**EXPLANATION OF THE TEST**

Syphilis is a venereal disease caused by the spirochete Treponema pallidum. Because the syphilis organism cannot be cultured in media, the diagnosis of syphilis depends on the correlation of clinical data with the specific antibody detected by serological tests. Serological screening tests for syphilis utilizing cardiolipin and lecithin, as antigens are simple to perform but false positives can occur. For professional use only. The One Step Syphilis Test is a chromatographic immunoassay for the qualitative detection of antibodies of all isotypes (IgG, IgM, IgA, etc.) against syphilis in serum, plasma or whole blood. The Syphilis test cassette has a letter T and C as the “Test Line” and the “Control Line” on the surface of the cassette. Both the “Test Line” and the “Control Line” in the result window are not visible before applying any samples. The “Control Line” is used for procedural control. The “Control Line” should always appear if the test procedure is performed properly and the test reagents are working correctly. A purple “Test line” will be visible in the Result Window if there are enough antibodies against syphilis in the sample. If antibodies against syphilis are not detected in the sample, no color appears in the “Test Line”. This test is intended for professional use as an aid in the detection of antibodies against syphilis.

**MATERIALS PROVIDED**

The Syphilis test kit contains the following items to perform the assay:
1. Syphilis test cassette.
2. Disposable sample dropper.
3. Instructions for use.

**PRECAUTIONS**

The One Step syphilis test devices should be stored at room temperature 4 – 30 ºC (40 – 86 ºF). The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

**SPECIMEN COLLECTION AND STORAGE**

Whole Blood specimen collection: Collect an anticoagulated blood sample (sodium heparin or lithium heparin). Whole blood samples must be tested within 24 hours of drawing.

Plasma/Serum specimen collection:
1. Centrifuge whole blood to get a plasma/serum specimen.
2. If specimens are not immediately tested they should be refrigerated at 2 – 8 ºC. For storage periods greater than three days, freezing is recommended.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assay.

**WARNINGS**

- For in vitro diagnostic use only.
- Do not eat or smoke while handling specimens.
- Wear protective gloves while handling specimens.
- Wash hands thoroughly afterwards.
- Avoid splashing or aerosol formation.
- Clean up spills thoroughly using an appropriate disinfectant.
- Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- Do not use the test kit if the pouch is damaged or the seal is broken.

**PROCEDURE OF THE TEST**

1. Remove the test disk from the foil pouch, and place it on a flat, dry surface.
2. Holding the sample dropper above the test disk and add 1 hanging drop into the Sample Well. After the drop is absorbed into the Sample Well, add another hanging drop, repeat the procedure until a total of 3 hanging drops (total about 120 µl of blood) have been added to the Sample Well. If specimen drops are added too quickly, specially for blood specimen, it may cause clogging of the Sample Well.
3. As the test begins to work, you will see purple color move across the Result Window in the center of the test disk.

**NOTE:** If no flow is seen in the result window after 30 seconds, add a 4th hanging drop of blood into the sample well.

4. Interpret test results at 5 to 10 minutes. Do not interpret test result after 15 minutes.

**CAUTION:** The above interpretation time is based on reading the test results at room temperature of 15 to 30 ºC. If your room temperature is significantly lower than 15 ºC, then the interpretation time should be properly increased.

**INTERPRETATION OF THE TEST**

1. A color band will appear at the left section of the result window to show that the test is working properly. This band is the Control Band.
2. The right section of the result window indicates the test results. If another color band appears at the right section of the result window, this band is the Test Band.

**NEGATIVE**

- One color band
  - The presence of only one band within the Result Window indicates a negative result.

**POSITIVE**

- The presence of two color bands (“T” band and “C” band) within the result window regardless of which band appears first indicates a positive result.

**NOTE:** Generally, the higher the analyte level in the specimen, the stronger the “T” band color will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the color of the “T” band will be very faint.

**INVALID**

After performing the test and no purple color band is visible within the result window, this result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

**NOTE:** A positive result will not change once it has been established at 15 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after 15 minutes.
LIMITATIONS OF THE TEST

A negative result does not preclude the possibility of infection with syphilis. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

SPECIFICITY AND INTERFERENCE STUDY

Determine the Specificity of the One Step Syphilis test.
An in-house study is conducted with 3 separate lots of the One Step Syphilis Test. Specimens tested include Serum with triglyceride concentrations up to 500 mg/ml, Serum with Bilirubin concentrations up to 10 mg/100ml, Prostatic acid phosphatase with concentrations up to 1000 mIU/ml and Albumin with concentrations up to 20 mg/ml. All of the above were analyzed and did not show interference or cross reactivity with the test.

REFERENCES


SYMBOLS

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