

# Syphilis

Rapid test for the detection of *Treponema pallidum* infection in human serum, plasma and whole blood  
Produkt-# 21.200



## INTENDED USE

The Syphilis Rapid Screen Test is a qualitative test for the detection of antibodies to *Treponema pallidum* in human serum, plasma and whole blood. 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<sup>1</sup>, 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<sup>2</sup>. 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<sup>3</sup>, 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 chromatographic 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. Dropper vial with buffer
4. One set of test instruction.

## MATERIAL & REAGENTS REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Specimen collection containers
3. Lancet (optional – only whole blood from a fingertip puncture is used)

## STORAGE & STABILITY

- Store the test kit refrigerated or at room temperature (4-30°C).
- 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

Dutch Diagnostics BV  
Hekkehorst 3 – 7207 BS Zutphen  
The Netherlands

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 a 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.

### Whole Blood

1. Fresh blood e.g. from a fingertip puncture must be used immediately to prevent clotting. Disinfect the puncture site with alcohol or another disinfectant. Massage the hand in the direction of the fingertip without touching the puncture site. Prick the fingertip with a sterile lancet. Wipe the first drop of blood. Rub the hand from wrist to palm to get a sufficient amount of blood.  
Whole blood from venipuncture containing anticoagulants can be stored at 2-8 °C for up to two days. Whole blood samples must not be frozen.

## ASSAY PROCEDURE

Allow test device, buffer, 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 drops of serum or plasma** (approximately 40-50 µl) to the round sample well. Remove top from buffer vial and add **1 drop of buffer** into the sample well. Start the timer.

Phone: +31 575 512 300  
Fax: +31 575 510 164  
E-mail: info@dutch-diagnostics.com

# Syphilis

Rapid test for the detection of *Treponema pallidum* infection in human serum, plasma and whole blood  
Produkt-# 21.200









For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and transfer **2 drops of venipuncture whole blood** to the round sample well. Remove top from buffer vial and add **1 drop of buffer** into the sample well. Start the timer.

For **Fingertip Puncture Whole Blood** specimen: Transfer **2 hanging drops** from the fingertip into the round sample well by moving the finger over the well. Make sure that the finger has no direct contact to the well. **Immediately add 2 drops of buffer** from the buffer vial. Start the timer.

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.

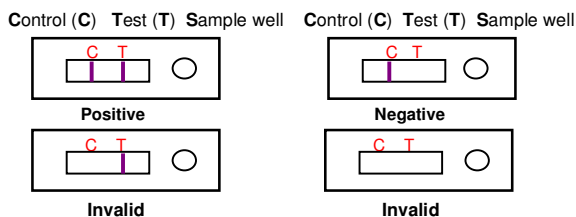
2. Tichonova, L., K. Borisenko, H.Ward, A.meheus, et al. 1997. Lancet 350:210-213
3. Norgard M.V., N.R. Chamberlain, M.A. Swancutt, et al. 1986. Infect Immun 54:500-506.

## SYMBOLS

	For in-vitro diagnostic use only		For single use only
	Content		Expiry date
	Lot number		Store at room temperature

Rev.:12/02/2008 JB

## INTERPRETATION OF RESULTS



### 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, plasma and whole blood.
- 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.
- It is possible that the test does not yield any results if whole blood specimens have a high viscosity or if the whole blood specimens have been stored for more than 2 days. In this case the test should be repeated with a new test card using a plasma or serum specimen of the same patient.

## REFERENCES

1. Centers for Disease Control and Prevention. 1995. Morbid. Mortal. Weekly Rep. 34:53S-74S.

**Dutch Diagnostics BV**  
**Hekkehorst 3 – 7207 BS Zutphen**  
**The Netherlands**

**Phone: +31 575 512 300**  
**Fax: +31 575 510 164**  
**E-mail: info@dutch-diagnostics.com**