



Chlamydia Chlamydia Rapid Test Device (Swab/Urine)

A rapid test for the qualitative detection of Chlamydia antigen in female cervical swab, male urethral swab and male urine specimens.

For professional in vitro diagnostic use only

INTENDED USE

The Chlamydia Rapid Test Device (Swab/Urine) is a rapid chromatographic immunoassay for the qualitative detection of *Chlamydia trachomatis* in female cervical swab, male urethral swab and male urine specimens to aid in the diagnosis of Chlamydia infection

SUMMARY

Chlamydia trachomatis is the most common cause of sexually transmitted venereal infection in the world. It is composed of elementary bodies (the infectious form) and reticulates 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, pelvic inflammatory disease (PID) and increased incidence of ectopic pregnancy and infertility. 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. At least 40% of the nongonococcal urethritis cases are associated with Chlamydia infection. Approximately 70% of women with endocervical infections and up to 50% of men with urethral infections are asymptomatic. Traditionally, Chlamydia infection has been diagnosed by detection of Chlamydia inclusions in tissue culture cells. Culture method is the most sensitive and specific laboratory method, but it is labor intensive, expensive, long (48-72 hours) and not routinely available in most institutions.

The Chlamydia Rapid Test Device (Swab/Urine) is a rapid test to qualitatively detect the Chlamydia antigen from female cervical swab, male urethral swab and male urine specimens, providing results in 10 minutes. The test utilizes antibody specific for Chlamydia to selectively detect Chlamydia antigen from female cervical swab, male urethral swab and male urine specimens.

PRINCIPLE

The Chlamydia Rapid Test Device (Swab/Urine) is a qualitative, lateral flow immunoassay for the detection of Chlamydia antigen from female cervical swab, male urethral

swab and male urine specimens.

In this test, antibody specific to the Chlamydia antigen is coated on the test line region of the test. During testing, the extracted antigen solution reacts with an antibody to Chlamydia that is coated onto particles. The mixture migrates up to react with the antibody to Chlamydia on the membrane and generates a colored line in the test line 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.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- The test device should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- Use only sterile, Dacron swabs to obtain endocervical specimens.

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

- The Chlamydia Rapid Test Device (Swab/Urine) can be performed using female cervical swab, male urethral swab and male urine specimens.
- The quality of specimens obtained is of extreme importance. Detection of Chlamydia requires a vigorous and thorough collection technique that provides cellular material rather than lysis body fluids.
- To collect **Female Cervical Swab Specimens:**
 - Use the swab provided in the kit.. Alternatively, any plastic-shaft Dacron 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, and then withdraw the swab. Avoid contamination from exocervical or vaginal cells. Do not use 0.9% sodium chloride to treat swabs before collecting samples.

- 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 Dacron swabs should be used for urethral specimen collection.
 - Instruct patients not to urinate for at least one hour prior to specimen collection.
 - Insert the swab into the urethra about 2-4 cm, rotate the swab 360° in one direction (clockwise or counterclockwise), let stand for 10 seconds and then withdraw. Do not use 0.9% sodium chloride to treat swabs before collecting samples.
 - If the test is to be conducted immediately, put the swab into the extraction tube.
- To collect **Male Urine Specimens:**
 - Collect 15-30 mL of clean first morning urine in a sterile urine cup. First morning urine specimens are preferred to achieve the highest concentrations of Chlamydia antigen.
 - Mix the urine specimen by inverting the container. Transfer 10 mL of the urine specimen into a centrifuge tube, add 10 mL distilled water and centrifuge at 3,000 rpm for 15 minutes.
 - Carefully discard the supernatant, keep the tube inverted and remove any supernatant from the rim of tube by blotting onto absorbent paper.
 - If the test is to be conducted immediately, treat the urine pellet according to the Directions for Use.

It is recommended that specimens be processed as soon as possible after collection. If immediate testing is not possible, the patient swab specimens should be placed in a dry transport tube for storage or transport. The swabs may be stored for 4-6 hours at room temperature (15-30°C) or 24-72 hours refrigerated (2-8°C). The urine specimens can be stored refrigerated (2-8°C) for 24 hours. Do not freeze. All specimens should be allowed to reach room temperature (15-30°C) before testing.

MATERIALS

Materials Provided

- Test devices
- Test tubes
- Dropper tips
- Sterile female cervical swabs

- Reagent A (0.2M NaOH)
- Reagent B (0.2N HCl)
- Workstation
- Quantitative pipette
- Package insert

Materials Required But Not Provided

- Timer
- Urine cup
- Centrifuge tube (for male urine specimens only)
- Positive control
- Sterile male urethral swabs
- Steele female cervical swabs
- Negative control

DIRECTIONS FOR USE

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

1. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Extract the Chlamydia antigen according to the specimen type.

For Female Cervical or Male Urethral Swab Specimens:

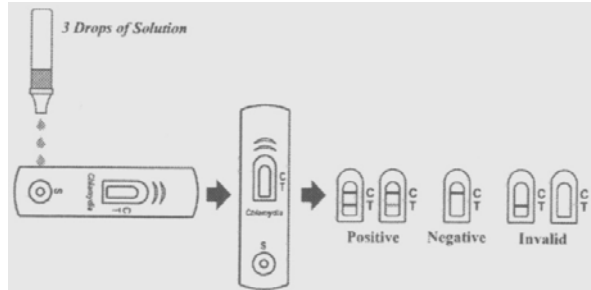
- Hold the Reagent A bottle vertically and add 5 full drops of Reagent A (approximately 300 µL) to the extraction tube. Reagent A is colorless.
- Immediately insert the swab, compress the bottom of the tube and rotate the swab 15 times. Let stand for 2 minutes
- Fill the quantitative pipette for Reagent B up to the marked line (approximately 220 µL) then add the Reagent B to the extraction tube. The solution will turn cloudy. Compress the bottom of tube and rotate the swab 15 times until the solution turns to a clear color with a slight green or blue tint. If the swab is bloody, the color will turn yellow or brown. Let stand for 1 minute.
- Press the swab against the side of the 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 the extraction tube.

For Male Urine Specimens:

- Fill the quantitative pipette for Reagent B to the marked line (approximately 220 µL) then add the Reagent B to the urine pellet in the centrifuge tube, then draw the liquid up and down with a pipette to vigorously mix until the suspension is homogeneous.
 - Transfer all the solution in the centrifuge tube to an extraction tube. Let stand for 1 minute. Hold the Reagent A bottle upright and add 5 full drops of Reagent A (approximately 300 µL) then add to the extraction tube. Vortex or tap the bottom of the tube to mix the solution. Let stand for 2 minutes.
 - Fit the dropper tip on top of the extraction tube.
3. Place the test device on a clean and level surface. Add 3

full drops of the extracted solution (approximately 100 µL) to the specimen well (S) of the test device, and start the timer. Avoid trapping air bubbles in the specimen well (S).

4. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not read results after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

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: One colored line appears in the control line region (C). No apparent colored line appears in the test line region (T)

INVALID: Control line fails to appear. Insufficient sample 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 device. 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

1. The Chlamydia Rapid Test Device (Swab/Urine) is for *in vitro* diagnostic use only. This test should be used for the detection of Chlamydia antigen from female cervical swab, male urethral swab and male urine specimens. Neither the quantitative value nor the rate of increase in Chlamydia antigen concentration can be determined by this qualitative test.

2. This test will only indicate the presence of Chlamydia antigen in specimens from both viable and non-viable Chlamydiae. Performance with other specimens has not been assessed.
3. Detection of 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

For women attending STD clinics and other high-risk populations, the prevalence of Chlamydia infection has been reported to be 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. Normal carriage rates of Chlamydia in asymptomatic men are less than 5%.

PERFORMANCE CHARACTERISTICS

Sensitivity

The Chlamydia Rapid Test Device (Swab/Urine) has been evaluated with specimens obtained from patients of STD clinics. PCR is used as the reference method for the Chlamydia Rapid Test Device (Swab/Urine). Specimens were considered positive if PCR indicated a positive result. Specimens were considered negative if PCR indicated a negative result. The results show that Chlamydia Rapid Test Device (Swab/Urine) has a high sensitivity relative to PCR.

Specificity

The Chlamydia Rapid Test Device (Swab/Urine) uses an antibody that is highly specific for Chlamydia antigen in female cervical swab, male urethral swab and male urine specimens. The results show that the Chlamydia Rapid Test Device (Swab/Urine) has a high specificity relative to PCR.

For Female Cervical Swab Specimens:

Method	Results	PCR		Total Results
		Positive	Negative	
Chlamydia Rapid Test Device	Positive	46	3	49
	Negative	6	87	93
Total Results		52	90	142

Relative Sensitivity: 88.5% (76.6% - 95.6%)

Relative Accuracy: 93.7% (88.3% - 97.1%)

Relative Specificity: 96.7% (90.6% - 99.3%)

For Male Urethral Swab Specimens:

Method		PCR		Total
Chlamydia	Results	Positive	Negative	Results
Rapid Test	Positive	40	8	48
Device	Negative	11	104	115
Total Results		51	112	163

Relative Sensitivity: 78.4% (64.7% - 88.7%)

Relative Accuracy: 88.3% (82.4% - 92.8%)

Relative Specificity: 92.9% (86.4% - 96.9%)

For Male Urine Specimens:

Method		PCR		Total
Chlamydia	Results	Positive	Negative	Results
Rapid Test	Positive	20	0	20
Device	Negative	2	35	37
Total Results		22	35	57

Relative Sensitivity: 90.9% (70.8% - 98.9%)

Relative Accuracy: 96.5% (87.9% - 99.6%)

Relative Specificity: >99.0% (90.0% - 100.0%)

Cross-Reactivity

The antibody used in the Chlamydia Rapid Test Device (Swab/Urine) has been shown to detect all known Chlamydia serovars. Chlamydia psittaci and Chlamydia pneumoniae strains have not yet been tested with the Chlamydia Rapid Test Device (Swab/Urine). Cross reactivity with other organisms has been studied using suspensions of 10⁹ Colony Forming Units (CFU)/mL. The following organisms were found negative when tested with the Chlamydia Rapid Test Device (Swab/Urine):

Acinetobacter calcoaceticus
Pseudomonas aeruginosa
Proteus mirabilis
Acinetobacter spp
Neisseria meningitidis
Neisseria gonorrhoea
Enterococcus faecalis
Salmonella choleraesuis
Group B/C Streptococcus
Enterococcus faecium
Candida albicans
Haemophilus influenzae
Staphylococcus aureus
Proteus vulgaris
Branhamella catarrhalis
Klebsiella pneumoniae
Gardnerella vaginalis

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