todylaboratories®

Rapid Tests

CE IVD REF C61RT1002

Syphilis Rapid Test Cassette (Serum/Plasma) Package Insert

A rapid test for the diagnosis of Syphilis to detect antibodies (IgG and IgM) to *Treponema Pallidum* (TP) qualitatively in serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The Syphilis Rapid Test Cassette (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) 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.[1] Relatively little is known about the organism in comparison with other bacterial pathogens. According to the Center for Disease Control (CDC), the numbers of cases of Syphilis infection has markedly increased since 1985.[2] Some key factors that have contributed to this rise include the crack cocaine epidemic and the high incidence of prostitution among drug users. One study reported a substantial epidemiological correlation between the acquisition and transmission of the HIV virus and Syphilis. 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.[3]
The Syphilis Rapid Test Cassette (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 serum or plasma.

PRINCIPLE

The Syphilis Rapid Test Cassette (Serum/Plasma) is a qualitative membrane based immunoassay for the detection of *TP* antibodies (IgG and IgM) in serum or plasma. In this test procedure, recombinant Syphilis antigen is immobilized in the test line region of the test. After specimen is added to the specimen well of the test Cassette, it reacts with Syphilis antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized Syphilis antigen. The double antigen test format can detect both IgG and IgM in specimens. If the specimen contains *TP* antibodies, a colored line will appear in the test line 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 in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains Syphilis antigen coated particles and Syphilis antigen coated on the membrane.

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 or test cassettes are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain 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.
- Theusedtestshouldbediscardedaccordingtolocalregulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°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 FREEZE.** Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION

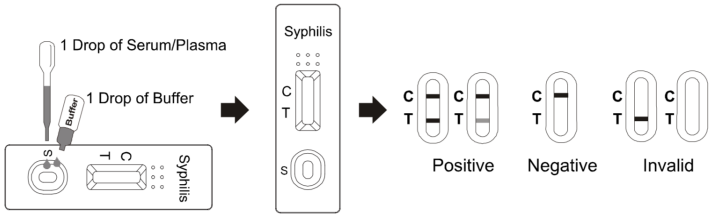
- The Syphilis Rapid Test Cassette (Serum/Plasma) can be performed using serum or plasma. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. 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. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS

Materials provided
• Test Cassettes • Package Insert • Buffer • Dropper
Materials required but not provided
• Specimen Collection Containers • Centrifuge • Timer • Test tubes

DIRECTIONS FOR USE

Allow the test, specimen and/or controls to reach room temperature (15-30°C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the cassette on a clean and level surface. Hold the dropper vertically and transfer 1 drop of serum or plasma (approx.40ul) to the specimen well of the test cassette, then add 1 drop of buffer (approx. 40ul) and start the timer. Avoid trapping air bubbles in the specimen well.
3. Wait for color line(s) appear. Read the result at 5 minutes, do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)
POSITIVE:* Two distinct colored lines appear. One colored line should be in the control line region (C) and another apparent red line should be in the test line region (T).
***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 color in the test line region (T) should be considered positive.
NEGATIVE: One colored line appears in the control region (C). No apparent red or pink 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 using the test cassette immediately and contact your local distributor.

QUALITY CONTROL

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 test cassette; 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.

LIMITATIONS

1. The Syphilis Rapid Test Cassette (Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of *TP* antibodies in serum or plasma specimens only. Neither the quantitative value nor the rate of increase in *TP* antibodies can be determined by this qualitative test.
2. The Syphilis Rapid Test Cassette (Serum/Plasma) will only indicate the presence of *TP* antibodies in the specimen 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 symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *TP* infection.

EXPECTED VALUES

The Syphilis Rapid Test Cassette (Serum/Plasma) has been compared with a leading commercial TPPA Syphilis test, demonstrating an overall accuracy greater than or equal to 99.9%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity
The Syphilis Rapid Test Cassette (Serum/Plasma) 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 Rapid Test Cassette (Serum/Plasma) is >99.9% and the relative specificity is 99.8%.

Method		TPPA		Total Result
Syphilis Rapid Test Cassette(Serum/Plasma)	Results	Positive	Negative	
	Positive	150	1	151
	Negative	0	599	599
Total Result		150	600	750

Relative sensitivity: >99.9% (95%CI*: 98.0%~100.0%);
Relative specificity: 99.8% (95%CI*: 99.1%~100.0%);
Accuracy: 99.9% (95%CI*: 99.3%~100.0%).
*Confidence Intervals

Precision
Intra-Assay
Within-run precision has been determined by using 15 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.
Inter-Assay
Between-run precision has been determined by 15 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the Syphilis Rapid Test Cassette (Serum/Plasma) have been tested over a 3-day period using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.
Cross-reactivity
The Syphilis Rapid Test Cassette (Serum/Plasma) has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, HCV, HIV, H. Pylori, MONO, CMV, Rubella and 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: 2g/dL
Creatin: 200 mg/dL	Caffeine: 20 mg/dL	Gentisic Acid: 20 mg/dL
Albumin: 2 g/dL	Hemoglobin 1.1 mg/dL	Oxalic Acid: 600mg/dL
Bilirubin: 1g/dL		

None of the substances at the concentration tested interfered in the assay.

BIBLIOGRAPHY

1. Fraser CM. Complete genome sequence of Treponema Pallidum, 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. Johnson PC. Testing for Syphilis. Dermatologic Clinic (1994); 12 Jan: 9-17.
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Tody Laboratories Int. SRL
22 Vadul Moldovei, s1, OP 18, Bucharest, CP 014033, ROMANIA
+4021 269 00 00 +4021 269 06 41
ISO 15189, 17043, 9001, 13485
www.todylaboratories.com