

## INTRODUCTION

One Step Anti-Syphilis strip Test is a rapid, direct binding test for the visual detection of anti-syphilis antibodies in serum. It is used as an aid in the diagnosis of syphilis infection. Test results are read visually without any instrument. It is based on the principle of double antigen sandwich immunoassay for determination of syphilis antibodies in serum. Purified recombinant syphilis antigens are employed to identify anti-Syphilis antibodies specifically. This one step test is very sensitive and only takes about 10 to 20 minutes.

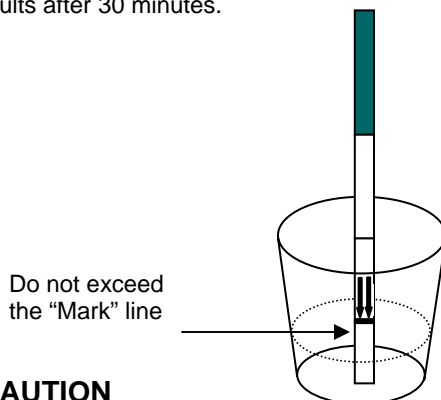
## SPECIMEN COLLECTION & PREPARATION

For serum, collect blood into a container without anticoagulant. Allow the blood to clot and separate the serum from the clot. Use the serum for testing.

If the specimen cannot be tested on the day of collection, store the serum specimen in a refrigerator or freezer. Stir and bring the specimens to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

## TEST PROCEDURE

1. When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test kit from the pouch and use it as soon as possible.
2. Following the illustration, dip the test strip with the arrow side pointing down into the vessel of serum for about 10 seconds. Do not immerse past the marker line. Take the strip out and lay it on a clean, dry and non-absorbent surface.
3. Wait for 10 minutes and read results. It is important that the background is clear before the result is read. Do not read results after 30 minutes.



## PRECAUTION

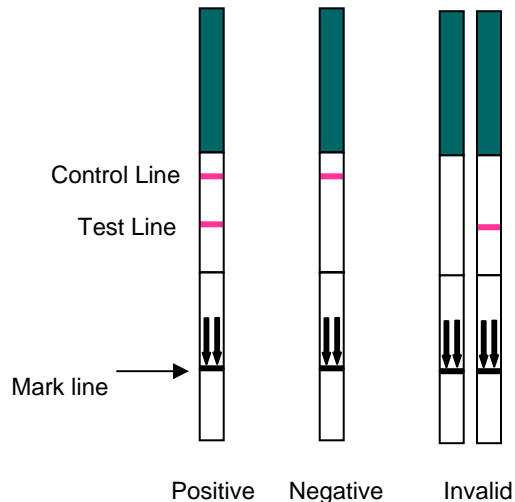
1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.
4. Keep out of the reach of children.

## STORAGE AND STABILITY

The test kit can be stored at temperatures between 2 to 30°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

## INTERPRETATION OF RESULTS

- **Negative:** Only one colored band appears on the control (C) region. No apparent band on the test (T) region.
- **Positive:** In addition to a pink colored control (C) band, a distinct pink colored band will also appear in the test (T) region.
- **Invalid:** A total absence of color in both regions or no colored line appears on the control (C) region is an indication of procedure error and/or the test reagent deterioration. Repeat the test with a new kit.



## LIMITATIONS

1. As with all diagnostic tests, all results must be considered with other clinical information available to the physician. A definite clinical diagnosis should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. This test kit is for the detection of *TP* antibodies in serum specimen. This test is for *in vitro* diagnostic use only. Neither the quantitative value nor the rate of increase in *TP* antibodies can be determined by this qualitative test.
3. This kit will only indicate the presence of *TP* antibodies in the specimen and should not be used as the sole criteria for the diagnosis of *TP* infection.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *TP* infection.

## SENSITIVITY & SPECIFICITY

To establish the sensitivity and specificity of IND Diagnostic One-step Syphilis test kit relative to other rates of qualitative serum Syphilis tests, 305 clinic samples were studied. Another commercially available qualitative test kit (Diasorin Syphilis) was used to compare with IND Diagnostic One-step Syphilis test kit for relative sensitivity and specificity in 305 serum samples. Only 1 sample was discordant, the agreement is 99.67%.