

In vitro Diagnostics

INTENDED USE

Sensit Syphilis Ab Rapid Test Kit is a qualitative immunochromatographic assay for the detection of antibodies against Syphilis in human blood/Serum. Sensit Syphilis Ab Rapid Test is only intended for initial screening and reactive samples should be confirmed by a supplemental assay such as ELISA.

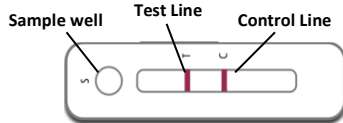
SUMMARY & TEST DESCRIPTION

Syphilis is a systemic disease from the outset and is caused by the spirochaete, *Treponema pallidum* (T.pallidum). The infection can be classified as congenital (transmitted from mother to child in utero) or acquired (through sex or blood transfusion). The signs and symptoms of syphilis vary depending in which of the four stages it presents (primary, secondary, latent, and tertiary). The primary stage classically presents with a single chancre (a firm, painless, non-itchy skin ulceration), secondary syphilis with a diffuse rash which frequently involves the palms of the hands and soles of the feet, latent syphilis with little to no symptoms, and tertiary syphilis with gummas, neurological, or cardiac symptoms.

Sensit Syphilis Rapid Test contains a test device for Syphilis Ab, which utilizes Recombinant antigen of Syphilis as the capture molecule and Syphilis Ag -CGC as the detection molecule

TEST PRINCIPLE

Sensit Syphilis Rapid Test works on chromatographic immunoassay. Basic components of test strip includes: a) Conjugate pad which contains Syphilis Recombinant Antigen, colloidal gold conjugated; b) a nitrocellulose membrane strip containing two lines T: Syphilis Ag and C: Goat Anti-Mouse.



Test sample that is added to the sample well (S), with adequate amount of buffer migrates from the sample pad along the conjugate pad where syphilis antibodies present in the sample will bind to Colloidal Gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zone where the complex will bind to the immobilized syphilis recombinant antigen (on test line) producing a visible line on the membrane. If the respective antibodies are not present in the sample, no reaction occurs in the capture zone and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

REAGENTS & MATERIALS PROVIDED

1. Each Kit contains 10 test devices, each sealed in a foil pouch containing following items:
 - a. OneTest card
 - b. Dessicant
2. Assay Diluent in dropper bottle – 3 nos
3. Instruction Leaflet

SAMPLE COLLECTION & PREPARATION

- Blood Specimen: Collect the whole blood using a syringe or vacutainer into a container containing anticoagulants such as heparin, EDTA or sodium citrate by venipuncture.
- Serum: Collect the whole blood using a syringe or vacutainer (NOT containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Leave the syringe or vacutainer, preferably at an angle, to settle for 30 minutes. Once blood coagulates, centrifuge the blood to get serum specimen as supernatant.
- If the specimen is not used for testing immediately, they should be refrigerated at 2~8°C.
- For storage period longer than 5 days, freezing is recommended. Store at -20°C
- The specimen should be brought to room temperature prior to use.

Treat the specimen as infectious and handle with standard biosafety measures.

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TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 10µl of sample to the Sample well "S"

(To take 10 µl, aspirate only up to the bubble point in the dropper provided). (Refer Diagram .1.)



3. When the sample is fully absorbed, add 2 drops of the diluent provided with the assay to the sample hole.
4. Wait for 10-15 minutes and interpret results. All results where control band does not appear are considered invalid.

INTERPRETATION OF TEST RESULT

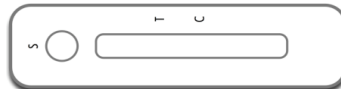
Positive: Color bands at position T and C



Negative: Color bands at position C alone



Invalid: Color band at C does not appear



Manufactured by

ubio Biotechnology Systems Pvt Ltd
 Plot # 15A, Biotechnology Zone
 Kalamassery, Cochin, Kerala, India 683503
 Ph:, +91-484-2970043

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