Syphilis Rapid Test Strip (Serum/Plasma) Package Insert

REF L031-10411	English

A rapid test for the qualitative detection of antibodies (IgG and IgM) to Treponema Pallidum (TP) in serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The ACON Syphilis 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.

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.[3] One study reported a substantial epidemiological correlation between the acquisition and transmission of the HIV virus and Syphilis.[4]
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 antibodies 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.[5]
The ACON Syphilis Rapid Test Strip (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 ACON Syphilis Rapid Test Strip (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 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 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.

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 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 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

- The kit can be stored at room temperature or refrigerated (2-30°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 use the components beyond the expiration date.
- **DO NOT FREEZE.**

SPECIMEN COLLECTION AND PREPARATION

- The ACON Syphilis 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.
- 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 strips
- Package insert
- Droppers

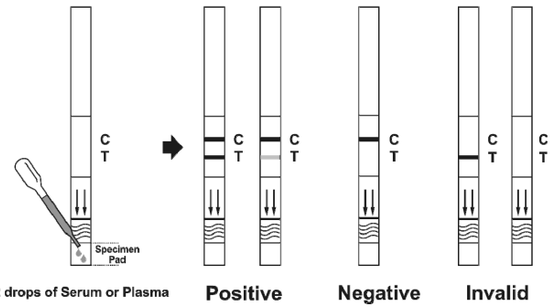
Materials Required But Not Provided

- Specimen collection containers
- Timer
- Centrifuge

DIRECTIONS FOR USE

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

1. Remove the test strip from the foil pouch and use it as soon as possible.
2. Hold the dropper vertically and **transfer 2 drops of serum or plasma** (approximately 60 μL) onto the Specimen Pad of the test strip and start the timer. 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 previous illustration)
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 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

1. The ACON 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.
2. The ACON Syphilis 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.
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 ACON Syphilis Rapid Test Strip (Serum/Plasma) has been compared with a leading commercial Syphilis test, demonstrating an overall accuracy greater than or equal to 99%.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The ACON Syphilis Rapid Test Strip (Serum/Plasma) has been compared to a leading commercial Syphilis test using clinical specimens. The results show that the relative sensitivity of the ACON Syphilis Rapid Test Strip (Serum/Plasma) is >99%, and the relative specificity is >99%.

Method		Leading Commercial Syphilis test		Total Results
Syphilis Test Strip	Results	Positive	Negative	
	Positive	169	1	170
	Negative	1	259	260
Total Results		170	260	430

Sensitivity: 99.4% (96.8%-100%)* Specificity: 99.6% (97.9%-100%)*
Accuracy: 99.5% (98.3%-99.9%)* *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 ACON Syphilis Rapid Test Strip (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. Claire M. Fraser. *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. Aral R. Marx. *Crack, sex and STD*, Sexually Transmitted Diseases, 1991; 18:92-101
4. J.N. Wasserheit. *Epidemiological Synergy: Interrelationships between human immunodeficiency virus infection and other sexually transmitted diseases*, Sexually Transmitted Diseases 1992; 19:61-77
5. Johnson Phillip C. *Testing for Syphilis*, Dermatologic Clinic 1994; 12 Jan: 9-17

Index of Symbols

	Manufacturer	Σ	Tests per kit	30°C / 2°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: 1150875201
Effective date: 2016-05-12