ASPEN® Syphilis

Syphilis Rapid Test Strip (Serum/Plasma/WB) Package Insert

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

INTENDED USE

The Aspen Syphilis Rapid Test strip (Serum/Plasma/Whole blood) is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to Treponema Pallidum (TP) in serum, plasma or whole blood 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 number 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 strip (Serum / Plasma / whole blood) 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 / plasma / whole blood.

PRINCIPLE

The Aspen Syphilis Rapid Test strip (Serum /Plasma /Whole blood) is a qualitative membrane based immunoassay for the detection of TP antibodies (IgG and IgM) in whole blood, 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 strip, 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.

REAGENT

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 use test if pouch is damaged.
- Do not eat, drink or smoke in the area where the specimens or test strips are handled.
- 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, disposable gloves and eye protection when specimens are assayed.
- The used tests, specimens and potentially contaminated materials should be discarded according to the local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

The test is stable through the expiration date printed on the sealed pouch 2-30°C. DO NOT FREEZE. Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The Aspen Syphilis rapid test strip can be performed using Serum / Plasma / Whole blood.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimen at room temperature for prolonged periods. 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 specimen to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimen should not be frozen and thawed repeatedly.

MATERIAL PROVIDED

- Test strips
- Droppers
- Strip support
- Buffer
- Package insert

Material required but not provided

Specimen Collection containers, Centrifuge, Timer, Test tubes

DIRECTIONS FOR USE

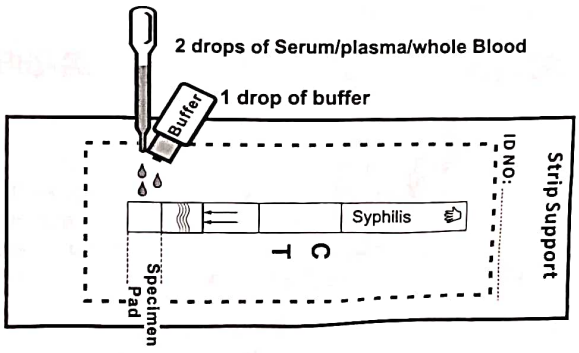
Note: Bring the test device, specimen and buffer to the room temperature if stored at 2-8°C.

Remove the strips from the sealed pouch.

- Peel off the tape from the strip support and stick the test strip in middle of the strip support as shown in below picture.

1. Add **2 drops** (50µl) of **Serum/ Plasma / Whole blood** to the specimen pad of the test strip using dropper/ pipette.

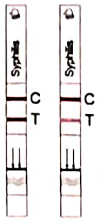
2. Add **1 drop** of **buffer** (40µl). Read result at **10 minutes**. (Do not interpret the result after 30 minutes).



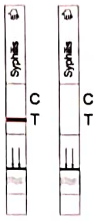
INTERPRETATION OF RESULTS

NEGATIVE : Pink/Purple line at **C** only

POSITIVE : Pink/Purple lines at **C & T**



INVALID : If control line does not appear, the test is invalid. In this case, please repeat the test using another device following the test procedure correctly.



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 adequate membrane wicking.

LIMITATIONS

1. The Aspen Syphilis Rapid Test strip (Serum /Plasma /Whole blood) is for in vitro diagnostic use only. The test should be used for the detection of TP antibodies in serum, plasma or whole blood specimens only. Neither the quantitative value nor the rate of increase in TP antibodies can be determined by this qualitative test.
2. The Aspen Syphilis Rapid Test strip (Serum /Plasma /Whole blood) 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 Aspen Syphilis Rapid Test Strip (Serum/Plasma/Whole blood) has been compared with a leading commercial TPPA Syphilis test, demonstrating an overall accuracy greater than or equal to 99.8%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Aspen Syphilis Rapid Test strip (Serum /Plasma /Whole blood) has correctly identified specimens of a performance 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 strip is >99.9% and the relative specificity is 99.7%.

Method	TPPA			Total Result
Aspen Syphilis Rapid Test Strip(serum/Plasma/WB)	Results	Positive	Negative	
	Positive	130	1	131
	Negative	0	299	299
Total Result		130	300	430

Relative sensitivity: >99.9% (95%CI*: 97.7%~100.0%);
Relative specificity: 99.7% (95%CI*: 98.2%~100.0%);
Accuracy: 99.8% (95%CI*: 98.2%~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 strip (Serum/Plasma/WB) 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 Aspen Syphilis Rapid Test Strip (Serum/Plasma/WB) 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	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 2g/dL	Albumin: 2 g/dL
Creatin: 200 mg/dL	Hemoglobin 1.1 mg/dL
Bilirubin: 1g/dL	Oxalic Acid: 600mg/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 HIVinfected 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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