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

**INTRODUCTION:**
Treponema pallidum (TP) is the causative agent of the venereal disease Syphilis. TP is a spirochete bacterium with an outer envelope and a cytoplasmic membrane. Relatively little is known about the organism in comparison with other 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 acquisition and transmission of the HIV virus and syphilis.

**TEST PRINCIPLE:**
The Syphilis Dipstick Test (Serum or Plasma) is a qualitative membrane device based immunoassay for the detection of TP antibodies (IgA and IgM) in serum or plasma. In this test procedure recombinant 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 appear only in the test region. Appearance of Control line indicating that proper volume of specimen does not contain TP antibodies, a colored line will appear only in 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) Do not handle 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 or Plasma.
g) Use the Test Strip up to 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.
k) Do not interpret the result after 30 MINUTES.
l) Do not smoke, eat drink or apply cosmetics during the assay.
m) For in vitro Diagnostic Use only.
n) For single use only.

**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 up to 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 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:**

![Image of test results](image-url)
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 quantitative 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 result does not preclude the possibility of TP infection.

5. All positive samples must undergo confirmation tests.

**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 commercial 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.

<table>
<thead>
<tr>
<th>Methods</th>
<th>TPHA</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bhat Bio-Scan Syphilis Dipstick Test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sensitivity</td>
<td>99.7% (98.6%-100.0%)</td>
<td></td>
</tr>
<tr>
<td>Specificity</td>
<td>99.6% (98.5%-100.0%)</td>
<td></td>
</tr>
<tr>
<td>Positive Results</td>
<td></td>
<td></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</td>
<td>385</td>
<td>495</td>
</tr>
<tr>
<td>Negative Results</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>880</td>
<td></td>
</tr>
</tbody>
</table>

**REFERENCE:**


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

- Temperature Limitation
- Date of Manufacture
- In vitro Diagnostic Device
- Batch Code
- Company name & address
- Refer Operating Instructions
- Use by
- Company
- Authorized Representative in European Community
- Do Not Reuse