Core™ Syphilis
Rapid Test for the detection of IgM and IgG class of treponema specific antibodies during syphilis in serum/plasma and Whole Blood.
CAT N°: SYP-170020

INTRODUCTION
CORE-Syphilis is a one step rapid, self-performing, qualitative, two site double antigen sandwich immunoassay for the detection of syphilis.

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 pre-natal 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 is a modified TPHA, which qualitatively detects the presence of IgM and IgG class of treponema specific antibodies during syphilis in serum,plasma, or whole blood specimen within 15 minutes.

PRINCIPLE
CORE-Syphilis utilizes the principle of immunochromatography in a unique two-site immunoassay on a membrane. As the test sample laterally flows through the membrane on the device, 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 antigen coated on the membrane leading to the formation of a pink to a deep purple coloured band at the test region ‘T’ which confirms a positive result. Absence of this coloured band in test region ‘T’ indicates a negative result. The unreacted conjugate and the unbound complex if any move further on the membrane and are subsequently immobilized by the anti-rabbit antibodies coated on the control region ‘C’ of the membrane assembly, forming a pink to a deep purple coloured band. The control band serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED
Each individual KITS contains:
1. Test device: Membrane assembly predispensed with recombinant treponema pallidum antigen-colloidal gold conjugate, recombinant treponema pallidum antigen and anti-rabbit antiserum coated at the respective regions.
2. Diluent Buffer.
3. Disposable plastic dropper.
4. Desiccant pouch.

STORAGE AND STABILITY
The sealed pouches in the test kit and the sample running buffer may be stored between 4°C to 30°C for the duration of the shelf life as indicated on the pouch and the vial. After first opening of the sample running buffer vial, the buffer is stable until the expiration date, if kept at 4°C to 30°C. Do not freeze the kit or components.

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 biosafety guidelines for handling and disposal of potentially infective material.
6. 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.
7. If the pouch of the test device is damaged, discard the device and take a new one for the test.

SPECIMEN COLLECTION AND PREPARATION

Whole Blood Samples:
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 2-8°C for up to 72 hours before testing. Do not use hemolysed, clotted or contaminated blood samples for performing the test.

Serum / Plasma.
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 2-8°C for up to 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, open the pouch and remove the device. Once opened, the device must be used immediately.
2. With the help of the dropper provided, dispense two drops (of whole blood (50µl)) or one drop (serum / plasma (25µl)) into the sample well ‘S’.
3. Add 2 drops of diluent buffer from the bottle provided.
4. At the end of 15 minutes read the results as follows:

NEGATIVE:

POSITIVE:

C T S
C T S

Negative: Only one colored band appears on the control region ‘C’
Positive: In addition to the control band, a distinct colored band also appears on the test region ‘T’

7. The test should be considered invalid if neither the test band not the control band appears. Repeat the test with a new device.
8. Although, depending on the concentration of treponemal antibodies in the specimen, positive results may appear as early as 2 minutes, negative results must be confirmed only at the end of 15 minutes.

REMARK:
To control the proper test performance, it is recommended to include internal control samples.

TEST PERFORMANCE

1. Diagnostic specificity:
A total of 200 samples were tested with the Core Syphilis. The diagnostic specificity is determined as 100%.