



CORTEZ DIAGNOSTICS, INC.

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See external label



2°C-30°C



$\Sigma=25$ or 50 tests



Catalog #176502-1

OneStep Syphilis RapiDip InstaTest

Cat. No. 176502-1

INTRODUCTION

OneStep Syphilis RapiDip InstaTest Test is a rapid direct binding test for the visual detection of anti-syphilis antibodies in serum 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.

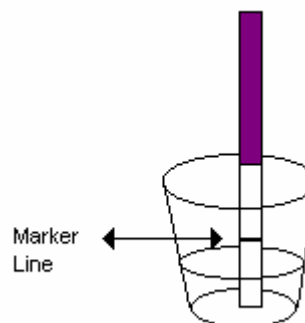
SPECIMEN COLLECTION

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. Bring the specimens to room temperature before testing. Do not freeze and thaw the specimen repeatedly.

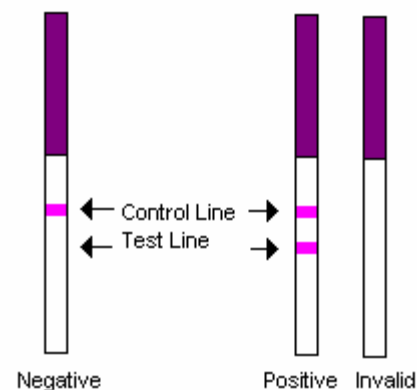
TEST PROCEDURE

1. Allow the sealed Anti-Syphilis test pouch, serum specimens and control solution to reach room temperature (18-30°C).
2. Remove the test device from the sealed pouch.
3. Immerse the strip into the serum with the arrow end pointing towards the serum. Do not immerse past the marker line. Take the strip out after 5 seconds and lay the strip flat on a clean, dry, non-absorbent surface (e.g., mouth of the serum container).
4. Wait 10-20 minutes and read results. Do not read results after 30 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 both regions is an indication of procedure error and/or that the test reagent has deteriorated.



STORAGE AND STABILITY

The test kits can be stored at room temperature (18 to 30°C) in the sealed pouch to the date of expiration. The test kits should be kept away from direct sunlight, moisture and heat.

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.



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