

Version-1.0

**RAPITEST™****SYPHILIS****INTRODUCTION:**

RAPITEST™ SYPHILIS Dipstick Test is a qualitative, two site sandwich assay for the detection of ( IgG and IgM ) antibodies to specific *Treponema pallidum* (Syphilis) in human serum / plasma. Recombinant Syphilis antigens are employed to identify Syphilis antibodies specifically. This test is very sensitive and rapid. Results are interpreted in less than 20 minutes. Test results are read visually without any instruments.

**PRINCIPLE:**

RAPITEST™ Syphilis Lateral Flow Dipstick Test is a membrane based test, which is coated with recombinant antigen specific to *Treponema pallidum* antibodies at test region "T". The control Region "C" is coated with goat anti Rabbit IgG. When the test sample moves further on the membrane assembly, the gold conjugated syphilis antigen complexes with the *Treponema pallidum* antibodies in the serum sample. This complex moves further on the membrane and will be trapped by the *Treponema pallidum* antigen coated on the test region "T", resulting in the formation of pink / purple colour line on the test region which confirms the presence of *Treponema pallidum* (syphilis) antibodies in the serum. Absence of this band on the test region indicates no reaction. The unreacted conjugate moves further on the membrane, and ends up in forming coloured control line. The control line serves to validate the test result. No band at region "C" indicates that the test is "INVALID".

**KIT CONTENTS:**

RAPITEST™ Syphilis Dipstick Test is supplied with

1. RAPITEST™ Syphilis Dipstick Test pouched with a silica gel as drying agent.
2. Instruction Manual.

**STORAGE AND STABILITY**

1. The test kit can be stored at temperatures between 2°C to 30°C in the sealed pouch to the date of expiration.
2. The test kit should be kept away from direct sunlight, moisture and heat.
3. DO NOT FREEZE.

**PRECAUTION:**

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.
4. Not for medicinal use.
5. Do not intermix reagents from different lot.
6. Do not change the sequence of addition of reagents.
7. Follow standard guidelines for personal safety, handling and disposal of potentially infectious materials.
8. Do not use Whole blood / turbid serum samples.
9. Testing of pooled sample is not recommended

**SPECIMEN COLLECTION & PREPARATION:**

RAPITEST™ Syphilis Dipstick Test can be run on serum and plasma samples. The test works best on fresh samples. For serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. Use the serum for testing. For plasma samples, separate the plasma by centrifugation. If the specimen cannot be tested on the day of collection, store the specimen in refrigerator (at 2 to 4°C) for up to 3 days. If testing cannot be done within 3 days, specimen should be stored in a freezer (at -20°C or colder). Make sure to stir and bring the specimen to room temperature before testing. Do not freeze and thaw the specimen repeatedly.



**TEST PROCEDURE:**

1. When you are ready to begin testing, open the lid of the container and take strips from the pouch and use it as soon as possible.
2. Dip the membrane strip vertically (Arrows pointing downwards) in to the serum/plasma sample. **Do not dip the strips in to the sample above the Red marked Line**, which leads to improper flow.
3. Read the test result within **5-20** minutes.

**DO NOT READ RESULTS AFTER 20 MINUTES.  
READING TOO LATE CAN GIVE FALSE RESULTS.**

**INTERPRETATION OF RESULTS:****NEGATIVE:**

Only one colored band appears on the control region(C) region. No apparent band on the test (T) region(C) region. No apparent band on the test (T)



NEGATIVE

**POSITIVE:**

In addition to a pink colored control (C) band, a distinct pink colored band will also appear in the test (T) region



POSITIVE

**INVALID:**

A total absence of color in both regions is an indication of procedure error and/or that the test reagent has deteriorated. Repeat with a new test kit. If the problem persists, discontinue using the test kit immediately.



INVALID

**NOTE:**

1. Test line either dark or light pink in color should be considered reactive.
2. All initially reactive samples should be subjected to centrifugation at 10000 rpm for 10 min. The test should be repeated with supernatant collected after centrifugation. If no band appears on repetition it indicates a falsely reactive sample. A truly reactive sample will not show much change in its color intensity after centrifugation.
3. The false reactivity of the sample is generally due to the presence of suspended particulate matter in the serum which may or may not be visible to the naked eye.
4. Sample found to be reactive by the above screening test must be confirmed by standard supplemental assay, like Western Blot.
5. If the test result is negative and clinical symptoms persist, additional follow-up tests using other clinical methods are recommended. A negative result at any time does not preclude the possibility of Syphilis infections.

**PERFORMANCE AND CHARACTERISTICS:**

In an in-house trial, one thousand and hundred samples were tested in parallel with a licensed commercially available ELISA Kit and RAPITEST™ Syphilis. The results obtained as follows.

Sample	No. of Samples	Licensed ELISA Kit	RAPITEST™ Syphilis
Negative for syphilis antibodies	900	900	900
Positive for Ab. to syphilis	200	200	199

Based on this evaluation the sensitivity of RAPITEST™ Syphilis is 99.5% and specificity of RAPITEST™ Syphilis is 100%

**BIBLIOGRAPHY**

1. Centers for Disease Control and Prevention. Chlamydia trachomatis infections: policy guidelines from prevention and control. Morbid. Mortal. Weekly Rep. 1995; 34:53S-74S.
2. Tichonova, L., K. Borisenko, H. Ward, A. meheus, et al. Epidemics of syphilis in the Russian Federation: Trends, origins, and priorities for control. Lancet 1997; 350:210-213.
3. Gerbase, A. C., J. T. Rowley, D. H. Heymann, S. F. Berkley, and P. Piot. Global prevalence and incidence estimates of selected curable STDs. Sex. Transm. Infect 1998; 74:S12-S16.
4. Luger AFH. Serological Diagnosis of Syphilis: Current methods. In: Young H, McMillan A, eds. Immunological diagnosis of sexually transmitted diseases. New York: Marcel Decker, 1988: 249-274.

