Syphilis Antibody (cassette) (RAP-4617)

Effective 14 Dec. 2008 **USA: RUO**

INTRODUCTION
Syphilis Antibody Test is a 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 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, 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.

TEST PRINCIPLE
This Rapid Test employs chromatographic lateral flow test device in a cassette format. Colloidal gold conjugated recombinant antigens (Au-Ag) corresponding to TP antigens (P47, P45, P17, P15) are dry-immobilized at the end of 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 sample, TP antibodies (anti-TP) will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until 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 aggregating in a red line, which indicates the validity of the test.

REAGENTS AND MATERIALS SUPPLIED
Each kit contains:
1. Syphilis Test device in foil pouch
   Test card
2. Product insert

MATERIALS NOT PROVIDED
1. Sepcimen collection container
2. Timer

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 2-30°C for the duration of the shelf life as indicated on the pouch.

PRECAUTIONS

1. This kit is for ***IN VITRO*** use. (For ***Research Use Only*** in the United States).
2. This kit is for ***PROFESSIONAL*** use only.
3. Read the instructions carefully before performing the test.
4. This product does not contain any human source materials.
5. Do not use kit contents after the expiration date.
6. Handle all specimens as potentially infectious.
7. 7. 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 121º C for at least 20 min. alternatively, they can be treated with 0.5% Sodium Hypochlorite for 1-2 hours before disposal.
8. Do not pipette reagent by mouth and no smoking or eating while performing assays.
9. 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. Fresh serum / plasma is preferable. Serum / plasma may be stored at 2-8°C up to 3 days in case of delay in testing. For long-term storage, freeze the specimen at -20°C for 3 months or -70°C for longer periods.
3. The test works best on fresh whole blood samples. If testing cannot be done immediately, Blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate should be stored at 2-8ºC up to 3 days. Blood samples should not be frozen.
4. Repeated freezing and thawing of the specimen should be avoided.
5. Do not use haemolysed, clotted, contaminated, lipamic and viscous/turbid specimen.
6. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
7. Do not heat inactivate the sample.
8. Shipment of samples should comply with local regulations for transport of etiologic agents.

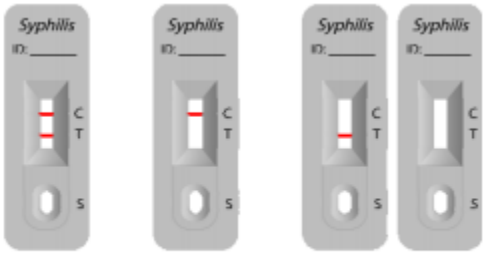
PROCEDURE

For Test Card:

1. Bring the kit components to room temperature before testing.
2. Open the pouch and remove the Card. Once opened, the test card must be used immediately.
3. Label the test card with patient's identity.
4. Apply 3 drops (120-150 L) of serum, plasma or whole blood to the sample well marked as "S'.
5. At the end of 15 minutes read the results. A strong positive sample may show result earlier.

INTERPRETATION OF RESULTS

Test card



1. Positive: Both control line and the test line appear. It indicates the antibodies to T. Pallidum have been detected.

2. Negative: Only control line appears.

3. Invalid Result: If after 15 minutes no line is visible within the Control Zone, the result is invalid. The test should be repeated with a new test card.

QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which is not provided with this test kit may be commercially available.

LIMITATIONS

1. The test is for qualitative detection of anti-T. Pallidum antibodies in human serum, plasma or blood sample and dose not indicate the quantity of the antibodies.
2. The test is for *in vitro* use. In the United States this kit is for research 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.

PERFORMANCE CHARACTERISTICS

1. Accuracy

In clinical evaluations of the performance of this anti-TP Rapid Test, 1540 confirmed negative and 539 positive samples were tested. A sensitivity of 99.60% (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.

	ELISA Syphilis Test		
Rapid Syphilis Test		*Positive*	*Negative*
	Positive	537	1
	Negative	2	1539
	Agreement	99.60%	99.93%

2. Interference

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

REFERENCES

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