Syphilis Ab Rapid Test Device (Serum/Plasma)

IVD For professional *in vitro* diagnostic use only.

Store at 2-30°C

CE

INTENDED USE

The Syphilis Ab Rapid Test Device is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies including IgG and IgM to *Treponema pallidum* (*TP*) in human serum or plasma to aid in the diagnosis of infection with *TP*.

INTRODUCTION

Syphilis is a disease caused by infection with the spirochete *Treponema pallidum*. The infection is systemic and the disease is characterized by periods of latency. These features, together with the fact that T pallidum cannot be isolated in culture, mean that serologic techniques play a major role in the diagnosis and follow-up of treatment for syphilis.

Syphilis is categorized by an early primary infection in which patients may have non-specific symptoms, and potentially, genital lesions. Patients tested by serology during the primary phase may be negative for antibodies, especially if testing is performed during the first 1 to 2 weeks after symptom onset. As the disease progresses into the secondary phase, antibodies to T pallidum reach peak titers, and may persist indefinitely regardless of the disease state or prior therapy. Therefore, detection of antibodies to nontreponemal antigens, such as cardiolipin (a lipoidal antigen released by host cells damaged by T pallidum) may help to differentiate between active and past syphilis infection. Nontreponemal antibodies are detected by the rapid plasma reagin (RPR) assay, which is typically positive during current infection and negative following treatment or during late/latent forms of syphilis.

The Atlas Syphilis Rapid Test Device (Serum/Plasma) 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 or plasma.

PRINCIPLE

The Syphilis Rapid Test Cassette (Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of TP antibodies (IgG and IgM) in 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 Device, 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.

MATERIALS

MATERIALS PROVIDED

- Test devices (Contains Syphilis antigen coated particles and Syphilis antigen coated on the membrane).
- Buffer
- Plastic Dropper.
- Package insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen Collection containers.
- Timer.
- Centrifuge.
- Test tubes.

PACKAGEING CONTENT

REF **8.04.42.0.0001 (1 Test cassette, Buffer)**

REF **8.04.42.0.0020 (20 Test cassette, 1x3 ml Buffer)**

REF **8.04.42.0.0025 (25 Test cassette, 1x3 ml Buffer)**

REF **8.04.42.0.0030 (30 Test cassette, 1x3 ml Buffer)**

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.
- Do not use the test if the label was not available or damaged.
- All specimens should be considered potentially hazardous and in the same manner as infectious agent.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Autoclave the used test and it should be discarded according to local regulations.
- The test should be performed in a well-lit area.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C).
- The test is stable through the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION

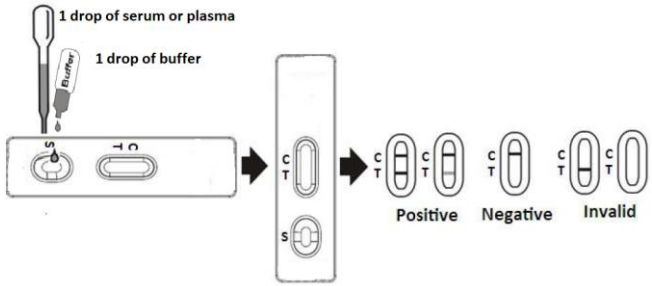
- Atlas Syphilis Rapid Test Device (Serum/Plasma) can be performed using serum or plasma samples.
- Plasma shall be collected with tube containing sodium heparin.
- Serum shall be collected with no anticoagulant tubes.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens.
- Testing shall 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.

PROCEDURE

Do not open pouch until you are ready to test the sample.

- **Allow test device, serum/plasma specimen, and/or controls to equilibrate to room temperature (15-30°C.) prior to testing.**

1. Remove the test device from the sealed pouch and use it as soon as possible. Place the test device on a clean and level surface.
2. Hold the dropper vertically and transfer **1 drop of serum or plasma (approximately 40 µL)** to the specimen area of the test device, then add **1 drop of Buffer (approximately 40 µL)** and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at **5 minutes**. Do not interpret the result after **20 minutes**.



INTERPRETATION OF RESULTS

1. **NEGATIVE RESULT**: If only the C line is developed, the test indicates that no detectable anti-*TP* antibodies in the specimen. The result is negative or non-reactive.
2. **POSITIVE RESULT**: If the both C and T lines are developed, the test indicates the presence of anti-*TP* antibodies in the specimen. The result is positive or reactive.

   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.
3. **INVALID:** If no C line is developed, the assay is invalid regardless of color development on the T line as indicated below. Repeat the assay with a new device.

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.

LIMITATIONS

- Atlas Syphilis Rapid Test Device (Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of *TP* antibodies in serum, plasma specimens only. Neither the quantitative value nor the rate of increase in *TP* antibodies can be determined by this qualitative test.
- Atlas Syphilis Rapid Test Device (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.
- The assay should be performed in normal room temperature.

EXPECTED VALUES

Atlas Syphilis Rapid Test Device (Serum/Plasma) 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 Syphilis Rapid Test Device (Serum/Plasma) has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial TPPA (Treponema Pallidum Particle Agglutination) test using clinical specimens. The results show that the relative sensitivity of the Syphilis Rapid Test Device (Serum/Plasma) is >99.9% and the relative specificity is 99.7%.

Syphilis Rapid Test Device vs. TPPA

Method		TPPA		Total Results
Syphilis Rapid Test Device	Results	Positive	Negative	
	Positive	130	1	131
	Negative	0	299	299
Total Results		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 Cassette (Serum/Plasma) 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 Syphilis Rapid Test Device (Serum/Plasma) 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 low positive specimens.

Acetaminophen	20 mg/dL	Caffeine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL	Gentisic Acid	20 mg/dL
Ascorbic Acid	20mg/ml	Albumin	2000mg/dL
Creatine	200 mg/dL	Hemoglobin	1.1 mg/dL
Bilirubin	1000mg/dL	Oxalic Acid	600mg/dL

None of the substances at the concentration tested interfered in the assay.

REFERENCES

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 HIV-infected 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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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry