Assay+ Syphilis Antibody Rapid Test

REF Catalog No. TP-25

IVD *In Vitro* Diagnostic

INTENDED USE:

Assay+ Syphilis Antibody Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies including IgG, IgM and IgA to Treponema pallidum (Tp) in human serum, plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Tp. Any reactive specimen with the Assay+ Syphilis Ab Combo Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION:

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 three 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 anti-treponemal IgM, which can be detected within 4 to7 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. With the aid of this easy-operating, time-saving test, you may read testing results within 20 minutes.

Antibodies to Treponema pallidum can last for several years or even decades in the serum of a patient with untreated latent syphilis. Antigens such as Rapid Plasma Reagin (RPR) and Tp bacterial extracts have been used in syphilis serological tests for decades. However, RPR antigen is a nontreponemal antigen derived from bovine heart. Antibodies to RPR antigen do not develop until 1-4 weeks after the appearance of the chancre, thus this antigen lacks sensitivity to primary syphilis. The Tp extracts are prepared from inoculated rabbit testis and contain contaminated materials such as flagella which can lead to cross-reactions with borreliae and leptospires in the serological test. In addition, the composition of extracts may vary from lot to lot. Recently, several highly immunogenic Tp specific antigens have been identified and used as an alternative to the traditional antigens with the advantages of high specificity and reproducibility. Assay+ Syphilis antibody Rapid Test was developed to detect antibodies (IgM, IgG and IgA) to recombinant antigens of Tp in serum, plasma or whole blood. The test can be performed by minimally trained personnel and without cumbersome laboratory equipment.

TEST PRINCIPLE:

This anti-TP Rapid Test employs chromatographic lateral flow test where colloidal gold conjugated multiple recombinant TP antigens immobilized at the conjugate pad, and similar TP antigens are coated on the membrane. An internal control is included by using mouse IgG conjugated gold and anti-mouse IgG coated on the membrane. 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.

STORAGE:

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.

SPECIMEN COLLECTION AND PREPARATION

Fresh serum or plasma samples can be used. Care should be taken to ensure blood full clotting and any visible particulate matter in the sample should be removed by centrifugation Avoid the use of highly hemolytic, turbid, microorganism contaminated samples or samples stored for over 30 days 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 SUPPLIED:

1. A pouch
2. One cassette test device in pouch

Assay+ Syphilis Antibody Rapid Test

3. One plastic pipette and desiccate in pouch
4. One bottle of diluent buffer
5. One user introduction

MATERIALS REUQIRED BUT NOT PROVIDED:

1. Clock or timer
2. Centrifuge

ASSAY PROCEDURE

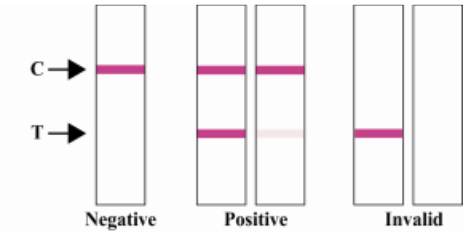
1. Allow the test cassette to reach room temperature. 2. Open the pouch and pipette 40-50ul µl plasma or serum into the well on the cassette, then add 1 drop of sample diluent into the sample window. Do not allow the sample to overflow. 3. Place the cassette on flat surface and read the results within 30 minutes, Do not read the results after 30 minutes.

RESULTS:

Positive result: Appearance of red line in Test zone in addition to the control line indicates that the test device is invalid, should use a new cassette to 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.

Invalid: One red control 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.

LIMITATIONS OF PROCEDURE

- 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.
- 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.
- 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.
- 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
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 cassette 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. Do not modify the test procedure.
9. Do not reuse the test device, autoclave before disposal.
10. A test giving an invalid result should be repeated.
11. Plasma or serum that has been chemically treated, heated, diluted, or otherwise modified may give inaccurate results.

INQUIRE AND GENERAL INFORMATION

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