Syphilis Rapid Test

Specimen: Whole Blood/Serum/Plasma

Package Insert

REF ISY-N402	English

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

【INTENDED USE】

The Syphilis Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to *Treponema Pallidum* (*TP*) in human whole blood, serum or plasma as an aid in the diagnosis of Syphilis.
The product is intended to be used by trained laboratory personnel. For laboratory use only.
The test provides preliminary test results. Negative results will not preclude *Treponema Pallidum* infection and they can't be used as the sole basis for treatment or other management decision.
Not for Self-testing use. Not for near-patient use. Not for blood donor screening.

【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] Syphilis is a systemic human disease due to *Treponema pallidum subsp pallidum* (*T. pallidum*) and classified as acquired or congenital. Acquired syphilis (usually by sexual contact) is divided into early and late syphilis. Early syphilis includes primary, secondary and early latent syphilis. The European Centre for Disease Prevention and Control (ECDC) defines early syphilis (infectious syphilis) as syphilis acquired ≤1 year previously and the World Health Organisation (WHO) as syphilis acquired ≤2 years previously. Late syphilis includes late latent and tertiary syphilis (gummatous, cardiovascular and neurosyphilis).[3]
The Syphilis Rapid Test 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 whole blood, serum or plasma.

【PRINCIPLE】

The Syphilis Rapid Test is a qualitative membrane based immunoassay for the detection of *TP* antibodies (IgG and IgM) in whole blood, 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 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.

【WARNINGS AND PRECAUTIONS】

Please read all the information in this package insert before performing the test.

- For laboratory 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 may adversely affect results.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority.

【STORAGE AND STABILITY】

The kit can be stored 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.
Note: It is suggested to use test cassette within one hour after removing it from the foil pouch.

【SPECIMEN COLLECTION AND PREPARATION】

- The Syphilis Rapid Test can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect **Fingerstick Whole Blood specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 80 μL. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well of the test.
- 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°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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.
- EDTA K2, Heparin sodium, Sodium Citrate and Potassium oxalate can be used as the anticoagulant tube for collecting the blood specimen.

【MATERIALS】

Materials provided

	Kit size	40T/kit	25T/kit
Components	Test cassettes	40	25
	Package insert	1	1
	Droppers	40	25
	Buffer 3 mL (PBS, 0.02% Proclin 300, ⩽0.02% NaN_3, 0.5% Casein-Na)	1	1

Materials required but not provided

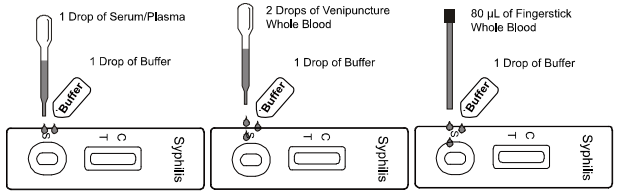
- Specimen collection containers
- Centrifuge
- Timer
- Sterile lancet
- Capillary tube
- Alcohol swab

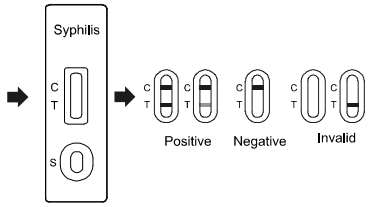
【DIRECTIONS FOR USE】

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

1. Remove the test cassette from the sealed pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the test cassette on a clean and level surface.
   For **Serum or Plasma** specimen: Hold the dropper vertically and **transfer 1 drop of serum or plasma** (approximately 40 μL) to the specimen well, then **add 1 drop of buffer** (approximately 40 μL),and start the timer, see illustration below.
   For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 80 μL) to the specimen well, then **add 1 drop of buffer** (approximately 40 μL), and start the timer. See illustration below.
   For **Fingerstick Whole Blood** specimen:
   - To use a capillary tube: Fill the capillary tube **and transfer approximately 80 μL of fingerstick whole blood specimen** to the specimen well of test cassette, 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.

Note: It is suggested not to use the buffer beyond 6 months after opening the vial.





【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two colored lines appear. One colored line should be in the control line region (C) and another 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.
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.

【LIMITATIONS】

1. The Syphilis Rapid Test is for *in vitro* diagnostic use only. The test should be used for the detection of *TP* antibodies in whole blood, 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 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.
5. The hematocrit of the whole blood should be between 25% and 65%.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

The Syphilis Rapid Test has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. ELISA served as the reference method for the Syphilis Rapid Test. The specimen was considered positive if the ELISA result was positive. The specimen was also considered negative if the ELISA result was negative.

Method		ELISA		Total Results
	Results	Positive	Negative	
Syphilis Rapid Test	Positive	165	1	166
	Negative	1	234	235
Total Results		166	235	401

Relative Sensitivity: 99.4%(95%CI*: 96.7%-100.0%) *Confidence Interval
Relative Specificity: 99.6% (95%CI*: 97.7%-100.0%)
Accuracy: 99.5% (95%CI*: 98.2%-99.9%)

Hook Effect

There is no dose hook effect with the Syphilis Rapid Test.

Precision-Repeatability

Precision-repeatability has been determined by using four specimens: negative, low positive, middle positive and high positive. The study was performed 5 replicates per day for 5 consecutive days by one operator using 1 lot of Syphilis Rapid Test. No difference was detected in intra lot.

Precision-Reproducibility

Precision-reproducibility has been determined by using four specimens: negative, low positive, middle positive and high positive. The study was performed 5 replicates per day for 5 consecutive days in 3 different sites using 3 separate lots of Syphilis Rapid Test (one lot per site), and three operators per site. No difference was detected between days, sites, lots and operators.

Cross-reactivity

The Syphilis Rapid Test has been tested by HAV, HEV, 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 positive specimens.

Acetaminophen: 20 mg/dL	Hemoglobin: 1000 mg/dL
Gentisic Acid: 20 mg/dL	Ascoribic acid: 20 mg/mL
Creatin: 200 mg/dL	Oxalic Acid: 60 mg/dL
Bilirubin: 1000 mg/dL	Uric acid: 20 mg/mL
Caffeine: 20 mg/dL	Aspirin: 20 mg/dL
Methanol: 10%	Human serum Albumin: 2000 mg/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: 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. M. Janier, V. Hegyi, N. Dupin, et al,. *2014 European guideline on the management of syphilis,* J Eur Acad Dermatol Venereol 2014; 28(12):1581-93

Index of Symbols

	Consult instructions for use or consult electronic instructions for use	Σ	Contains sufficient for <n> tests	2°C 30°C	Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community/European Union		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer	UDI	Unique device identifier

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Number: 146305102
Revision Date: 2023-05-19