

Syphilis Strip Rapid Test (Serum / Plasma)

INTENDED USE

First View Syphilis Strip Rapid Test 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.

SUMMARY

Syphilis is a sexually transmitted infection caused by the bacterium *Treponemapallidum*. The signs and symptoms of syphilis depend on one of the four stages (primary, secondary, latent and tertiary). Syphilis is a notify able disease in many countries, including Canada, the European Union and the United States. Syphilis has been serologically diagnosed by anti *Treponemapallidum* Antibody tests with the advantage of having improved specificity. The First View Syphilis Strip Rapid Test was developed to detect antibodies to *Treponemapallidum* antigens in serum/plasma.

PRINCIPLE

After addition of the serum/plasma sample to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with recombinant *Treponemapallidum* specific antigens (15, 17, 47 kDA) and Mouse IgG. If the sample contains detectable levels of the *Treponemapallidum* antibodies, it reacts with the gold conjugated recombinant *Treponemapallidum* specific antigens to form a complex. This complex moves further and reacts with recombinant *Treponemapallidum* specific antigens (15, 17, 47 kDA) pre-coated test line on the nitrocellulose membrane area to form colored band. The mouse IgG conjugated colloidal gold particles move further to the goat anti-mouse IgG coated control area to form a colored band (Control line). The appearance of test line and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control and should always appear if the test is performed as per the procedure and reagents are working properly

REAGENTS AND MATEREIALS PROVIDED

- Test Strips
- Package Insert (Instruction for use)

MATERIALS MAY BE REQUIRED BUT NOT PROVIDED

- Positive Control
- Negative Control

MATERIALS REQUIRED BUT NOT PROVIDE

- Timer
- Digital Clock
- Specimen collection container Tube

WARNINGS AND PRECAUTIONS:

For in Vitro Diagnostic Use

- This package insert must be read completely before performing the test.
- The test device should remain in the sealed pouch until use
- Do not use expired devices.
- Do not use the kit if the cassette package is damaged or the seal is broken.
- Bring all reagent to room temperature (15-30°C) before use.
- Do not use hemolyzed blood specimens for testing.
- Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after performing the test.
- Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
- Dispose of all specimens and material used to perform the test as bio-hazardous waste.

REAGENT PREPARATION AND STORAGE

INSTRUCTIONS: All reagents are ready to use as supplied. Store unused test device unopened at 2-30 °C, ensure that the test device brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperature 30°C.

SPECIMEN COLLECTION, STORAGE AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

1. Plasma

- **Step 1:** Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively, in Vacutainer®) by venipuncture.
- **Step 2:** Separate the plasma by centrifugation.
- **Step 3:** Carefully withdraw the plasma into a new pre-labeled tube.

2. Serum

- **Step 1:** Collect blood specimen into a red top collection tube (containing no anti coagulants in Vacutainer®) by venipuncture.
- **Step 2:** Allow the blood to clot.
- **Step 3:** Separate the serum by centrifugation.
- **Step 4:** Carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting store specimens at 2-8°C if not tested immediately for up to 5 days. The specimens should be frozen at -20°C for longer storage.

DIRECTIONS FOR USE

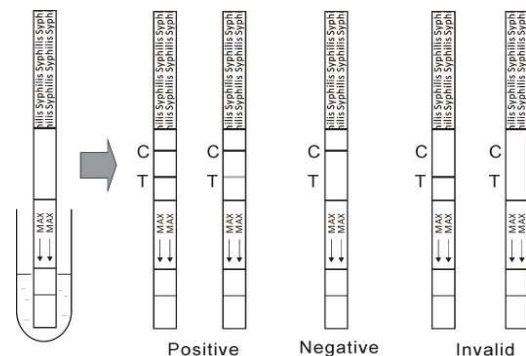
Allow test cassette, specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

- Bring the pouch to room temperature before opening it.
- Remove the test strip from the sealed pouch and use it as soon as possible.
- Collect at least **150µL** of serum or plasma in a sample container
- With arrows pointing toward the specimen, dip the strip into the specimen and start the timer.
- Don't allow the specimen to reach above the maximum level (**MAX**) indicated by the arrows on the strip.
- Wait for the colored line(s) to appear. The test result should be read at 10- 15 minutes.

Note. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

(Please refer to the illustration)



Positive Results:

If both the 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

Negative Results:

If only the C line is developed, the test indicates that no detectable anti-TP antibody is present in the specimen. The result is negative or non-reactive.

Invalid Results:

If No band is visible within the result window after performing the test, the result is considered invalid. It may be due to not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen should be retested using a new test kit.

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 Strip (Serum / Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of *TP* antibodies in serum or plasma specimens only. Neither the quantitative value nor the rate of increase in *TP* antibodies can be determined by this qualitative test.
- This test 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.
- Test strips should be used immediately after being taken from the package. Avoid exposing the test strips in the air for too long before use.
- The strips may be stored under room temperature and dry condition. If refrigerated, the strips should be brought to room temperature before testing.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy: The First View Syphilis Rapid Test Card (Serum/Plasma) has been compared to a leading commercial Syphilis test using clinical specimens. The results show that the relative sensitivity of the First View Syphilis Rapid Test Card (Serum/Plasma) is >99%, and the relative specificity is >99%.

Method		Leading Commercial Syphilis Test	
		Positive	Negative
First View Syphilis Strip Rapid Test	Results		
	Positive	169	1
	Negative	1	259
Total Result		170	260

Relative Sensitivity: 99.4%

Relative Specificity: 99.6%

Over all Agreement: 99.5%

Precision

Intra-Assay: Within-run precision has been determined by using 15 replicates off our specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, Within-run precision has been determined by using 15 replicates off our 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 Strip Rapid Test (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 Strip Rapid Test (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.

3. Interfering Substances

The following potentially interfering substances were added to Syphilis negative and positive specimens.

Acetaminophen	20 mg/dL	Caffeine	20 mg/dL
Acetyl salicylic Acid	20 mg/dL	Gentisic Acid	20 mg/dL
Ascorbic Acid	2g/dL	Albumin	2g/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.

REFERENCES

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- Johnson Phillip C. *Testing for Syphilis*, Dermatologic Clinic 1994; 12 Jan: 9-17