NEWSCEN
NEWSCEN COAST BIO-PHARMACEUTICAL CO., LTD.
NO. 65 Sixth Ave, TEDA Tianjin, 300457, P. R. China
Web(EN): www.newscenbiotech.com
E-mail: export@newscen.com

CE IVD

Newscen Treponema Pallidum (TP) Antibody Rapid Test

【For the qualitative detection of Syphilis antibodies in serum/ plasma and whole blood】

INTENDED USE

The Treponema Pallidum (TP) Antibody Rapid Test is a qualitative test for the detection of antibodies to TP in human serum/ plasma and whole blood. It is considered as an initial screening test for TP antibodies. All positive specimens must be confirmed with Western Blot or other qualified EIA.

PRINCIPLE

The Treponema Pallidum (TP) antibody rapid test is a chromatographic immunoassay (CIA) for the detection of antibodies to Syphilis in human serum, plasma or whole blood. Syphilis specific antigens are pre-coated onto membrane as a capture reagent on the test zone. During the test, specimen is allowed to react with the colloidal gold particles, which have been labeled with Syphilis specific antigens. Antibodies to Syphilis, if present, a red line will develop on the membrane. Absence of this red line in the test zone suggests a negative result. To serve as a procedural control, a red line in the control zone will always appear regardless the presence of antibodies to Syphilis.

COMPONENTS

REAGENTS AND MATERIALS PROVIDED

Each kit contains:
1. Test cassettes (individually pouched)
2. Each pouch contains one cassette with one desiccant bag and one plastic dropper
3. Diluent buffer
4. Instruction for use

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer or stopwatch
2. Blood collection devices, for the testing of venipuncture whole blood, serum or plasma
3. Biohazard disposal container
4. Disposable gloves

For fingerstick samples, the following materials are required:

Alcohol pad
Sterile lancet
Sterile gauze or cotton

WARNING AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. All the waste and specimen should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal.
3. Make sure the test is not expired (EXP Date is indicated on the kit box).
4. Do not use the test if the pouch has been perforated.
5. If micro pipette is used, calibrate it frequently to assure the accuracy of dispensing. Use a different disposal pipette tip for each specimen in order to avoid cross-contaminations.
6. Do not modify the test procedure.
7. Each test is for single use only.
8. Always interpret the results under good light conditions to avoid misreading of the results.
9. Different batch of product components cannot be mixed.
10. If desiccant bag is not present in the pouch, DO NOT USE the test.
11. Always add accurate volume of specimen by following the instruction.
12. Icteric,lipemic,hemolyzed,chemically treated, heat treated, diluted, or otherwise modified may cause erroneous results. Do not freeze.

STORAGE

Treponema Pallidum (TP) antibody rapid test should be stored at room temperature (2-30°C, do not freeze) for 24 months from the date of manufacture. Keep the test cassette in sealed pouch until use. Once you have taken the test cassette out of the pouch, perform the test as early as possible (within 1 hour) to avoid test cassette from becoming moist. Do not use the test beyond the indicated expiration date.
The diluent buffer should be stored at room temperature (2-30°C, do not freeze).

SAMPLE COLLECTION AND TEST PREPARATION

Fingerstick Specimens (Whole Blood)

1. Clean the area to be lanced with an alcohol pad.
2. Squeeze the end of the fingertip and pierce it with a sterile lancet.
3. Wipe away the first drop of blood with sterile gauze or cotton; collect the sample from the second drop.
4. Use dropper to obtain appropriate amount of fresh blood and dispense into the sample well.

Fingerstick whole blood should be used immediately after collection.
Serum/Plasma specimens: fresh serum or plasma specimen can be used. No special patient preparation required.

Plasma

1. Collect whole blood into a collection tube (containing EDTA, Na-citrate or heparin) by venipuncture.
2. Separate the plasma by centrifugation.

Serum

1. Collect whole blood into a collection tube (containing no anticoagulants) by venipuncture.
2. Allow the blood to clot.

3. Separate the serum by centrifugation.
Any visible particulate matter in the specimen should be removed by centrifugation or filtration. Avoid using of hemolytic, turbid, microorganism contaminated specimens or specimens stored for over 5 days at 4°C. Specimen should be stored frozen at -20°C for maximum 3 months. Avoid specimen deterioration by multiple freeze-thaw cycles.

ASSAY PROCEDURE

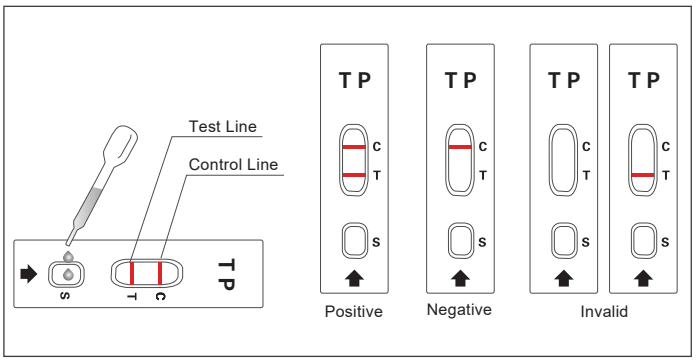
Serum or Plasma Sample

Add 50-80μL or 2-3 drops of serum or plasma into sample well. Observe the result in 20 minutes. Do not read the result after 30 minutes.

Whole Blood Sample

Add 1 drop of whole blood into sample well, after all blood completely absorbed. Add 1-2 drops of whole blood diluent. Observe the result in 20 minutes. Do not read the result after 30 minutes.

INTERPRETATION OF RESULTS



Note: 'C' – Control line; 'T' – Test line

1. ***Negative***: No apparent band in the test zone (T), only one red band appears in the control zone (C). This indicates that no TP antibodies have been detected.
2. ***Positive***: In addition to one red band in the control zone (C), a red band will appear in the test zone (T). This indicates that the specimen contains TP antibodies.
3. ***Invalid***: If no band appears in the control zone (C), regardless of the presence or absence of band in the test zone (T). It indicates a possible error in performing the test. The test should be repeated using a new device.

Built-In Control

Treponema Pallidum (TP) antibody rapid test has a built-in procedural control that demonstrates assay validity. A red line appeared on the control zone (C) indicates that the test runs correctly.

LIMITATION

1. This Rapid Test is a qualitative test for the detection of antibodies to TP. The intensity of the test band does not correlate with the antibody concentration in the specimen.
2. A negative result for an individual subject indicates absence of detectable antibodies to TP. However, a negative test result does not preclude the possibility of exposure to or infection with TP.
3. A negative result can occur if the quantity of the antibodies to TP 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.
4. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
5. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PERFORMANCE CHARACTERISTICS

Product performance shall be carried out with national reference products or enterprise reference products. National reference product verification shall meet the requirements of national reference products, and enterprise reference product verification shall meet the following requirements.

1. ***Conformity rate of positive reference products***: 10 positive serum samples of enterprise reference products were tested, and the conformity rate of positive reference products was 10/10.
2. ***Conformity rate of negative reference products***: 20 corporate reference negative serum samples were tested, and the negative reference conformity rate was 20/20.
3. ***Minimum detection amount***: the minimum detection of the testing is 3 copies of serum, L1 should be positive, L2 can be positive or negative, L3 should be negative.
4. ***Precision***: 10 test reagents were tested in parallel with the precision serum of the enterprise, and the test results should be consistent and the color should be uniform.
5. ***Clinical sample compliance***: A total of 1010 clinical samples were tested for validation, of which 379 were positive and 631 were negative. The test results are as follows:

Method		Syphilis Rapid Test (TP)		Total Results
	Total Results	Positive	Negative	
Contrast Reagent	Positive	330(A)	1(B)	331
	Negative	49(C)	630(D)	679
Total Results		379	631	1010

Sensitivity= A/(A+B)*100%= 99.7%
Specificity= D/(C+D)*100%= 92.8%
Total Accuracy= (A+D)/ (A+B+C+D)*100%=95.0%

REFERENCE

1. Centers for Disease Control (CDC. Chlamydia trachomatis infections. Policy guidelines for prevention and control[J]. MMWR supplements, 1985, 34(3): 53S.
2. Tichonova L, Borisenko K, Ward H, et al. Epidemics of syphilis in the Russian Federation: trends, origins, and priorities for control[J]. The Lancet, 1997, 350(9072): 210-213.
3. Gerbase A C, Rowley J T, Heymann D H L, et al. Global prevalence and incidence estimates of selected curable STDs [J]. Sexually transmitted infections, 1998, 74(1): S12.
4. Luger A F H. Serological diagnosis of syphilis: current methods[J]. Immunological diagnosis of sexually transmitted diseases. New York: Marcel Decker, 1988: 249-274.
5. Baker-Zander S A, Hook III E W, Bonin P, et al. Antigens of Treponema pallidum recognized by IgG and IgM antibodies during syphilis in humans[J]. Journal of Infectious Diseases, 1985, 151(2): 264-272.
6. Norgard M V, Chamberlain N R, Swancutt M A, et al. Cloning and expression of the major 47-kilodalton surface immunogen of Treponema pallidum in Escherichia coli[J]. Infection and immunity, 1986, 54(2): 500-506.

INDEX OF SYMBOLS

	Do not re-use
REF	Catalogue number
IVD	For In Vitro Diagnostic medical device
	Use by date
	Date of manufacture
	Temperature limitation
	Consult instructions for use
EC REP	Authorized Representative in the European Community
LOT	Batch code
	Contains sufficient for < n > tests
CE	CE Mark
	Manufacturer

Product disclaimer: This product has been manufactured under strict GMP regulation to ensure the diagnostic accuracy of the test. It is out of control of the manufacture when the test is performed in diverse environment and by diverse group of individuals that may affect the results to a certain degree.

Note: The manufacturer, the distributor, or its associates will not be liable for any losses, claims, liability, costs or damages, whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether a positive or negative by use of this product.

NEWSCEN COAST BIO-PHARMACEUTICAL CO., LTD.
No. 65, 6th Street, Tianjin TEDA, 300457, Tianjin, PEOPLE'S REPUBLIC OF CHINA
Tel: +86(22)25321648
Fax: +86(22)25328062
Web(CN): www.newscen.com
Web(EN): www.newscenbiotech.com
E-mail: export@newscen.com