**SYPHILIS CARD TEST**

For Professional Use

A Rapid card test to detect antibodies to *Treponema pallidum* (TP) in human serum or plasma

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**INTENDED USE:** Syphilis card test Bhat Bio scan® is a rapid card test to detect antibodies to Treponema Pallidum in Human serum or plasma.

**INTRODUCTION:** Treponema Pallidum (TP) is the causative agent of the venereal disease syphilis. TP is procheter bacterium with an outer envelope and cytoplasmic membrane. relatively little known 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 in 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 chacre at the site of inoculation, the antibody response to the TP bacterium can be detected with in 4 to 7 days after the chancre appears. the infection remains detectable until the patient received adequate treatment. The syphillis 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 (IgM & IgG) quantitatively in serum or plasma.

**TEST PRINCIPLE:** The Bhat Bioscan Syphillis rapid test device (serum/plasma) is a qualitative membrane device based immunoassay for the detection of TP antibodies (IgM & IgG) in serum or plasma. In this test procedure, recombinant syphilis antigen is immobilised 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 immobilizes syphilis antigen. the double antigen test format can detect both IgG and IgM 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 the test line region, indicating a negative result. To serve a procedural control a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane licking has occurred.

**STORAGE AND STABILITY:** Kit should be stored between 2°C-30°C in the sealed pouch. The test kit is stable until the expiration date mentioned on the pouch when stored under these conditions.

**PACK SIZE:** Available in packs of 10’s, 25’s and 50’s.

<table>
<thead>
<tr>
<th>PACK SIZE</th>
<th>10 Tests</th>
<th>25 Tests</th>
<th>50 Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Device</td>
<td>10 Nos.</td>
<td>25 Nos.</td>
<td>50 Nos.</td>
</tr>
<tr>
<td>2 ml dropper</td>
<td>10 Nos.</td>
<td>25 Nos.</td>
<td>50 Nos.</td>
</tr>
<tr>
<td>Stilcage</td>
<td>10 Nos.</td>
<td>25 Nos.</td>
<td>50 Nos.</td>
</tr>
<tr>
<td>Pack insert</td>
<td>1 No.</td>
<td>1 No.</td>
<td>1 No.</td>
</tr>
</tbody>
</table>

**MATERIAL REQUIRED BUT NOT PROVIDED:**

- a) Sterilized vial
- b) Disposable gloves
- c) Micro pipette(1-10µl)
- d) Sodium hypochlorite solution (free available chlorine 50-500mg/L)
- e) Autoclaved Tips

**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) Use whole blood.

f) Carefully serve the prescribed number of drops to be added, 2 drops of serum or plasma.

g) Use the test device soon after it is removed from the pouch.

h) Do not use the test device, 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 60 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 whole blood sample, which is stored for more than 3 days 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. 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 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. Cross contamination of reagents or samples can cause erroneous results.

**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 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.

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 2 drops of serum or plasma into 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.

INTERPRETATION OF RESULTS:

If only one line appears at control the result is negative for Syphilis.

If only two lines appeared at Control (C) and (T) the result is Positive for Syphilis.

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.

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 and Specificity and Accuracy.

The Bhat Bioscan Syphilis card test has correctly identified specimens of a sero conversion panel and had been compared to a leading commercial TPHA brand syphilis test kit using the clinical specimens. The result shows the relative sensitivity of Syphilis card test Serum/plasma as 99.7% and the specificity of 99.6%.

**Syphilis Card Test Bhat BioSCAN VS TPHA**

<table>
<thead>
<tr>
<th>Method</th>
<th>TPHA</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syphilis Card Test Bhat BioSCAN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Results</td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>Positive</td>
<td>384</td>
<td>2</td>
</tr>
<tr>
<td>Negative</td>
<td>1</td>
<td>493</td>
</tr>
<tr>
<td>Total Results</td>
<td>385</td>
<td>495</td>
</tr>
</tbody>
</table>

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

*Syphilis card Test Bhat Bio-SCAN Serum/Plasma is for *in vitro* diagnostic use only. The test should be used for the detection of TP antibodies in serum or plasma 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) will only indicate the presence of TP antibodies in the specimen and should not be used as 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 results 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 sequences of Treponema Pallidum, the Syphilis Spirochete, Science, 1998; 281 July 375-381.

NOTE:: Even after the best effort is made to supply the product as per the sample submitted but due to continuous R & D, the company reserves the right to improve/change any specifications/components without prior information/notice to the buyer.

LIMITED EXPRESSED WARRANTY OF MANUFACTURER

The manufacturer limits the warranty to this test kit, as much as that the test kit will function as an in vitro diagnostic assay within the Nature of Sample. Procedure limitations and specifications as described in the product instruction manual, when used strictly in accordance with the instructions contained. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer’s liability is limited to the replacement of the product or refund of the purchase price of the product and in no case liable to claim of any kind for amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

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

Manufactured in India by:

**Bhat Bio - Tech India (P) Ltd.**

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