SYPHILIS CARD TEST

BHAT Bio-Scan

For Professional Use

A Rapid Card Test to detect Antibodies to *Treponema Pallidum* (TP) in human serum or plasma or **whole blood** IVD

READ THE PACK INSERT CAREFULLY BEFORE PERFORMING THE TEST

REF **BSC-WB**

INTENDED USE : BHAT BIO SCAN® Syphilis Care testis a rapid Card test to detect antibodies to Treponema Pallidum in human serum or plasma or whole blood

INTRODUCTION :

Treponema Pallidum (TP) is the causative agent of the venereal disease syphilis. TP is a spirochete bacterium with an outer envelpoe and a cytoplasmic membrane. Relatively little is know about the organism in comparison with other bacterial pathogens. According to the Center for Disease Control (CDC), the number of cases of syphilis infection has markedly increased since 1985. Some key factors that have contributed to this rise include the crack cocaine epidemic and the high incidence of prostitution among drug users. One study reported a substantial epidemiological correlation between the acquisition and transmission of the HIV virus and Syphilis. Multiple clinical stages and long periods of latent, asymptomatic infection are characteristic of Syphilis. Primary Syphilis is defined by the presence of a chancre at the site of inoculation. The antibody response to the ***TP*** bacterium can be detected within 4 to 7 days after the chancre appears. The infection remains detectable until the patient receives adequate treatment. The Syphilis Rapid Test Device (Serum/Plasma) utilizes a double antigen combination of a Syphilis antigen coated particle and Syphilis antigen immobilized on membrane to detect ***TP*** antibodies (IgG and IgM) qualitatively and selectively in serum or plasma or whole blood.

TEST PRINCIPLE :

The BHAT BIO SCAN® Syphilis Rapid Test Device (Serum/Plasma) is a qualitative membrane device based immunoassay for the detection of *TP* antibodies (IgG , IgM and IgA) in serum or plasma.In this test procedure, recombinant Syphilis antigen is immobilized in the test line region of the device. After a specimen is added to the specimen well of the device, it reacts with Syphilis antigen coated particles in the test. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized Syphilis antigen. The double antigen test format can detect both IgG , IgM and IgA in specimens. If the specimen contains *TP* antibodies, a colored line will appear in the test line region, indicating a positive result. If the specimen does not contain *TP* antibodies, a colored line will not appear in this reagion, indicating 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 & STABILITY : Store between 2-30°C. Do not freeze. The Kit is stable until the expiry date mentioned on the Pouch, when stored under the above condition.

PACK SIZE : Available in packs of 10's, 20's and 50's.

CONTENTS OF THE KIT :

PACK SIZE	10 TEST	20 TEST	50 TEST
Test Device	10 Nos.	20 Nos.	50 Nos.
30µl Dropper	10 Nos.	20 Nos.	50 Nos.
Silicagel	10 Nos.	20 Nos.	50 Nos.
Diluent	0.6ml	1.2ml	3.0ml
Pack Insert	1 No.	1 No.	1 No.

MATERIAL REQUIRED BUT NOT PROVIDED :

a) Sterilized Vial
b) Disposable Gloves
c) Precession Pipette
d) Sodium hypochlorite Solution (Free available Chlorine 50-500mg/L)
e) Autoclaved Tips

WARNINGS & PRECAUTIONS :

1. Read this Pack Insert carefully.
2. DO NOT FREEZE THE KITS.
3. Do not use after the expiration date.
4. Use only serum / plasma specimen. Further more do not use umbilical cord blood, because it prevents colloidal gold from migrating and can interface with result.
5 Carefully observe the prescribed number of drops to be added 2 drops of serum or plasma. For whole blood test add 1 drop (30 µl) of whole blood and one drop test diluent only.
6. If the kit is refrigerated should be brought down to room temperature before testing. Assay should be conducted at room temperature (15-30°C)
7. Use the kit soon after removing from the pouch.
8. Do not use the test device, if the pouch seal is broken or silicagel pouch white in colour.
9. Frozen specimens should be brought to room temperature before testing. Specimen should not be repeatedly frozen and thawed.
10. Specimen with extremely high concentrations of red blood cells, fibrin should be recentrifuged before using.
11. For In vitro Diagnostic Use only.

All human serum and plasma samples should be considered to be potentially infectious. 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. 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 not containing acid may be mixed with sodium hypochlorite so that the final mixture contains 50-500 mg/l available chlorine. Allow 30 minutes for decontamination.

Note : Liquid waste containing acid must be neutralized with a proportional amount of base prior to the addition of sodium hypochlorite. Spills should be wiped up throughly 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. Reagents are stored between 2-30°C. Avoid unnecessary exposure to light. Do not use reagents after expiration date.Do not mix or interchange reagents from different kits or kit batches. cross contamination of reagents or samples can cause erroneous results. Use a new pipette tip for each sample. Optimal results are obtained by strictly adhering to the test protocol. Accurate and precise pipetting, as well as following the exact time and temperature requirements, is essential. Once the assay has been started, all steps should be performed without interruption.

SPECIMEN : Fresh Serum or Plasma or **whole blood** can be used for testing.

SPECIMEN COLLECTION & PREPARATION :

a. Collect blood in a clean, dry, sterilized vial and allow it to clot. Separate the Serum by centrifugation at 5000 r.p.m. for 15 minutes at room temperature.

b. if serum is not to be assayed immediately it should be stored at 2-8°C or if storing more than 3 days then freeze the specimen at-20°C or below.

Specimen collection & Preparations (Collection by Veni Puncture) :

a). Collect whole blood in to a sterilized vial (Containing EDTA, Citrate or Heparin) by veni puncture.

b). If specimens are not immediately tested, they should be refrigerated at 2-8°C.

c). When stored at 2-8°C the whole blood sample be used with in 3days.

ASSAY PROCEDURE :

1. Bring the pouch to room temperature.
2. Remove the device from the pouch just prior to testing.
3. Place the device on flat surface.
4. Add 2drops of serum or plasma in to the sample window.
5. Interpret the test result in 10 minutes. DO NOT INTERPRET AFTER 30 MINUTES.
6. Any line appearing after 30 minutes would be of no diagnostic value.

Alterative PROCEDURE :

1. Bring the pouch to room temperature.
2. Remove the device from the pouch just prior to testing.
3. Place the device on flat surface.
4. **Add 1 drop (30µl) of whole blood in to the sample window (S) and allow to** soak in.
5. Add one drop of diluent provided in the drop bottle in the sample window(S).
6. Interpret the test result in 10 minutes. DO NOT INTERPRET AFTER 30 MINUTES.
7. Any line appearing after 30 minutes would be of no diagnostic value.

INTERPRETATION OF THE TEST RESULTS :

NEGATIVE

1. NEGATIVE : The Presence of only one band at 'C' (Control Line) within in the result window indicates a Negative Result.

POSITIVE

2. POSITIVE : The presence of two bands at 'C' (Control Line) and 'T' (Test Line) within the result window, no matter which band appears first, indicates that sample is reactive or Syphilis.

INVALID

3. INVALID : If no lines appear or only test line appears with in the result window, after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen to be re-tested with new device.

PERFORMANCE CHARACTERISTICS :

Clinical Sensitivity, Specificity and Accuracy

The BHAT BIO SCAN® Syphilis Rapid Test Device (Serum or Plasma) has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial TPHA Syphilis test using clinical specimens. The results show that the relative sensitivity of the Syphilis Rapid Test Device (Serum/Plasma) is 99.7% and the relative specificity is 99.6%.

BHAT BIO SCAN® Syphilis Rapid Test Device vs. TPHA.

Method		TPHA		Total Results
BHAT BIO SCAN® Syphilis Rapid Test Device	Results	Positive	Negative	
	Positive	384	2	386
	Negative	1	493	494
Total Results		385	495	880

Relative Sensitivity : 99.7% (98.6%-100.0%)
Relative Specificity : 99.6% (98.5%-100.0%)*.

LIMITATIONS :

1. The BHAT BIO SCAN® Syphilis Rapid Test Device (Serum/Plasma/whole blood) is for in vitro diagnostic use only. The test should be used for the detection of *TP* antibodies in serum or plasma or whole blood specimens only . Neither the quantitative value nor the rate of increase in *TP* antibodies can be determined by this qualitative test.

2. The BHAT BIO SCAN® Syphilis Rapid Test Device (Serum/Plasma/whole blood) will only indicate the presence of *TP* antibodies in the specimen and should not be used as the sole criteria for the diagnosis of *TP* infection.

3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *TP* infection.

References :

1. Claire FM. *Complete genome sequence of Treponema Pallidum, the Syphilis spirochete,* Science 1998 ; 281 July 375-381.
2. Center for Disease Control. *Recommendations for diagnosing and treating Syphilis in HIV-infected patients,* MMWR Morb. Mortal Wkly Rep. 1988; 37:601.
3. Marx AR. *Crack, sex and STD,* Sexually Transmitted Diseases, 1991: 18:92-101.
4. Wasserheit JN. *Epidemiological Synergy, Interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases,* 1992 ; 19 : 61-77.
5. Johnson PC. Testing for Syphilis, Dermatologic Clinic 1994; 12 Jan: 9-17.

BS ISO-15223-1:2012(E) MEDICAL DEVICES SYMBOL

2°C 30°C	Temperature Limitation	2001-06	Date of Manufacture
LOT	Batch Code		Company name & address
	Use by	Company	Company name
IVD	In vitro Diagnostic Device	EC REP	Authorised Representative in European Community
	Consult Instructions For Use		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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