2. To the reagent drop, add one drop of whole blood. Mix well with applicator stick or tooth pick.
3. Rock the slide gently back and forth.
4. Observe for agglutination at the end of two minutes.

Peripheral drying should not be interpreted as a positive test result.

B. Tube test :

1. Prepare a 2-5% suspension of the cells to be tested in isotonic saline.
2. To the two small test tubes (“2x3/8”) labeled test (T) and control (C). Add one drop of above cell suspension using a Pasteur pipette.
3. Add one drop Anti-AB reagent to tube (T) and Normal saline to tube (C) and mix well.
4. Centrifuge for one minute at 1000rpm or allow the tubes to stand at RT (25-30° C) for 15-60 minutes.
5. Gently dislodge cell button and observe for agglutination.

INTERPRETATION OF RESULTS :

1. Agglutination of red blood cells in presence of Anti-AB indicates the presence of A&B antigen on red blood cells (Group A &B).
2. Absence of agglutination of red blood cells in presence of Anti-AB indicates absence of A&B antigens.
3. No interpretation should be made if the agglutination appears in negative control with either slide test or tube test.

TROUBLE SHOOTING :

FALSE POSITIVE	
Cause	Remedy
1. Contaminated blood specimen or reagents	Make sure that there is no contamination of blood specimen or reagent. Use clean slide 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 anti coagulant is not added to the sample

FALSE NEGATIVE	
Cause Contamination of blood specimens or reagents	Remedy Make sure that there is no contamination of blood specimen or reagent Use clean slide or tube for testing. Do not read the result after 2 minutes.

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

ACCURACY :

Bhat- Bioscan®Anti-AB Test meets the requirements when tested against DCI approved kit.

SENSITIVITY :

1. Blood Group A

No. of Blood Group A samples tested	120
No. of Positive results by Anti-AB (IgM) kit	120

2. Blood Group B

No. of Blood Group B samples tested	89
No. of Positive results by Anti-AB (IgM) kit	89

3. Blood Group AB

No. of AB Blood Group samples tested	84
No. of Positive results by Anti-AB (IgM) kit	84

Sensitivity of Anti-AB (IgM) kit is estimated to be 100% (120/120),(89/89),(84/84) assuming 100% reactivity by comparing with other kits.

SPECIFICITY :

4. Blood Group O

No. of Blood Group O samples tested	85
No. of Positive results by Anti-AB (IgM) kit	0

Specificity of Anti-AB (IgM) kit is estimated to be 100%(0 out of 85).

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.

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) MEDICALDEVICES 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		KEEPAWAY FROM SUNLIGHT
	KEEPDRY	NON STERILE	NON-STERILE	CONTROL −	NEGATIVE CONTROL
CONTROL +	POSITIVE CONTROL				

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