

## One Step Rapid Test for Syphilis/TP MaxLINE Syphilis/TP Rapid Strip Test Serum/Plasma Test Protocol

### ORDERING INFORMATION

Ref. No.	Pack Size
AVSYPST-25	25 Tests
AVSYPST-50	50 Tests
AVSYPST-100	100 Test

**NOTE : 25T, 50T Pack Sizes are not available for domestic trade.**

### INTENDED USE

The Syphilis/TP Rapid Test Strip (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.

### PRODUCT FEATURES :

1. Lateral Flow Immuno Chromatography Assay.
2. Double Antigen Sandwich Principle.
3. Detects IgA, IgM, IgG Antibodies.
4. Uses *Treponema* specific recombinant Antigens .
5. Relative sensitivity : 99.7%
6. Relative specificity: 99.6%
7. Accuracy : 99.7%
8. Has been compared with a leading commercial TPHA Syphilis test demonstrating the over all accuracy greater than equal to 99.7%.

### INTRODUCTION

*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 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 antibody 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. The Syphilis Ultra Rapid Test Strip (Serum/ Plasma) utilizes a double antigen combination of a Syphilis antigen coated particle and Syphilis antigen immobilized on the membrane to detect TP antibodies (IgA, IgM and IgG) qualitatively and selectively in serum or plasma.

### PRINCIPLE

The Syphilis / TP Rapid Test Strip (Serum/ Plasma) is a qualitative membrane strip based immunoassay for the detection of TP antibodies (IgA, IgM and IgG) in serum or plasma. In this test procedure, recombinant Syphilis antigen is immobilized in the test line region of the strip. 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 strip and interacts with the immobilized Syphilis antigen. The double antigen test format can detect both IgA, IgM and IgG in specimens. If the specimen contains TP antibodies, a red line will appear in the test line region, indicating a positive result. If the specimen does not contain TP antibodies, a red line will not appear in this region, indicating a negative result. To serve as a procedural control, a pink line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

### STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (4-30°C). The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

### KIT CONTAINS

Ref. No.	Pack Size	Test Strip	Product Insert
AVSYPST-25	25 Tests	25 Nos.	1 No.
AVSYPST-50	50 Tests	50 Nos.	1 No.
AVSYPST-100	100 Tests	100 Nos.	1 No.

### MATERIALS

#### 1. Materials Provided

Each kit contains :

- a) Individually packed test strip
- b) Product insert

#### 2. Materials Required But Not Provided

- Specimen collection containers
- Centrifuge (for serum/ plasma separation only)
- Stop Watch

### 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 all procedures and follow 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.

### SPECIMEN COLLECTION AND PREPARATION

- The Syphilis / TP Rapid Test Strip (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.

### TEST PROCEDURE

1. Allow the test strip, specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
2. Remove the test strip from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one Hour.
3. For **Serum or Plasma** specimens: Dip the Strip in to the serum/Plasma Sample vertically for (approximately 10 Second).

### ILLUSTRATION



Wait for the red line(s) to appear. The result should be read at 5-20 minutes. Do not interpret the result after 25 minutes.

### INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

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

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

#### QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is considered 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.

#### EXPECTED VALUES

The Syphilis / TP Rapid Test Strip (Serum/ Plasma) has been compared with a leading commercial TPHA Syphilis test, demonstrating an overall accuracy greater than or equal to 99.7%.

#### PERFORMANCE CHARACTERISTICS

##### Sensitivity

The Syphilis / TP Rapid Test Strip (Serum/ Plasma) has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial TPHA Syphilis test using clinical specimens. The results show that the relative sensitivity of the Syphilis Rapid Test Strip (Serum/Plasma) is 99.7%.

##### Specificity

The Syphilis / TP Rapid Test Strip (Serum/Plasma) uses an antigen that is highly specific for TP antibodies in whole blood, serum or plasma. The results show that the relative specificity of the Syphilis Rapid Test Strip (Serum/Plasma) is 99.6%.

Method	TPHA		Total Results
	Positive	Negative	
Syphilis Test Device	Results Positive	384	386
	Negative	1	493
Total Results		385	495

Relative Sensitivity: 99.7%

Specificity: 99.6% Relative Accuracy: 99.7%

\* 95% Confidence Interval

#### Precision

##### Intra-Assay

Within-run precision has been determined by testing 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.

##### Inter-Assay

Between-run precision has been determined by testing 15 replicates on the same three specimens : a negative, a low positive and a high positive. Three different lots of the Syphilis Ultra Rapid Test Strip (Whole Blood/Serum/Plasma) have been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 99% of the time.

#### 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.

#### DISCLAIMER:

The manufacturer has take every precaution to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by user error and/or environmental factors. A person who is the subject of the diagnosis should consult a clinician for further confirmation of the result.

#### WARNING:

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

#### LIMITATION OF THE PROCEDURE















- The Syphilis / TP Rapid Test Strip (Serum/ Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of TP antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in TP antibodies can be determined by this qualitative test.
- The Syphilis / TP Rapid Test Strip (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.
- 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.

#### REFERENCE

- Claire M. Fraser. Complete genome sequence of *Treponema Pallidum*, the Syphilis spirochete, Science 1998; 281 July: 375-381.

Relative

#### Symbols Used on Pack

	Catalogue Number		Warning/Caution
	Batch No.		In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Do Not Reuse		Contains sufficient no. of test



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