CE

Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

OneStep Gonorrhea RapiCard™ InstaTest

REF 176510-1-44

IVD | See external | 2°C - 30°C | 20 Tests

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.

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)

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.

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

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

Materials provided with the test kits

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

Materials Required But Not Provided

- Sterile maleurethral swabs

PRECAUTIONS

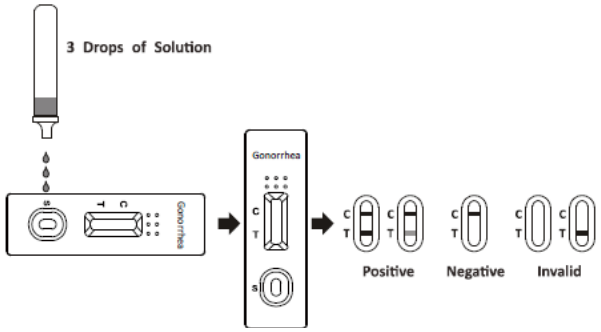
1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout 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

ASSAY PROCEDURE

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

Diagnostic Automation/ Cortez Diagnostics, Inc.
21250 Califa St, Suite 102 and 116, Woodland Hills, CA 91367 USA Phone: 818-591-3030, Fax : 818-591-8383
Email: onestep@rapidtest.com Website: www.rapidtest.com

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

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.

PERFORMACE CHARACTERISTCS

Clinical Study
The Gonorrhea Rapid Test Cassette (Swab) has been evaluated with specimens obtained from patients of STD clinics. Culture is used as the reference method for the Gonorrhea Rapid Test 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
Conorrhea Rapid Test Cassette	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
Conorrhea Rapid Test Cassette	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 Gonorrhea Rapid Test Cassette (Swab)

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

STORAGE

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.

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

1. The Gonorrhea Rapid Test Cassette (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.

Diagnostic Automation/ Cortez Diagnostics, Inc.
21250 Califa St, Suite 102 and 116, Woodland Hills, CA 91367 USA Phone: 818-591-3030, Fax : 818-591-8383
Email: onestep@rapidtest.com Website: www.rapidtest.com

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.

EXPECTED VALUE

Gonorrhea is a common adult disease around the world. With 351,852 Gonorrhea cases reported in 2002 (125.0 cases per 100,000 person), Gonorrhea is the second most frequently reported communicable disease in the United States. Gonorrhea remains a frequently reported sexually transmitted disease, with an estimated more than 300,000 new infections occurring each year in the United States.2A significant proportion of those with infection are asymptomatic (up to 80% among women and 10% among men) and many victims will not go to see the doctor, making the prevalence higher than the report rate in fact. For example, In 1997, health care workers reported 324,901 cases of Gonorrhea in the United States to the U.S. Centers for Disease Control and Prevention (CDC) while the Institute of Medicine, however, estimates that 650,000~800,000 cases of Gonorrhea occur annually in the United States. Worldwide, an estimated 62 million new cases of Gonorrhea occurred in 1997.(2,3,4) A significant number of women may be asymptomatic and may be at risk for chronic or disseminated infection.(4) In the case of pregnant women, there is a potential risk of passage of Gonorrhea to the newborn.(5)

REFERENCE

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)
3. Forbes B.A., Sahm D.F., Weissfeld A.S. Neisseria and Moraxella catarrhalis. Bailey & Scott's Diagnostic Microbiology, Tenth Edition, Mosby, St. Louis, 597-605 (1998).
4. Summary of the Notifiable Diseases, United States, 1998, Morbidity and Mortality Weekly Report (1999), 47(53): 1-93.
5. National Institute of Allergy and Infectious Diseases, National Institute of Health, US Department of Health and Human Services, NIAID Fact Sheet on Gonorrhea, October 2004.

ISO 13485
ISO 9001

Diagnostic Automation/
Cortez Diagnostics, Inc.
21250 Califa St, Suite 102 and 116,
Woodland Hills, California 91367 USA

Date Adopted	**2017-01-12**
REF **176510-1-44**	**CORTEZ- OneStep Gonorrhea RapiCard™ InstaTest**
EC REP	**CEpartner4U , Esdoornlaan 13, 3951DB Maarn. The Netherlands.** www.cepartner4u.eu

Revision Date: **2014-12-16**