Syphilis Cassette Rapid Test

(Whole Blood/Serum/Plasam)

INTENDED USE

The Syphilis Rapid Test is a rapid immunoassay for the qualitative detection of antibodies (IgG and IgM) to Treponema Pallidum (Tp) in whole blood,serum or plasma to aid in the diagnosis of Syphilis.

INTRODUCTION

Syphilis is a disease caused by Spirochete bacterium called Treponema pallidum (TP). If untreated, the organisms move throughout the body and can cause damage to many organs, making syphilis a life-threatening disease if not treated early fully. The serological response to syphilis involves production of antibodies to a wide range of antigens, including non-specific antibodies and specific anti-TP antibodies. The first detectable response to infection is the production of specific anti-treponemal IgM, which can be detected within 4 to 7 days after the chancre appears and until the end of the second week of infection; anti-treponemal IgG appears at about four weeks later. By the time syphilis disease symptoms develop, most patients have both detectable IgG and IgM.

PRINCIPLE

The Syphilis Rapid Test is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. In this test procedure, recombinant Syphilis antigen is immobilized in the test line region of the strip.

After specimen is added to the specimen well of the device, it reacts with Syphilis antigen coated particles in the test. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized Syphilis antigens. If the specimen contains Tp antibodies, a coloured line will appear in the test line region indicating a positive result.

The double antigen test can detect both IgM and IgG in specimens. If the specimen does not contain Tp antibodies, a coloured line will not appear in this region, indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

PRODUCT CONTENTS

The Syphilis Rapid Test contains Syphilis antigen coated particles and Syphilis antigen coated on the membrane.

MATERIALS SUPPLIED

1.Test device 2 Pipette dropper 3.Desiccant 4.Buffer (for whole blood only) 5.Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Specimen collection containers.
3. Lancets (for fingerstick whole blood only)
4. Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
5. Centrifuge (for plasma only)

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C.

If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

WARNINGS AND PRECAUTIONS

1. For professional In Vitro diagnostic use only.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re- use under any circumstances.
5. Handel all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
7. Humidity and temperature can adversely affect results

SPECIMEN COLLECTION

The Syphilis Rapid Test can be performed using either whole blood ,serum or plasma.

1. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens can be used.

To collect Fingerstick whole Blood Specimens:

Wash the patients' hand with soap and warm water or clean with an alcohol swab

Puncture the skip with a sterile lancet. Wipe away the first sign of blood

Gently form a rounded drop of blood over the puncture site and add the fingerstick whole blood specimen to test device **using a capillary tube**

Touch the end of capillary tube to blood until filled to approximately 50ul

Place the bulb onto the top end of the capillary tube dispense the whole blood into the specimen well (s) of the test device.

Add the fingerstick whole blood specimen to the test device by **using hanging drops:**

Position the patient's finger so that the drop of blood is just abobe the specimen well (s) of the test device

Allow 2 hanging drops of fingerstick whoel blood to fall into the specimen well (s) of the test device, or move the patient's finger so that the hanging drop touches the specimen (s) . Avoid touching the finger directly to the specimen we (s).

2. 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.
3. 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.
4. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of aetiologic agents.

TEST PROCEDURE

Allow the test, specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test 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 test on a clean and level surface.

For Serum or Plasma:

Hold the dropper vertically and transfer 3 full drops of serum or plasma (approx. 75 µl) and start the timer. Avoid air bubbles. See illustration below.

For Venipuncture Whole Blood specimens:

Hold the dropper vertically and transfer 3 drops of whole blood (approximately 75ul) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 25ul) and start the time. See illustration below.

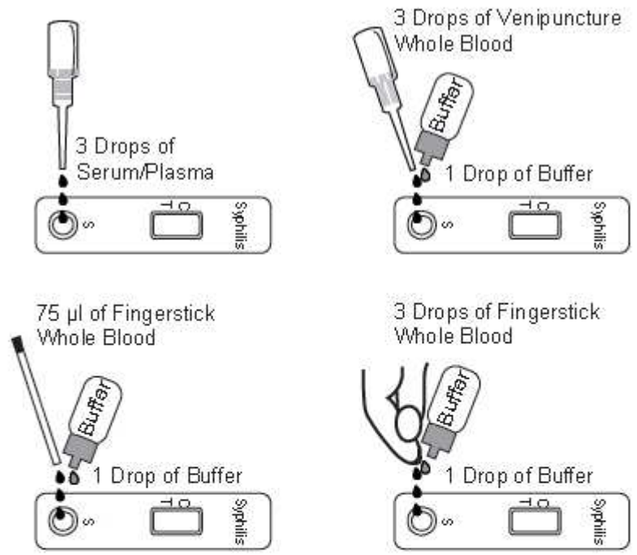
For Fingerstick Whole Blood specimens:

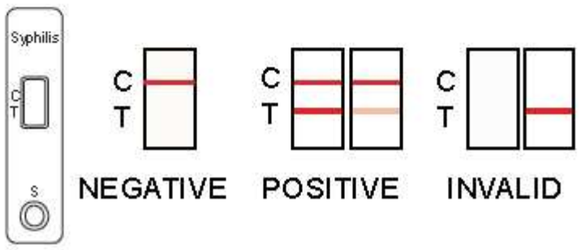
To use a capillary tube: Fill the capillary tube and transfer approximately 75ul of fingerstick whole blood specimen into the specimen well (S) of the test device, then add 1 drop of buffer (approximately 25ul) and start the timer. See illustration below.

To use hanging drops: Allow 3 hanging drops of fingerstick whole blood specimen (approximately 75ul) to fall into the center of the specimen well (s) of the test device, then add 1 drop of buffer (approximately 25ul) and start the timer. See illustration below

3. Wait for the coloured line(s) to appear. Read results in 15 minutes. *Do not interpret the result after 15 minutes.*

INTERPRETATION OF RESULTS





Positive: Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).

Negative: One coloured line appears in the control line region(C). No line appears in the test line region (T).

Invalid: Control line fails to appear.

QUALITY CONTROL

A procedural control is included in the test. A coloured line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The Syphilis Rapid Test is for in vitro diagnostic use only. The test should be used for the detection of Tp antibodies in serum or plasma specimens only. Neither the quantitative value nor the rate of increase in Tp antibodies can be determined by this qualitative test.
2. The Syphilis Rapid Test will only indicate the presence of Tp antibodies in the specimen and should not be used as the sole criteria for the diagnosis of Tp infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Tp infection.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The Syphilis Rapid Test has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial TPHA Syphilis test using clinical specimens. The results show that the relative sensitivity of The TP One Step Rapid Test is greater than 99.9%, and the relative specificity is 99.7%.

REFERRENCE

1. Center for Disease Control. Recommendations for diagnosing and treating Syphilis in HIV-infected patients. MMWR Morb. Mortal Wkly Rep. (1988); 37: 601.
2. Fraser CM. Complete genome sequence of Treponema Pallidum, the Syphilis spirochete. Science (1998); 281 July: 375-381.