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Syphilis Ab Combo Rapid Test Kit (Colloidal Gold) Instruction for Use

Read this instruction carefully before use
A rapid test for the qualitative detection of Syphilis Antibody *in human* serum, plasma or whole blood. *For professional medical institutions use only,Not for self testing.*

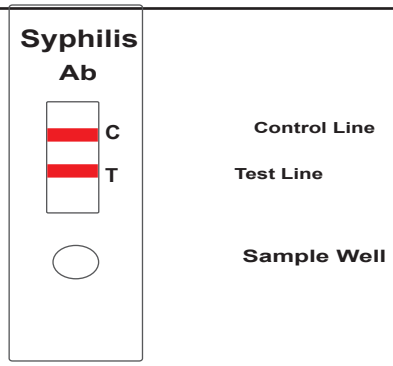
PRODUCT NAME
Syphilis Ab Combo Rapid Test Kit (Colloidal Gold)

SPECIFICATION
25 tests/kit, 5 tests/kit, 1 tests/kit

INTENDED USE
The Syphilis Ab Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies including IgG, IgM, and IgA to Treponema pallidum (Tp) in human serum, plasma or whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Tp. Any reactive specimen with the Syphilis Ab Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY AND EXPLANATION THE TEST
Tp, a spirochete bacterium, is the causative agent of the venereal disease syphilis. Although syphilis rates are declining in the United States after an epidemic outbreak between 1986 and 19901, the incidence of syphilis in Europe has increased since 1992, especially in the countries of the Russian Federation, where peaks of 263 cases per 100,000 have been reported 2. In 1995, WHO reported 12 million new cases of syphilis3. Currently, the positive rate of syphilis serological tests in HIV-infected individuals has been rising recently.
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 weeks4. These antibodies could last for several years or even decades in the serum of a patient with untreated latent syphilis 5.
Antigens such as Rapid Plasma Cardiolipin antigen (RPR) and Tp bacterial extracts have been used in the syphilis serological tests for decades.However, RPR antigen is a non-treponema antigen, derived from bovine heart. Antibody to RPR antigen does not develop until 1-4 weeks after the appearance of the chancre, thus this antigen lacks of sensitivity to primary syphilis. The Tp extracts are prepared from inoculated rabbit testis and contain a certain amount of contaminated materials such as flagella, which can lead to cross reactions with borreliae and leptospires in the serological test. In addition, the composition of extracts may vary from lot to lot. Recently, several highly immunogenic Tp specific antigens have been identified and used as an alternative to the traditional antigens with the advantages of high specificity and reproducibility 6-9. The Syphilis Ab Rapid Test permits the measurement of antibodies (IgM, IgG and IgA) to recombinant antigens of Tp in blood rapidly and reliably without instrumentation.

PRINCIPLE
The Syphilis Ab Combo Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant Tp antigens conjugated with colloid gold (Tp conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated recombinant Tp antigens, and the C band is pre-coated with goat anti-rabbit IgG antibody.



When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. Anti-Tp antibody, if present in the specimen will bind to the Tp conjugates. The immunocomplex is then captured on the membrane by the pre-coated Tp antigen, forming a burgundy colored T band, indicating a Tp antibody positive test result. Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless of color development on the T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

Components	40tests/kit	25tests/kit	5test/kit
Cassettes	40 cassettes with dependent sealed foil pouch	25 cassettes with dependent sealed foil pouch	5 cassette with dependent sealed foil pouch
Sample Diluent Solution with dropper	7ml/bottle	5ml/bottle	300ul/tube
Transfer tube	25 pcs	5 pcs	1 pcs
Package insert	1	1	1

MATERIALIS REQUIRED BUT NOT PROVIDED
Clock or Timer

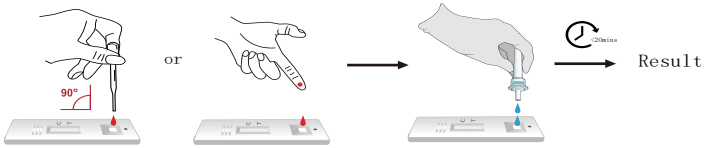
WARNINGS AND PRECAUTIONS
For in Vitro Diagnostic Use
1.This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2.Do not open the sealed pouch, unless ready to conduct the assay.
3.Do not use expired devices.
4.Bring all reagents to room temperature (15°C-30°C) before use.
5.Do not use the components in any other type of test kit as a substitute for the components in this kit.
6.Do not use hemolized blood specimen for testing.
7.Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8.Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9.Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10.Dispose of all specimens and materials used to perform the test as biohazardous waste.
11.Handle the Negative and Positive Control in the same manner as patient specimens.
12.The testing results should be read within 25 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 25 minutes may give erroneous results.
13.Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS
All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND HANDLING
Consider any materials of human origin as infectious and handle them using standard biosafety procedures.
Plasma
1.Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer®) by veinpuncture.
2.Separate the plasma by centrifugation.
3.Carefully withdraw the plasma into new pre-labeled tube.
Serum
1.Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
2.Allow the blood to clot.
3.Separate the serum by centrifugation.
4.Carefully withdraw the serum into a new pre-labeled tube.
5.Test specimens as soon as possible after collecting. Store specimens at 2°C to 8°C if not tested immediately.
6.Store specimens at 2°C to 8°C up to 5 days. The specimens should be frozen at -20°C for longer storage
Blood
Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use any hemolized blood for testing.
Whole blood specimens should be stored in refrigeration (2°C-8°C) if not tested immediately. The specimens must be tested within 24 hours of collection.Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

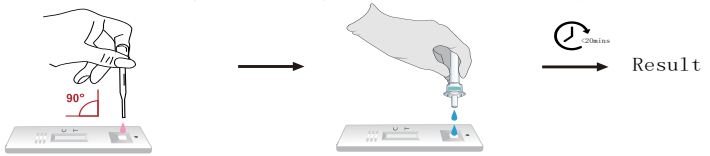
ASSAY PROCEDURE
Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen. Once thawed, mix the specimen well prior to assay.
Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.
Step 3: Be sure to label the device with specimen's ID number.

Step 4: For whole blood test
- Apply 1 drop of whole blood (about 30-35 μL) into the sample well.
- Then add 2 dropS (about 60-70 μL) of Sample Diluent immediately.



1 drop of Whole Blood 2 drops of Buffer

For serum or plasma test
- Fill the pipette dropper with the specimen.
- Holding the dropper vertically, dispense 1 drop (about 30-35 μL) of specimen into the sample well making sure that there are no air bubbles.
- Then add 2 dropS (about 60-70 μL) of Sample Diluent immediately.



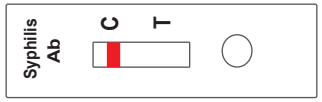
1 drop of serum/plasma 2 drops of Buffer

Step 5: Set up timer.
Step 6: Results can be read in 20 minutes. Positive results can be visible in as short as 1 minute.
Don't read results after 30 minutes.To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

Using individual Syphilis Ab Rapid Test Kit cassettes as described in the Assay Procedure above, run 1 Positive Control and 1 Negative Control (provided upon request if the external quality controls are not available in testing lab) under the following circumstances to monitor test performance:
1.A new operator uses the kit, prior to performing testing of specimens.
2.A new test kit is used.
3.A new shipment of kits is used.
4.The temperature used during storage of the kit fall outside of 2°C-30°C.
5.The temperature of the test area falls outside of 15°C-30°C.

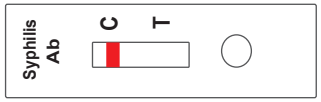
Expected results are as follows:
Negative Control
Only the C band shows color development. The T band shows no color development.



Positive Control
Both C and T bands show color development.

INTERPRETATION OF ASSAY RESULT

Negative Control
If only the C band is developed, the test indicates that no detectable anti-Tp antibody is present in the specimen. The result is negative.



Positive Control
If both C and T bands are developed, the test indicates for the presence of anti-Tp antibody in the specimen. The result is positive.

Samples with positive or reactive results should be confirmed with alternative testing method(s) such as ELISA or PCR and clinical findings before a diagnostic decision is made.

INVALID:
If no C band is developed, the assay is invalid regardless of color development on the T band as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

Clinical Performance
A total of 500 patient samples from susceptible subjects were tested by the Syphilis Ab Rapid Test and by TPHA test (Serodia TP-PA, Fuji-rebio Inc., Japan). Comparison for all subjects is showed in the following table.Virus NS1 Rapid Test and by a commercial EIA. Comparison for all subjects is showed in the following table:

	Syphilis Ab Combo Rapid Test		
TPPA	Positive	Negative	Total
Positive	90	2	92
Negative	2	406	408
Total	92	408	500

Relative Sensitivity:97.83% , Relative Specificity:99.51%, Overall Agreement:99.2%

Precision
Within run and between run precisions have been determined by testing 15 replicates with three of the samples: a negative, a weak positive, and a strong positive sample. The negative, weaker positive, and strong positive samples were correctly identified in all of the tests each time.

LMITATIONS OF TEST

1.The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of anti-Tp antibody in serum, plasma or whole blood from individual subjects. Failure to follow the procedure may give inaccurate results.
2.The Syphilis Ab Rapid Test is limited to the qualitative detection of anti-Tp antibody in human serum or plasma. The intensity of the test band does not linear correlation with the antibody titer in the specimen.
3.A negative result for an individual subject indicates absence of detectable anti-Tp antibody. However, a negative test result does not preclude the possibility of exposure to or infection with Tp.
4.A negative result can occur if the quantity of the anti-Tp antibody present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
5.Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
6.The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

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