Size : 137 x 218 mm

CE

Syphicheck®

Rapid Test for Syphilis
(Modified TPHA)
DIPSTICK

INTENDED USE

Syphicheck® 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*.
Syphicheck® 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

Syphicheck® 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

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	401020025
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ADDITIONAL MATERIAL REQUIRED

12 x 75 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 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.

NOTE

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.

Colour	C	M	Y	K
Black	0	0	0	100
Orange	0	60	100	0

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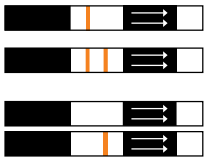
5. Handle all specimens as potentially infectious.
6. Follow standard bio-safety guidelines for handling and disposal of potentially infective material.

SPECIMEN COLLECTION AND PREPARATION

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

1. 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.
2. Add three drops of diluent buffer into a clean (12 x 75) mm test tube by holding the dropper bottle vertically.
3. With the help of the 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.

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.

6. 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

1. In an in-house evaluation Syphicheck® 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.)	Syphicheck®
Positive Sample	57	57	57
Negative Sample	46	46	46

2. Syphicheck® was evaluated with WHO International Standard, **1st IS for human syphilitic plasma IgG and IgM (NIBSC code:05/132)** and was found to show a sensitivity of 0.02 IU/ml.

REMARKS

1. Syphicheck® 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. Syphicheck® 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.

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

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.

Size : 137 x 218 mm

SYMBOL KEYS

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

Size : 137 x 218 mm

Manufactured by:

Zephyr Biomedicals

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EC REP

CMC Medical Devices & Drugs S.L., Spain.

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