



ONE STEP Anti-TP(Treponema Pallidum /Syphilis) TEST

(Serum/ Plasma)

FOR IN VITRO DIAGNOSTIC USE ONLY

INTENDED USE

The Advanced Quality™ One Step Anti-TP (Treponema Pallidum / Syphilis) Test is a rapid, serological, immunochromatographic assay for the detection of antibodies to syphilis antigen in human serum. 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 Advanced Quality One Step Anti-TP (Treponema Pallidum / Syphilis) Antibody Test uses a double antigens "sandwich principle"¹ for the detection of Syphilis antibody in human serum. A recombinant syphilis antigen (TP Ag 2) was immobilized on the test band region, and an antibody to syphilis on the control band region of nitrocellulose membrane. Another syphilis 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 syphilis 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 device should be stored at 4-30°C in sealed barrier pouch and under dry condition. The shelf life is eighteen months after the date of manufacture.

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 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 for nonradioactive material⁶ or 2% Glutaraldehyde for spills containing radioactive material.⁷
4. Devices used for the assay should be sterilized before being disposed.
5. Do not use beyond expiration date.

MATERIALS PROVIDED

25 Test Strips per canister

MATERIALS REQUIRED BUT NOT PROVIDED

1. Microtiterwell (or other specimen container)
2. Pipet
3. Clock/Timer

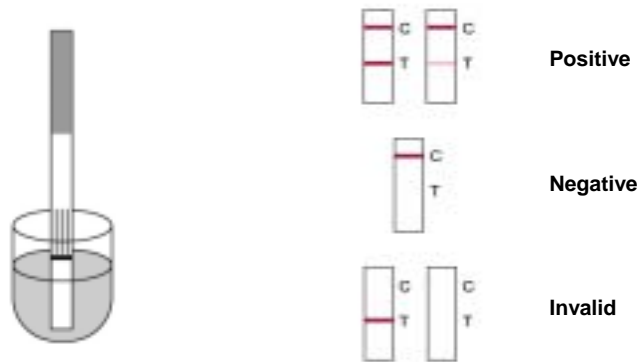
BEFORE TESTING

1. Bring all reagents and specimens to room temperature.
2. Prepare at least 100µl of serum specimen in a microtiterwell or other container, and label specimen ID number.
3. Remove the test strips to be used from the pack and seal container immediately to prevent the rest of the strips from absorbing moisture.

ASSAY PROCEDURES

1. Immerse the test strip into serum or plasma sample with the arrows pointing towards the specimen. (Keep the level of sample below the maximum line marked on the strip.)

2. Hold the test strip in the sample until a reddish color appear at the lower edge of the test membrane (approximately 10 seconds).
3. Withdraw the test strip from sample and lay it down on a clean surface.
4. Interpret the test results at 15 minutes. **Do not interpret the results after 20 minutes.**



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 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 test band nor control band appears. The specimen should be tested again using a new device.

LIMITATIONS

The assay should be performed in normal room temperature.

1. Test strips should be used immediately after being taken from the package. Avoid exposing the test strips in the air for too long before use.

2. The strips may be stored under room temperature and dry condition. If refrigerated, the strips should be brought to room temperature before testing.
3. Do not interpret result after 20 minutes. However, positive result could be interpreted within 20 minutes.

BIBLIOGRAPHY

1. Peters, RL, Collins, MJ, O'Beirne, AJ, Howton, PA, Hourihan, SL, and Thomas, SF, Enzyme-linked immunosorbent assay for detection of antibodies to murine hepatitis virus. *J. Clin. Microbiol.* 10:595-597, 1979.
2. U. S. Department of Health and Human Services. Biosafety in microbiological and biomedical laboratories. HHS Publication (NIH) 88-8395. Washington: U.S. Government Printing Office, May 1988.
3. World Health Organization. Laboratory biosafety manual. Geneva. World Health Organization, 1983.
4. National Committee for Clinical Laboratory Standards. Protection of laboratory workers from infectious disease transmitted by blood, body fluids, and tissue: Tentative guideline. NCCLS Document M29-T. Villanova, PA.: NCCLS, 1989.
5. Cawley Centers for Disease Control. Recommendation for prevention of HIV transmission in healthcare setting. *MMWR* 36, Supplement No. 2S, 1987.