OneStep Syphilis RapiDip™ InstaTest (Whole Blood, Serum, Plasma)

Cat# 176502-1-12

IVD See external Label 2°C 30°C 40 Tests

Sensitivity	**99.63 %**
Specificity	**99.93%**

INTENDED USE

Cortez Diagnostics Inc. Syphilis is a single use, rapid test strip intended for qualitative detection of antibodies to Treponema pallidum in whole blood, serum and plasma samples. It is intended for use in medical institution as an aid for the diagnosis and management of patients related to infection with T. pallidum (also known as syphilis) and for screening of blood donors, or blood products as well.

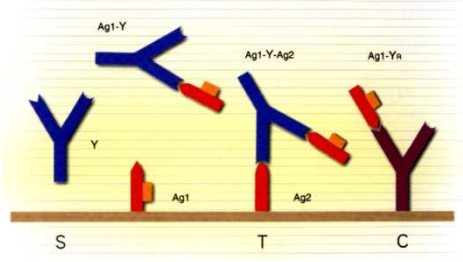
SUMMARY AND EXPLANATION

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, which is defined by the presence of the chancre at the site of inoculation syphilis may be further divided into primary, secondary, and early latent syphilis; late syphilis includes late latent 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 antitreponemal IgM, which can be detected within 4 to7 days after the chancre appears and until the end of the second week of infection; antitreponemal IgG appears at about four weeks later. By the time that symptoms develop, most patients have detectable IgG and IgM.

With the aid of this easy-operating, time-saving test, you may read testing results within 20 minutes. In addition, avoiding tedious procedure and high sensitivity performance are also of-note advantages of this test over other tests commercially available.

TEST PRINCIPLE

This anti-TP Rapid Test employs chromatographic lateral flow test strip where colloidal gold conjugated recombinant antigens (Au-Ag) corresponding to TP antigens (P47, P45, P17 and P15) are dry-immobilized at the end of the strip. In order to capture the the TP antibodies, TP antigens are bond on the strip. The test has integrated quality control which uses rabbit anti-TP monoclonal antibodies bond at the end of the strip. When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate. If present in sample, TP antibodies (anti-TP) will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until they are captured by bond TP antigens generating a visible red line. If there are no anti-TP antibodies in sample, no red line is formed. The gold conjugate will continue to migrate alone until it is captured by the rabbit anti-TP aggregating in a red line, which indicates the validity of the test.



Y T. pallidum Antibodies in sample (anti-TP)
Ag1 TP Au-Ag in S (Sample Pad Window)
Ag1-Y Au-Ag- anti-TP Complex
Ag2 TP antigens immobilized in the T Zone
Ag1-Y-Ag2 Antigen Sandwich Complex in the T Zone
Ag1-YR Au-Ag-Rabbit anti-TP complex in the C Zone

SPECIMEN COLLECTION AND PREPARATION

Whole blood samples:
Wash your hands with soap and warm water. Choose a puncture site on the fingertip. Clean the fingertip with Alcohol Prep Pad. Place a Safety Lancet on a selected puncture site. Forcefully press the tip of the Safety Lance against your fingertip. Wipe away the first drop of blood with sterile gauze or cotton. Using Disposable Pipette, collect blood from the puncture site. Alternatively - draw blood following laboratory procedure for obtaining venous blood. Do not test whole blood samples if older than 3days.

Serum/plasma samples:
Fresh serum or plasma samples can be used. No special patient preparation required. Care should be taken to ensure blood full clotting and any visible particulate matter in the sample should be removed by centrifugation or filtration. Avoid the use of highly hemolytic, turbid, microorganism contaminated samples or samples stored for over 30days at 2-8°C. Store samples at 2-8°C. Samples not required for assay within 3 days should be stored frozen (-20°C or lower). Avoid sample deterioration by multiple freeze-thaw cycles.

-Plasma: Collect whole blood into a collection tube (containing EDTA, citrate or heparin, respectively) by venipuncture. Separate the plasma by centrifugation.

-Serum: Collect whole blood into a collection tube (containing no anticoagulants) by venipuncture. Allow the blood to clot. Separate by centrifugation.

MATERIALS AND COMPONENTS

Materials provided with the test kits

Anti-TP colloidal gold rapid test strips packed in foil pouch, 1×3ml vial of sample diluent, instructions for use.

Materials required but not provided

1. Alcohol prep-pad
2. Disposable pipettes
3. Clock or timer
4. Specimen collection container
5. Centrifuge
6. Biohazard waste container
7. Sterile gauze or cotton

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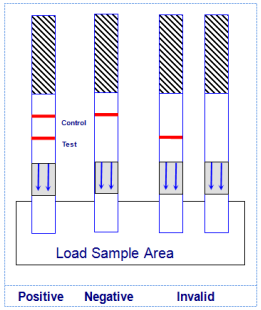
ASSAY PROCEDURE

1. Allow the test strip to reach room temperature.
2. **Procedure for whole blood samples**: Open the pouch and pipette 40µl whole blood into the arrow indicated end of the strip. Add 1 drop of sample diluent into the sample window. (If 1 drop of sample diluent failed to make some highly viscous whole blood sample properly flow on the membrane, please add 1 more drop.)
3. **Procedure for serum/plasma samples:** Open the pouch and pipette 80µl of serum or plasma into the arrow indicated end of the strip.
4. Avoid dropping sample or buffer beyond the area indicated with arrows. Do not allow the sample to overflow. Place the strip on flat surface and read the results within 30 minutes. A positive test line may appear after 30 minutes - this is a False Positive Result - do not read the results after 30 minutes.

RESULTS

- **Positive result**: Appearance of second red line in addition to the control line indicates that antibodies to Treponema pallidum have been detected using this anti-TP Rapid Test.
- **Negative result:** If no red line appears in addition to the control line within 30 minutes, this indicates that no antibodies to Treponema pallidum have been detected with this anti-TP Rapid Test. However, this does not exclude the possibility from infection with Treponema pallidum.
- **Quality Control:** One red line will always appear indicating the validity of the test. If no red line appears, the test is invalid - discard the test and repeat with new sample and new strip.



The positive result obtained with this anti-TP Rapid Test alone cannot be the final diagnosis of Syphilis. Any positive result must be interpreted in conjunction with the patient clinical history and another laboratory testing results. Follow-up and supplementary testing with other analytical system (e.g. ELISA, WB) is required to confirm any positive result.

PERFORMANCE CHARACTERISTICS

In clinical evaluations of the performance of this anti-TP Rapid Test, 1540 confirmed negative and 539 positive samples were tested. A sensitivity of 99.63% (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.

LIMITATIONS OF PROCEDURE

1. Negative results do not exclude the possibility of T. pallidum exposure or infection. Infection through recent exposure (seroconversion) to TP may not be detectable. For positive results, line intensity cannot be used to evaluate the anti-TP antibody levels. A test giving an invalid result should be repeated.
2. If, after retesting of the initially reactive samples, the test results are negative, these samples should be considered as non-repeatable (false positive) and interpreted as negative. As with many very sensitive rapid diagnostic tests, false positive results can occur due to the several reasons, most of which are related but not limited to the quality of the sample and exposition of the test to humidity.
3. This kit is intended ONLY for testing of individual samples. Do not use it for testing of cadaver samples, saliva, urine or other body fluids, or pooled (mixed) blood.
4. This is a qualitative assay and the results cannot be use to measure antibodies concentrations.

PRECAUTIONS

1. This test is for *In Vitro Use Only* IVD
2. FOR PROFESSIONAL USE ONLY
3. All the waste and sample should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal.
4. Once taking the strip out of the pouch, carry out your testing as early as possible (no more than 20 minutes) to avoid moisture. The nitrocellulose membrane can absorb water, which can affect the test chromatography performance.
5. The performance characteristics of the test depend on sample quality and preparation. For strong reactive samples, the red line (corresponding to the Test Zone (T)) may appear in 3-5 minutes after sample loading, but for weak reactive samples, the red line may appear in 15 minutes. To obtain accurate assay results, the test results must be read within 30 minutes. Results obtained after 30 minutes can lead to incorrect interpretation.
6. Do not use beyond expiration date.
7. If automatic pipette is used, calibrate it frequently to assure the accuracy of dispensing. Use different disposal pipette tips for each specimen in order to avoid cross-contaminations.
8. Do not modify the test procedure.
9. Do not reuse the test strips. Autoclave before disposal.
10. A test giving an invalid result should be repeated.
11. Blood that has been chemically treated, heated, diluted, or otherwise modified may give inaccurate results.

Storage and Stability

This test can be stored at room temperature (2-30°C, do not freeze!) for 18 months from the date of manufacture (see label on strip pouch). Use immediately after opening.

REFERENCES

1. Fraser CM, et al. Complete genome sequence of Treponema pallidum, the syphilis spirochete. Science 1998; 281:375.
2. Holmes KK, Lemon SM, Mardh P, Piot P, Sparling PF, Stamm WE, Wasserheit JM, Weisner PF. Chapters 33-36. In Sexually transmitted diseases, 3rd ed. New York: McGraw-Hill,1999.
3. Hook EW III, Martin DH, Stephens J, Smith BS, Smith K. A randomized, comparative pilot study of azithromycin versus benzathine penicillin G for treatment of early syphilis. Sex Transm Dis 2002 Aug; 29(8):486-490.

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ISO 13485
ISO 9001

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	176502-1-12
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