

One-Step Anti-TP Rapid Test

INTENDED USE

The One Step Anti-TP(Treponema Pallidum /Syphilis) Test is a rapid, serological, immunochromatographic assay for the detection of antibodies to Treponema Pallidum antigen in human whole blood, serum or plasma. The test is used to obtain a visual, qualitative result and is intended for healthcare professional use. Applications of the test include: screen test for sex transmitted diseases (STD's) among high-risk group of people, regular health examinations, and field screen test for blood bank.

SUMMARY AND BIOLOGICAL PRINCIPLE OF THE ASSAY

The One Step Anti-TP(Treponema Pallidum /Syphilis) Test uses a double antigens “sandwich principle”¹ for the detection of Treponema Pallidum antibody in human serum. A recombinant Treponema Pallidum antigen (TP Ag 2) was immobilized on the test band region, and an antibody to Treponema Pallidum on the control band region of nitrocellulose membrane. Another Treponema Pallidum antigen (TP Ag 1), coupled with colloidal gold particles, is dried on a conjugate pad. During the assay, the specimen is allowed to react with the colored conjugate (antigen-colloid gold conjugate); the mixture then migrates chromatographically along the membrane by capillary action. If the specimen contains Treponema Pallidum antibody, the recombinant antigen immobilized on the membrane will capture the antibody-antigen-colloidal gold complex and form a colored test band on the membrane, indicating a positive result. Absence of the test band suggests a negative result. To serve as a procedural control, a colored band at control region always appears in the test area.

STORAGE AND EXPIRATION

The test kits must be stored at 2-30 in the sealed pouch and under dry conditions.

PRECAUTIONS

It is recommended that all specimens be handled in accordance with Biosafety Level 2 practices as described in the CDC NIH Publication, Biosafety in Microbiological and Biomedical Laboratories², or other equivalent guidelines.³⁻⁴

1. For in vitro diagnostic use only.
2. All whole blood, serum or plasma specimens should be treated as infectious material. Do not contact the test card without wearing safety gloves.
3. Clean and disinfect all spills of specimens and reagents using a suitable disinfectant,⁵ such as 1% Sodium Hypochlorite.
4. Devices used for the assay should be sterilized before being disposed.
5. Do not use beyond expiration date.

MATERIALS PROVIDED

- Test cards / test strips, individually foil pouched with a desiccant

- Package insert
- Sample dispensing plastic dropper with each test pouch.(for card only)

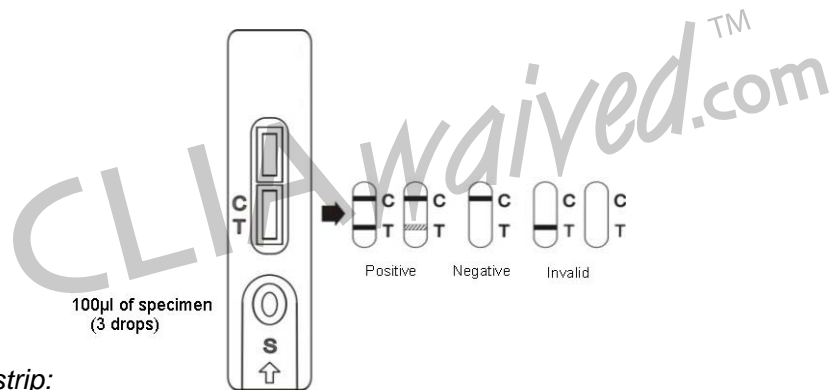
MATERIALS REQUIRED BUT NOT PROVIDED

- Pipettes to deliver 100µl of sample
- Positive and negative controls

ASSAY PROCEDURES Do not open pouch until you are ready to test the sample.

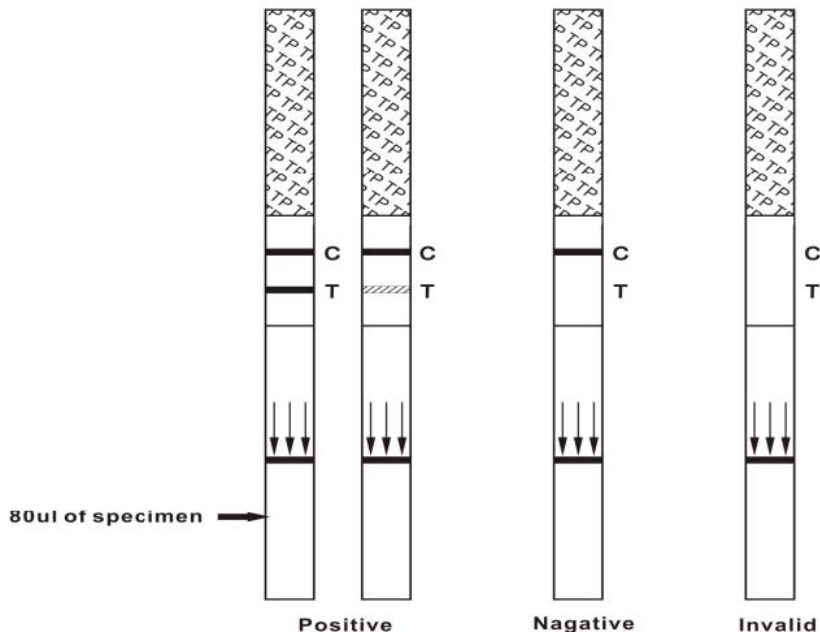
For test card:

1. Bring all reagents and specimens to room temperature.
2. Remove the test card from the foil pouch and place on a clean dry surface.
3. Identify the test card for each specimen or control.
4. Dispense 100µl (3 drops) of the specimen or control into the circular sample well on the card.
5. Interpret the test results at 15 minutes. **Do not interpret the results after 20 minutes.**



For test strip:

1. Bring all reagents and specimens to room temperature.
2. Remove the test strip from the foil pouch and place on a clean dry surface.
3. Identify the test strip for each specimen or control.
4. Apply at least 60µl of specimen to the sample pad behind the (↓↓↓) mark at the bottom of test strip.
5. Interpret the test results at 15 minutes. **Do not interpret the results after 20 minutes.**



Caution: Use a clean pipette or tip for every sample to avoid cross-contamination.

INTERPRETATION OF RESULTS

The presence or absence of syphilis antibody provides useful information on the status of individuals with infection of syphilis.

1. **Negative:** Only one purplish red colored band appears on the control region.
2. **Positive:** In addition to the control band, a distinct colored band also appears on the test region.
3. **Invalid:** Neither purplish red test band nor purplish red control band appears. The specimen should be tested again using a new device.

LIMITATIONS

1. The assay should be performed in normal room temperature.
2. Test cards/strips should be used immediately after being taken from the package. Avoid exposing the test strips in the air for too long before use.
3. The test cards/strips may be stored under room temperature and dry condition. If refrigerated, the strips should be brought to room temperature before testing.

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