One-Step Syphilis Rapid Test Device

Diagnocure (India)™

INTENDED USE

The Syphilis Rapid Screen Test is a qualitative test for the detection of antibodies to Treponema. pallidum in human serum and plasma. It is considered as an initial screening test for antibodies against T. pallidum. All positive specimens must be confirmed with Western Blot or other qualified ELISA.

SUMMARY AND EXPLANATION OF THE TEST

Treponema pallidum, a spirochete bacterium with an outer envelope and a cytoplasmic membrane, is the causative agent of the venereal disease syphilis. Although syphilis rates are declining in the United States after an epidemic between 1986 and 1990[1], the incidence of syphilis in Europe has increased since 1992, especially in the countries of the Russia Federation, where peaks of 263 cases per 100,000 have been reported[2]. In addition, the positive rate of syphilis serological test in HIV-infected individuals has been rising recently.

The serological detection of specific antibodies to T. pallidum has been long recognized in the diagnosis of syphilis since the nature course of the infection is characterized by periods without clinical manifestations. The antibodies response to T. pallidum can be detected within 4 to 7 days after the syphilis chancre appears[3], allowing the early detection and diagnosis of syphilis infection.

A variety of antigens have been used in the syphilis serological tests, such as Rapid Plasma Cardiolipin antigen(RPR) or VDRL antigen, T. pallidum extracts derived from in vitro culture or inoculated rabbit testis. However, RPR and VDRL antigens are not treponemal specific. Whole T. pallidum extracts are not reproducible and contain a certain amount of contaminating materials such as flagella, which may lead to a nonspecific reaction in the assay of test serum.

The Syphilis Rapid Screen Test is a latest generation chromatographic immunoassay which utilizes multiple T. pallidum-specific recombinant antigens to detect the antibodies against T.pallidum in human serum or plasma. The test is user friendly, highly sensitive and specific.

TEST PRINCIPLE

The Syphilis Rapid Screen Test kit is a double antigen mediated chromato-graphic immunoassay. It is composed of a pad containing recombinant T. pallidum specific antigens conjugated with burgundy colored colloid gold (rTP conjugates) and specific recombinant T. pallidum antigens that have been immobilized on the test result line region (T) of the nitrocellulose membrane of the test. During the test, syphilis antibodies in the patient samples migrate through the conjugate pad where they bind to the colored rTP conjugates. The antibody-rTP conjugates are then captured by the rTP antigens immobilized on the membrane, forming a burgundy colored band on the test region (T), indicating a positive test result. Absence of this band in the test window suggests a negative result. The test contains an internal control in the control region (C) which should always demonstrate a burgundy colored band regardless of the presence of syphilis antibody.

MATERIAL & REAGENTS PROVIDED

1. Single test cassettes sealed in pouch containing a desiccant.
2. Disposable pipettes sealed in foil pouch together with the test
3. One set of test instruction.

MATERIAL & REAGENTS REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Specimen collection containers

STORAGE & STABILITY

- Store the test kit refrigerated or at room temperature (4-30ºC).
- Do not freeze the kit and avoid exposure to temperatures higher than 30 °C.
- Each test may be used until the expiration date printed on the pouch if it remains sealed in the foil pouch containing desiccant.

WARNING AND PRECAUTIONS

- This test is for professional in vitro diagnostic use only.
- Instructions must be followed to obtain accurate results.
- Do not open the sealed pouch, unless ready to start the test procedure.
- Do not use after the expiration date or if the pouch has been damaged.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.
- All patient samples should be treated as if capable of transmitting disease. Proper handling and disposal methods should be established.

SPECIMEN COLLECTION & STORAGE

PLASMA

1. Have a certified phlebotomist collect blood into an appropriate collection tube (containing EDTA, citrate or heparin, respectively) by vein puncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma for testing. Plasma can be stored at 2-8°C for up to two weeks. If it will not be tested within two weeks plasma samples should be frozen.

SERUM

1. Have certified phlebotomist collect plasma into an appropriate collection tube (containing no anticoagulants) by vein puncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum for testing. Serum can be stored at 2-8°C for up to two weeks. If it will not be tested within two weeks serum samples should be frozen.

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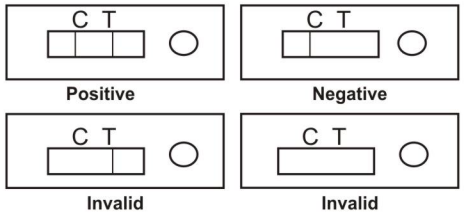
ASSAY PROCEDURE

Allow test device, sample material, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the device on a clean and level surface. For **Serum or Plasma** specimen: Hold the dropper vertically and transfer 2-3 drops of serum or plasma (approximately 60-70 µl) to the round sample well. Start the timer.
3. Wait for the red line(s) to appear. The result should be read at 10 minutes. Do not interpret the result later than 30 minutes after addition of the sample.

INTERPRETATION OF RESULTS

Control **(C)** **T**est **(T)** **S**ample well **C**ontrol **(C)** **T**est **(T)** Sample well



NEGATIVE :

Only one line appears at the control region C. The absence of a line in the test result line region (T) indicates that no syphilis antibodies are detected.

POSITIVE :

Two lines appear. One line is in the control region C (control line), the other one in the test result line region T. A red test result line in the T region indicates that sample contains syphilis antibodies. The color intensity of the test result line (T) may vary from faint pink to an intense burgundy.

INVALID :

If no control line develops the assay is invalid even if the test result line (T) is formed. In this case, repeat the assay with a new test device.

LIMITATION OF THE TEST

- The Syphilis Rapid Screen Test is limited to the qualitative detection of syphilis antibody in human serum and plasma.
- The test is a qualitative screening assay only and should not be used for quantifying the amount of anti-syphilis antibodies according to the color intensity or width of the test result line.
- A negative result does not rule out syphilis infection because the antibodies against T. pallidum may be absent at the time the specimen is taken or may not be present in sufficient quantities to be detected at an early stage of infection.
- As with all diagnostic tests, all results must be interpreted together with other clinical information and should not be used as sole basis for a diagnosis. The results obtained with this test should only be used as an adjunct to other diagnostic procedures and information available to the physician.

REFERENCES

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3. Norgard M.V., N.R. Chamberlain, M.A. Swancutt, et al. 1986. Infect Immun 54:500-506.

Diagnocure™ (India)

Mfg. & Marketed by : **Diagnocure™** (India)
2, F/F, E. C., Chambaghat, Solan-173213 (H.P.) INDIA
Customer Care No. : + 91-1792 230156
E-mail : info.diagnocureindia@gmail.com