ONE STEP SYPHILIS VIRUS TEST
(Serum/Plasma/Whole blood)

One step rapid strip Test for detection of Syphilis Antibody in serum/plasma/Whole Blood.
Only for *In vitro Diagnostics* use

ORDER INFORMATION

REF	CONT
SYPS 50	50 Tests

CLINICAL SIGNIFICANCE

Syphilis is sexually transmitted (venereal) disease caused by the spirochete Treponema pallidum. The disease can also be transmitted congenitally thereby attaining its importance in antental screening. After injection the host forms non-treponemal anti lipoidal antibodies (regains) to the lipoidal material released from the damaged host cells as well as treponema specific antibodies. Serological tests for non-treponemal antibodies such as VDRL, RPR, TRUST etc. are useful as screening tests. Test for treponema specific antibodies such as TPHA, FTA-ABS, rapid treponema antibody tests are gaining importance as screening as well as confirmatory tests because they detect the presence of antibodies specific to Treponema pallidum.
One step Syphilis strip test is a modified TPHA, which qualitatively detects the presence of IgM and IgG class of treponema specific antibodies during syphilis in serum or plasma or whole blood specimens within 15 minutes.

PRINCIPLE

One step Syphilis strip test utilizes the principle of immunochromatography, a unique two-site immunoassay on a membrane. As the test conjugate forms through the membrane assembly of the test card, the recombinant Treponema antigen-colloidal gold conjugate forms a complex with Treponema specific antibodies in the sample. This complex moves further on the membrane leading to the formation of a pink to deep purple colored band at the test region which confirms a positive test result. Absence of this colored band in test region indicates a negative test result. The unreacted conjugate and the unbound complex if any along with rabbit IgG gold conjugate move further on the membrane and are subsequently immobilized by the goat anti-rabbit antibodies coated at the control region of the membrane assembly, forming a pink to deep purple coloured band. The control band serves to validate the test results.

KIT COMPONENTS

Test Strip , product insert, sample Dropper and Assay Buffer.

STORAGE & STABILITY

Store as packaged in the sealed pouch at 2-30 °C. The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use. Do not freeze.

PRECAUTIONS

1. For professional in vitro diagnostic use only. Do not use after expiration date.
2. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
3. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.

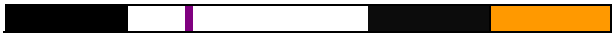
SPECIMEN COLLECTION & PREPARATION

1. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens should be used.
2. Do not leave the specimens at room temperature for prolonged periods.
3. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.

DIRECTION FOR USE

1. Remove the “Reaction Strip” from its foil wrapper by tearing along the “splice”.
2. Put test strip on flat horizontal surface and add 25 µL (1 Drop) of serum/plasma/Whole Blood on to sample pad by the sample dropper.
3. Add 1 drop (40 µL) of Buffer on strip.
4. Allow reaction to occur in next 15-20 minutes.
5. The test should be read between 15-20 minutes after dipping the specimen in the samples.

INTERPRETATION OF RESULTS



NEGATIVE: Only one pink to deep purple colored band appears on the dipstick.

POSITIVE: Two distinct pink to deep purple colored bands appear on the dipstick.

INVALID: The test should be considered invalid if neither the test band nor the control band appears. Repeat the test with a new dipstick.
Although, depending on the concentration of the treponemal antibodies in the specimen, positive results may appear as early as 2 to3 minutes, negative results must be confirmed only at the end of 15 minutes.

QUALITY CONTROL

Internal procedural controls are included in the test:
- A red line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

1. The test procedure, precautions and interpretation of results for this test must be followed when testing.
2. The intensity of the red color in the test line regions (T) will vary depending on the concentration of antigen present in the specimen. However, neither the quantitative value nor the rate of increasing antigen can be determined by this qualitative test.
3. A negative result can occur if the quantity of the anti- syphilis antibodies 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. Other clinically available tests are required. 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.

BIBLIOGRAPHY

1. Syphilis: New Diagnostic Direction, H. Young, international Journal of STD and AIDS, 1992, 3: 391-413.
2. Clinical Laboratory Diagnostics: Use and Assessment of Clinical Laboratory Results, Lothar Thomas, 1st Edition, 1998, TH Books.
3. AABB Technical Manual, 13th Edition, 1999.
4. Clinical Diagnosis and Diagnosis and Management by laboratory methods, John Bernard Henry, 17th Edition, 1979, W.B. Saunders Company.
1. Van der Poel, C.L., H.T.M. Cuypers, H.W. Reesink, and P.N. Lelie. Confirmation of Syphilis infection by new four-antigen recombinant immunobiot assay. Lancet 1991: 337:317
2. Wiber, J.Decelopment and use of laboratory tests for hepatitis C infection: a review. J. Clin. Immunoassay 1993; 16:204.

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