

One Step ANTI-Syphilis Whole Blood/Serum/Plasma Rapid Test

Cat. No.: TP 334

1. INTENDED USE

One Step Treponema Pallidum (TP) Antibody Test is a rapid and convenient immunochromatographic assay used for the qualitative detection of antibodies against Treponema pallidum in human serum, plasma and whole blood 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.

2. 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 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.

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 the presence of TP antibodies in blood samples. Specific TP antigens are 1) conjugated with colloidal gold and deposited on the conjugate pad, and 2) immobilized on the test line on the nitrocellulose membrane. When sample is added the gold-antigen conjugate is rehydrated and the TP antibodies, if any in the sample, will interact with the gold conjugated antigen. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone (T) where they are captured by immobilized antigen, forming a visible pink line (Test band, indicate positive results). If TP antibodies are absent in the sample, no pink 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 pink control line in the Control Zone is an indication of an invalid result.

3. PACKAGE CONTENTS

- 1) Pouch contents: Test Cassette, Sample dropper, Desiccant.
- 2) Sample buffer (4 ml) per bottle for 25 tests.
- 3) Test instruction.

4. WARNINGS AND PRECAUTIONS

- 1) For professional in vitro diagnostic use only.
- 2) Do not reuse.
- 3) Do not use if the pouch seal or its packaging is compromised.
- 4) Do not use after the expiration date shown on the pouch.
- 5) Do not mix and interchange different specimens.
- 6) Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.
- 7) Wash hands thoroughly after finishing the tests.
- 8) Do not eat, drink or smoke in the area where the specimens or kits are handled.
- 9) Clean up spills thoroughly with appropriate disinfectants.
- 10) Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- 11) Dispose of 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.
- 12) Keep out of children's reach.

5. SPECIMEN PREPARATION

- 1) The One-Step Syphilis test is performed on human serum, plasma and whole blood.
- 2) For serum samples, collect blood in a tube without anticoagulant and allow it to clot.
- 3) For plasma samples, collect blood in a tube containing anticoagulant.
- 4) Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- 5) Remove the whole blood from the clot or red cells, respectively, as soon as possible to avoid hemolysis. Lipemic, icteric, or hemolyzed specimens may give inconsistent test result. Specimens, of containing precipitate, should be clarified prior to testing.
- 6) If specimens are not to be tested they should be refrigerated immediately at 2 to 8°C, if storage periods greater than 3 days are anticipated, the specimen should be frozen. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.
- 7) Do not use heat-inactive specimens.

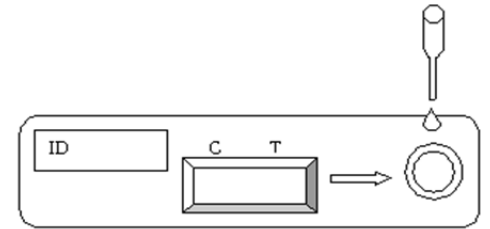
6. TEST PROCEDURE

1) Review specimen collection instructions. Test device, specimens and controls should be brought to room temperature (2-30°C) prior to testing.

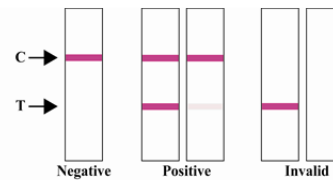
2) Remove the test device from its protective pouch (bring the device to room temperature before opening of the pouch to avoid condensation of moisture on the membrane). Label the device with patient or control identifications.

3) Use the dropper or pipette to withdraw specimen from the specimen collection container and dispense 1 drop (20ul) into the sample well, and then dispense 2 drops (approximately 90ul), sample buffer into the sample well. For each sample or control, use a separate container, dropper or pipette and device.

- 4) Wait for 10-20 minutes and read results.
- 5) Do not read results after 30 minutes.



7. 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 the test still fails, please contact the distributor with the lot number

8. STORAGE AND STABILITY

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

9. LIMITATIONS

- 1) This product is an in vitro diagnostic test designed for professional use only.
- 2) Humidity and temperature can adversely affect results.
- 3) The instructions for the use of the test should be followed during testing procedures.
- 4) Anti-coagulants such as heparin, EDTA, and citrate do not affect the test result.
- 5) 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.

6) Although the test demonstrates 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.

10. 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 TP test	Positive	151	1	152
	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- Lymphotropic 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 Cannabinol 10 mg/dl

Acetylsalicylic acid	20 mg/dl	Ethanol	1%
Ascorbic acid	20 mg/dl	Methanol	1%
Caffeine	20 mg/dl	Heparin	1%
Gentesic acid	20 mg/dl	Citrate	3.2%
Phenylpropanolamine	20 mg/dl	Albumin	2,000 mg/dl
Salicylic acid	20 mg/dl	Glucose	2,000 mg/dl
EDTA	80 mg/dl	Bilirubin	2,000 mg/dl
Benzoyllecgonine	10 mg/dl	Hemoglobin	2,000 mg/dl
Atropine	20 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.

11. REFERENCES

- 1) Stoner B, Schmid G, Guraib M, Adam T, Broutet N. Use of maternal syphilis seroprevalence data to estimate the global morbidity of congenital syphilis. Amsterdam: Meeting of the International Society for Sexually Transmitted Diseases Research (ISSTD); July 10-13 2005
- 2) <http://www.eatq.org/eatq/Global-HIV-News/HIV-STIs/HIV-co-infection-common-with-syphilis>
- 3) Evaluation of the Determine Syphilis TP assay for the detection of antibodies against *Treponema pallidum* for the serodiagnosis of syphilis. Y.-H. Zhuang & Y. Tian & Y. Chen & J. Tang & J.-Q. Wang & P. Li & Q. Li & Y.-Q. Jiang Eur J Clin Microbiol Infect Dis. 2011 Aug 25; 21866323.
- 4) Clinical evaluation of four recombinant *Treponema pallidum* antigen-based rapid diagnostic tests for syphilis. J Li, H-Y Zheng,* L-N Wang, Y-X Liu, X-F Wang, X-R Liu Journal of the European Academy of Dermatology and Venereology, Volume 23, Issue 6, pages 648 - 650, June 2009.
- 5) Prospective, Multi-Centre Clinic-Based Evaluation of Four Rapid Diagnostic Tests for Syphilis. D Mabey, R W Peeling, R Ballard, A S Benzaken, E Galban, J Changalucha, D Everett, R Balira, D Fitzgerald, P Joseph, S Nerette, J Li, and H Zheng STI, 2006;82(Suppl V):v13-v16.
- 6) Evaluation of the Determine Rapid Syphilis TP Assay Using Sera Theresa Diaz,1,2* Maria de Gloria Bonecini Almeida,2 Ingebourg Georg,3 Suely de Carvalho Maia,3 Rogerio Vails de Souza,4 and Lauri E. Markowitz5 Clinical and Diagnostic Laboratory Immunology, January 2004, p. 98-101, Vol. 11, No. 1.
- 7) Rolfs RT et al. A randomized trial of enhanced therapy for early syphilis in patients with and without human immunodeficiency virus infection. The Syphilis and HIV Study Group. N Engl J Med 1997 Jul 31; 337:307-14.
- 8) Berger JR et al. Syphilitic cerebral gumma with HIV infection. Neurology 1992 Jul; 7:1282-7.
- 9) Gordon SM et al. The response of symptomatic neurosyphilis to high-dose intravenous penicillin G in patients with human immunodeficiency virus infection. N Engl J Med 1994 Dec 1; 331:1469- 73.
- 10) Musher DM and Baughn RE. Neurosyphilis in HIV-infected persons. N Engl J Med 1994 Dec 1; 331:1516-7.
- 11) Horowitz HW et al. Cerebral syphilitic gumma confirmed by the polymerase chain reaction in a man with human immunodeficiency virus infection. N Engl J Med 1994 Dec 1; 331:1488-91.
- 12) Katz DA et al. Neurosyphilis. A comparative study of the effects of infection with human immunodeficiency virus. Arch Neurol 1993 Mar; 50:243-9.
- 13) Berry CD et al. Neurologic relapse after benzathine penicillin therapy for secondary syphilis in a patient with HIV infection. N Engl J Med 1987 Jun 18; 316:1587-9.
- 14) Diaz T, de Gloria Bonecini Almeida M, Georg I, et al. Evaluation of the Determine Rapid Syphilis TP assay using sera. Clin Diag Lab Immunol 2004; 11:98 -101.
- 15) Bulletin of the World Health Organization 2004;82:439^46.
- 16) <http://whqlibdoc.who.int/publications/2007>

ATLAS LINK TECHNOLOGY CO., LTD

Road Xing Min, Guan South Industry Zone, 065500 Langfang City, Hebei Province, CHINA

Web: <https://www.invitro-test.com>

Revision: 20180501B