One Step Cassette Style Syphilis (TP) Serum/Plasma Test

INTENDED USE

One Step *Treponema Pallidum (TP)* Antibody Test is a rapid and convenient immunochromatographic assay for the qualitative detection of antibodies against *Treponema pallidum* in human serum and plasma sample. It is intended for professional use as an aid in diagnosis of Syphilis. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

SUMMARY AND PRINCIPLE OF THE ASSAY

Syphilis is a sexually transmitted infection caused by the spirochete bacterium Treponema pallidum (TP) subspecies pallidum. The primary route of transmission is through sexual contact; however, it may also be transmitted from mother to fetus during pregnancy or at birth, resulting in congenital syphilis. Congenital syphilis is a serious but preventable disease which can be eliminated with effective screening and treatment of syphilis in pregnant women. The early detection and treatment of infection in pregnant women is crucial in preventing and controlling maternal and congenital syphilis. Multiple clinical stages and long periods of latent, asymptomatic infection are characteristic of Syphilis. Primary syphilis is defined by the presence of a chance 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.

The Treponema pallidum cannot be cultured on artificial media and thus the diagnosis of syphilis depends on clinical manifestations and results from serological tests of specific TP antibodies.

One Step TP test is an antibody-capture immunochromatographic assay, detecting presence of TP antibodies in blood samples. Specific TP antigens are 1) conjugated with colloidal gold and deposited on conjugate pad, and 2) immobilized on test line on the nitrocellulose membrane. When the serum or plasma sample is added, it rehydrates the gold-antigen conjugate. and the TP antibodies, if any in samples, interact with the gold conjugated antigen. The antigen-antibody-gold complex will migrate toward test window until the Test Zone (T) where they are captured by immobilized antigen, forming a visible red line (Test band, indicate positive results). If TP antibodies are absent in the sample, no red line will appear in the Test Zone (T)

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a colored control line in the Control Zone is an indication of an invalid result.

PACKAGE CONTENTS

- Pouch contents: Test Cassette, Sample dropper, Desiccant

MATERIALS REQUIRED BUT NOT PROVIDED

- Clean, specimen collection container
- Clock or timer

WARNING AND PRECAUTIONS

- For Professional *in vitro* diagnostic use only.
- Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious material and performing the assay.
- Wash hands thoroughly after finishing the tests.

- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- Keep out of the reach of children. children's reach.

SPECIMEN PREPARATION

- For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
- For plasma samples, collect blood in a tube containing anticoagulant.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- The blood may be stored at 2ºC to 8ºC for up to three days if the tests cannot be performed immediately. Ensure that the blood samples should be allowed to attain room temperature prior to use.

TEST PROCEDURES

1

Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a leveled surface.

2

For Serum/plasma Sample:

- Holding the sample dropper vertically, add three full drops (120 µl) of specimen without air bubbles into the sample well that is marked with an arrow on the testing device

Read the result in 10 minutes. Read results as shown under interpretation of Results

3

NOTE: Specimens with high concentrations of TP antibodies may produce positive result in as little as 1 minute. Confirm negatives in 10-20 minutes.

DO NOT INTERPRET RESULTS AFTER 30 MINUTES

RESULT INTERPRETATIONS

Negative
A pink colored band appears only at the control region (C), indicating a negative result for *Treponema pallidum*.

Positive
A clear pink control band (C) and a detectable test band (T) appear, indicating a positive result for *Treponema pallidum* .

Invalid
No visible band at the control region (C). Repeat with a new test device. If test still fails, please contact the distributor with the lot number

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

- Test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The bottle containing the buffer should be stored at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

- This product is an *in vitro* diagnostic test designed for professional use only.
- Humidity and temperature can adversely affect results.
- The instruction for use of the test should be followed during testing procedures.
- Anti-coagulants such as heparin, EDTA, and citrate do not affect the test result.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrate superior accuracy in detecting Treponema pallidum, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1. Diagnostic Sensitivity and Specificity

The clinical performance of One Step TP Test has been evaluated by a comparison study with a currently marketed TP test device at external clinical sites. 320 clinic samples were studied, of them, only 2 samples showing discordant, The details of result are tabulated below

		Results of commercial kits		Subtotal
		Positive	Negative	
Results of One-step	Positive	151	1	152
TP **test**	Negative	1	167	168
Subtotal		152	168	320

Specificity: 167/ 168 =99.4%
Sensitivity: 151/ 152 = 99.3%
Overall agreement: (151+167) / 320 = 99.4%

2. Analytic Specificity

The effect of seromarkers associated with unrelated medical conditions on the specificity of the One Step TP Antibody Test was assessed using a panel of specimens. The seromarkers studied were：Human immunodeficiency virus(HIV), hepatitis B virus seromarkers (HBsAg, anti-HBc IgG/IgM, and anti-HBs), hepatitis A virus IgM (anti-HAV), herpes simplex virus IgG (HSV), cytomegalovirus(CMV) IgG/IgM, Epstein-Barr Virus（EBV)IgG/IgM, human T- Lymphotrophic virus(HTLV), rubella IgM, anti-E. Coli, *Helicobacter pylori*(HP) IgG/IgM, mycoplasma IgM, C-reactive protein (CRP), antistreptolysin O titre (ASOT), rheumatoid factor (RF). Two tests from each of the two lots of HCV Antibody Rapid tests were carried out for each of the panel samples. The test panel was comprised of 185 HCV antibody negative specimens. Of the 185 specimens, 85 contained one or more of the seromarkers while 100 were health negative specimens. The results demonstrated that One Step TP Antibody Test kits have no significant cross-reactivity with these specimens.

3. Reactivity with Low Titre TP Antibody Performance Panel

A low titre TP antibody panel consisting of 6 specimens and a Performance panel consisting of 20 members, obtained from a commercial source (Syphilis Qualification Panel QSS701, ACCURUN 155 Anti-Treponema Positive control Series 5000), were tested in comparison with CE licensed anti-TP EIA tests. The results of the study demonstrated that One Step TP Antibody Test was capable of detecting antibodies against TP similarly to the licensed anti-TP EIA tests.

4. Reactivity with National Reference of Anti-Syphilis Serum Control Panel (National Institute for the control of Pharmaceutical and Biological Product

One Step TP Antibody test device has been test with SFDA standard panel consist of very specific 10 positive and 20 negative samples. For positive samples, TP device test positive for all 10 positive sample; For 20 negative samples, there is 1 samples tested very weak positive. The test results meet the requirement of panel. The detail results show as table below:

Panel Positive Sample Test										
Sample NO	P1	P2	P3	P4	P5	P6	P7	P8	P9	P1
Test Result	+	+	+	+	+	+	+	+	+	+
Panel Negative Sample Test										
Sample NO	N1	N2	N3	N4	N5	N6	N7	N8	N9	N1
Test Result	-	-	-	-	-	-	-	-	-	-
Sample NO	N1	N1	N1	N1	N1	N1	N1	N1	N1	N2
Test Result	-	+	-	-	-	-	-	-	-	-

5. Interference

The following substances and conditions were found not to interfere with the test. List of potentially interfering chemical analytes and concentrations tested are as follows:

Acetaminophen	20 mg/dl
Acetylsalicylic acid	20 mg/dl
Ascorbic acid	20 mg/dl
Caffeine	20 mg/dl
Gentesic acid	20 mg/dl
Phenylpropanolamine	20 mg/dl
Salicylic acid	20 mg/dl
EDTA	80 mg/dl
Benzoylecgonine	10 mg/dl
Atropine	20 mg/dl
Cannabinol	10 mg/dl
Ethanol	1%
Methanol	1%
Heparin	1%

Citrate	3.2%
Albumin	2,000 mg/dl
Glucose	2,000 mg/dl
Bilirubin	2,000 mg/dl
Hemoglobin	2,000 mg/dl

6. Reproducibility

The precision was determined by replicate assays of both positive and negative samples with devices from three different production lots. The resultant data indicated no appreciable difference between lot variation when testing both positive and negative samples across three different lots.

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INDEX OF SYMBOLS

	Do not reuse		Batch code
	In vitro diagnostic medical device		Use by
	Temperature limitation		Contains sufficient for < n > tests
	Caution		Catalog number
	Manufacturer		Consult instructions for use
	Authorized representative in the European community		CE Mark

MANUFACTUER

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