PARAMCARE LIFE SCIENCES PVT. LTD.
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**PARAMCARE™**

# SYPHILIS RAPID TEST KIT

## (Serum/Plasma/Whole blood)

**One step Rapid Test Kit for detection of Syphilis antibody in Serum or Plasma or Whole blood.**

**Only for *In Vitro Diagnostic* Use**

## ORDER INFORMATION

| Pack Size | REF |
|---|---|
| 01 Test | PSYP 01 |
| 05 Tests | PSYP 05 |
| 10 Tests | PSYP 10 |
| 25 Tests | PSYP 25 |
| 50 Tests | PSYP 50 |

## 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 antental 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

Syphilis Rapid Test Kit 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 colored 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.

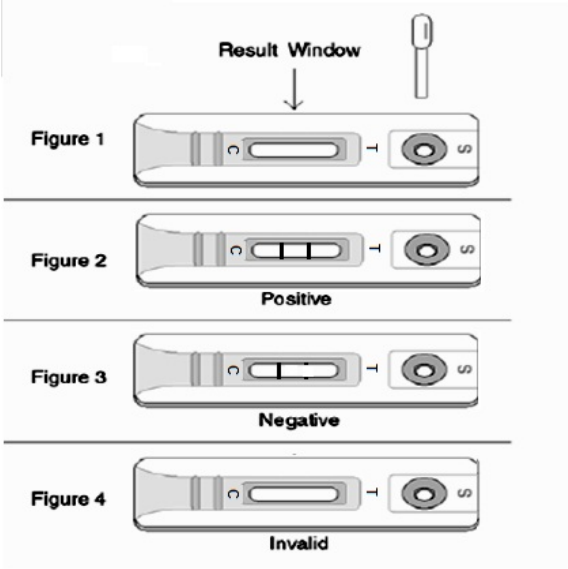
## SPECIMEN COLLECTION & PRESERVATION

1. Syphilis Test Device (Serum/Plasma/whole blood) can be performed using serum, plasma or whole blood.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

## DIRECTION FOR USE

1. Add 1 drop (25 µl) of Serum/Plasma/whole blood) in sample well "S".
2. Add 1 drop (40 µl) 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/Plasma/whole blood) sample.

Note: Do not interpret the results after 20 minutes




## INTERPRETATION OF RESULTS

1. **Negative**: Only one pink-purple colored line appears at the control zone 'C' (Control line) the test result is negative
2. **Positive**: In addition to the colored line in the control region a clearly distinguishable pink purple colored 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 cassette/test.

## LIMITATIONS

1. Syphilis Rapid Test Kit detects the presence of Treponemal 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 reagin test such as VDRL, RPR.
4. Step Syphilis Rapid Test Kit detects Treponemal antibodies in serum/plasma/whole blood; other body fluid may not give accurate results.
5. In immunocompromised patients the test results must be interpreted with caution.

## BIBLIOGRAPHY

1. Syphilis: New Diagnostic Direction, H. Young, international Journal of STD and AIDS, 1992, 3: 391-413.
2. Clinical Laboratory Diagnostics: Use and Assessment of Clinical Laboratory Results, Lothar Thomas, 1st Edition, 1998, TH Books.
3. AABB Technical Manual, 13th Edition, 1999.
4. Clinical Diagnosis and Diagnosis and Management by laboratory methods, John Bernard Henry, 17th Edition, 1979, W.B. Saunders Company.

## GLOSSARY OF SYMBOL

| | |
|---|---|
|  | Consult Instruction for Use |
|  | Catalog Number |
|  | Store between |
|  | Manufacturer |
|  | Keep away from sunlight |

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2,
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