



# SEROCHECK-Tp™

Rapid Test for Syphilis  
(Modified TPHA)

DEVICE

## INTENDED USE

**Serocheck-Tp™** (Device) 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, and 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*.

**Serocheck-Tp™** (Device) 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

**Serocheck-Tp™** (Device) utilizes the principle of agglutination of antibodies / antisera with respective antigen in immunochromatography format along with use of nano gold particles as agglutination revealing agent. The conjugate pad contains two components, recombinant Treponema antigens conjugated to colloidal gold and rabbit globulin conjugated to colloidal gold. As the test sample flows through the membrane assembly of the test device, the recombinant Treponema antigen-colloidal gold conjugate forms a complex with Treponema specific antibodies in the sample and travels further on the membrane due to capillary action along with the rabbit globulin-colloidal gold conjugate. This complex moves further on the membrane to the test region where it is immobilized by another recombinant Treponema antigens coated on the membrane leading to the formation of a pink to deep purple coloured band at the test region 'T'. Absence of this coloured band in test region 'T' indicates a negative test result.

The unreacted conjugate and unbound complex, if any, along with rabbit globulin - gold conjugate moves further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membrane at the control region 'C', forming a pink to deep purple coloured band. This control band acts as a procedural control and serves to validate the results.

## REAGENTS AND MATERIALS SUPPLIED

**Serocheck-Tp™** (Device) kit has following components:

- A. Individual pouch containing:
  1. **DEVICE** Membrane assembly pre-dispensed with recombinant *Treponema pallidum* antigen colloidal gold conjugate, recombinant *Treponema pallidum* antigen and Agglutinating sera for rabbit globulin coated at windows 'T' & 'C' respectively.
  2. **PIPETTE** Disposable plastic sample applicator.
  3. Desiccant Pouch.
- B. **BUF** Sample running buffer in a dropper bottle.
- C. Package insert.

<b>REF</b>	501100025
	25 Test

## OPTIONAL MATERIAL REQUIRED

Calibrated micropipette capable of delivering 25µl of sample accurately.

## STORAGE AND STABILITY

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

## NOTES

1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE. For professional use.
2. Do not use the kit beyond expiry date and do not reuse the test device.
3. Read the instructions carefully before performing the test.

- Handle all specimens as potentially infectious.
- Follow standard bio-safety guidelines for handling and disposal of potentially infective material.
- Contact with 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.
- Sample running 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.

### SAMPLE COLLECTION

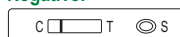
No special preparation of patient is necessary prior to specimen collection by approved techniques. Though fresh serum/ plasma is preferable, serum/ plasma specimens may be stored at 2°C to 8°C for up to 72 hours, in case of delay in testing. Do not use haemolysed or contaminated specimens. Turbid specimens 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.

- Bring the sealed pouch to room temperature, if the pouch of the 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.
- Tighten the cap of the Sample running buffer provided with the kit in the clockwise direction to pierce the dropper bottle nozzle.
- With the help of applicator provided in the pouch dispense one drop (approx. 25 µl) of serum / plasma to the sample port "S". Alternatively, 25 µl of serum / plasma may be delivered in the sample port "S" using a micropipette.
- Immediately add one drop of Sample running buffer from the buffer bottle to the sample port "S".
- Read the results at the end of **15 minutes** as follows:

#### Negative:



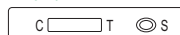
Appearance of only one pink to deep purple coloured band on the device.

#### Positive:



Appearance of two distinct pink to deep purple coloured bands on the device.

#### Invalid:



The test should be considered invalid if no bands appear on the device. The test should also be considered invalid if only test band appears and no control band appears. Repeat the test with a new device ensuring that the test procedure has been followed accurately.



- Although, depending on the concentration of Treponemal antibodies in the specimen, positive results may appear as early as 2 to 3 minutes, negative results should be confirmed only at the end of 15 minutes.

### PERFORMANCE CHARACTERISTICS

- In an in-house evaluation, 50 known Positive and 220 known Negative samples were tested with **Serocheck-Tp™** (Device) and compared with commercial Rapid and ELISA kits. The results obtained were as follows:

Samples	Total No. of samples tested	Commercial ELISA	Commercial Rapid Test	Serocheck-Tp™ (Device)	Sensitivity (95% CI)	PPV
Syphilis Positive	50 nos	49 nos	49 nos	49 nos	98.00% (99.63% to 100.00%)	100%

\* PPV: Positive Predictive Value

Samples	Total No. of samples tested	Commercial ELISA	Serocheck-Tp™ (Device)	Sensitivity (95% CI)	NPV
Syphilis Negative	220 nos	220 nos	220 nos	100.00% (98.34% to 100.00%)	100%

\* NPV: Negative Predictive Value

Based on the above study,  
Specificity of **Serocheck-Tp™** (Device) is 100%.  
Sensitivity of **Serocheck-Tp™** (Device) is 98%.

2. **Serocheck-Tp™** (Device) was evaluated with SYPHILIS PERFORMANCE PANEL (NIB-SYPHILIS-01/2017) obtained from NATIONAL INSTITUTE OF BIOLOGICALS (NIB) consisting of 25 nos. reactive and 25 nos. non-reactive plasma samples. The results obtained were as follows:

ID of Syphilis reactive samples	<b>Serocheck-Tp™</b> (Device)	ID of Syphilis non-reactive samples	<b>Serocheck-Tp™</b> (Device)
V1	POSITIVE	N1	NEGATIVE
V2	POSITIVE	N2	NEGATIVE
V3	POSITIVE	N3	NEGATIVE
V4	POSITIVE	N4	NEGATIVE
V5	POSITIVE	N5	NEGATIVE
V6	POSITIVE	N6	NEGATIVE
V7	POSITIVE	N7	NEGATIVE
V8	POSITIVE	N8	NEGATIVE
V9	POSITIVE	N9	NEGATIVE
V10	POSITIVE	N10	NEGATIVE
V11	POSITIVE	N11	NEGATIVE
V12	POSITIVE	N12	NEGATIVE
V13	POSITIVE	N13	NEGATIVE
V14	POSITIVE	N14	NEGATIVE
V15	POSITIVE	N15	NEGATIVE
V16	POSITIVE	N16	NEGATIVE
V17	POSITIVE	N17	NEGATIVE
V18	POSITIVE	N18	NEGATIVE
V19	POSITIVE	N19	NEGATIVE
V20	POSITIVE	N20	NEGATIVE
V21	POSITIVE	N21	NEGATIVE
V22	POSITIVE	N22	NEGATIVE
V23	POSITIVE	N23	NEGATIVE
V24	POSITIVE	N24	NEGATIVE
V25	POSITIVE	N25	NEGATIVE

**Note:** From the above evaluation, it can be noted that **Serocheck-Tp™** (Device) shows results which are co-relating with results provided by NATIONAL INSTITUTE OF BIOLOGICALS (NIB).

#### LIMITATIONS OF THE TEST

1. **Serocheck-Tp™** (Device) 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. **Serocheck-Tp™** (Device) 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.
6. As with all diagnostic tests, results must be co-related 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	 Do not reuse
 Manufacturer	<b>IVD</b> <i>In vitro</i> Diagnostic Medical Device	 This side up	<b>BUF</b> Sample Running Buffer
 Use by	<b>REF</b> Catalogue Number	<b>DEVICE</b> Device	<b>EC REP</b> Authorised Representative in the European Community
 Contains sufficient for <n> tests	<b>LOT</b> Batch Number / Lot Number	<b>PIPETTE</b> Disposable Plastic Sample Applicator	



Manufactured by:

**Zephyr Biomedicals**

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**EC REP**

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

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