Accu-Screen Syphilis Rapid Test Strip Package Insert

A rapid test for qualitative detection of Syphilis antibodies in Human Serum,Plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The Syphilis Rapid Test Strip is a rapid chromatographic immunoassay for the qualitative detection of antibodies to Treponema Pallidum in serum or plasma.

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.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 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 chancer 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 Rapid Test Strip utilizes a double antigen combination of a syphilis antigen coated particle and syphilis antigen to detect TP antibodies (IgG and IgM) qualitatively and selectively in Serum /Plasma.

PRINCIPLE

The Syphilis Rapid Test Strip is a qualitative membrane strip based immunoassay for the detection of TP antibodies (IgG and IgM) in Serum.In this test procedure,recombinant syphilis antigen is immobilized in the test line region of the strip. After a Serum/Plasma specimen is placed in the specimen well,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 strip and interacts with the immobilized syphilis antigen.If the specimen contains TP antibodies, a colored line will appear in the test line region indicating a positive result.The double antigen test format 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 at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test Strip contains recombinant TP antigen conjugated colloid gold and TP antigen coated the membrane

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test must remain in the sealed pouch until use.
- 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 the testing and follow standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Standard personal hygiene measures should be taken in the case of ingestion or direct eye contact with the buffer.
- 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℃). 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 beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The Syphilis Rapid Test Strip 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.
- 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℃ for up to 3 days. For long term storage,specimens should be kept below -20℃. 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
- Buffer
- Droppers
- Package insert

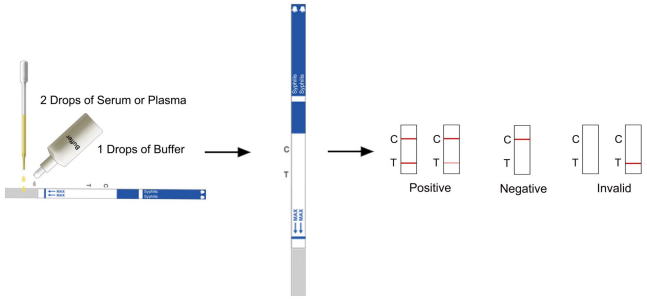
Materials Required But Not Provided

- Specimen collection Containers
- Timer
- Centrifuge
- Heparinized capillary tubes and dispensing bulb

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it.Remove the test Strip from the sealed pouch and use it as soon as possible.
2. Place the Strip on a clean and level surface.
3. Hold the dropper vertically and **transfer 2 drops of serum or plasma (approximately 50μL)** to the specimen area,then **add 1 drops of buffer (approximately 40μL)**,and start the timer.See illustration below.
4. Wait for the colored line(s) to appear.**Read results at 15 minutes.**Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two distinct colored lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).
***NOTE:** The intensity of color in the test line region (T) will vary depending on the concentration of TP antibody present in the specimen.Therefore,any shade in the test region indicates positive result.
NEGATIVE:One colored line appears in the control line region (C). No apparent colored line appears in the test line region (T).
INVALID:No line appears in the control line region (C). If this occurs,read the directions again and repeat the test with a new test. If the result is still invalid,stop 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.
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.

LIMATIONS

1. The Syphilis Rapid Test Strip 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.
2. The Syphilis Rapid Test Strip will only indicate the presence of TP antibodies in the specimen and should not be used as the sole criteria for the diagnosis of Syphilis 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 Strip has been compared with another leading rapid test.The correlation between these two systems is 98%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Syphilis Rapid Test Strip has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial TPPA Treponema Pallidum test using clinical specimens.The results show that the relative sensitivity of the Syphilis Rapid Test Strip is >99.9% and the relative specificity is 99.8%.

Method				Total Results
Syphilis Rapid Test Strip	Results	Positive	Negative	
	Positive	300	0	300
	Negative	0	300	300
Total Results		300	300	600

Relative Sensitivity: >99.0% (99.0%-100.0%)*
Relative Specificity:>99.0% (99.0%-100.0%)*
Accuracy: >99.5% (99.5%-100.0%)*
* Confidence Interval

Intra-Assay

Within-run precision has been determined by using 20 replicates of four different specimens containing different concentrations of TP antibody. The negative,positive values were correctly identified 100% of the time.

Inter-Assay

Between-run precision has been determined by 20 independent assays on the same four different specimens containing different concentrations of TP antibody.Three different lots of Syphilis Rapid Test Strip have been tested over a 3-month period using above negative and positive specimens. The specimens were correctly identified 100% of the time.

Cross-Reactivity

The Syphilis Rapid Test Strip 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 TP antibody 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:	1000mg/dL
Bilirubin:	1g/dL	Oxalic Acid:	60mg/dL

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

BIBLIOGRAPHY

1. Claire M. Fraser. Complete genome sequence of Treponema Pallidum, the Syphilis spirochete, Science 1998; 281 July: 375-381
2. Johnson Phillip C.Testing for Syphilis, Dermatologic Clinic 1994; 12 Jan: 9-17

SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical Strip		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction foe use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC

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CE

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