A rapid test for the qualitative detection of Treponema Pallidum (TP) in whole blood, serum or plasma.

For professional in vitro diagnostic use only.

INTENDED USE
The Syphilis Test is a rapid chromatographic immunocassay for the qualitative detection of antibodies (IgG and IgM) to Treponema Pallidum (TP) in whole blood, serum or plasma to aid in the diagnosis of Syphilis.

SUMMARY
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.1 Relatively little is 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 since 1985.2 Some key factors that have contributed to this rise include the crack cocaine epidemic and the high incidence of prostitution among drug users.2 One study reported a substantial epidemiological correlation between the acquisition and transmission of the HIV virus and Syphilis.6

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.5

The Syphilis Ultra Rapid Test Device (Whole Blood/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) quantitatively and selectively in whole blood, serum or plasma.

PRINCIPLE
The Syphilis Test is a qualitative membrane device based immunocassay for the detection of TP antibodies (IgG and IgM) in whole blood, 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 and IgM in specimens. If the specimen contains TP antibodies, a coloured line will appear in the test line region, indicating a positive result. If the specimen does not contain TP antibodies, a coloured line will not appear in this region, indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS
The test device contains Syphilis antigen coated particles and Syphilis antigen coated on the membrane.

PRECAUTIONS
- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY
Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION
- The Syphilis Ultra Rapid Test Device (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect fingerstick whole blood specimens:
  1. Wash the patient’s hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  2. Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  3. Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  4. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  5a. Add the fingerstick whole blood specimen to the test device by using a sample dropper:
    - Slightly squeeze the bulb and fill the sample dropper. Avoid air bubbles. Then squeeze the bulb to dispense 2 drops (approximately 50 µl) into the specimenwell (S) of the test device.
  5b. Add the fingerstick whole blood specimen to the test device by using hanging drops:
    - Position the patient’s finger so that the drop of blood is just above the specimen well (S) of the test device.
    - Allow 2 hanging drops of fingerstick whole blood to fall into the specimen well (S) of the test device, or move the patient’s finger so that the hanging drop touches the specimen well (S). Avoid touching the finger directly to the specimen well (S). Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear non-haemolysed specimens.
    - Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below 20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
    - Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
    - If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
# SYphilis Test

## Materials

### Materials Provided
- Syphilis Test device
- Disposable specimen droppers
- Buffer (for whole blood only)
- Droppers
- Package insert

### Materials Required But Not Provided
- Specimen collection containers (for venipuncture whole blood)
- Lancet (for fingerstick whole blood only)
- Centrifuge (for plasma only / serum)
- Timer

## Directions for Use

1. Allow the test device, specimen, buffer and/or controls to reach room temperature (15-30°C prior to testing)

2. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

<table>
<thead>
<tr>
<th>Serum or Plasma</th>
<th>Venipuncture Whole Blood</th>
<th>Fingerstick Whole Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3</strong> Hold the dropper vertically and transfer 3 drops of serum or plasma (approximately 75 µl) into the specimen well (S) of the test device.</td>
<td><strong>Sample Dropper:</strong> Hold the dropper vertically and transfer 2 drops of whole blood (approximately 50 µl) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µl) and start the timer.</td>
<td><strong>To use a sample dropper:</strong> Fill the sample dropper tube and transfer 2 drops (approximately 50 µl) of finger-stick whole blood specimen into the specimen well (S) of the test device. <strong>To use hanging drops:</strong> Allow 2 hanging drops of fingerstick whole blood specimen (approximately 50 µl) to fall into the centre of the specimen well (S) of the test device.</td>
</tr>
<tr>
<td><strong>4</strong> Start the timer</td>
<td><strong>Add 1 drop of buffer (approximately 40 µl) and start the timer. See illustration below.</strong></td>
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</tr>
<tr>
<td><strong>5</strong> Wait for the coloured line(s) to appear. <strong>Read results at 10 minutes. Do not read results after 30 minutes.</strong></td>
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</table>
**SYMPHILIS TEST**

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**INTERPRETATION OF RESULTS**

**POSITIVE**: Two distinct coloured lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).

*NOTE*: The intensity of the colour in the test line region (T) will vary depending on the concentration of TP antibodies present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered positive.

**NEGATIVE**: One coloured line appears in the control line region (C). No line appears in the test line region (T).

**INVALID**: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**QUALITY CONTROL**

A procedural control is included in the test. A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

**LIMITATIONS**

1. The Syphillis Ultra Rapid Test Device (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of TP antibodies in whole blood, 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 Syphillis Ultra Rapid Test Device (Whole Blood/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 at any time preclude the possibility of TP infection.

**EXPECTED VALUES**

The Syphillis Ultra Rapid Test Device (Whole Blood/Serum/Plasma) has been compared with a leading commercial TPHA Syphilis test, demonstrating an overall accuracy greater than or equal to 99.7%.

**PERFORMANCE CHARACTERISTICS**

**Clinical Sensitivity, Specificity and Accuracy**

The Syphillis Ultra Rapid Test Device (Whole Blood/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 Syphillis Ultra Rapid Test Device (Whole Blood/Serum/Plasma) is 99.7%, and the relative specificity is 99.6%.

<table>
<thead>
<tr>
<th>Syphilis Ultra Rapid Test Device Method</th>
<th>TPHA Results</th>
<th>Total Results</th>
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<tbody>
<tr>
<td>Positive</td>
<td>384</td>
<td>386</td>
</tr>
<tr>
<td>Negative</td>
<td>493</td>
<td>495</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%)*
Relative Accuracy: 99.7% (99.0%-99.9%)*   * 95% Confidence Interval

**Precision**

**Intra-Assay**

Within-run precision has been determined by testing 10 replicates of four specimens: a negative, a low positive, middle positive and a high positive. The negative, low positive, middle positive and high positive values were correctly identified 99% of the time.

**Inter-Assay**

Between-run precision has been determined by testing 10 replicates on the same four specimens: a negative, a low positive, middle positive and a high positive. Three different lots of the Syphillis Ultra Rapid Test Device (Whole Blood/Serum/Plasma) have been tested over a 3-month period using negative, low positive, middle positive and high positive specimens. The specimens were correctly identified 99% of the time.

**BIBLIOGRAPHY**

1. Claire FM. Complete genome sequence of Treponema Pallidum, the Syphilis spirochete, Science 1998; 281 July: 375-381.


<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Contents sufficient for &lt;n&gt; tests</th>
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<tbody>
<tr>
<td>IVD</td>
<td>For in vitro diagnostic use only</td>
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<tr>
<td></td>
<td>LOT</td>
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<td>For single use only</td>
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<td></td>
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<td>Store at</td>
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ulti med Products (Deutschland) GmbH
Reeshoop 1 • 22926 Ahrensburg
Telefon: 04102 - 80090
Fax: 04102 - 50082
e-mail: info@ultimed.de

Distributor:
ulti med Products (Belgium) BVBA
Honzebroekstraat 137 • 8800 Roeselare
Phone: +32 +51 200 425
Fax: +32 +51 200 449
e-mail: belgium@ultimed.org

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