Size : 137 x 218 mm

VioTUBE™ Syphilis

Rapid Test for Syphilis
(Modified TPHA)

DIPSTICK

INTENDED USE

VioTUBE™ Syphilis is a rapid, qualitative, two site double antigen sandwich immunoassay for the detection of syphilis in human serum or plasma specimens. For Professional Use.

SUMMARY

Syphilis is a sexually transmitted (venereal) disease caused by the spirochete *Treponema pallidum*. The disease can also be transmitted congenitally thereby attaining its importance in antenatal screening. After infection the host forms non-treponemal anti lipoidal antibodies (reagins) 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. Tests 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*.
VioTUBE™ Syphilis is a modified TPHA, which qualitatively detects the presence of IgM and IgG class of treponema specific antibodies during syphilis in serum or plasma specimens within 15 minutes.

PRINCIPLE

VioTUBE™ Syphilis utilizes the principle of agglutination of antibodies/ antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. As the test sample flows through the membrane assembly of the test dipstick, the recombinant Treponema antigen-colloidal gold conjugate forms a complex with Treponema specific antibodies in the sample. This complex moves further on the membrane to the test region where it is immobilized by the recombinant *Treponema pallidum* antigens coated on the membrane leading to the formation of a pink to deep purple coloured band at the test region which confirms a positive test result. Absence of this coloured band in test region indicates a negative test result. The unreacted conjugate and the unbound complex if any, along with rabbit globulin- gold conjugate move further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the control region of the membrane assembly, forming a pink to deep purple coloured band. The control band serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

VioTUBE™ Syphilis kit contains:

A. Each individual pouch contains:
   1. DIPSTICK : Membrane assembly pre-dispensed with recombinant *Treponema pallidum* antigen-colloidal gold conjugate, recombinant *Treponema pallidum* antigen and Agglutinating sera for rabbit globulin coated at the respective regions.
   2. PIPETTE : Disposable Plastic Sample Applicator.
   3. Desiccant pouch.

B. BUF : Diluent Buffer in a dropper bottle.
C. Package insert.

REF	703040010
Σ	10 T

OPTIONAL MATERIAL REQUIRED

Calibrated micropipette capable of delivering 25 µl sample accurately.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 4°C to 30°C for the duration of shelf life as indicated on the pouch. After first opening of the diluent buffer, the buffer is stable until the expiry date mentioned on the buffer label, if kept at 4°C to 30°C. DO NOT FREEZE.

NOTES

(1) For in vitro diagnostic use only. NOT FOR MEDICINAL USE. (2) Do not use the kit beyond expiry date and do not re-use the test device. (3) Read the instructions carefully before performing the test. (4) Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm. (5) Handle all specimens as potentially infectious. (6) Follow standard bio -safety guidelines for handling and disposal of potentially infective material.

SPECIMEN COLLECTION AND PREPARATION

No special preparation of patient is necessary prior to specimen collection by approved techniques. Though fresh serum/

Colour	C	M	Y	K
Mauve	30	100	0	0
Black	0	0	0	100

Size : 137 x 218 mm

plasma is preferable, serum/plasma specimens may be stored at 2°C to 8°C for up to 24 hours, in case of delay in testing. Do not use haemolysed or contaminated specimens. Turbid specimens should be centrifuged or allowed to settle and only the clear supernatant should be used for testing.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring kit components, specimen to room temperature prior to testing. Open the pouch and remove the dipstick. Once opened, the dipstick must be used immediately.
2. Add three drops of diluent buffer into a clean (12 x 75) mm test tube by holding the buffer bottle vertically.
3. With the help of the sample applicator provided dispense one drop of serum/plasma to the sample pad just below the arrows.
4. With the arrows pointing downwards place the dipstick with the sample into the test tube containing diluent buffer.
5. Read the results at the end of 15 minutes as follows:

Negative : Appearance of only one pink to deep purple coloured band on the dipstick .

Positive: Appearance of two distinct pink to deep purple coloured bands on the dipstick.

6. The test should be considered invalid if neither the test band nor the control band appears. Repeat the test with a new dipstick.
7. Although, depending on the concentration of treponemal antibodies in the specimen, positive results may appear as early as 2 to 3 minutes, negative results must be confirmed only at the end of 15 minutes.

PERFORMANCE CHARACTERISTICS

In an in-house evaluation **VioTUBE™ Syphilis** was run in parallel against standard TPHA, 100% correlation was found in 103 samples.

Sample	Total No. of Sample Tested	Immutrep TPHA (Omega Diagnostics U.K.)	VioTUBE™ Syphilis
Positive Sample	57	57	57
Negative Sample	46	46	46

REMARKS

(1) **VioTUBE™ Syphilis** detects the presence of treponemal antibodies; thus a positive result indicates a past or present infection. Positive results should be evaluated in co-relation with the clinical condition before arriving at a final diagnosis. (2) Low levels of antibodies to *Treponema pallidum* such as those present at a very early primary stage of infection can give a negative result. But a negative result does not exclude the possibility of exposure to or infection with *Treponema pallidum*. Retesting is indicated after two weeks if clinically syphilis is still suspected. (3) In order to assess the clinical response to treatment it is advisable to use a reagin test such as VDRL, RPR. (4) **VioTUBE™ Syphilis** detects Treponemal antibodies in serum/ plasma; other body fluids may not give accurate results. (5) In immunocompromised patients the test results must be interpreted with caution.

BIBLIOGRAPHY

(1) Syphilis: New Diagnostic Directions, 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 Management by Laboratory Methods, John Bernard Henry, 17th Edition, 1979, W.B.Saunders Company. (5) Data on file: Zephyr Biomedicals.

SYMBOL KEYS

Temperature Limitation	Consult Instructions for use	Date of Manufacture	Contains sufficient for <n> tests
Manufacturer	IVD *In vitro* Diagnostic Medical Device	This side up	Do not reuse
Use by	REF Catalogue Number	DIPSTICK Dipstick	BUF Diluent Buffer
LOT Batch Number / Lot Number		PIPETTE Disposable Plastic Sample Applicator	

Manufactured by:

Zephyr Biomedicals

A Division of Tulip Diagnostics (P) Ltd.

M 46-47, Phase III B, Verna Industrial Estate, Verna, Goa - 403 722, INDIA.

Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

0817/VER-01