Diagnostic Automation/Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

OneStep Gonorrhea RapiCard™ InstaTest

REF 176510

PIC ID176510VV86

IVD See External Label 2°C-30°C 20 Tests

Gonorrhea RapiCard™ InstaTest	
Principle	Rapid Chromatographic Immunoassay
Detection	Qualitative
Specificity	Male = 97.1% Female = 96.9%
Sensitivity	Male = 91.6% Female = 94.4%

PRODUCT FEATURES

- High Sensitivity and Specificity
- Built in Internal Controls
- Simplified Workflow, Non-invasive, and Safe
- Rapid and Faster Results

A rapid test for the qualitative detection of Gonorrhea antigen in female cervical swab and male urethral swab specimens. For professional in vitro diagnostic use only.

INTENDED USE

Cortez Diagnostics, Inc. OneStep Gonorrhea RapiCard™ InstaTest is a rapid chromatographic immunoassay for the qualitative detection of Neisseria gonorrhoeae in female cervical swab and male urethral swab specimens to aid in the diagnosis of Gonorrhea infection.

SIGNIFICANCE AND SUMMARY

Gonorrhea is a sexually transmitted disease caused by the bacterium Neisseria gonorrhoeae. Gonorrhea is one of the most common infectious bacterial diseases and is most frequently transmitted during sexual intercourse, including vaginal, oral and anal sex. The causative organism can infect the throat, producing a severe sore throat. It can infect the anus and rectum, producing a condition called proctitis. With females, it can infect the vagina, causing irritation with drainage (vaginitis). Infection of the urethra may cause urethritis with burning, painful urination, and a discharge. When women have symptoms, they often note vaginal discharge, increased urinary frequency, and urinary discomfort. Spread of the organism to the fallopian tubes and abdomen may cause severe lower-abdominal pain and fever. The average incubation for Gonorrhea is approximately 2 to 5 days following sexual contact with an infected partner. However, symptoms may appear as late as 2 weeks. A preliminary diagnosis of Gonorrhea can be made at the time of examination. (1) In women, Gonorrhea is a common cause of pelvic inflammatory disease (PID). PID can lead to internal abscesses and long-lasting, chronic pelvic pain. PID can damage the fallopian tubes enough to cause infertility or increase the risk of ectopic pregnancy (2). A smear or swab of urethral or cervical discharge may be taken and tested using a Gonorrhea Rapid Test Cassette (Swab)

ASSAY PRINCIPLE

Cortez Diagnostics, Inc. OneStep Gonorrhea RapiCard™ InstaTest is a qualitative, lateral flow immunoassay for the detection of Gonorrhea antigen from female cervical and male urethral. In the test, antibody specific to the Gonorrhea antigen is coated on the test line region of the test. During testing, the extracted antigen solution reacts with an antibody to Gonorrhea that is coated onto particles. The mixture migrates up to react with the antibody to Gonorrhea on the membrane and generates a color line in the test region. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENT

The test contains Gonorrhea antibody coated particles and Gonorrhea antibodies coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. The used test should be discarded according to local regulations.
6. Humidity and temperature can adversely affect results.
7. Do not use test if pouch is damaged.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

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SPECIMEN COLLECTION AND PREPARATION

- Cortez Diagnostics, Inc. OneStep Gonorrhea RapiCard™ InstaTest can be performed using female cervical swab and male urethral swab specimens.
- The quality of specimens obtained is of extreme importance. Detection of Gonorrhea antigen requires a vigorous and thorough collection technique that provides adequate amount of antigen.

To collect *Female Cervical Swab Specimen*:

- Use the swab provided in the kit. Alternatively, any plastic-shaft swab may be use.
- Before specimen collection, remove excess mucus from the endocervical area with a cotton ball and discard. The swab should be inserted into the endocervical canal, past the squamocolumnar junction until most of the tip is no longer visible. This will permit acquisition of columnar or cuboidal epithelial cells, which are the main reservoir of the Gonorrhea organism. Firmly rotate the swab 360° in one direction (clockwise or counterclockwise), let stand for 15 seconds, then withdraw the swab. Avoid contamination from exocervical or vaginal cells. Do not use 0.9% sodium chloride to treat swabs before collection specimens.
- If the test is to be conducted immediately, put the swab into the extraction tube.

To collect *Male Urethral Swab Specimens*:

- Standard plastic-or wire-shaft sterile swabs should be used for urethral specimen collection. Instruct patients not to urinate for at least 1 hour period to specimen collection.
- Insert the swab into the urethral about 2-4cm, rotate the swab 360° in one direction (clockwise or counterclockwise), let stand for 10 seconds, then withdraw. Do not use 0.9% sodium chloride to treat swabs before collection swab.
- If the test is to be conducted immediately, put the swab into the extraction tube.
- It is recommended that specimens be processed as soon as possible after collection. If immediately testing is not possible, the patient swab specimens should be placed in a dry transport tube for storage or transport. The swab may be stored for 4-6 hours at room temperature (15-30°C) or 24-72 hours refrigerated (2-8°C) for 24 hours. Do not freeze. All specimens should be allowed to reach the room temperature (15-30°C) before testing.

MATERIALS AND COMPONENTS

Materials provided with the test kit

- Test Cassette
- Extraction reagent 1 (0.15M NaOH)
- Extraction reagent 2 (0.2M HCl)
- Package Insert
- Extraction tubes
- Sterie female cervical swabs
- Workstation
- Drooper tips

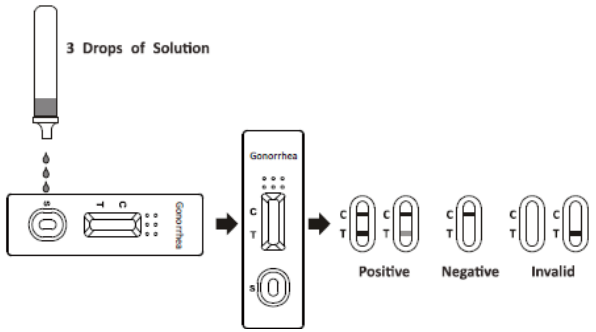
Materials Required But Not Provided

- Sterile male urethral swabs
- Timer

ASSAY PROCEDURE

Allow the test, reagents, swab specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the seal pouch and use it as soon as possible. Best result will be obtained if the test is performed immediately after opening the foil pouch.
2. Extract the Gonorrhea antigen according to the specimen type.
   - Hold the reagent 1 bottle vertically and add **5 drops of reagent 1** (approx. 300ul) to the extraction tube. Reagent 1 is colorless. Immediately insert the swab, compress the bottom of tube and rotate swab 15 times. Let stand for 2 minutes.
   - Hold the reagent 2 bottle vertically add **4 drops of reagent 2** (approx. 200ul) to the extraction tube. The solution would turn turbid. Compress the bottle of tube and rotate the swab 15 times until the solution turn clear with a slight green or blue tint. If the swab is bloody, the color will turn yellow or brown. Let stand 1 minute.
   - Press the swab against the side of tube and withdraw the swab while squeezing the tube. Keep as much liquid in the tube as possible. Fit the dropper tip on top of extraction tube.
3. Place the test cassette on a clean and level surface. Add 3 full drops of the extracted solution (approx. 100ul) to the specimen well of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well.
4. Wait for the color to appear. Read the result at 10 minutes; do not interpret the result after 30 minutes.



RESULTS

(Please refer to the illustration above)

POSITIVE: *Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). A positive result indicates that Gonorrhea was detected in the specimen.

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Gonorrhea present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that Gonorrhea antigen is not present in the specimen, or is present below the detectable level of the test.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE PROCEDURE

1. The OneStep Gonorrhea RapiCard™ InstaTest (Swab) is for in vitro diagnostic use only. This test should be used for the detection of Gonorrhea antigen from female cervical swab and male urethral swab specimens. Neither the quantitative value nor the rate of increase in Gonorrhea antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Gonorrhea antigen in specimens from both viable and non-viable Neisseria gonorrhoeae. Performance with specimens other than female cervical swabs and male urethral swabs has not been assessed.
3. Detection of gonococcus is dependent on the number of organisms present in the specimen. This can be affected by specimen collection methods and patient factors such as age, history of Sexually Transmitted Diseases (STDs), presence of symptoms, etc. The minimum detection level of this test may vary according to serovar. Therefore, the test results should be interpreted in conjunction with other laboratory and clinical data available to the physician.
4. Therapeutic failure or success cannot be determined as antigen may persist following appropriate antimicrobial therapy.
5. Excessive blood on the swab may cause false positive results.
6. Endocervical samples from female patients should not be collected during menstrual period.

PERFORMANCE CHARACTERISTICS

Clinical Study
The OneStep Gonorrhea RapiCard™ InstaTest (Swab) has been evaluated with specimens obtained from patients of STD clinics. Culture is used as the reference method for the OneStep Gonorrhea RapiCard™ InstaTest Cassette (Swab). Specimens were considered positive if culture indicated a positive result. Specimens were considered negative if culture indicated a negative result.

For Female Cervical Swab Specimens

Method		Culture		Total Result
OneStep Gonorrhea RapiCard™ InstaTest	Result	Positive	Negative	
	Positive	67	3	70
	Negative	4	95	99
Total Result		71	98	169

Relative Sensitivity: 94.4% (95%CI*: 86.2%-98.4%)
Relative Specificity: 96.9% (95%CI*: 91.3%-99.4%)
Accuracy: 95.9% (95%CI*: 91.7%-98.3%)
*Confidence Interval

For Male Urethral Swab Specimens

Method		Culture		Total Result
OneStep Gonorrhea RapiCard™ InstaTest	Result	Positive	Negative	
	Positive	98	3	101
	Negative	9	100	109
Total Result		107	103	210

Relative Sensitivity: 91.6% (95%CI*: 84.6%-96.1%)
Relative Specificity: 97.1% (95%CI*: 91.7%-99.4%)
Accuracy: 94.3% (95%CI*: 90.2%-97.0%)
*Confidence Interval

Cross Reactivity
Intra/Inter-assay
Within-run and Between-run precision have been determined with three different lots by using Gonorrhea negative; low, middle and high positive specimens. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified >99% of the time.

Cross Reactivity
Cross reactivity with other organisms has been studied using suspensions of 107 Colony Forming Units (CFU)/test. The following organisms were found negative when tested with the OneStep Gonorrhea RapiCard™ InstaTest (Swab)

Acinetobacter calcoaceticus
Proteus mirabilis
Gardnerella vaginalis
Enterococcus faecalis
Group B/C Streptococcus
Candida albicans
Staphylococcus aureus
Klebsiella pneumoniae
Pseudomona aeruginosa
Acinetobacter spp
Chlamydia trachomatis
Salmonella choleraesius
Enterococcus faecium
Hemophilus influenzae
Proteus vulgaris

REFERENCES

1. Knapp, J.S. et al. Neisseria gonorrhoeae. Manual of Clinical Microbiology, Sixth Edition, ASM Press, Washington DC., 324-325 (1995).
2. Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines 2002. Morbidity and Mortality Weekly Report (2002), 51(RR-6)

MANUFACTURER AND BRAND DETAILS

ISO 13485:2016

ISO 13485 Quality Management for Medical Devices CERTIFIED

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