Cypress Diagnostics

Code 353 Syphilis Quick Test

50 devices individually pouched
1 vial assay diluent

Syphilis Quick Test

A qualitative screening test kit for the detection of antibodies to Treponema pallidum in human serum, plasma or whole blood

Intended Use
The Cypress Diagnostics Syphilis Quick Test is a single use, immunochromatographic screening test for the qualitative detection of antibodies of all isotypes (IgG, IgM, IgA) against Treponema pallidum. This test is intended for use by medical professionals as an aid on the diagnosis of syphilis.

Summary and explanation
Treponema pallidum (TP) is the causative agent of the venereal disease syphilis. Syphilis is a disease caused by the spirochetal bacterium Treponema pallidum. Clinical diagnostic issues related to syphilis are the detection of syphilis antibodies in human blood by immunoassay. Among the existing immunological method, the confirmatory treponemal tests are the agglutination format such as the T. pallidum hemagglutination assay (TPHA) and the immunostaining analysis by fluorescent treponemal antibody adsorption test (FTA-ABS). Recently, the ELISA format and immunochromatography format (rapid) to detect antibody of T. pallidum are available. Since even highly purified antigens from inoculated TP may contain a certain amount of contaminating materials such as flagella of TP, native PT antigen may cause a non-specific reaction in the assay of test serum samples, and this may result in lower sensitivity and poor reproducibility. To circumvent these potential problems in immunoassays, researchers have constructed TP genes for the expression of recombinant antigens in bacterium systems such as E. coli and focused on TP membrane protein, which are definitely immunogenic. The major immunoreactive antigens of these membrane proteins have been reported to have a MW of 47, 42, 17, and 15 KDa based on western blot analysis.

The Cypress Diagnostics Syphilis Quick Test provides an excellent methodology for detecting Treponema pallidum antibodies. It is a rapid immunochromatographic test that is simple and easy to use.

Principle of the Test
The Cypress Diagnostics Syphilis Quick Test contains a membrane strip, which is pre-coated with recombinant Treponema pallidum antigens (17, 15 KDa) on test region. The recombinant Treponema pallidum antigens-colloid gold conjugate (17, 15 KDa), patient sample and sample diluent moves along the membrane chromatographically to the test region (T) and forms a visible line as the antigen-antibody-antigen gold particle complex forms. Therefore, the formation of a visible line in the test region (T) indicates a positive result for the detection of Treponema pallidum specific antibodies (IgG, IgA, IgM). When the Treponema pallidum specific antibodies (IgG, IgA, IgM) are absent in the sample, no visible colored line will appear in the test region (T). The Control Line (C) is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working.

Kit components:
Each kit contains following items:
- 50 Cypress Diagnostics Syphilis Quick Test devices in individually foil pouched with desiccant
- 1 vial of diluent
- 1 instruction leaflet.

Additional Materials required:
- Timer

Storage and stability
The Syphilis quick test devices should be stored at room temperature between 8° and 30°C. Diluent can be stored between 2 and 30°C. Do not use tests beyond expiration date that appears on the foil pouch. The test is sensitive to humidity as well as heat. Perform the test immediately after removing it from the foil pouch. Do not use test devices when the seal is broken.

Warnings and precautions:
- The Cypress Diagnostics Syphilis Quick Test is for in vitro use only.
- The instruction must be followed exactly to get accurate results. Anyone performing an assay with this product must be trained in its use and must be experienced in laboratory procedures.
- Use fresh test device for every sample. The device is not reusable.
- Use separate disposable pipettes or pipette tips for each sample to avoid cross-contamination.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling samples.
- Avoid splashing and aerosol formation.
- Clean up spills thoroughly using an appropriate disinfectant. Decontaminate and dispose of all samples, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- Care should be taken to avoid contamination of the end of the bottle when dropping of assay diluent into the sample well.

Sample collection
The Cypress Diagnostics Syphilis Quick Test is performed on whole blood, serum or plasma.

Whole Blood:
The Cypress Diagnostics Syphilis Quick Test is performed on whole blood, serum or plasma.

Serum:
Serum is used from whole blood collected aseptically by venipuncture into a clean tube without anticoagulant.

Plasma:
Plasma is used from whole blood collected aseptically by venipuncture into a clean tube without anticoagulant.
Patient serum and plasma samples perform best when tested immediately after collection. If not to be tested immediately, the samples should be refrigerated immediately following collection at 2-8°C and can be used up to 3 days. If testing within 3 days is not possible, the samples should be frozen (-20°C or colder).

Samples containing precipitate may yield inconsistent test results. Such samples must be clarified prior to assaying. The use of hemolytic, lipaemic, icteric or rheumatoid factors containing samples should be avoided because it can lead to impaired results.

**Test Procedure**

Allow test sample and test device to come to room temperature prior to testing. Frozen samples should be allowed to thaw vertically in a rack before testing. Avoid repeatedly freezing and thawing test samples. Plasma or serum samples containing a precipitate may yield inconsistent test results. Such samples must be clarified prior to assaying.

1. Remove the required number of syphilis test devices from their wrappers by tearing the wrapper and place them on a flat surface (it is not necessary to remove the desiccant).
2. Label the test unit with patient name or identification number.
3. Blood samples: Add 20 µl of the blood sample with micropipette to the sample (S) well of the device. Plasma or serum samples: Add 10 µl of the sample with a micropipette to the sample (S) well of the device.
4. Invert the assay diluent bottle and hold it vertically (not at an angle) over the sample well. Add the diluent slowly dropwise, 3–4 drops (±110 µl) into the sample (S) well and start the timer.
5. As the test begins to work, you will see purple color move across the result window in the center of the test device.
6. Interpret test results at 5–20 minutes. A positive result will not change once it has been established at 20 minutes. However, in order to prevent any incorrect results, the result should not be interpreted after 20 minutes.
7. Especially, when you use the whole blood, please interpret the test results within 10 minutes. In this case, do not interpret after 10 minutes.

Caution: The above interpreting time is based on reading the test results at room temperature. If your room temperature is significantly lower than 10 degrees C, then the interpreting time should be properly extended to another 10 minutes.

**Interpretation of Results**

- A colored line will appear in the left section of the result window to show that the test is working properly. This line is the Control Line ("C").
- The right section of the result window indicates the test results. If a colored line appears in the right section of the result window, this line is the Test Line ("T").

**Negative Result:**

The presence of only one purple colored line in the control area ("C") with no colored line in the test area ("T") indicates a negative result.

**Positive Result:**

The presence of two colored lines ("T"-line and "C"-line) within the result window, no matter which line appears first, indicates a positive result for TP antibodies.

**Invalid Result:**

If there is no distinct control line ("C") visible in the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the test be repeated with a new device.

**Quality Control**

A purple colored line should always appear in the control area ("C") if the test has been performed correctly and the device is working properly.

**Expected values**

The Cypress Diagnostics Syphilis Quick test has been compared with a leading commercial TPHA syphilis test. The overall accuracy is greater or equal to 99,0%.

**Limitations of the Procedure**

- The Cypress Diagnostics Syphilis Quick Test will only indicate the presence of TP antibodies in the sample and should not be used as the sole criteria for the diagnosis of TP infection.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- If the test result is negative and clinical symptom still 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**

**Sensitivity and specificity**

The Cypress Diagnostics Syphilis Quick test has been tested with positive and negative clinical samples tested by a leading commercial TPHA syphilis test. The result shows that the Cypress Diagnostics Syphilis Quick test is very accurate to TPHA.

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Relative sensitivity : 99.3% (152/153)
Relative specificity : 99.5% (209/210)

**Precision**

Within-run and between-run precisions have been determined by the testing 3 replicates of 6 samples: a negative, a low positive, 2 medium positive and 2 strong positive. All values were correctly identified 100% of the time.

**Bibliography**


Langdorp, 07.2008