One Step Rapid Test for Syphilis/TP

MaxLINE Syphilis/TP Rapid Test

Serum/Plasma/Whole Blood Test Protocol

ORDERING INFORMATION

Ref. No.	Pack Size
AVSYPWB-10	10 Tests
AVSYPWB-20	20 Tests
AVSYPWB-25	25 Tests
AVSYPWB-30	30 Tests
AVSYPWB-50	50 Tests

NOTE : 10T, 20T, 25T, 30T Pack Sizes are not available for domestic trade.

INTENDED USE

The Syphilis/TP Rapid Test Device (Whole blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgA, IgM, IgG) to Treponema Pallidum (TP) in whole blood/serum/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. Relative Accuracy : 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 Device (Whole blood/Serum/Plasma) utilize a double antigen combination of a Syphilis antigen coated particle and Syphilis antigen immobilized on membrane to detect TP antibodies (IgA/IgG/IgM) qualitatively and selectively in (Whole blood/Serum/Plasma).

PRINCIPLE

The Syphilis *TP* Rapid Test Device (Whole blood/Serum/Plasma) is a qualitative membrane device based immunoassay for the detection of *TP* antibodies (IgA/IgG/IgM) in Whole blood/Serum/Plasma. In this test procedure, recombinant Syphilis antigen is immobilized in the test line region of the device. After a specimen is added to the specimen well of the device, it reacts with Syphilis antigen coated particles in the test. 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/IgG/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.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (4-30°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 after the expiration date.

KIT CONTAINS

Ref. No.	Pack Size	Test Device	Buffer Vial	Product Insert
AVSYPWB-10	10 Tests	10 Nos.	1 No.	1 No.
AVSYPWB-20	20 Tests	20 Nos.	1 No.	1 No.
AVSYPWB-25	25 Tests	25 Nos.	1 No.	1 No.
AVSYPWB-30	30 Tests	30 Nos.	2 Nos.	1 No.
AVSYPWB-50	50 Tests	50 Nos.	3 Nos.	1 No.

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.
- 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 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 Device (Whole blood/Serum/Plasma) can be performed using Whole blood/Serum/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 devices
- Droppers
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- Package insert

Materials Required But Not Provided

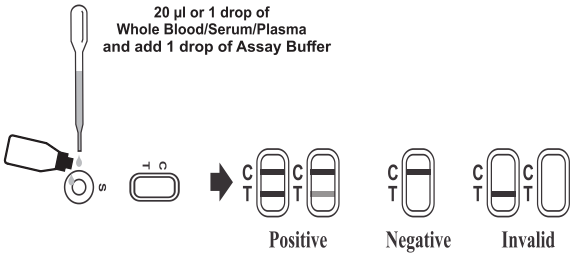
- Specimen collection containers
- Centrifuge (for serum/ plasma separation only)
- Timer

TEST PROCEDURE

1. Allow the test device, specimen, and/or controls to reach room temperature (15-30°C) prior to testing.
2. Remove the test device 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. Place the device on a clean and level surface.
4. For **Whole Blood/Serum/Plasma** specimens: Hold the dropper vertically and transfer 1 drops of Whole blood/Serum/Plasma (approximately 20 µL) into the specimen well (S) of the test device and then add 1 drop of Assay Buffer (approximately 35µL) and start the timer. See illustration below.

INTERPRETATION OF RESULTS

(Please refer to the below illustration)



Wait for the colored line(s) to appear. Read results at 5-20 minutes. Do not read results after 25 minutes.

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

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

NEGATIVE: One colored line appears in the control line region ©. No 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 device. 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 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 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 Device (Whole Blood/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

Clinical Sensitivity, Specificity and Accuracy

The Syphilis /*TP* Rapid Test Device (Whole Blood/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 /*TP* Rapid Test Device (Whole Blood/Serum/Plasma) is 99.7%, and the relative specificity is 99.6%.

Syphilis / *TP* Rapid Test Device vs. TPHA

Method		MaxLINE Syphilis / TP		TPHA		Total Result
Syphilis / *TP* Rapid Test Device	Results	Positive	Negative	Positive	Negative	
	Positive	384	2	386	0	386
	Negative	1	493	0	494	494
Total Results		385	495	386	494	880

Relative Sensitivity: 99.7%
Relative Specificity: 99 .6%
Relative Accuracy: 99.7%
* 95% Confidence Interval

PRECISION

Intra-Assay

Within-run precision has been determined by testing 10 replicates of four specimens : a negative, a low positive, middle positive and a high positive. The negative, low positive, middle positive and high positive values were correctly identified 99% of the time.

Inter-Assay

Between-run precision has been determined by testing 10 replicates on the same four specimens : a negative, a low positive, middle positive and a high positive. Three different lots of the Syphilis Ultra Rapid Test Device (Whole Blood/Serum/Plasma) have been tested over a 3-month period using negative, low positive, middle 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.

LIMITATIONS

1. The Syphilis / *TP* Rapid Test Device (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of TP antibodies in Whole blood/Serum/Plasma specimens only. neither the quantitative value nor the rate of increase in TP antibodies can be determine by this qualitative test.
2. The Syphilis / *TP* Rapid Test Device (Whole Blood/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.

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.

REFERENCE

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

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	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
2	Do Not Reuse	Σ	Contains sufficient no. of test

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