

SBio Syphilis Test **DIPSTICK**

Rapid test for Syphilis (Modified TPHA)

REF	90212025
Σ	25 T



Temperature Limitation	Do not use if package is damaged	PIPETTE Disposable Plastic Sample Applicator	EC REP Authorised Representative in the European Community
Use by	Consult Instructions for use	DIPSTICK Dipstick	BUF Diluent Buffer
Date of Manufacture	REF Catalogue Number	Contains sufficient for ≤ 25 tests	Do not reuse
LOT Batch Number/ Lot Number	IVD In vitro Diagnostic Medical Device	This side up	Syphilis Rapid test for syphilis

INTENDED USE

SBio Syphilis Test is a rapid, qualitative, two site double antigen sandwich immunoassay for the detection of antibodies to *Treponema pallidum* (Syphilis) in human serum/ plasma specimen. 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*.

SBio Syphilis 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 specimens within 15 minutes.

PRINCIPLE

SBio Syphilis Test 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

SBio Syphilis Test kit contains:

A. Individual pouches, each containing:

- 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.

- PIPETTE**: Disposable plastic sample applicator.
- Desiccant pouch.
- BUF**: Diluent Buffer in a dropper bottle.
- Package insert.

ADDITIONAL MATERIAL REQUIRED

(12 x75) mm glass test tubes and stopwatch.

OPTIONAL MATERIAL REQUIRED

Calibrated micropipette capable of delivering 25 µl sample accurately.

STORAGE AND STABILITY

The sealed pouches in the test kit & the kit component 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

- For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
- Do not use the kit beyond expiry date and do not re-use the test dipstick.
- Read the instructions carefully before performing the test.
- 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.
- Handle all specimens as potentially infectious.
- Do not intermix the reagents from different lots.
- 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/ plasma is preferable, serum/plasma specimens may be stored at 2°C to 8°C for up to 72 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

Bring kit components, specimen to room temperature prior to testing.

- Open the pouch and remove the dipstick. Label the dipstick with patient's identity. Once opened, the dipstick must be used immediately.
- Add three drops of diluent buffer into a clean (12 x 75) mm test tube by holding the dropper bottle vertically.
- With the help of the applicator provided dispense one drop of

- serum/ plasma to the sample pad just below the arrows.
- With the arrows pointing downwards place the dipstick with the sample into the test tube containing diluent buffer.
 - 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.



Invalid : The test should be considered invalid if neither the test band nor the control band appears. The test should also be considered invalid if only the test band appears and no control band appears. Repeat the test with a new dipstick.



- 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 SBio Syphilis Test was run in parallel against standard TPHA, 100% correlation was found in 103 samples.

Sample	Total No. of Sample Tested	Immutrep A (Omega Diagnostics U.K.)	SBio Syphilis Test
Positive Sample	57	57	57
Negative Sample	46	46	46

REMARKS

- SBio Syphilis Test 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.

- 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.
- In order to assess the clinical response to treatment it is advisable to use a reagent test such as VDRL, RPR.
- SBio Syphilis Test detects Treponemal antibodies in serum/ plasma; other body fluids may not give accurate results.
- In immunocompromised patients the test results must be interpreted with caution.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

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- Clinical Laboratory Diagnostics: Use and Assessment of Clinical Laboratory Results, Lothar Thomas, 1st Edition, 1998, TH-Books.
- AABB Technical Manual, 13th Edition, 1999.
- Clinical Diagnosis and Management by Laboratory Methods, John Bernard Henry, 17th Edition, 1979, W.B. Saunders Company.

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EC REP

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