Test-it™ Syphilis Whole Blood Test
FOR THE QUALITATIVE ASSESSMENT OF ANTIBODIES AGAINST
T. PALLIDUM IN HUMAN SERUM, PLASMA OR WHOLE BLOOD

INTENDED USE
Test-it Syphilis Whole Blood Test is a unique rapid immunochromatographic assay for the detection of antibodies to Treponema pallidum in human whole blood, serum or plasma. The assay is used as a screening or confirmatory test for T. pallidum infection (also known as Syphilis).

SUMMARY
Syphilis is a disease caused by Spirochete bacterium called Treponema pallidum (TP). If untreated, the organisms move throughout the body and can cause damage to many organs, making syphilis a life-threatening disease if not treated early enough. People who have been infected with syphilis experience different symptoms during the 3 stages of the disease. Early stage is defined by the presence of a chancre at the site of inoculation, and is further divided into primary, secondary, and early latent syphilis; Late stage syphilis includes late latent syphilis and the various forms of tertiary syphilis. The serological response to syphilis involves production of antibodies to a wide range of antigens, including non-specific antibodies and specific anti-TP antibodies. The first detectable response to infection is the production of specific anti-treponemal IgM, which can be detected within 4 to 7 days after the chancre appears and until the end of the second week of infection; anti-treponemal IgG appears at about four weeks later. By the time that symptoms develop, most patients have detectable IgG and IgM.

TEST PRINCIPLE
The Test-it Syphilis Whole Blood Test employs the latest generation of recombinant Treponema pallidum antigens in a one step chromatographic lateral flow test device. Colloidal gold conjugated recombinant antigens (Au-Ag) corresponding to TP antigens (P47, P45, P17, P15) are dry-immobilized at the end of the nitrocellulose membrane strip. TP antigens are bond at the Test Zone (T) and rabbit anti-TP antibodies are bond at the Control Zone (C). When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate. If present in a sample, TP antibodies (anti-TP) will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip to the Test Zone (T) where they are captured by TP antigens generating a visible red line. If there are no anti-TP antibodies in sample, no red line is formed in the Test Zone (T). The gold conjugate will continue to migrate alone until it is captured in the Control Zone(C) by the rabbit anti-TP formation of in a red line, which indicates the validity of the test.

MATERIAL PROVIDED
NO RUNNING BUFFER REQUIRED – THIS IS A TRUE “ONE STEP” TEST

MATERIALS REQUIRED BUT NOT SUPPLIED
Specimen collection container and timer

STORAGE
The sealed pouches in the test kit may be stored between 4-30°C for the duration of the shelf life as indicated on the pouch. When stored as indicated the test kit will have a 24 month shelf life from date of manufacture.

PRECAUTIONS
1. This kit is for in vitro diagnostic and professional use only.
2. Read the instructions carefully before performing the test.
3. This product does not contain any human source materials.
4. Do not use kit contents after the expiry date.
5. Handle all specimens as potentially infectious.
6. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. When the assay procedure is complete, dispose specimens after autoclaving them at 121°C for at least 20 min. Alternatively, it can be treated with 0.5% Sodium Hypochlorite for 6 hours before disposal.
7. Do not smoke or eat while performing assays.
8. Wear gloves during the whole procedure.

SPECIMEN COLLECTION AND PREPARATION
1. No prior special preparation of the patient is required before sample collection by approved techniques.
2. The test works best on fresh whole blood samples. However, if testing cannot be done immediately, blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate should be stored at 2-8°C up to 3 days. Blood samples should not be frozen.
3. Repeated freezing and thawing of the specimen should be avoided.
4. Do not use haemolysed, clotted, contaminated, lipaemic and viscous/turbid specimen.
5. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
6. Do not heat inactivate the sample.
7. Shipment of samples should comply with local regulations for transport of etiologic agents.
TEST PROCEDURE
1. Bring the kit components to room temperature before testing.
2. Open the foil pouch and remove the test. Once opened, the test must be used immediately.
3. Label the test with patient’s identity (name or number).
4. Use the pipette provided with the test (inside the foil pouch) to add 2 drops (80 μL) of whole blood, serum or plasma to the sample well marked “S”.
5. At the end of 15 minutes read the results.

Note: Some positive results may appear as early as 10 minutes.

INTERPRETATION OF RESULTS

Positive:
Two coloured bands appear within 15 minutes. One coloured band appears in the Control Zone (C) and another coloured band appears in the Test Zone (T). The test result is positive and valid. Even if the bands are very faint, the test result should be considered as positive result.

Negative:
One coloured band appears in the Control Zone (C) within 15 minutes. No coloured band appears in the Test Zone (T). The test result is negative and valid.

Invalid result:
No coloured band appears in the Control Zone (C) within 15 minutes. The test result is invalid. Repeat the test with a new test device.

Note: After 15 minutes the result is valid for up to 1 hour.

PERFORMANCE CHARACTERISTICS:
In clinical evaluations of the performance of this anti-TP Rapid Test, 1541 confirmed negative and 539 positive samples were tested. A sensitivity of 99.60% (537/539) and a specificity of 99.93% (1539/1540) were obtained. Overall, agreement with the reference ELISA test is 99.70%. Accuracy of 99% was determined, based on internal Quality Control standards. No cross-reactivity was observed with specimens from patients infected with HAV, HIV, HCV, HBV, HTLV, and CMV.

<table>
<thead>
<tr>
<th>ELISA Syphilis Test</th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test-it™ Rapid Syphilis Test</td>
<td>537</td>
<td>1</td>
</tr>
<tr>
<td>Negative</td>
<td>2</td>
<td>1,539</td>
</tr>
<tr>
<td>Agreement</td>
<td>99.60%</td>
<td>99.93%</td>
</tr>
</tbody>
</table>

In comparison with FTA-ABS performed on 459 samples (80 positive and 379 negative), the Test-it Syphilis Whole Blood Test showed a sensitivity of 97.5% and specificity of 99.5%.

Interference:
No interference was found with bilirubin (10 mg/dl), haemoglobin (20 mg/dl) or triglycerides (600 mg/dl) on the sensitivity and specificity of the test.

LIMITATIONS:
1. The test is for the qualitative detection of anti-*Treponema pallidum* antibodies in human serum, plasma or whole blood. It does not indicate the quantity or the antibodies or degree of infection.
2. The test is for *in vitro* diagnostic use only.
3. As in case of all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test but should rather be made after all the clinical findings have been evaluated.

BIBLIOGRAPHY

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