TB-CARD TEST

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

READ THE PACK INSERT CAREFULLY BEFORE PERFORMING THE TEST

Catalogue No. : TSC - 10

DESCRIPTION : BHAT BIO-SCAN TB-CARD test is a rapid two step immuno assay for the qualitative detection of Anti-TB antibodies in human serum or plasma. The test is to be used as an aid in the (isotypes IgG, IgM & IgA) 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 Bio-Scan 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 Bio-Scan TB-CARD Test Device (Serum/Plasma) is a qualitative, solid phase, two-site sandwich immunoassay for the detection of anti-TB antibodies in serum or plasma specimens. The membrance 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 Bio-Scan TB-CARD Test can be stored at any temperature between 2-30^{o}C in the original pouch. DO NOT FREEZE THE TEST KIT. The stability of the Bhat Bio-Scan TB-CARD tests is 24 months from date of manufacturing under the above mentioned storage conditions.

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

TB-SCAN TEST KIT CONTENTS :

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

MATERIAL REQUIRED BUT NOT PROVIDED :

1. Sterilized vial
2. Disposable gloves
3. Precession pipette
4. Sodium hypochlorite Solution (free available chlorine 50-500mg/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 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

SPECIMEN COLLECTION

1. It is recommended to use fresh sample 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 :

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.

INTERPRETATION RESULTS

NEGATIVE : Appearance of only one pink/purple line at CONTROL zone (C) indicates that sample does not contain anti-TB 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 Bio-Scan 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 even if tuberculosis antibodies are present. A negative result at any time does not preclude the possibility of infection with tuberculosis.

PERFORMANCE CHARACTERISTICS :

Clinical Sensitivity, Specificity and Accuracy : The Bhat Bio-Scan TB-CARD Test Device (Serum/Plasma) has been calibrated against samples that have been collected from individuals found to be either smear positive/negative or culture positive/negative. The results show that the relative sensitivity of the Tuberculosis Rapid Test Device (Serum/Plasma) is 83.0%, the relative specificity is 98.9% and the relative accuracy is 95.6%.

TB Tuberculosis Rapid Test Device vs. Smear/Culture

Method	Smear/Culture			Total Results
Tuberculosis Rapid Test Device	Results	Positive	Negative	
	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%)*

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