A rapid test for the diagnosis of Syphilis in whole blood, serum or plasma.

INTENDED USE

The Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic 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.

SUMMARY

Treponema Pallidum (TP) is the causative agent of the venereal disease syphilis. TP is a spirochete, a member of the bacterial group that is enveloped in an outer cell wall. Relative size is about 15 µm x 0.3 µm. Some factors that have contributed to this rise include the crack cocaine epidemic and the high incidence of venereal disease among drug users. Over 250,000 new cases of the acquired immunodeficiency syndrome (AIDS) have been reported since 1981 and 90% of these cases are associated with infection of the HIV virus and Syphilis. Syphilis and HIV are transmitted sexually. Syphilis is a specific and long standing infection characteristic of the HIV virus. Primary Syphilis is defined by the presence of a chancre at the site of inoculation. The antibodies present in the TP bacterium can cause a false positive test result in the first two weeks after infection. The double drop test format can detect both IgG and IgM antibodies in specimens. If the specimen contains TP antibodies, a colored line will appear in the test result area, indicating a positive result. If the specimen does not contain TP antibodies, a colored line will not appear. The test procedure and result interpretation are the same for all serum and plasma specimens. The Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) utilizes a double antigen combination of a Syphilis antigen coated particle and Syphilis antigen immobilized on membrane to detect TP antibodies (IgG and IgM) qualitatively and selectively in whole blood, serum or plasma.}

FEATURES

• Results show in vitro diagnostic use only. Do not use after expiration date.
• Do not drink or smoke in the area where the specimens or kits are handled.
• Do not use if package is damaged.
• Handle all specimens as if they contain infectious agents. Observe established precautions to prevent microbial hazards throughout all procedures and follow the standard procedures for proper disposal of infectious waste. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are handled. The use test should be discontinued according to local regulations. Wound, surface, and nail cuts should be dressed with antiseptic and bandage. All equipment used should be labeled as biohazardous and disposed of in the biohazardous waste container. Storage and Stability

Store the sealed pouch either at room temperature or refrigerated (2-8°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION

• The Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum, or plasma.
• To collect Fingerstick Whole Blood specimens:
  - Hold the tip of a finger between two fingers, or with a warm towel or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingers of the middle or ring finger.
  - Put the finger on a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from the top of the finger to form a droplet of blood over the puncture site.
  - Add 2 drops of whole blood specimen to the test by using a capillary tube:
    - Touch the end of the capillary tube to the blood until filled to approximately 80 µL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the blood into the specimen area of test cassette.
  - Add 1 drop of buffer to the test:
    - Place the buffer bag on the top of the cassette.
    - Remove the test card and add 1 drop of buffer to the test area (approximately 40 µL). Then start the timer. See illustration below.
  - To use a capillary tube:
    - Fill the capillary tube and transfer approximately 80 µL of fingerstick whole blood specimen to the test cassette area, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

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

TEST PROCEDURE

1. Remove the test cassette from the sealed pouch and use as soon as possible.
2. Place the test cassette on a clean and stable surface.
3. For Serum or Plasma specimens:
   - Hold the dropper vertically and transfer 1 drop of serum or plasma containing 40 µL (μL) to the specimen area, then add 1 drop of buffer (approximately 40 µL), and start the timer, see illustration below.
   - For Whole Blood specimens:
     - Hold the dropper vertically and transfer 2 drops of whole blood containing 80 µL (μL) to the specimen area, then add 1 drop of buffer (approximately 40 µL), and start the timer. See illustration below.
   - For Fingerstick Whole Blood specimens:
     - Add the Fingerstick Whole Blood specimen to the test by using a capillary tube:
       - Touch the end of the capillary tube to the blood until filled to approximately 80 µL. Avoid air bubbles.
       - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the blood into the specimen area of test cassette.
     - Add 1 drop of buffer to the test:
       - Place the buffer bag on the top of the cassette.
       - Remove the test card and add 1 drop of buffer to the test area (approximately 40 µL). Then start the timer. See illustration below.

INTERPRETATION OF RESULTS

(please refer to the illustration above)

POSITIVE: Two lines appear. One colored line should appear in the control line region (C) and another colored line should appear in the test line region (T). *Note: The intensity of the color in the test line region (T) will vary depending on the concentration of TP antibodies present in the specimen. Therefore, any shade of color in the test line region (T) should be considered as positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue the test kit immediately and contact your local distributor.

PRODUCT PERFORMANCE

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered 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 test performance.

The Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial TPHA Syphilis test, demonstrating an overall accuracy greater than or equal to 98.9%.

EXPECTED RESULTS

Relative sensitivity: 99.9% (95%CI*: 98.9%-100%)
Relative specificity: 99.9% (95%CI*: 98.3%-100%)
Positive accuracy: 99.8% (95%CI*: 98.9%-100%)

Precision

Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

Cross-reactivity

The Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by HAMA, RF, MOMP, HBsAb, HBsAb, HCV, HIV, H. PYO, MONO, CMV, TOXO, positive specimens. The results showed no cross-reactivity.

INTERFERING SUBSTANCES

The following potentially interfering substances were added to Syphilis negative and positive specimens:

- Acetaminophen: 20 mg/dL
- Acetylsalicylic Acid: 20 mg/dL
- Ascorbic Acid: 2 g/dL
- Creatine: 200 mg/dL
- Bilirubin: 1 g/dL
- Oxalic Acid: 600 mg/dL

Precision of Results in the Syphilis Rapid Test Cassette (Whole Blood/Serum/Plasma) have been determined by reagents authentication, see instructions for use.

1. M. M. Frank. Complete genome sequence of Treponema Pallidum, the Syphilis spirochete.

Index of Symbols

*Note: the intensity of the color in the test line region (T) will vary depending on the concentration of TP antibodies present in the specimen. Therefore, any shade of color in the test line region (T) should be considered as positive.

1. Do not reuse
2. Authorized Representative
3. Do not use if package is damaged
4. Authorized Representative
5. Use by
6. Store between 2-8°C
7. Lot Number
8. Manufacturer
9. Use by
10. Do not use if package is damaged
11. Authorized Representative
12. Authorized Representative

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