

Gonorrhea and Chlamydia Combo Rapid Test Cassette (Swab) Package Insert

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

【INTENDED USE】

The Gonorrhea and Chlamydia Combo Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* in female cervical swab and male urethral swab specimens to aid in the diagnosis of Gonorrhea and Chlamydia infection.

【SUMMARY】

Gonorrhea and Chlamydia are very common STDs accounting for nearly 45% of all STD cases. A combination testing of the two helps in simultaneous testing for the two most common causative agents of STDs. Gonorrhea is a sexually transmitted disease caused by the bacterium

Neisseria gonorrhoeae. It is most frequently transmitted during sexual intercourse, including vaginal, oral and anal sex. It can infect the throat, producing a severe sore throat, can infect the anus and rectum, producing a condition called proctitis. In females, it can infect the vagina, causing irritation with drainage (vaginits). 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 Chlamydia trachomatis is the most common cause of sexually transmitted venereal infection in the world. Composed of elementary bodies (the infectious form) and reticulate or inclusions bodies (the replicating form), Chlamydia trachomatis has both a high prevalence and asymptomatic carriage rate, with frequent serious complications in both women and neonates. Complications of Chlamydia infection in women include cervicitis, urethritis, endometritis, PID and increased incidence of ectopic pregnancy and infertility.³ Vertical transmission of the disease during parturition from mother to neonate can result in inclusion conjunctivitis pneumonia. In men, complications of Chlamydia infection include urethritis and epididymitis. Approximately 70% of women with endocervical infections and up to 50% of men with urethral infections are asymptomatic.

The Gonorrhea and Chlamydia Combo Rapid Test Cassette (Swab) is a rapid test to qualitatively detect the Gonorrhea and Chlamydia antigen from female cervical swab and male urethral swab specimens.

【PRINCIPLE】

The Gonorrhea and Chlamydia Combo Rapid Test Cassette (Swab) is a qualitative, lateral flow immunoassay for the detection of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* in female cervical and male urethral swab specimens. In the test, antibodies specific to the Gonorrhea and Chlamydia antigen is coated on the test line region of the test. During testing, the extracted antigen solution reacts with antibodies against Gonorrhea and Chlamydia antigens that is coated onto particles. The mixture migrates up to react with the antibodies against Gonorrhea and Chlamydia antigens on the membrane and generates a color line in the test region. The presence of this colored line in the test line region (T) of gonorrhea indicates a positive result for gonorrhea and the presence of a colored line in the test line region (T) of chlamydia indicates a positive result for chlamydia. The absence of a colored line in either test line region for gonorrhea or test line region for chlamydia indicates a negative result for the respective organism. 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 and Chlamydia antibodies coated particles and Gonorrhea and Chlamydia antibodies coated on the membrane.

【PRECAUTIONS】

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- 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.

【SPECIMEN COLLECTION AND PREPARATION】

- The Gonorrhea and Chlamydia Combo Rapid Test Cassette (Swab) can be performed using female cervical swab and male urethral swab specimens.
- The quality of specimens obtained is of extreme importance. Detection of Gonorrhea and Chlamydia antigens requires a vigorous and thorough collection technique that provides cellular material rather than just body fluids.
- To collect **Female Cervical Swab Specimen**:
 - Use the swab provided in the kit. Alternatively, any plastic-shaft swab may be used.
 - 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

Chlamydia 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 2-4 cm, 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 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】

Materials Provided

- Test Cassettes
- Extraction Reagent 1 (0.2M NaOH)
- Extraction Reagent 2 (0.2 M HCl)
- Package Insert

Materials Required But Not Provided

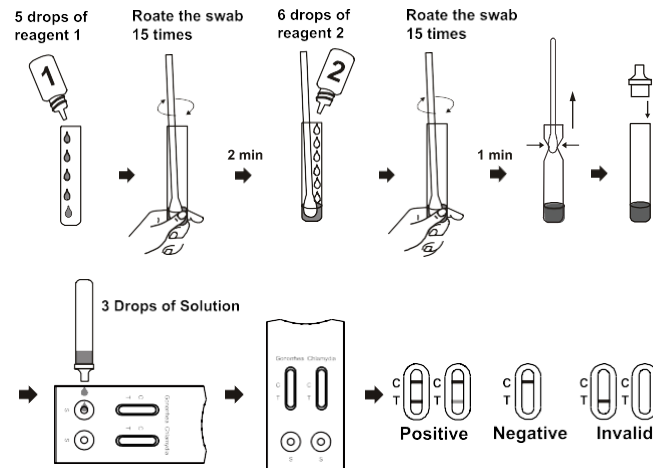
- Sterile Male Urethral Swabs
- Extraction Tubes
- Sterile Female Cervical Swabs
- Workstation
- Dropper Tips
- Timer

【DIRECTIONS FOR USE】

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

- Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
- Extract the Chlamydia antigen according to the specimen type.
- For Female Cervical or Male Urethral Swab Specimen:**
 - 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 **6 drops of reagent 2** (approx. 250ul) 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.
- Place the test cassette on a clean and level surface. **Add 3 full drops of the extracted solution (approx. 100ul)** to each specimen wells of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well.
- Wait for the colored line(s) to appear. **Read the result at 10 minutes**; do not interpret the result after 20 minutes.

Note: It is recommended to use the buffer within 6 months after opening the vial.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE for Gonorrhea:* Two colored lines appear in the Gonorrhea window. One line should be in the control line region (C) and another line should be in the test line region (T) in the Gonorrhea window.

POSITIVE for Chlamydia:* Two colored lines appear in the Chlamydia window. One line should be in the control line region (C) and another line should be in the test line region (T) in the Chlamydia window.

POSITIVE for Gonorrhea and Chlamydia:* Two colored lines appear in both windows. One line should be in the control line region (C) and another line should be in the test line region

*NOTE: The shade of color in the test line region (T) may vary, but it should be considered positive whenever there is even a faint colored line.

NEGATIVE for Chlamydia and Gonorrhea: Only colored lines appear in the control line regions (C) of both Gonorrhea and Chlamydia windows. No apparent colored line appears in the test line region (T) of either Gonorrhea or Chlamydia window.

INVALID: No line appears in the control line region (C). If this occurs, read the directions again and repeat the test with a new test. If the result is still invalid, stop using the test kit immediately and contact your local distributor.

【QUALITY CONTROL】

Internal procedural controls are included in the test individually for both two sections. Two colored lines appearing in control line regions (C) for both two sections are the internal procedural controls. It confirms sufficient specimen volume 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】

- The Gonorrhea and Chlamydia Combo Rapid Test Cassette (Swab) is for in vitro diagnostic

use only. This test should be used for the detection of Gonorrhea and/or Chlamydia antigen from female cervical swab and male urethral swab specimens. Neither the quantitative value nor the rate of increase in Gonorrhea or Chlamydia antigen concentration can be determined by this qualitative test.

- This test will only indicate the presence of Gonorrhea and/or Chlamydia antigen in specimens from both viable and non-viable *Neisseria gonorrhoeae* and *Chlamydia trachomatis*. Performance with specimens other than female cervical swabs and male urethral swabs has not been assessed.

(T) in both of Gonorrhea and Chlamydia windows.

3. Detection of Gonorrhea and Chlamydia 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.

【EXPECTED VALUES】

Gonorrhea is a common adult disease around the world. With 351,852 Gonorrhea cases reported in 2002 (125.0 cases per 100,000 people), a significant proportion of those with infection are asymptomatic and many victims will not go to see the doctor, making the prevalence higher than the report rate in fact. 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

For women attending STD clinics and other high-risk populations, the prevalence of Chlamydia infection has been repeated to between 20% and 30%. In a low-risk population such as those patients attending obstetrics and gynecology clinics, the prevalence is approximately 5% or less. Reports show that for men attending STD clinics, the prevalence of Chlamydia infection is approximately 8% in asymptomatic men and 11% in symptomatic men.^{1,2} Normal carriage rates of Chlamydia in asymptomatic men are less than 5%.³

【PERFORMANCE CHARACTERISTICS】

Clinical Study

The Gonorrhea and Chlamydia Combo 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 and PCR is used as the reference method for the Chlamydia Rapid Test cassette. The results show that Gonorrhea and Chlamydia Combo Rapid Test cassette (Swab) has a high sensitivity and specificity relative to the reference method.

Gonorrhea:

For **Female Cervical Swab Specimens**

Method		Culture		Total Results
Gonorrhea Rapid Test Cassette (Swab)	Results	Positive	Negative	
	Positive	67	3	70
	Negative	4	95	99
Total Results		71	98	169

Relative Sensitivity: 94.4% (95%CI*: 86.2%-98.4%) *Confidence

Interval Relative Specificity: 96.9% (95%CI*: 91.3%-99.4%)

Overall Accuracy: 95.9% (95%CI*: 91.7%-98.3%)

For **Male Urethral Swab Specimens**

Method		Culture		Total Results
Gonorrhea Rapid Test Cassette (Swab)	Results	Positive	Negative	
	Positive	98	3	101
	Negative	9	100	109
Total Results		107	103	210

Relative Sensitivity: 91.6% (95%CI*: 84.6%-96.1%) *Confidence

Interval Relative Specificity: 97.1% (95%CI*: 91.7%-99.4%)

Overall Accuracy: 94.3% (95%CI*: 90.2%-97.0%)

Chlamydia:

For **Female Cervical Swab Specimens**

Method		PCR		Total Results
Chlamydia Rapid Test Cassette (Swab)	Results	Positive	Negative	
	Positive	42	4	46
	Negative	3	156	159
Total Results		45	160	205

Relative Sensitivity: 93.3% (95%CI*: 81.7%-98.6%) *Confidence

Interval Relative Specificity: 97.5% (95%CI*: 93.7%-99.3%)

Overall Accuracy: 96.6% (95%CI*: 93.1%-98.6%)

For Male Urethral Swab Specimens

Method	PCR		Total Results
	Results		
Chlamydia Rapid Test Cassette (Swab)	Positive	50	55
	Negative	8	123
	Total Results	58	178

Relative Sensitivity: 86.2% (95%CI*: 74.6%-93.9%)
Relative Specificity: 95.8% (95%CI*: 90.5%-98.6%)
Overall Accuracy: 92.7% (95%CI*: 87.8%-96.1%)

*Confidence Interval

Precision
Intra/Inter-assay

Within-run and Between-run precision have been determined with three different lots by using Gonorrhea negative; low, middle and high Gonorrhea positive specimens, Chlamydia negative, low, middle and high Chlamydia 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 of Gonorrhea and Chlamydia with other organisms has been studied using suspensions of 10⁷ org/test. The following organisms were found negative when tested with the Gonorrhea and Chlamydia Combo Rapid Test Cassette (Swab) and did not produce any positive result either for Gonorrhea or Chlamydia:

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

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- Jaschek, G. et al Direct Detection of Chlamydia trachomatis in Urine Specimens from Symptomatic and Asymptomatic Men by Using a Rapid Polymerase Chain Reaction Assay. J. Clinical Microbiology, 31,1209-1212, (1993).
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Index of Symbols

	Attention, see instructions for use		Tests per kit		Do not reuse
	For in vitro diagnostic use only		Use by		Catalog #
	Store between 2-30°C		Lot Number		Consult Instructions for Use
	Do not use if package is damaged		Manufacturer		



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