Size : 137 mm x 218 mm

CE

Syphicheck® - WB

Rapid Test for Syphilis
(Modified TPHA)
DEVICE

INTENDED USE

Syphicheck® - WB is a rapid, qualitative, two site double antigen sandwich immunoassay for the detection of antibodies to *Treponema pallidum* (Syphilis) in human serum / plasma / Whole blood 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*.
Syphicheck® - WB is a modified TPHA, which qualitatively detects the presence of IgM and IgG class of Treponema specific antibodies during syphilis in whole blood, serum or plasma specimens within 15 minutes.

PRINCIPLE

Syphicheck® - WB 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 device , the recombinant *Treponema pallidum* antigens (47 kDa, 17 kDa) - 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 (47 kDa, 17 kDa) coated on the membrane leading to the formation of a pink to deep purple coloured band at the test region 'T' which confirms a positive test result. Absence of this coloured band in test region 'T' indicates a negative test result. The unreacted conjugate and the unbound complex if any, along with rabbit globulin - colloidal gold conjugate move further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membrane at the control region, forming a pink/purple coloured band. This control band serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

A. Each individual pouch contains:
   1. DEVICE : Membrane assembly predispensed with recombinant *Treponema pallidum* antigens (47 kDa, 17 kDa)-colloidal gold conjugate, rabbit globulin-colloidal gold conjugate, recombinant *Treponema pallidum* antigens (47 kDa, 17 kDa) 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	401030025
Σ	25 T

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/ carton. 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.
5. Handle all specimens as potentially infectious.
6. Do not intermix the reagents from different lots.
7. Follow standard bio-safety guidelines for handling and disposal of potentially infective material.

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

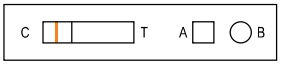
SPECIMEN COLLECTION AND PREPARATION

- **Whole Blood as sample:**
  Fresh blood from finger prick / puncture may be used as a test specimen. For collection of whole blood as a test specimen, EDTA or Heparin or Oxalate can be used as a suitable anticoagulant. The specimen should be collected in a clean glass or plastic container. If immediate testing is not possible then the specimen may be stored at 2^{0}C to 8^{0}C for upto 72 hours before testing. Do not use haemolysed, clotted or contaminated blood samples for performing the test.
- **Serum or Plasma as sample:**
  No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum/ plasma is preferable, serum/ plasma specimens may be stored at 2^{0}C to 8^{0}C for upto 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.

1. Bring the sealed pouch to room temperature, if the pouch of the test device is damaged, discard the device and take a new one for the test. Open the pouch, remove the device and place it on a flat surface. Label the device with patient's identity. Once opened, the device must be used immediately. Check the colour of the desiccant. It should be blue, if it has turned colourless or faint blue or Pink, discard the device and use another device. ***Once opened, the device must be used immediately.***
2. Tighten the cap of the diluent buffer provided with the kit in the clock wise direction to pierce the dropper bottle nozzle.
3. With the help of the applicator provided dispense one drop (approx. 25 µl) of serum / plasma or whole blood to the sample port 'A'. Alternatively 25 µl of serum / plasma or whole blood specimen may be delivered in the sample port 'A' using a micropipette.
4. Immediately add four drops of diluent buffer from the diluent buffer bottle to reagent port 'B'.
5. Read the results at the end of **15 minutes** as follows:



Negative: Appearance of only one pink to deep pink/purple coloured band at the control window 'C'.

Positive: In addition to the control band, a distinct pink/purple coloured band also appears at the test window 'T'.

Invalid: The test should be considered invalid if neither the test band nor the control band appear. Repeat the test with a new device.

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

Internal evaluation

1. In an in-house evaluation **Syphicheck® - WB** was run in parallel against standard TPHA, 100% correlation was found in 103 samples.
2. **Syphicheck® - WB** was evaluated with Syphilis Mixed Titer Performance Panel (PSS202) obtained from Boston Biomedica Inc., USA. It was found that **Syphicheck® - WB** is as sensitive as some of the Enzyme Linked Immunosorbent Assays.
3. **Syphicheck® - WB** 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.

External evaluation

Syphicheck® - WB was evaluated by WHO (SDI) at various evaluation center for sensitivity and specificity, the combined result of **Syphicheck® - WB** sensitivity is found to be 95.3% and of specificity is found to 93.7%.

REMARKS

1. **Syphicheck® - WB** 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® - WB** detects treponemal antibodies in whole blood/ serum/ plasma; other body fluids may not give accurate results.

5. In immunocompromised patients the test results must be interpreted with caution. Testing of pooled samples is not recommended.
6. As with all diagnostic tests, result must correlated with clinical findings.

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.

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	DEVICE Device
Σ 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

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.

EC REP

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

0920/VER-03