Syphilis (Tp) Ab Rapid Test Cassette (Colloidal Gold)

Cassette

Instruction for Use

A lateral flow immunochromatographic assay for the qualitative detection of antibodies including IgG, IgM, and IgA to Treponema pallidum (Tp) in human whole blood, serum or plasma.

CE IVD REF

In Vitro Diagnosis
For Professional Use

PACKAGING SPECIFICATION

1T/box,10T/box,20T/box,25T/box,40T/box,50T/box

INTENDED USE

The Syphilis (Tp) Ab Rapid Test Cassette (Colloidal Gold) is a lateral flow immunochromatographic assay for the qualitative detection of antibodies including IgG, IgM, and IgA to Treponema pallidum (Tp) in human whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Tp. The test is recommended for professional use only. All results must be interpreted together with other clinical information or other diagnosis methods available to the physician.

SUMMARY

Syphilis is believed to have infected 12 million people worldwide in 1999, with greater than 90 percent of cases in the developing world.[1] It is a sexually transmitted infection caused by the spirochete bacterium Treponema pallidum (Tp) subspecies pallidum, which is a spiral-shaped, Gram-negative, highly mobile bacterium.[2,3] Serological detection of anti-Tp antibody has been long recognized in the diagnosis of syphilis since the natural course of the infection was characterized by periods without clinical manifestations. Both IgM and IgG antibodies were detected in sera from patients with primary and secondary syphilis. The IgM antibody may be detectable towards the second week of infection, while IgG antibody appears later, at about 4 weeks. These antibodies could last for several years or even decades in the serum of a patient with untreated latent syphilis. The Syphilis (Tp) Ab Rapid Test permits the measurement of antibodies (IgM, IgG and IgA) to recombinant antigens of *Tp* in human whole blood, serum or plasma in a manner of user friendly, highly sensitive and specific without additional instrumentation.

TEST PRINCIPLE

The Syphilis (Tp) Ab Rapid Test Cassette (Colloidal Gold) is a qualitative, membrane based immunoassay for the qualitative detection of antibodies including IgG, IgM, and IgA to *Treponema pallidum* (*Tp*) in human whole blood, serum or plasma.

The membrane of the test strip contained in the cassette is pre-coated with recombinant Tp antigens. During testing, the specimen is added into the sample pad and antibodies to Tp if present will react with Tp antigens coated particles in the membrane strip. The mixture then migrates upwards by capillary action on the membrane and reacts with recombinant Tp antigens on the membrane in the test line (T) region. If the specimen contains IgG, IgM, or IgA antibodies to Tp, a pink test line (T) will appear, indicating a positive result. If the specimen does not contain IgG, IgM, or IgA antibodies to Tp, the test line (T) will not appear, indicating a negative result. The test contains an internal control line (C) which should always exhibit a pink line regardless of the color in the test region. Otherwise, the test result is invalid and the specimen must be retested with a new device.

REAGENTS AND MATERIALS PROVIDED

Test devices. Test cassettes are individually sealed in a foil pouch with a dropper and a package of desiccant.
Assay buffer
Instruction for use

MATERIALS REQUIRED BUT NOT PROVIDED

Clock or Timer
Clean containers for the collection of specimen
Lancets (for fingerstick whole blood only)
Centrifuge (for plasma only)
Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

PRECAUTIONS

1. For professional and IN VITRO diagnostic use only.
2. The test should remain in the sealed pouch until use.
3. Do not use the kit if the foil pouch is punctured or not well sealed.
4. Do not reuse or use kits after the expiration date.
5. Do not mix components from kits with different lot number.
6. Avoid microbial contamination of reagents.
7. Wear gloves during the whole process and avoid reagents or specimen spilling-out. Wash hands thoroughly afterwards.
8. Handle all specimens as if they contain infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving for at least one hour. Alternatively, treat with a 0.5 or 1% solution of sodium hypochlorite for one hour before disposal.
9. Dispose the used kit after decontamination of all liquids or solid wastes by following the local law or laboratory rule.

STORAGE AND STABILITY

Store the kit in cool and dry places at a temperature between 2-30°C. **Do not freeze.** The shelf-life of the kit under these storage conditions is 24 months.

SPECIMEN COLLECTION AND PREPARATION

The Syphilis (Tp) Ab Rapid Test Cassette (Colloidal Gold) can be performed using whole blood (from either venipuncture or fingerstick), serum or plasma.

To collect Fingerstick Whole Blood specimens:

1. Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
2. Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
3. Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
4. Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
5. **Add the Fingerstick Whole Blood specimen to the test by using a capillary tube:**
   1) Touch the end of the capillary tube to the blood until filled to approximately 50µL. Avoid air bubbles.
   2) 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 cassette.

   Add the Fingerstick Whole Blood specimen to the test by using hanging drops:
   1) Position the patient's finger so that the drop of blood is just above the specimen well of the test cassette.
   2) Allow 2 hanging drops of fingerstick whole blood to fall into the center of the specimen well of the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen well. Avoid touching the finger directly to the specimen well.
6. **Do not freeze whole blood specimens.** Whole blood collected by fingerstick should be tested immediately.
7. Separate the **serum or plasma** from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
8. 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.
9. 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.
10. If specimens are to be shipped, they should be packed in compliance with national regulations covering the transportation of etiologic agents.

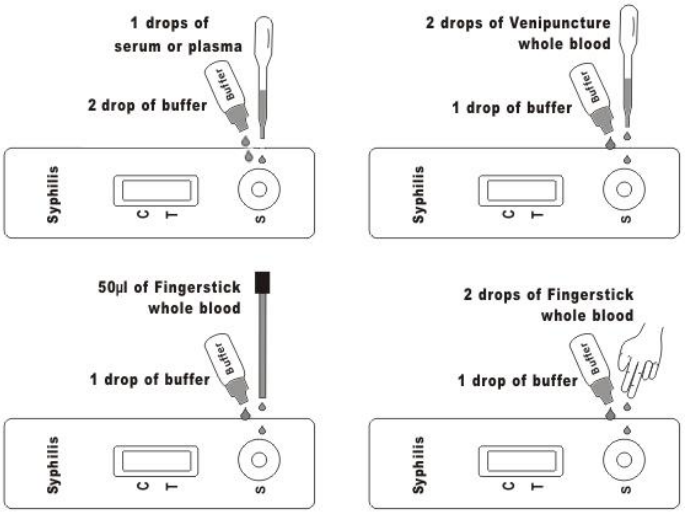
ASSAY PROCEDURE

Test device, patient's samples, and controls should be brought to room temperature (15-30℃) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test cassette from the foil pouch. Place it on a clean and level surface. Be sure to label it with specimen's ID number.
2. **For Serum or Plasma specimen:**
   Hold the dropper vertically and transfer 1 drop (about 25µL) of serum or plasma into the specimen well of the test cassette, then add 2 drop of buffer (approximately 80µL) and start the timer. See illustration below.
   For venipuncture whole blood specimen:
   Hold the dropper vertically and transfer 2 drops of whole blood (approximately 50µL) to the specimen well, then add 1 drop of buffer (approximately 40µL), and start the timer. See illustration below.
   For Fingerstick whole blood specimen:
   To use a capillary tube: Fill the capillary tube and transfer approximately 50µL of fingerstick whole blood specimen to the specimen well of the test cassette, then add 1 drop of buffer (approximately 40µL) and start the timer. See illustration below.
   To use hanging drops: Allow 2 hanging drops of fingerstick whole blood specimen (approximately 50µL) to fall into the specimen well of the test cassette, then add 1 drop of buffer (approximately 40µL) and

start the timer. See illustration below.

3. Wait for colored lines to appear and read results at 15 minutes. **Don't read result after 20 minutes.**



INTERPRETATION OF ASSAY RESULT

(Please refer to the above illustration)

NEGATIVE: If only the Control (c) line appears, it indicates no detectable anti-Tp antibodies in the specimen. The result is negative.

POSITIVE: If both Control (c) line and Test (T) line appear, the test indicates the presence of anti-Tp antibodies in the specimen. The result is positive.
The intensity of the test line ("T") may be less than that of the control line ("C"); this still means positive result.
Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

INVALID: If no Control (c) line is developed, the assay is invalid regardless of color development on the Test (T) line as indicated. Repeat the assay with a new device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

PERFORMANCE CHARACTERISTICS

To study the clinical sensitivity and specificity of Syphilis (Tp) Ab Rapid Test Cassette (Colloidal Gold), 1049 clinically confirmed samples were tested by Syphilis (Tp) Ab WB/S/P Rapid Test and a leading commercial rapid test. The results are shown as in below Table1.

Relative Evaluation Results		Commercial Syphilis (Tp) Ab Rapid Test Cassette (Colloidal Gold).		Total
		Positive	Negative	
Syphilis (Tp) Ab Rapid Test Cassette (Colloidal Gold)	Positive	335	3	338
	Negative	0	711	711
Total		335	714	1049
Sensitivity = 335/(335+0)×100% =100%				
Specificity = 711/(3+711)×100% =99.58%				
Accuracy=（335+714）/(335+0+3+711)×100%=99.71%				

Table 1：

The test results for Syphilis (Tp) Ab WB/S/P Rapid Test are as below::
Sensitivity = 335/(335+0)×100% =100%
Specificity = 711/(3+711)×100% =99.58%
Accuracy=（335+714）/(335+0+3+711)×100%=99.71%

Interference:

No interference observed in the interference study of Syphilis (Tp) Ab Rapid Test Cassette (Colloidal Gold) tested with laboratory strains of common infectious diseases.

LIMITATIONS OF TEST

1. Failure to follow the procedures of assay and test result interpretation may give inaccurate results.
2. All results must be interpreted together with other clinical information available to the physician.
3. The Treponema Pallidum Antibody Rapid Test (Colloidal Gold Method)（Whole blood/Serum/Plasma） is limited to the qualitative detection of anti-*Tp* antibodies in human whole blood, serum or plasma.
4. A negative result for an individual subject indicates absence of detectable anti-*Tp* antibody, but does not preclude the possibility of exposure to or infection with *Tp*.

BIBLIOGRAPHY

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3. Karp, G; Schlaeffer, F, Jotkowitz, A, Riesenberg, K (2009 Jan). "Syphilis and HIV co-infection". European journal of internal medicine 20 (1): 9–13.
4. Kent ME, Romanelli F (February 2008). "Reexamining syphilis: an update on epidemiology, clinical manifestations, and management". Ann Pharmacother 42 (2): 226–36

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Index of Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

Manufacturer:
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