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 Kit 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* 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 specialised 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 containing:
   a. 1 × Test Kit
   b. 1 × Desiccant Pouch
   c. 1 × Dropper
2. Buffer

STORAGE AND STABILITY

- Keep the test kit between 2 - 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 use.

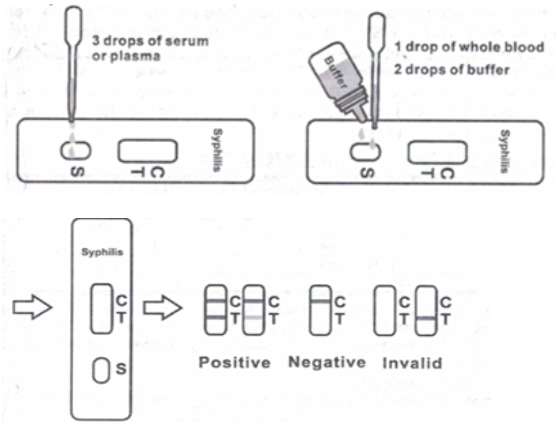
SPECIMEN COLLECTION

1. The Syphilis Antibody test can be performed using whole blood, 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.
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. Do not freeze a whole blood specimen. Bring specimens to room temperature prior to testing.
5. Frozen specimens must be completely thawed and mixed well kakprior to testing. Specimens should not be frozen and thawed repeatedly.
6. Do not use samples showing gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

TEST PROCEDURE

Allow the test kit, 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 kit from the sealed pouch and use it within one hour.
2. Place the kit on a clean and level surface.
3. **For Whole blood specimens:** Hold the dropper vertically and transfer 1 drop of whole blood (approx. 35 µL) to the specimen area, then add 2 drops of buffer (approx. 70 µL), and start the timer.
4. **For the serum or plasma specimen:** Hold the dropper vertically and add 3 drops of serum or plasma (about 100µl) to the specimen area, 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)

PERFORMANCE CHARACTERISTICS

A side-by-side comparison was conducted using the Syphilis Antibody Rapid Test and commercially available Syphilis rapid tests. A statistical comparison was made between the results, yielding a clinical sensitivity of 99.69%, a clinical specificity of 99.16% and an accuracy of 99.32%.

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 criterion 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.

REFERENCES

1. Claire M. Fraser. "Complete genome sequence of Treponema Pallidium, the syphilis spirochete", Science 1998; 281 July: 375-381.
2. Center for Disease Control. "Recommendations for diagnosing and treating syphilis in HIV-infected patients", MMWR Morb. Mortal Wkly Rep. 1988; 37: 601
3. Phillip C. Johnson. "Testing for Syphilis", Dermatologic Clinic 1994; 12 Jan: 9-17.
4. Young, H. "Syphilis Serology", Dermatol Clin1998; 16 (4): 691-8.
5. Romanowski, B, E. Forsey, et.al, "Detection of Treponema Pallidum by a fluorescentmonoclonal antibody test", Sex Trans Dis 1987;14 (3): 156-9.
6. Rusnak, JM, C. Butzin, et.al. "False-positive rapid plasma reagin tests in humanimmunodeficiency infection virus and relationship to anti-cardiolipin antibody andserum immunegolobulin levels", J. Infect Dis1994; 169 (6): 1356-9

novala BIOTECH