CE

# SEROCHECK-Tp™

**Rapid Test for Syphilis**
**(Modified TPHA)**
**DIPSTICK**

## INTENDED USE

**Serocheck-Tp**™ 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**™ 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**™ 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, 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. Absence of this coloured band in test region 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, 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**™ kit has following components:

A. DIPSTICK Dipstick container with individual pouches and desiccant.
   Each individual pouch contain 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.
B. Dipstick Holder.
C. Package insert

| | |
|---|---|
| REF | 501090025 |
| Σ | 25 Test |

## STORAGE AND STABILITY

**Serocheck-Tp**™ kit is stable upto the expiry date mentioned on the label, when stored at 4°C to 30°C. The desiccant provided in the container reduces the moisture content during packing, storage and transit. On opening of the sealed container, the desiccants are dysfunctional; however the individual sealed pouches containing the dipstick membrane assembly are stable upto the expiry date mentioned on the pouch/label. Once the pouch is opened, the dipstick must be used immediately.

## MATERIALS REQUIRED BUT NOT PROVIDED

1. Disinfectant
2. Disposable gloves
3. Biohazard waste container
4. Micropipette/Sample dropper capable of delivering 50µl sample.

## SAMPLE COLLECTION

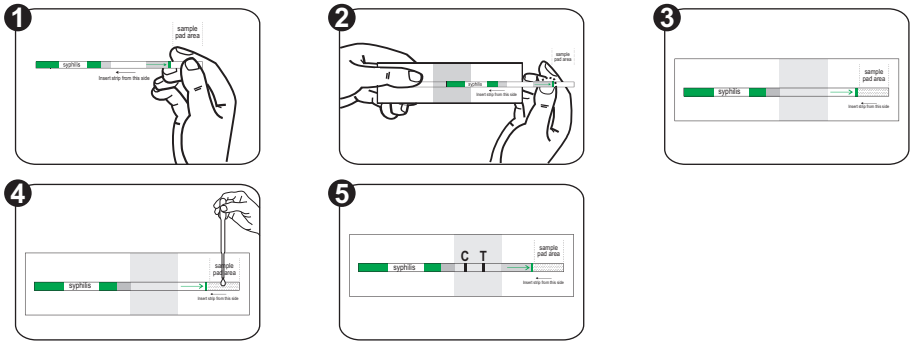
No special preparation of patient is necessary prior to specimen collection by approved techniques. Though fresh serum/ plasma is preferable, serum/ plasma specimens may be stored at 2°C to 8°C for up to 72 hours, in case of delay in testing. Do not use haemolysed or contaminated specimens. Turbid specimens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

## NOTES

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 bio-safety guidelines for handling and disposal of potentially infective material.
6. 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.

## TESTING PROCEDURE AND INTERPRETATION OF RESULTS

1. Retrieve the dipstick from the pouch as per instructions on the bottle label .
2. Hold the dipstick from the arrow mark & insert into the dipstick holder by bending the dipstick holder slightly.
3. While inserting the dipstick into the holder ensure that it is held from the arrow mark at the sample pad & inserted through the coloured end which is green in colour as shown in the pictorial below.
4. Align the dipstick with the drawing on the dipstick holder ensuring that the test area is covered with the film.
5. Label the Dipstick holder with patient's identity.
6. Using a micropipette or sample dropper, dispense 50µl of serum/plasma sample onto the sample pad just below the arrows.
7. Read the results at the end of 15 minutes.




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

## PERFORMANCE CHARACTERISTICS

**Internal Evaluation I**

In an in-house evaluation, 51 known Positive and 208 known Negative samples were tested with **Serocheck-Tp™** and compared with commercial Rapid and Elisa kit. The results obtained were as follows:

| Sample | Total No. of samples tested | Commercial Rapid Test | Commercial ELISA | **Serocheck-Tp™** |
|---|---|---|---|---|
| Positive Sample | 51 | 50 | 51 | 50 |
| Negative Sample | 208 | 208 | 208 | 208 |

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

**Internal Evaluation II**

**Serocheck-Tp™** was evaluated with Syphilis ACCUSET Performance Panel (0820-0214) and Syphilis SEROCONVERSION Panel (0615-0017/PSS901-1.2) obtained from Sera care Life Sciences. The results obtained are given below:

**Evaluation with Syphilis ACCUSET Performance Panel (0820-0214)**

| Panel Member | Bio-Rad Bioplex® 2200 Syphilis IgG | Calbiotech EIA Syphilis IgM (s/co) | Trinity Biotech CAPTIA™ Syphilis IgG EIA (s/co) | Serocheck-Tp™ |
|---|---|---|---|---|
| 1 | NEGATIVE | 0.4 | 0.1 | NEGATIVE |
| 2 | NEGATIVE | 0.7 | 0.1 | NEGATIVE |
| 3 | POSITIVE | **4.1** | **4.0** | POSITIVE |
| 4 | POSITIVE | **4.7** | **5.1** | POSITIVE |
| 5 | POSITIVE | 0.6 | **4.4** | POSITIVE |
| 6 | POSITIVE | 0.8 | **3.5** | POSITIVE |
| 7 | POSITIVE | 0.6 | **3.8** | POSITIVE |
| 8 | POSITIVE | **2.0** | **3.9** | POSITIVE |
| 9 | POSITIVE | **1.8** | **3.8** | POSITIVE |
| 10 | POSITIVE | **2.2** | **4.1** | POSITIVE |
| 11 | POSITIVE | 0.7 | **4.7** | POSITIVE |
| 12 | POSITIVE | **2.4** | **4.2** | POSITIVE |
| 13 | POSITIVE | 0.5 | **3.8** | POSITIVE |
| 14 | POSITIVE | **1.6** | **3.4** | POSITIVE |
| 15 | POSITIVE | **1.2** | **2.8** | POSITIVE |
| 16 | POSITIVE | **3.5** | **3.9** | POSITIVE |
| 17 | POSITIVE | **4.1** | **4.6** | POSITIVE |
| 18 | POSITIVE | **2.4** | **4.6** | POSITIVE |
| 19 | POSITIVE | **>5.8** | **4.3** | POSITIVE |
| 20 | POSITIVE | **>5.8** | **4.3** | POSITIVE |

Note 1: Results in above data, other than that for **Serocheck-Tp™** are provided by Sera Care Life Sciences.
Note 2: Above *Treponemal* Immunoassay - IgG/IgM results other than **Serocheck-Tp™** are expressed as signal to cut-off ratios(s/co). Ratios > 1.0 are considered positive. Results are reported as a mean of duplicate testing. Results in bold are considered positive /reactive.

**Evaluation with Syphilis SEROCONVERSION Panel (0615-0017/PSS901)**

| Panel Member | DiaSorin Liasion Treponema Syphilis | Olympus PK™ TP Syphilis | Fujirebio Serodia® TPPA Syphilis | Trinity Biotech MarBlot Syphilis IgG | Trinity Biotech MarBlot Syphilis IgM | Serocheck-Tp™ |
|---|---|---|---|---|---|---|
| PSS901-01 | NEGATIVE | NEGATIVE | NEGATIVE | NEGATIVE | NEGATIVE | NEGATIVE |
| PSS901-02 | NEGATIVE | NEGATIVE | NEGATIVE | NEGATIVE | NEGATIVE | NEGATIVE |
| PSS901-03 | NEGATIVE | NEGATIVE | NEGATIVE | NEGATIVE | NEGATIVE | NEGATIVE |
| PSS901-04 | NEGATIVE | NEGATIVE | NEGATIVE | NEGATIVE | NEGATIVE | NEGATIVE |
| PSS901-05 | NEGATIVE | NEGATIVE | NEGATIVE | NEGATIVE | NEGATIVE | NEGATIVE |
| PSS901-06 | **POSITIVE** | NEGATIVE | **POSITIVE** | INDETERMINATE | **POSITIVE** | **POSITIVE** |
| PSS901-07 | **POSITIVE** | **POSITIVE** | **POSITIVE** | INDETERMINATE | **POSITIVE** | **POSITIVE** |
| PSS901-08 | **POSITIVE** | **POSITIVE** | **POSITIVE** | INDETERMINATE | **POSITIVE** | **POSITIVE** |
| PSS901-09 | **POSITIVE** | **POSITIVE** | **POSITIVE** | **POSITIVE** | **POSITIVE** | **POSITIVE** |

Note: Results in above data, other than that for **Serocheck-Tp™** are provided by Sera Care Life Sciences.
From the above evaluation, it can be noted that **Serocheck-Tp™** shows results which are co-relating with above anti-*Treponemal* quantitative and qualitative antibody assays.

## LIMITATIONS OF THE TEST

1. **Serocheck-Tp™** 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™** 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.
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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 | | This side up |
| | Manufacturer | IVD | *In vitro* Diagnostic Medical Device | LOT | Batch Number / Lot Number | DIPSTICK | Dipstick | | |
| | Use by | REF | Catalogue Number | Σ | Contains sufficient for <n> tests | EC REP | Authorised Representative in the European Community | | |


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EC REP

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


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