

# Syphilis Antibody Rapid Test Kit

## INTENDED USE

The Syphilis Antibody Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies to *Treponema pallidum* in human whole blood, serum, or plasma that aid in the diagnosis of infection with *Treponema pallidum*.

## INTRODUCTION

The Syphilis Rapid Test Cassette/Strip is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies to *Treponema pallidum* in human whole blood, serum, or plasma. It provides an aid in the diagnosis of infection with *Treponema pallidum*. Syphilis is a sexually transmitted infection caused by the spirochete bacterium *Treponema pallidum* subspecies pallidum. The primary route of transmission is through sexual contact; it may also be transmitted from mother to fetus during pregnancy or at birth, resulting in congenital syphilis. Other human diseases caused by related *Treponema pallidum* include yaws (subspecies pertenue), pinta (subspecies carateum), and bejel (subspecies endemicum). The signs and symptoms of syphilis vary depending on which of the four stages it presents (primary, secondary, latent, and tertiary). The Syphilis Rapid Test detects antibodies to *Treponema pallidum* infection in human whole blood, serum, or plasma. The test is easy to perform and requires no specialized equipment. Visual interpretation provides an accurate qualitative result. It is a useful on-site aid in the diagnosis of Syphilis infection. Diagnosis of Syphilis infection by antibody immunoassay can reduce the number of patients requiring endoscopy.

## PRINCIPLE

The Syphilis Rapid Test is an immunoassay based on the principle of the double antigen-sandwich technique. During testing, a whole blood, serum, or plasma specimen migrates upward by capillary action. The antibodies to *Treponema Pallidum* if present in the specimen will bind to the Syphilis conjugates. The immune complex is then captured on the membrane by the pre-coated Syphilis antigens, and a visible colored line will show up in the test line region indicating a positive result. If antibodies to *Treponema Pallidum* are not present or are present below the detectable level, a colored line will not form in the test line region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

## MATERIALS AND METHOD

1. Individual sealed pouches, each pouch contains:
  - a. 1 × Test Card
  - b. 1 × Desiccant Pouch
  - c. 1 × Dropper
2. Extraction kit
3. Sampling Tubes

## STORAGE AND STABILITY

- Keep the test kit between (4 - 30°C) in a dry, cool place. Avoid freezing.
- The kit is stable within the expiry date printed on the product label and outer packaging. Do not use later than the specified date.
- The package should be sealed until it is required for the use.

## **SPECIMEN COLLECTION**

1. The Syphilis Antibody test can be performed using serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid haemolysis. Use only clear, non-haemolyzed specimens.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
4. Serum and plasma specimens may be stored at 2 - 8 °C for up to 3 days. For long term storage, specimens should be kept below -20°C.
5. Bring specimens to room temperature prior to testing.
6. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
7. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

## **TEST PROCEDURE**

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

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
2. Place the cassette on a clean and level surface.
3. For the serum or plasma specimen: Hold the dropper vertically and add three drops (about 100µl) to the test device's specimen well (S). Then, set the timer.
4. For whole blood specimens: Extract the serum and collect few serums with dropper. Hold the dropper vertically and transfer 1

drop of serum or plasma (approx. 35 µL) to the specimen area, then add 2 drops of buffer (approx. 70 µL), and start the timer.

5. Wait for the colored line(s) to appear. Read the results in 10 minutes. Do not interpret the result after 20 minutes.

## **RESULT:**

1. Two Pink Lines - (POSITIVE)
2. One Pink Line at (C) - (NEGATIVE)
3. No Pink Line - (INVALID)

## **LIMITATIONS**

1. The Syphilis Rapid Test Kit (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. It 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.
2. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
3. 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.