Syphilis Test Cassette

For Professional Use
Specimen: Serum/Plasma
Format: Cassette

Intended Use

Syphilis Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies to Treponema Pallidum (TP) in 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 bacterium with an outer envelope and a cytoplasmic membrane. Relatively little is known about the organism in comparison with other bacterial pathogens. According to the Center for Disease Control (CDC), the number of cases of syphilis infection has markedly increased since 1985. Some key factors that have contributed to this rise include the crack cocaine epidemic and the high incidence of prostitution among drugs user. One study reported a large number of HIV-infected females exhibited reactive syphilis serological test results.

Multiple clinical stages and long periods of latent, asymptomatic infection are characteristic of syphilis. Primary syphilis is defined by the presence of a chancre at the site of inoculation. The antibodies response to the TP bacterium can be detected within 4 to 7 days after the chancre appears. The infection remains detectable until the patient receives adequate treatment.

Principle

Syphilis Test contains a qualitative membrane strip based immunoassay for the detection of TP antibodies in serum or plasma. In this test procedure, recombinant syphilis antigen is immobilized in the test line region of the device. After a serum or plasma specimen is dropped to the sample well, it reacts with antigen coated gold particles that have been applied to the sample pad. This mixture migrates chromatographically along the length of the test and interacts with the immobilized syphilis antigen. If the specimen contains TP antibodies, a colored line will appear in the test region indicating a positive result. If the specimen does not contain TP antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Precautions

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as if they contained infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- The test procedure must be followed carefully.

Storage and Stability

The kit can be stored at temperature (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

Specimen Collection and Preparation

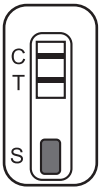
- Syphilis Test (Serum/Plasma) can be performed using either serum or plasma.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimen has been collected. Do not leave the specimen at room temperature for prolonged period. Specimen may be stored at 2-8°C for up to 3 days. For long-term storage, specimen should be kept below -20°C.
- Bring specimen to room temperature (15-30°C) prior to testing. Frozen specimen must be completely thawed and mixed well prior to testing. Specimen should not be frozen and thawed repeatedly.
- If specimen is to be shipped, it should be packed in compliance with national regulations covering the transportation of etiologic agents.

Test Procedure

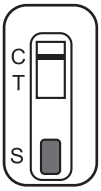
Allow the test device, specimen come to room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 2 drops of serum or plasma to the sample well of the test device.
3. Wait for the red line to appear. The result should be read between 10-20 minutes. Do not interpret the result after 20 minutes.
   Caution: The above interpreting time is based on reading the test results at room temperature range of 15-30°C. If your room temperature is significantly lower than 15 °C, then the interpreting time should be properly increased to 30 minutes.

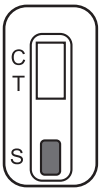
Interpretation of Results



Positive
Two red lines are visible in the control ("C") and test ("T") areas of the test window. The intensity of the test line may be weaker or darker than that of the control line; this still means positive result.



Negative
The control line appears in the test window, but the test line is not visible.



Invalid
The test is invalid if the control line is not visible. The test failed, or the test procedure was not followed properly. Verify the test procedure and repeat the test with a new test device.

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

Quality Control

A procedural control is included in the test. A red line appearing in the control region (C) is considered as an internal procedural control. It confirms sufficient specimen volume 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 proper test performance.

Limitation of The Procedure

1. Syphilis Test is for in vitro diagnostic use only. The test should be used for the detection of TP antibodies in serum or plasma specimen only. Neither the quantitative value nor the rate of increase in TP antibodies can be determined by this qualitative test.
2. Syphilis Test will only indicate the presence of TP antibodies in the specmen and should not be used as the sole criteria for the diagnosis of TP infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptom is persist, additional testing using other clinical methods is recommended. A negative result does not preclude the possibility of TP infection at any time.

Expected Values

Syphilis Test has been compared with a leading commercial TPPA syphilis test, demonstrating an overall accuracy greater or equal to 98%.

Performance Characteristics

Reference		TP Test Device		Total Results
Method	Result	Positive	Negative	
Commercial ELISA	Positive	144	2	146
	Negative	5	527	532
Total Results		149	529	678

Sensitivity
Syphilis Test has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial TPPA syphilis test using clinical specimens. The results show that the relative sensitivity of the Syphilis Test is 98. 6%.

Specificity
Syphilis Test uses an antigen that is highly specific for detecting TP antibodies in serum or plasma. The results show that the relative specificity of the Syphilis Test is 99.1 %.
Relative Sensitivity: 98. 6%
Relative Specificity: 99.1%

Precision
Within-run precision has been determined by using 15 replicates of three specimens: a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified 99% of the time.

INDEX OF SYMBOLS

	Do not re-use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use-by date
	Store at 2-30℃		Contains sufficient for <n>tests
	Caution	REF	Catalogue number
	Consult instructions for use		

Materials Provided

1.Syphilis Test Cassettes
2. Instruction for Use
3. Buffer
4. Pipette
5. Sterile lancet
6. Alcohol wipes