


**BHAT BIO-TECH INDIA (P) LTD.**

CE 1023

**BHAT Bio-Scan**

**ANTI - D**  
(MONOCLONAL)  
Blood grouping antibodies for  
Slide and Tube test

For Professional Use IVD

 READ THIS PACK INSERT  
CAREFULLY BEFORE PERFORMING THE TEST

An ISO  
9001 : 2008  
13485 : 2003  
& GMP  
Company

CATALOGUE No.: A-D  
**INTENDED USE:**  
 Anti-D (Monoclonal-IgM/IgG/IgM+IgG) is intended to use as a reagent for the detection of the 'D' 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-D is IgM/IgG/IgM+IgG class of monoclonal antibodies directed against human red blood cell antigen D. The antibodies are standardized for their potency, specificity and avidity.  
**PRINCIPLE:**  
 Human red blood cells possessing D antigen will agglutinate when mixed with Anti-D antibody, directed towards D antigen. Agglutination of red blood cells with Anti-D is a positive test reaction and indicates the presence of D antigens on the RBCs. Absence of agglutination of red blood cells with Anti-D is a negative test result and it indicates the absence of D 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

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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 kits are 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:** 1:512  
**Avidity:** 2-7 Seconds  
**CONTENTS OF THE KIT:** Anti-D (Monoclonal IgM/IgG/IgM+IgG) = 2ml/5ml/10ml.  
**MATERIALS REQUIRED BUT NOT PROVIDED:**  
 1. Slide or Tube 2. Lancet 3. Applicator sticks 4. Isotonic saline  
**AUXILIARY REAGENT NOT PROVIDED:**  
 Normal saline  
**SPECIMEN COLLECTION AND PREPARATION:**  
 No special preparation of the patient is required prior to sample collection by aproned technique. Samples should be stored at 2-8°C if not tested immediately. Do not use haemolysed sample. Anticoagulated using rariass anti coagulants should be tested with in the below mentioned time period. EDTA or heparin 2 days ACD or c pd 28 days clohed whole blood should be tesed with in 14 days

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**PRECAUTIONS:**

- For invitro diagnostic use only.
- Bring all reagents and specimens to Room temperature, prior to testing.
- Avoid using hemolysed sample.
- Microbial contamination should be avoided.
- 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 "Biosafety in Microbiological and Biomedical Laboratories", 1984.
- Never pipette by mouth.
- Do not smoke, eat or drink in areas in which specimens or kit reagents are handled.
- Wear disposable gloves while handling specimens and kit reagents. Afterwards wash hands carefully.
- Avoid splashing or forming aerosols.
- 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.

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Spills should be wiped thoroughly using either an iodophor disinfectant or sodium hypochlorite solution. Materials used to wipe up spills should be added to biohazardous 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 used 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-D 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 5% suspension of the red cells in individual's own plasma or in normal saline.  
 2. To the two small test tubes ("2x3/8") labeled test (T) and control (C). Add one drop

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of above cell suspension using a Pasteur pipette.  
 2. Add one drop of Anti D to tube (T) and one drop of 22% Bovine Albumin to tube (C).  
 3. Mix well and centrifuge for one minute at 1000rpm or allow the tubes to stand at RT (25-30°C) for 15-60 minutes.  
 4. Gently dislodge cell button and observe for agglutination.  
**INTERPRETATION OF RESULTS:**  
 1. Agglutination of red blood cells in presence of Anti-D indicates the presence of D (Rho) antigen on red blood cells.  
 2. Absence of agglutination of red blood cells in presence of Anti-D antibody with both tube and slide test is a negative test. It generally indicates that D (Rho) antigen is not demonstrable. However, this requires to be confirmed by indirect Coomb's test to rule out the possibility of the presence of D antigen, using Anti-D (Rho) Monoclonal (IgM/IgG/IgM+IgG).  
 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

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FALSE NEGATIVE	
Cause	Remedy
Contamination of blood specimens 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.

WEAKLY / DELAYED REACTION	
Cause	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

**ACCURACY:**  
 Bhat-Bioscan Anti-D Test meets the requirements when tested against DCI approved kit.  
**SENSITIVITY:**  
 1. Rh Positive

No. of Rh Positive samples tested	88
No. of Positive results by Anti-D (IgM/IgG/IgM+IgG) kit	88

Sensitivity of Anti D (IgM/IgG/IgM+IgG) kit is estimated to be 100% (88/88), assuming 100% reactivity by comparing with other kits.

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**SPECIFICITY:**  
 1. Rh Negative

















No. of Rh Negative samples tested	105
No. of Positive results by Anti-D (IgM/IgG/IgM+IgG) kit	0

Specificity of Anti-D (IgM/IgG/IgM+IgG) kit is estimated to be 100%(0/105).  
**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.

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**EN 980:2008 (E) MEDICAL DEVICES SYMBOL**

	Temperature Limitation		Date of Manufacture		In vitro Diagnostic Device		Batch Code
	Company name & address		Refer Operating Instructions		Use by		Company Name
	Authorized Representative in European Community		Do Not Reuse		Sufficient for		KEEP AWAY FROM SUNLIGHT
	KEEP DRY		NON-STERILE		NEGATIVE CONTROL		POSITIVE CONTROL

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