

# One Step Anti-TP (Treponema Pallidum) Test (Cassette)

Cat. No. DTS052  
Lot. No. (See product label)

## INTENDED USE

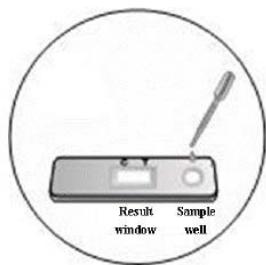
The One Step Anti-TP (Treponema Pallidum) is a rapid double antigen sandwich immunoassay for the qualitative detection of antibodies to Treponema Pallidum in human serum/plasma. The test is for a visual, qualitative result and is intended for healthcare professional use as an aid in the clinical assessment of syphilis infection.

## SPECIMEN COLLECTION AND PREPARATION

1. The test works best on fresh samples. It can be performed using either serum or plasma. Collect serum or plasma specimens following regular clinical laboratory procedures.
2. Only those specimens that are clean, clear and with good fluidity can be used for the assay. Avoid using hemolyzed, extremely thickened specimens.
3. The test works best on fresh samples. But if specimens cannot be tested on the day of collection, store in a refrigerator or freezer. Bring the specimens to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

## TEST PROCEDURE

1. Bring all reagents and specimens to room temperature.
2. When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test from the pouch.
3. Draw 0.1 ml (about 2-3 drops) of sample into the pipette, and dispense it into the sample well on the cassette.
4. Wait for 10-15 minutes and read results.
5. Do not read results after 20 minutes.



## INTERPRETATION OF RESULTS

### NEGATIVE

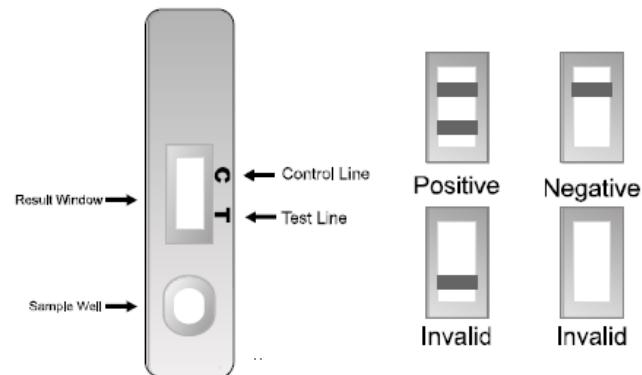
Only one colored band appears on the control region. No apparent band on the test region.

### POSITIVE

In addition to a pink colored control band, a distinct Pink colored band will also appear in the test region.

### INVALID

A total absence of color in either regions or only one color band appears on the test region indicate procedure error and/or the test reagent has deteriorated.



## STORAGE AND STABILITY

The test kit can be stored at temperature 4 °C to 30 °C (39°F - 86°F) in the sealed pouch to the date of expiration. The test kits should be kept away from direct sunlight, moisture and heat.

## PRECAUTION

1. Read directions for use carefully before performing this test. Pay attention to the position of the C and T line.
2. Do not use beyond the labelled expiration date.
3. Do not reuse the test devices.
4. Do not use if pouch is damaged or opened.
5. Do not touch the membrane on the strip.
6. Once open the pouch, the test device should be used immediately. Prolonged exposure to ambient humidity will cause product deterioration.
7. It is recommended that all specimens be used as if they are potentially infectious and handled in accordance with Biosafety Level 2 practices as described in the CDC NIH

- Publication: Biosafety in Microbiological and Biomedical laboratories [1], or other equivalent guidelines [2, 3].
8. Devices used for the assay should be sterilized before being disposed.

**LIMITATIONS OF THE TEST**

1. The results of this test should be interpreted in conjunction with other clinical and laboratory data.
2. For samples that are positive by this test, a more specific confirmatory test should be done. A clinical evaluation of the patient's information should be made by health care professionals before a final diagnosis is established.
3. The use of a rapid test alone is not sufficient to diagnose syphilis infection. Also, a negative result does not preclude the possibility of infection.
4. Avoid repeated freezing and thawing of reagents and specimens.
5. Grossly hemolyzed, icteric or lipemic specimens should be avoided.