Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

OneStep Gonorrhea RapiDip™ InstaTest

REF 176512-1

IVD See external Label 2°C-30°C 1 Test

Sensitivity	Cut-Off 1 x10⁵ bacteria / mL 99 %

INTENDED USE

Cortez Diagnostics, Inc. OneStep Gonorrhea RapiDip™ InstaTest is a, direct binding test for the visual detection of gonorrhea antigen, in the secretory specimen from urogenital system.

TEST PRINCIPLE

It is based on the principle of double sandwich immunoassay for detection of gonorrhea antigen in the secretory specimen or 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 long hours of culturing the collected specimen. Test results are not affected by medication that is being taken. Results are read visually without any instrumentation. This test is ideal for screening specimen samples containing at least 1 x 105 bacteria per mL.

SPECIMEN COLLECTION AND PREPARATION

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 2-3 cm 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 a microtube and add 6 drops (300 µL) specimen diluent 1 on the swab, rotate swab and squeeze. Discard the swab into an appropriate biohazard disposal container. Then add 2 drops (100 µL) diluent 2 into the microtube and mix well. Specimen collected in the diluent should be stored at 4-8ºC and tested within 24 hours.

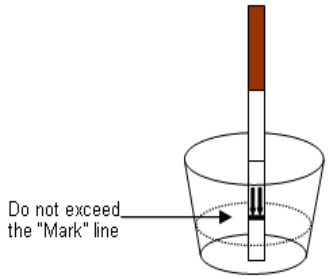
MATERIALS AND COMPONENTS

Materials provided with the test kits

1. Test kit
2. Specimen Diluent 1
3. Specimen Diluent 2
4. Swab

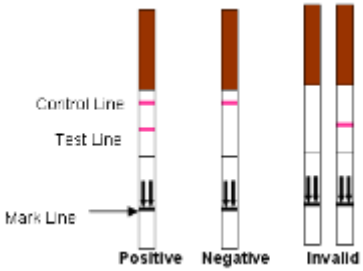
ASSAY PROCEDURE

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 pointing down into the specimen for about 10 seconds. Do not immerse past the marker line. Take the strip out and lay it flat on a clean, dry and non-absorbent surface.
3. Wait 10-20 minutes and read results. It is important that the background is clear before the result is read. Do not read results after 30 minutes.



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 in the control (C) region is an indication of procedure error and/or the test reagent deterioration. Repeat the test with a new kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



LIMITATIONS OF PROCEDURE

1. As with all Cortez 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. One-Step Gonorrhea Test is a presumptive, screening test for the presence of Neisseria gonorrheae.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 gonorrhea.

PRECAUTIONS

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. Patient specimens may contain infectious agents and should be handled as though capable of transmitting disease. Wear

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disposable gloves throughout the specimen collection and assay procedures.

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

ISO 13485 **ISO 9001** **Diagnostic Automation/** **Cortez Diagnostics, Inc.** **21250 Califa St, Suite 102 and 116,** **Woodland Hills, California 91367 USA**	
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REF **176512-1**	**CORTEZ- OneStep** **Gonorrhea** **RapiDip™ InstaTest**
EC REP	**CEpartner4U , Esdoornlaan 13,** **3951DB Maarn. The Netherlands.**
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