SYPHILIS DIPSTICK TEST

For Professional Use

A Rapid Strip test for the Qualitative Detection of Antibodies to *Treponema pallidum* (TP) in Human Serum or Plasma

READ THIS PACK INSERT CAREFULLY BEFORE PERFORMING THE TEST

IVD

REF **BSD**

INTENDED USE : The Syphilis Dipstick Test (Serum or Plasma) is a qualitative membrane device based immuno assay for the detection of TP antibodies (IgA and IgM) in Human Serum or Plasma.

INTRODUCTION :

Treponema pallidum (TP) is the causative agent of the veneral disease Syphilis. TP is a spirochete bacterium with an outer envelope and a cytoplasmic membrane. Relatively little is known about the organism in comparision with order bacterial pathogens. According to the centre 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 acqurisition and transmission of the HIV virus and syphilis.

Multiple clinical stages and long periods of latent, asymtomatic 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 appear. The infection remains detectable until the patient receives adequate treatment.The Syphilis Test strip (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 and selectively in serum or plasma.

TEST PRINCIPLE :

The Syphilis Dipstick Test (Serum/Plasma) is a qualitative membrane device based immunoasay for the detection of TP antibodies (IgA and IgM) in serum or plasma. In this test procedure recombinat syphilis antigen is immobilized in the test line region of the device. After dipping the strip in the specimen, 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 IgA and IgM in specimens. If the specimen contains TP antibodies, a colored line will apear in the test line region, indicating a positive result. If the specimen does not contain TP antibodies, a colored line will appear only int the control region. Appearance of Control line indicating that proper volume of specimen has been added and membrane wicking has occurred.

STORAGE AND 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 pack of 50 Tests.

CONTENTS OF THE KIT :

Pack Size	50 Test
Test Strip	50 Nos.
Silicagel	50 Nos.
Pack Insert	1 No.

WARNINGS & PRECAUTIONS :

In order to obtain reproducible result, the following rules must be observed:
a) Read this Pack insert carefully.
b) DO NOT FREEZE THE KITS. If refrigerated the kits should be brought to room temperature before testing. Assay should be conducted between 15-30°C.
c) Do not use umbilical cord blood because it prevents colloidal gold from migrating & can interfere with result.
d) Do not use the kits beyond their expiry date.
e) Do not Use whole blood.
f) Carefully Dip the Strip in Serum/Plasma.
g) Use the test Strip upto the max mark only.
h) Do not use the test Strip, if the pouch seal is broken.
i) Avoid any contamination among samples; for this purpose, disposable tips and sterilized vial should be used for each sample and reagent.
j) Read the result in 15-30 minutes.
DO NOT INTERPRET THE RESULT AFTER 30 MINUTES.
k) Do not smoke, eat drink or apply cosmetics during the assay.
l) For in vitro Diagnostic Use only.
m) For single use only.
n) Do not use the sample, which is stored for more than 3 days at 2-8°C as it may give false positive result.

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. Nee 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 it is capable of transmitting infection. The preferred method of disposal is autoclaving for a minimum of one hour at 121°C.

Liquid wasted 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 matte 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.

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 immediatly it should be stored at 2-8°C or if storing more than 3 days then freeze the specimen at -20°C or below.

ASSAY PROCEDURE :

1. Bring the Pouch to the room temperature.
2. Remove the strip from the Pouch just prior to testing.
3. Dip the strip in Serum or plasma upto the mark for 5-10 Seconds.
4. Remove the strip from the specimen and place on a flat surface.
5. Interpret the test results in 10 mins.
6. Any line appearing after 30 minutes would be fo no diagnostic value.

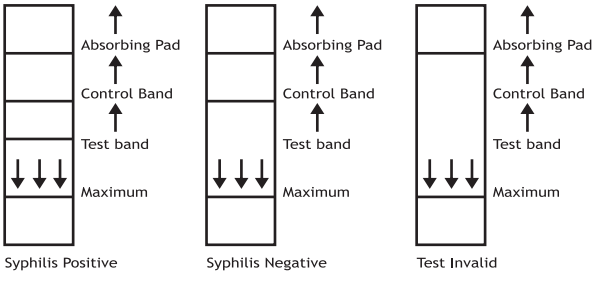
INTERPRETATION OF THE TEST RESULTS :

POSITIVE : The presence of two bands in the results area (Control & Test) no matter which band appears first, indicates that sample reactive for Syphilis.

NEGATIVE : The presence of only one band (Control Line) in the result area indicates a negative result.

INVALID : If no lines appear or only test line appears 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 strip.

INTERPRETATION OF RESULTS :



LIMITATIONS :

1. The Syphilis strip test (Serum/Plasma) is for invitro diagnostic use only. The test should be used for the detection of TP antibodies in serum or plasma specimens only. Neither the quantitive value nor the rate of increase in TP antibodies can be determined by this qualitative test.
2. The Syphilis strip test (Serum/Plasma) 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 results does at any time preclude the possibility of TP infection.
5. All positive samples must undergo confirmation test.

PERFORMANCE CHARACTERISTICS : Clinical Sensitivity, Specificity and Accuracy. The Syphilis strip test (Serum/Plasma) has correctly identified specimens of a seroconversion panel and has been compared to a leading comercial TPHA Syphilis test using clinical specimens. The results show that the relative sensitivity of the syphilis strip test (serum/plasma) is 99.7% and the relative specificity is 99.6% Syphilis Dipstick Test vs. TPHA.

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

Methods		TPHA		Total Results
Bhat Bio-Scan® Syphilis Dipstick Test	Results	Positive	Negative	
	Positive	384	2	385
	Negative	1	493	494
		385	495	880

REFERENCE :

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. MarxAR. Carck, Sex, and STD, Sexually Transmitted Diseases, 1991 : 19 : 92 101.

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

30°C 2°C	Temperature Limitation	2001-06	Date of Manufacture	IVD	In vitro Diagnostic Device
LOT	Batch Code		Company name & address		Refer Operating Instructions
	Use by	Company	Company name	EC REP	Authorised Representative in European Community
	Do Not Reuse				

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