



TB CARD TEST

Rapid test for qualitative detection of antibodies of Mycobacterium tuberculosis (MTB) in human serum or plasma or whole blood

For Professional use Only

READ THIS PACK INSERT CAREFULLY BEFORE PERFORMING THE TEST

Catalogue No. : TSC - 10

DESCRIPTION : Bhat Bioscan® TB Card test is a rapid one step immunoassay for the qualitative detection of anti TB antibodies(Iso types IgG, IgM and IgA) in human serum or plasma. Or whole blood The test is to be used as an aid in the diagnosis of infection due to Mycobacterium tuberculosis.

SUMMARY AND EXPLANATION : Mycobacteria tuberculosis is a micro organism which is indicated as an etiological agent of tuberculosis. The M.tuberculosis bacterium appears as a thin, beaded, straight or bent rod ranging from 1 to 10 µm long and 0.2 to 0.6 µm in width. The disease (TB) is spread primarily through airborne transmission by droplets during coughing, sneezing or talking, especially in poorly ventilated areas. According to WHO more than 8 million new case of active TB disease are diagnosed each year and over 2.9 million deaths are attributed to TB annually.

Several simple detection techniques have been used for the diagnosis of TB ie. skin test, sputum culture and chest X-rays. Newer tests such as PCR is also used in few laboratories but this test also prone to false positive in high incidence areas and is not cost effective nor easy to perform. The most suitable choice for the diagnosis of tuberculosis is serology. Many tests for the detection of antibodies in the patient specimen are currently available in the market. The Bhat Bioscan® TB Card Test belongs to a new generation of rapid immuno chromatographic assay and is one of the simplest, fastest, sensitive & specific test for the detection of MTB antibodies.

PRINCIPLE: The Bhat Bioscan® TB Card Test Device (Serum/Plasma or whole blood) is a qualitative, solid phase, two-site sandwich immunoassay for the detection of anti-TB antibodies in serum or plasma or whole blood specimens. The membrane is pre-coated with TB recombinant antigen on the test line region of the Device. During testing, the anti-TB antibodies, if present in serum or plasma specimen react with the particles coated with TB recombinant antigen. The mixture migrates upward on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

STORAGE AND STABILITY : The Bhat Bioscan® TB Card test can be stored at any temperature between 2-30°C in the original pouch. DO NOT FREEZE THE TEST KIT. The stability of Bhat Bioscan® TB Card Test is 24 months from date of manufacturing under the above mentioned storage conditions.

PACK SIZE : Available in Packs of 5 and 10 Test.

KIT CONTENTS :

Packsize	10 Test	5 Test
1. TB Test Devices	10 Nos	5 Nos
2. 2ml Dropper	10 Nos	5 Nos
3. Silicagel	10 Nos	5 Nos
4. Pack Insert	1 No.	1 No.
5. Assay Diluent	0.6ml	0.3ml

MATERIAL REQUIRED BUT NOT PROVIDED :

1. Sterilized vial
2. Disposable gloves
3. Precession pipette
4. Sodium hypochlorite Solution (free available chlorine 50 to 500mg/L)
5. Autoclaved Tips

PRECAUTIONS :

1. Read this Pack insert carefully.
2. DO NOT FREEZE THE KITS.
3. Do not use after the expiration date.
4. Use serum or plasma or whole blood specimen. Furthermore, do not use umbilical cord blood, because it prevents colloidal gold from migration and can interfere with results.
5. Carefully observe the prescribed number of drops to be added 2 DROPS OF SERUM OR PLASMA ONLY.

SPECIMEN : Fresh Serum or Plasma or whole blood

SPECIMEN COLLECTION

1. It is recommended to use fresh serum or plasma.
2. Patient samples are best if testing is performed immediately. Collect the specimen as per routinely used technique of blood collection and its separations. The specimen should be refrigerated maximum for 3 days and are to be shipped, they should be packed in compliance with regulations covering the transportation of etiologic agents.

TEST PROCEDURE :

A. FOR SERUM OR PLASMA

1. Remove the desired number of test units from its pouch and place on flat surface.
2. Label the test unit with patient name or identification number.
3. Add Two DROPS of serum or plasma into SAMPLE WELL (S) using provided dropper.
4. Read results between 10-30 minutes.

DO NOT READ ANY RESULT BEYOND 30 MINUTES.

5. Any line appearing after 30 minutes would be of no diagnostic value.

B. FOR WHOLE BLOOD

1. Remove the desired number of test units from its pouch and place on flat surface.
2. Label the test unit with patient name or identification number.
3. Add 2 drops of whole blood into SAMPLE WELL (S) using provided dropper and allow to soak in.
4. Add 1 drop of assay diluent into the same sample window(S).
5. Read the results between 10-30 minutes DO NOT READ ANY RESULT BEYOND 30 MINUTES.

INTERPRETATION RESULTS

NEGATIVE : Appearance of only one pink/purple line at CONTROL zone (C) indicates that sample does not contain MTB antibodies.



POSITIVE : Appearance of Two pink/purple lines, one at CONTROL zone (C) and another at Test zone (T), indicates that sample contains antibodies against MTB.



INVALID : If there is no distinct pink/purple band visible in the CONTROL zone the test is inconclusive. It is recommended, in the case, to repeat the test with a new device.

INVALID (RETEST)



LIMITATIONS : The Bhat Bioscan® TB Card Test procedure and the interpretation of the results must be followed closely. This assay is designed for detecting antibodies against tuberculosis in human serum or plasma. Any result from the testing of other body fluids or of pooled serum or plasma may not yield correct results based on current criteria. Therefore, other body fluids and pooled samples are not recommended in this assay. For positive specimens it is recommended that a more specific reference test be performed and clinical evaluation of the patient's situation should be performed before a final diagnosis is made. Rapid testing alone should not be used to diagnose tuberculosis infection ever if

Bhat Bioscan® TB Card Test Device vs. Smear/Culture

Method	Smear/Culture			Total Results
	Results	Positive	Negative	
Bhat Bioscan® TB Card Test	Positive	83	4	87
	Negative	17	369	386
Total Results		100	373	473

Relative Sensitivity : 83.0% (74.1% - 89.8%)*

Relative Specificity : 98.9% (97.3-99.7%)*

Relative Accuracy : 95.6% (93.3% - 97.2%)*

REFERENCES :

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EN 980:2008 (E) MEDICAL DEVICES SYMBOL					
	Temperature Limitation 2°C - 30°C		Date of Manufacture 2001-06		In vitro Diagnostic Device
	Batch Code		Company name & address		Refer Operating Instructions
	Use by		Company Name		Authorised Representative in European Community
	Do Not Reuse		Sufficient for		KEEP AWAY FROM SUNLIGHT
	KEEP DRY		NON-STERILE		NEGATIVE CONTROL
	POSITIVE CONTROL				
Authorised Representative in EC _____					



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