Syphilis Cassette SPW Test
Frequently Asked Questions (FAQ)

Q: How does the test work?
A: The Syphilis Rapid Test Cassette is a qualitative membrane based immunoassay for the detection of *Treponema Pallidum* (TP) antibodies (IgG and IgM) in whole blood, serum, or plasma. After a specimen is added to the specimen pad it reacts with Syphilis antigen coated particles that have been applied to the specimen pad. 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.

Q: What can this test help diagnose?
A: This test can help diagnose Syphilis infection caused by the *Treponema Pallidum* bacteria. The test uses Treponemal antibodies, the presence of which indicates a current or previous infection. A positive result indicates the presence of Treponemal antibodies, but further testing will be needed to confirm results.

Q: Can fingerstick blood be used for this test?
A: Yes, however whole blood collected by fingerstick should be tested immediately.

Q: Are there any limitations to this test?
A: Neither the quantitative value nor the rate of increase in *TP antibodies* can be determined by this qualitative test.

- The Syphilis Rapid Test Cassette 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.
- 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 symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *TP* infection.

Q: How accurate is the test?
A: The Syphilis Rapid Test Cassette has been evaluated in a clinical study in which it was compared with another leading commercial rapid test, demonstrating an overall accuracy of 99.4%. It features a relative sensitivity of 99.9% and relative specificity of 99.1%.

Q: How do I know that the test was run properly?
A: 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.

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