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"See Now" Syphilis CassetteTest CE

Serum/ Plasma

For in vitro Diagnosis Use
Product Code: SN 4.2

INTENDED USE

The *"See Now"* Treponema Pallidum (TP) Antibody Test is a rapid and convenient immunochromatographic *in vitro* assay. It is used for qualitative determination of TP IgG and IgM antibodies in human serum, plasma.

This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test. It is intended for professional use as an aid in the diagnosis of Syphilis.

.PRINCIPLE

The spirochete Treponema Pallidum (TP) is the pathogen of a sexually transmitted disease to cause Syphilis. As this organism cannot be cultured on artificial media, the diagnosis of Syphilis depends on the correlation of clinical data with the specific antibodies demonstrated by serological tests.

Multiple clinical stages and long periods of latent, asymptomatic infection are characteristic of Syphilis. Primary syphilis is defined by the presence of a chancre at the site of inoculation. The antibodies response to the TP bacterium can be detected within 4 to 7 days after the chancre appears. The infection remains detectable until the patient receives adequate treatment.

The principle of "*See Now*" TP Antibody Test is double antigen sandwiched, immunochromatographic assay. TP antigen is conjugated with colloidal gold particle and immobilized on the membrane. When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate to form antigen-antibody-gold complex. These complexes will continue to migrate along the strip until the test zone (T) where they are captured by the TP antigens to form a visible red line. The un-bound gold conjugate will continue to move to the Control Zone (C) forming a visible red line. If there are no antibodies in sample, a red line is only appeared at the C zone. To serve as an internal process control, a control band should always be seen after test is completed. Absence of a colored control line at the control region is an indication of an invalid result.

MATERIALS SUPPLIED

- Test Device, Specimen Pipette, Desiccant
- Test instruction

MATERIALS REQUIRED BUT NOT SUPPLIED

- Specimen collection container, Timer

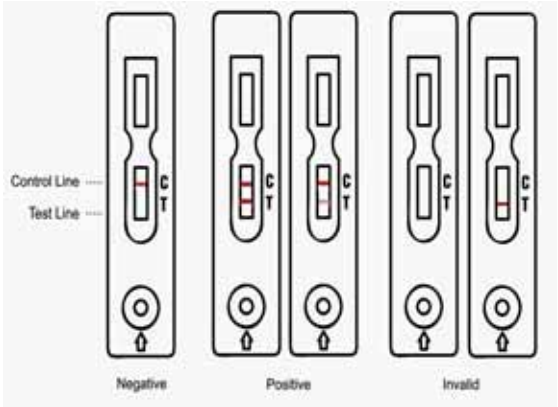
SPECIMEN PREPARATION

- Collect blood in a tube without anticoagulant for serum samples and allow to clot.
- For plasma samples, collect the blood in a tube containing anticoagulant.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.

TEST PROCEDURE

- Remove the test device from the sealed pouch by tearing at the notch. Then place the testing device on a level surface
- Holding the sample dropper vertically, add 5 drops (0.2 ml) of specimen without air bubbles into the sample well that is make with an arrow on the testing device.
- Read the result at 15 minutes. Ensure that the background of the test area is white before interpreting the results. Do not read the results after 30 minutes.

INTERPRETATION OF RESULTS



Negative

Only one pink colored band appears at the control region.

Positive

Distinct pink colored bands appear at the control and test line regions.

Invalid

No visible band at the control region. Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

STORAGE AND STABILITY

- Test device in the sealed pouch can be stored at 2-30ºC up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not reuse.
- Test device should remain sealed until use.

- Do not used after the expiration date shown on the pouch.
- Keep out of children's reach.

LIMITATION OF PROCEDURE

- This product is designed for in vitro diagnostic use only.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.