**Syphilis Rapid Screen Test**

The Syphilis Rapid Screen Test is a screening test for the qualitative detection of antibodies of Treponema Pallidum (TP) in whole blood/serum/plasma. Syphilis is a highly contagious disease caused by a bacterium called Treponema Pallidum. The disease is spread primarily through sexual transmission or intimate contact with an individual who has an open, wet syphilitic sore. Pregnant women with syphilis can pass it on to her baby and have a good chance of having a still birth. The Syphilis Rapid Screen Test helps in the diagnosis of syphilis.

**PRECAUTIONS**

1. Do not use the test kit beyond the expiration date.
2. Do not use the kit if the pouch is punctured or not well sealed.
3. For in vitro use only. Do not swallow.
4. All specimens from the body should be treated as potentially infectious.
5. Contaminated blood may give incorrect test results.
6. Discard after first use. The test cannot be used more than once.

**DISPOSAL:** The used-device has the risk of infection. Please dispose all used contents properly.

**CONTENTS SYPHILIS RAPID TEST KIT**

Each Kit Contains:
- Syphilis test card individually foil pouched with a desiccant (silicon gel)
- Plastic dropper
- Sample diluent
- Safety lancet
- Alcohol swab
- Package insert

**Material Required But Not Provided:**
- Timer

**STORAGE AND STABILITY**

The kit must be stored between 2-30°C.

---

**Do not open pouch until you are ready to test the sample.**

**ASSAY PROCEDURES FOR FINGER BLOOD**

1. Bring the syphilis test card, sample diluent, alcohol swab, safety lancet, plastic dropper to room temperature.
2. Take out the test card from the sealed pouch.
3. To perform the test, please follow the steps closely as follow (from picture 1 to picture 8).
ASSAY PROCEDURES AT CLINIC
1. Bring all reagents and specimens to room temperature.
2. Remove the test card from the foil pouch and place on a clean dry surface.
3. Identify the test card for each specimen or control.
4. **For whole blood testing:** Dispense one drop (30μl) of sample or control into the sample well on the card using the plastic dropper provided, then add one drop (50μl) of sample diluent into the same well. **For serum/plasma:** Dispense three to four drops (80-120 μl) of sample or control into the sample well on the card using the plastic dropper provided.
5. Interpret test results at 15 minutes. A positive result may be interpreted early, however read any negative at 15 minutes to ensure sample is negative and not a low concentration of syphilis antibodies. Do not interpret the result after 20 minutes.

It is recommended to run a known positive control and negative control in each performance to ensure the assay procedure.

READING THE TEST RESULTS
1. **Positive:** Both purplish read test band and purplish read control band appear on the membrane. The lower the antibody concentration, the weaker the test band.
2. **Negative:** Only the purplish red control band appears on the membrane. The absence of a test band indicates a negative result.
3. **Invalid:** There should always be a purplish red control band in the control region regardless of test result. If control band is not seen, the test is considered invalid. Repeat the test using a new test device.

**Note:** It is normal to have a slightly lightened control band with very strong positive samples as long as it is distinctly visible.

PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
104 serum samples were obtained for testing, then the testing results between the Syphilis Rapid Screen Test and the TPPA method were compared. The results of sensitivity and specificity between the two methods are shown in the table.

<table>
<thead>
<tr>
<th></th>
<th>Reagents</th>
<th>TPPA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>Syphilis Rapid Screen Test</td>
<td>52</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>50</td>
</tr>
<tr>
<td>Total</td>
<td>53</td>
<td>51</td>
</tr>
</tbody>
</table>

Sensitivity of the Syphilis Rapid Screen Test: 52/53 = 98.1%
Specificity of the Syphilis Rapid Screen Test: 50/51 = 98%

LIMITATIONS
1. As it is with any diagnostic procedure, a confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated.
2. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of syphilis antibody.

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 syphilis infection.

BIBLIOGRAPHY