

Science with a Mission, Inc. (SMI)  
602 Massapoag Avenue  
Sharon, MA 02067  
Tel. or Fax (781) 784-6907

Web Address: [www.sciencewithamission.org](http://www.sciencewithamission.org)

### Syphilis Test Cassette (Whole Blood)

*A rapid test for the diagnosis of syphilis by detection of antibodies to *Treponema pallidum* (TP) in serum, plasma or whole blood.*

*For professional in vitro diagnostic use only.*

#### Intended Use

The SMI Syphilis Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of antibodies 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.<sup>1</sup> 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.<sup>2</sup> 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 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.<sup>3</sup>

The SMI Syphilis Test Device utilizes a combination

of syphilis antigen coated particle and syphilis antigens to detect TP antibodies qualitatively and selectively in serum, plasma or serum.

#### Principle

This test is a qualitative membrane assay based on an immunoassay for the detection of TP antibodies in serum, plasma or whole blood. In this test procedure, syphilis antigens are immobilized in the test line region of the device. After adding serum, plasma or whole blood specimen to the test device, the specimen reacts with syphilis antigen coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test device and interacts with the immobilized syphilis antigens. 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 at the control line region if the test has been performed properly.

#### Reagents

The test device 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 kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing 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 being tested.
- Humidity and temperature can adversely affect results.

#### Storage & Stability

The kit can be stored at room temperature or refrigerated (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.

#### Materials

##### Materials provided:

- Test cassette
- Instructions
- 20uL transfer pipette
- Buffer

##### Materials required but not provided:

- Centrifuge (for serum or plasma samples)
- Timer

#### Specimen Collection & Preparation

- This Syphilis test can be performed using serum, plasma or whole blood.
- 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 specimens have been collected. Do not leave the specimens 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 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 federal regulations covering the transportation of etiologic agents.

#### Directions for Use:

**Allow the test device, serum, plasma or whole blood specimen to equilibrate 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. Add 20 µL of serum / plasma or whole blood

specimen to the sample well (S) using the transfer pipette. Follow this with 1 drop (approximately 30 µL) of buffer.

3. Start the timer and wait for the red line(s) to appear.

The result should be read between 15 and 20 minutes. It is important that the background is clear before the result is read.

### Interpretation of Results:

(Please refer to illustration)

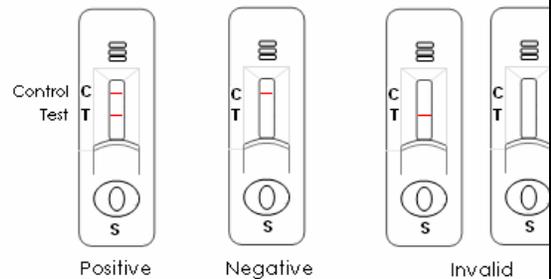
**POSITIVE\*: Two distinct red lines appear.** One line should be in the control region (C) and another line should be in the test region (T).

\* **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 in the test region (T) should be considered positive.

**NEGATIVE: One red line appears in the control region (C).** No apparent red or pink line appears in the test 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 Device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



**Note:** Low titers of *TP* antibodies might result in a faint line appearing in the test region (T) after a prolonged time. Do not interpret the result after 30 minutes.

### Quality Control

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required.

### Limitations

1. The SMI Syphilis Test Device is for the detection of *TP* antibodies in serum, plasma or whole blood. This test is for *in vitro* diagnostic use only. Neither the quantitative value nor the rate of increase in *TP* antibodies can be determined by this qualitative test.
2. This Test Device 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 AZOG One-Step Syphilis Test (precursor to our test) has been compared with a leading commercial FTA-ABS syphilis test, demonstrating an overall accuracy greater or equal to 98%.

### Bibliography

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5. Romanowski, B, E. Forsey, et.al, "Detection of *Treponema Pallidum* by a fluorescent monoclonal antibody test", *Sex Trans Dis* 1987; 14 (3): 156-9.
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