



CORE SYPHILIS - WB
Rapid Test for Syphilis
(Modified TPHA)
(DEVICE)

INTRODUCTION

CORE SYPHILIS – WB is a rapid, qualitative, two site double antigen sandwich immunoassay for the detection of syphilis. 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*.

CORE SYPHILIS - 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

CORE SYPHILIS – WB utilizes the principle of immunochromatography, a unique two –site immunoassay on a membrane. As the test sample flows through the membrane assembly of the test device , the recombinant Treponema antigens-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 '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 IgG colloidal gold conjugate move further on the membrane and are subsequently immobilized by the goat anti-rabbit antibodies coated on the membrane at the control region ' C' ,forming a pink to deep 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 predisposed with recombinant *Treponema pallidum* antigens-colloidal gold conjugate, recombinant *Treponema pallidum* antigens and goat anti- rabbit antiserum coated at the respective regions.
2.

PIPETTE

 : Disposable plastic dropper.
3. Desiccant pouch.

B.

BUF

 : 0.1 M Tris buffer with 0.1% Sodium azide.

REF	SYP-170020
Tests	25

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 4 - 30°C for the duration of shelf life as indicated on the pouch.

NOTE

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.
6. Diluent buffer contains sodium azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build-up in the plumbing.

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 2-8⁰C 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 2-8⁰C for upto 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

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. 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, discard the device and use another device.
2. With the help of the dropper provided dispense one drop of serum / plasma or whole blood to the sample port 'A'.
3. Add four drops of diluent buffer from the diluent buffer bottle to reagent port 'B'.
4. Read the results at the end of 15 minutes as follows:

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



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



5. The test should be considered invalid if neither the test band nor the control band appears. 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

CORE Syphilis – WB Rapid test for Syphilis was evaluated at various evaluation center for sensitivity and specificity, the combined result of **CORE Syphilis – WB** sensitivity is found to be 89.2% and of specificity is found to 96.2%.

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







REMARKS

1. **CORE Syphilis – 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. **CORE Syphilis - 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.

BIBLIOGRAPHY

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

SYMBOLS USED ON CORE Syphilis - WB LABELS

	Consult instructions for use
	Storage temperature
	Use by
LOT	Batch code
REF	Catalogue number
I V D	In vitro diagnostic medical device
DEVICE	Test Device
PIPETTE	Disposable Plastic Dropper
BUF	Diluent Buffer
	Date of Manufacture
	Manufactured By
	Contains sufficient for <n> tests

Manufactured by:
CORE DIAGNOSTICS
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