Syphilis Rapid Test Cassette (Serum/Plasma) Package Insert

REF L031-10431	English

A rapid, one step test for the diagnosis of Syphilis to detect antibodies (IgG and IgM) to Treponema Pallidum (TP) qualitatively in serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The Syphilis Rapid Test Cassette (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.

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.[1] 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.[2] 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 that 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 infection 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.[3]

The Syphilis Rapid Test Cassette (Serum/Plasma) utilizes a double antigen combination of a Syphilis antigen coated particles and a Syphilis antigen 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, 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 antigens. If the specimen contains *TP* antibodies, a colored line will appear in the test line region indicating a positive result. The double antigen test can detect both IgM and IgG in specimens. 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.

REAGENTS

The test 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 and 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 the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- 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

- The Syphilis Rapid Test Cassette (Serum/Plasma) can be performed using either serum or plasma.
- 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 local regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

- Test cassettes
- Droppers
- Package insert

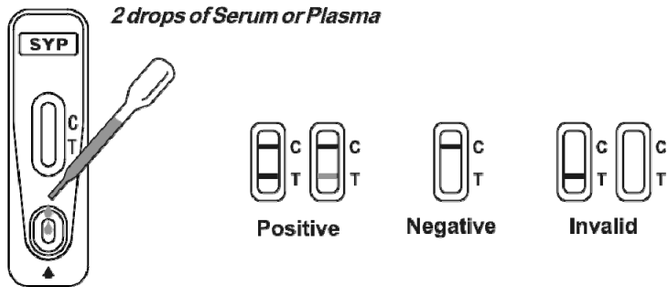
Materials Required But Not Provided

- Specimen collection container
- Centrifuge
- Timer

DIRECTIONS FOR USE

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

1. Remove the test cassette from the foil pouch and use it as soon as possible.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 2 full drops of serum or plasma** (approx. 60 μL) and start the timer. Avoid air bubbles. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes**. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two 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 (C). 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. 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 an internal procedural control. It confirms sufficient specimen volume and correct sample application to the specified specimen well.
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

1. The Syphilis Rapid Test Cassette (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.
2. The Syphilis Rapid Test Cassette (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.

EXPECTED VALUES

The Syphilis Rapid Test Cassette (Serum/Plasma) has been compared with a leading commercial ELISA Syphilis test, demonstrating an overall accuracy greater than or equal to 99.6%.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The Syphilis Rapid Test Cassette (Serum/Plasma) has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial ELISA Syphilis test using clinical specimens. The results show that the relative sensitivity of the Syphilis Rapid Test Cassette (Serum/Plasma) is greater than 99.9%, and the relative specificity is 99.3%.

***Syphilis* Test Cassette vs. ELISA**

Reference		Syphilis ELISA Results		Total Results
Method	**Results**	Positive	Negative	
Syphilis Rapid Test Cassette	Positive	170	2	172
	Negative	0	298	298
Total Results		170	300	470

Relative Sensitivity: 100% (97.9%-100.0%)* Relative Specificity: 99.3% (97.6%-99.9%)*
Accuracy: 99.6% (98.5%-100.0%)* *95% Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 10 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 10 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 using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

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.

Index of Symbols

	Manufacturer	Σ	Tests per kit	2°C 30°C	Store between 2-30°C
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
LOT	Lot Number	REF	Catalog #	EC REP	Authorized Representative

***ACON* Laboratories, Inc.**
10125 Mesa Rim Road,
San Diego, CA 92121, USA

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Number: 1150882801
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