

One step rapid Card Test for detection of Syphilis antibody in Serum or Plasma Only for *In Vitro* Diagnostic Use

ORDER INFORMATION

REF	CONT
SYPC 25	25 Tests
SYPC 50	50 Tests

CLINICAL SIGNIFICANCE

Syphilis is sexually transmitted (venereal) disease caused by the spirochete *Treponema pallidum*. The disease can also be transmitted congenitally thereby attaining its importance in antenatal screening. After injection the host forms non-treponemal anti lipoidal antibodies (regains) to the lipoidal material released from the damaged host cells as well as treponema specific antibodies. Serological tests for non-treponemal antibodies such as VDRL, RPR, and TRUST etc. are useful as screening tests. Test for treponema specific antibodies such as TPHA, FTA-ABS, rapid treponema antibody tests are gaining importance as screening as well as confirmatory tests because they detect the presence of antibodies specific to *Treponema pallidum*.

PRINCIPLE

One Step Syphilis card test utilizes the principle of immunochromatography, a unique two-site immunoassay on a membrane. As the test conjugate forms through the membrane assembly of the test card, the recombinant *Treponema* antigen-colloidal gold conjugate forms a complex with *Treponema* specific antibodies in the sample. This complex moves further on the membrane leading to the formation of a pink to deep purple colored band at the test region which confirms a positive test result. Absence of this colored band in test region indicates a negative test result. The unreacted conjugate and the unbound complex if any along with rabbit IgG gold conjugate move further on the membrane and are subsequently immobilized by the goat anti-rabbit antibodies coated at the control region of the membrane assembly, forming a pink to deep purple coloured band. The control band serves to validate the test results.

KIT COMPONENTS

Test Device, Assay buffer, Sample Dropper and Product Insert.

STORAGE AND STABILITY

The sealed pouches in the kit can be stored 2-30°C till the expiration date printed on the sealed pouch. **DO NOT FREEZE.**

PRECAUTIONS

1. Handle all specimens as if they contain infectious agents.
2. Wear protective disposable gloves when specimens are being tested.
3. The Device is sensitive to Humidity as well as heat. Therefore take out the device from seal pouch before test.
4. Dispose all the samples and kit properly as per the instruction after test in accordance in GLP
5. Read the instructions carefully before performing the test.

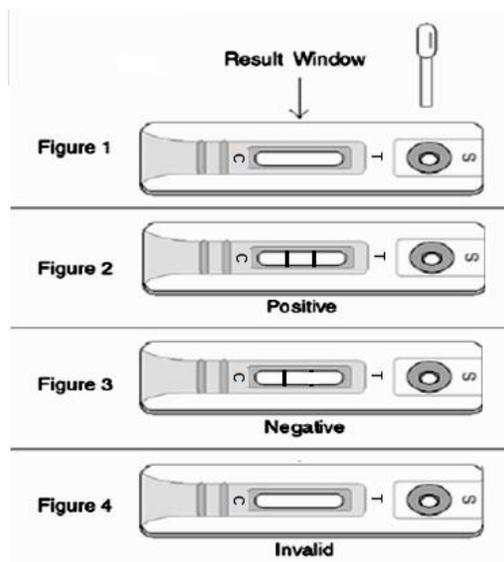
SPECIMEN COLLECTION & PRESERVATION

Fresh Serum or Plasma. If testing is not performed within 3 days of collection of specimen, the specimen should be refrigerated immediately at 2-8°C.

DIRECTION FOR USE

1. Add 1 drop (20 µl) of serum in sample well "S".
2. Add 1 drops of assay buffer in sample well "S".
3. Allow reaction to occur in next 15-20 minutes.

4. The test should be read between 15-20 minutes after addition of serum sample and buffer.



INTERPRETATION OF RESULTS

1. **Negative:** Only one pink-purple coloured line appears at the control zone 'C' (Control line) the test result is negative
2. **Positive:** In addition to the coloured line in the control region a clearly distinguishable pink purple coloured line also appears in the test region 'T' (Test line) indicating a positive result.
3. **Invalid:** If no line appears in the control as well as the test region, the test should be repeated with fresh card.

LIMITATIONS

1. One Step Syphilis Card Test detects the presence of *Treponema* antibodies; thus a positive result indicates a past or present infection. Positive results should be evaluated in co-relation with the clinical condition before arriving at a final diagnosis.
2. Low levels of antibodies to *Treponema pallidum* such as those present at a very early primary stage of infection can give a negative result. But a negative result does not exclude the possibility of exposure to or infection can give a negative result. But a negative result does not exclude the possibility of exposure to or infection with *Treponema pallidum*. Resting is indicated after two weeks if clinically syphilis is still suspected.
3. In order to assess the clinical response to treatment it is advisable to use a reagent test such as VDRL, RPR.
4. One Step Syphilis Card Test detects *Treponema* antibodies in serum/plasma; other body fluid may not give accurate results.
5. In immunocompromised patients the test results must be interpreted with caution.

BIBLIOGRAPHY

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