One Step Syphilis Whole Blood Test

INTENDED USE
One Step Syphilis Whole Blood Test Cassette is a rapid test for the visual detection of antibodies of Treponema Pallidum (TP) in whole blood as an aid in the diagnosis of syphilis infection.

For in vitro diagnostic use only. For professional use only.

SUMMARY
Syphilis is a curable infection caused by a bacterium called Treponema pallidum that is highly infectious. This infection is sexually transmitted, and can also be passed on from a mother to her fetus during pregnancy. The disease is spread primarily through sexual transmission or intimate contact with an individual who has an open, wet syphilitic sore. Syphilis has three distinctive stages in an untreated person. This most severe of the STD's is caused by a pathogen called spirochete Treponema Pallidum(TP), which is shaped much like a corkscrew, so it is able to burrow through the skin quite well and get to almost any place in the body, eventually. This sore marks the place where the syphilis pathogen entered the skin and body. Within a few weeks, it develops fever, chills, aches, headache, and swollen glands. Sometimes there is a rash occurred as well. The second stage is called the latent period. This is where the spirochetes invade the bloodstream, usually six to eight weeks after the appearance of the chancre sore. There may not be any symptoms at first. In this stage the person is no longer contagious, or able to spread the disease, but still has it. The most distinctive characteristic of the secondary stage is the appearance of the rash. If it remains untreated, it goes into the third stage of the disease, where brain damage can occur, as well as blindness, paralysis and disorientation, and damage to blood vessels, allowing clots and aneurysms to form. Most people do not reach these stages because there is treatment now. So One Step Syphilis Whole Blood Test can quickly aid in the early diagnoses and treating the disease in time.

PRINCIPLE
One Step Syphilis Whole Blood Test is based on the principle of double antigen-sandwich immunoassay for determination of TP antibodies in whole blood. Recombinant antigens TpN15, TpN17 and TpN47 are coated on the solid membrane. There are two coated lines in the result window. One is the test line (T), coated with recombinant antigens, the other is control line (C), coated with polyclonal antibodies. When add specimen to the sample well, the specimen is absorbed into the device by capillary action, mixes with the antigen-dye conjugate, and flows across the pre-coated membrane.

When the TP antibody levels in the specimen are at or above the target cut-off (the detection limit of the test), TP antibodies bind to the antigen-dye conjugate and are captured by recombinant antigens immobilized in the test region (T) of the device and forms Ag-Ab-Ag-Au precipitates. This produces a colored test band and indicates a positive result.

When the TP antibody levels in the specimen are zero or below the target cut-off, there is no visible colored band in the test region (T) of the device, and it indicates a negative result.

To serve as a procedure control, a colored line will appear at the control region (C), if the test has been performed properly.

PRECAUTIONS
1. This kit is for in vitro use only. Do not swallow.
2. All specimens should be treated as capable of transmitting diseases.
3. Icteric, lipemic, hemolyzed, heat treated and contaminated blood may cause erroneous results.
4. Discard after first use. The test cannot be used more than once.
5. Do not use test kit beyond the expiration date.
6. Do not use the kit if the pouch is punctured or not well sealed.
8. DISPOSAL OF THE DIAGNOSTIC: The used-device has the infectious risk. The process of disposing the diagnostic must follow the local infectious disposal law or laboratory regulation.

MATERIAL

MATERIAL PROVIDED
1. Individual sealed pouches, each containing:
   - Test device
   - Desiccant pouch
   - Dropper
2. One bottle of buffer solution (5 ml): 0.1M PBS, pH 7.2±0.2.
3. Leaflet with instructions for use.

MATERIAL NOT PROVIDED
1. Specimen collection containers
2. Sterile lancets (for fingerstick whole blood only)
3. Alcohol pads
4. Centrifuge (for plasma only)
5. Timer
6. Heparinized capillary tubes (for fingerstick whole blood only)

STORAGE AND STABILITY
1. Store at 4 °C ~ 30 °C in the sealed pouch up to the expiration date.
2. Keep away from sunlight, moisture and heat.
3. Do not freeze.

SPECIMEN COLLECTION AND PREPARATION
Whole blood collected by fingerstick:

1. Select the finger for puncture, usually the side of the fourth finger. Clean the area to be lanced with an alcohol pad. Allow the finger to dry thoroughly.
2. Using a sterile lancet, puncture the skin just off the centre of the finger pad. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed. Wipe away the first drop of blood with a sterile lancet. Allow a new drop of blood to form. If blood flow is inadequate, the subject’s finger may have to be gently massaged at the finger base to produce a droplet of sufficient volume. Avoid 'milking' the finger.
3. Touch the end of the capillary tube to the blood until filled to approximately 10µL. Avoid air bubbles. Whole blood samples collected by fingerstick should be used immediately after collection.

Whole blood collected by venipuncture:
1. Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube with suitable anticoagulant
2. It is recommended that specimens should be tested immediately. Do not leave the specimens at room temperature for prolonged periods. If the specimens are not tested immediately, they may be stored at 2°C ~ 8°C. It’s not suitable to test the whole blood samples which have been stored at 2°C ~ 8°C for more than 7days.

Bring specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Only clear, non-hemolyzed specimens can be used.

TEST PROCEDURE

Allow the device, buffer and specimen to equilibrate to room temperature (10°C ~30°C) prior to testing.

1. Remove a test cassette from the foil pouch by tearing at the notch and place it on a level surface.
2. Slowly add 10µl (the second tick mark line) of whole blood to the sample well(A) and then add 2 drops of dilution buffer to the buffer well(B).
3. As the test begins to work, you will see purple color move across the result window in the center of the test device.
4. Wait for 15 minutes and read the results. Do not read results after 30 minutes.
INTERPRETATION OF RESULTS

Positive (+)
Colored bands are visible in both the control region and the test region. It indicates a positive result for antibodies of TP in the specimen.

Negative (-)
A colored band is visible only in the control region. No color band appears in the test region. It indicates that the concentration of the TP antibodies of the specimen is zero or below the detection limit of the test.

Invalid
No visible band at all, or there is a visible band only in the test region but not in the control region. Repeat with a new test kit. If test still fails, please contact the distributor for technical assistance.

Note: There is no meaning attributed to line color intensity or width.

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

Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

LIMITATIONS OF PROCEDURE
1. This test has been developed for testing whole blood samples only. The performance of this test using other specimens has not been substantiated.
2. As it is with any diagnostic procedure, a confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of syphilis antibody.
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 syphilis infection.

PERFORMANCE CHARACTERISTICS
A. Sensitivity and Specificity

B. Precision
1. Within run precision was determined by using 10 replicates of four different serum specimens containing different concentrations of TP antibody. The negative and positive values were correctly identified 100% of the time.
2. Between run precision was determined by using the four different serum specimens containing different concentrations of TP antibody in 3 different lots of test devices. Again negative and positive results were correctly identified 100% of the time.

BIBLIOGRAPHY OF SUGGESTED READING

104 serum samples were obtained for testing then compared the testing results between One Step Syphilis Whole Blood Test kit and the TPPA method. The results of sensitivity and specificity between the two methods are shown below.

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<th>Reagents</th>
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<td>Negative</td>
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<tr>
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<td>50</td>
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<tr>
<td>Total</td>
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Sensitivity of One Step Syphilis Whole Blood Test: 53/53=100%
Specificity of One Step Syphilis Whole Blood Test: 50/51=98%