



## CORTEZ DIAGNOSTICS, INC.

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See external label



2°C-30°C



Σ=25 or 50 tests



Cat. #176512-1

## OneStep RapiDip Gonorrhea InstaTest

Cat. No. 176512-1

### INTRODUCTION

OneStep Strip Style Gonorrhea Test is a rapid direct binding test for the visual detection of gonorrhea antigen, in the secretory specimen and urine from urogenital system, as an aid in the diagnosis of gonococcus infection. It is based on the principle of double sandwich immunoassay for detection of gonorrhea antigen in the secretory specimen and urine. Monoclonal and polyclonal antibodies are employed to identify gonorrhea specifically. Both sensitivity and specificity of the test are higher than those of the present methods that often involve in long hours of culturing the collected specimen. Test results are not affected by medication that is under taking. Moreover test results are read visually without any instrument. This test is ideal for screening specimen sample containing equal to or more than  $1 \times 10^5$  bacteria per ml.

### SPECIAL FEATURES

- ✓ Test result is unambiguous and can be read in 10-20 minutes after completion of the test.
- ✓ Test kit is easy to operate and does not involve washing or comparison to standards.
- ✓ High specificity and high sensitivity is confirmed after each test kit is tested with other possible cross-reaction substances.

### MATERIALS PROVIDED

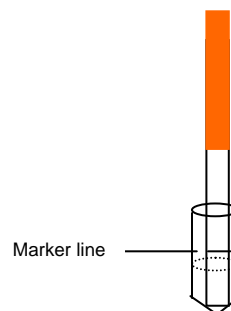
1. Test strip
2. Specimen diluent 1
3. Specimen diluent 2

### SPECIMEN COLLECTION

1. Use a swab to collect specimen in the following suggested method:
  - a) Male patients: Swab discharge from the opening of the urinary tract. If no discharge is present, insert the swab 2-3cm into the urinary tract, gently move a few turns and retrieve the swab.
  - b) Female patients: Swab discharge from the vaginal opening, then insert swab into vagina for half a minute and retrieve the swab.
2. Place the swab into the microtube and add 6 drops (300µL) specimen diluent 1 on the swab, rotate swab and squeeze. Discard the swab into a disinfectant container. Then add 2 drops (100µL) diluent 2 into the microtube, and mix well. Specimen collected in the diluent should be stored at 4-8°C and tested within 24 hours.

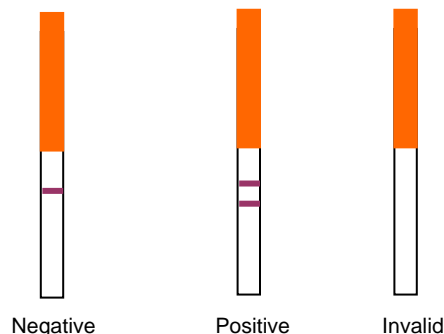
### TEST PROCEDURE

Following the illustration, dip the test strip with the arrow pointing down into the specimen for about 5 seconds. Do not immerse past the marker line. 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 the test reagent has been deteriorated.



Negative

Positive

Invalid

## STORAGE AND STABILITY

The test kits can be stored at room temperature (18 to 30°C) or in a refrigerator (0 to 4°C) in the sealed pouch to the date of expiration. The test kits should be kept away from direct sunlight, moisture and heat. If the test kit package was refrigerated, allow it to reach room temperature first before usage.

## PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Patient specimens may contain infectious agents and should be handled as though capable of transmitting disease. Wear disposable gloves throughout the specimen collection and assay procedures.

## LIMITATIONS OF TEST

1. One-Step Gonorrhea Test is a presumptive, screening test for the presence of *Neisseria gonorrhoeae*. If test results are negative but clinical symptoms are indicative of gonorrheal infection, further tests are recommended. Cell culture is the standard reference test method for the detection of *Neisseria gonorrhoeae*.

## PERFORMANCE CHARACTERISTICS

### Sensitivity & Specificity

The sensitivity of this test kit is 98.3% accurate. 150 patients were tested for gonorrheal infection and their swab specimens were tested in parallel using this One-Step Gonorrhea Test Kit and a conventional culture test. For calculating sensitivity and specificity, the cell culture result is assumed to be 100% accurate. The results are shown as follow:

Cell Culture	Cortez Diagnostics Gornorrhea Test Kit	
	Test Positive	Test Negative
True Positive	58	1
True Negative	2	89

Relative Sensitivity: 98.3%

Relative Specificity: 97.8%

## CROSS-REACTIVITY

The following microorganisms tested negative using the One-Step Gonorrhea Test Kit. The number of microorganisms in each test exceed  $10^8$  cells/mL.

☐ *Bacteroides spp*  
☐ *Campylobacter spp*  
☐ *Candida spp*  
☐ *Chlamydia spp*  
☐ *Citrobacter spp*  
☐ *Clostridium spp*  
☐ *Enterobacter spp*  
☐ *Escherichia coli*

☐ *Haemophilus influenzae*  
☐ *Herpes Simplex virus*  
☐ *Klebsiella spp*  
☐ *Lactobacillus spp*  
☐ *Listeria spp*  
☐ *Mycoplasma spp*  
☐ *Neisseria meningitides*

☐ *Proteus spp*  
☐ *Pseudomonas spp*  
☐ *Salmonella spp*  
☐ *Serratia spp*  
☐ *Shigella spp*  
☐ *Staphylococcus spp*  
☐ *Trichomonas spp*  
☐ *Yersinia spp*



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