Chlamydia Test

Chlamydia rapid test • cassette • swab/urine

ENGLISH

A rapid test for the qualitative detection of chlamydia antigen in female cervical swab, male urethral swab or male urine specimens.
For professional in vitro diagnostic use only.

[INTENDED USE]
The Chlamydia Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of chlamydia trachomatis in female cervical swab, male urethral swab or 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 reticulate or inclusion 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.[1] Vertical transmission of the disease during parturition from to neonate can result in inclusion conjunctivitis or pneumonia. In men, complications of chlamydia 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 (18-72 hours) and not routinely available in most situations.

The Chlamydia Rapid Test is a rapid test to qualitatively detect the chlamydia antigen from female cervical swab, male urethral swab or male urine specimens.

[PRINCIPLE]
The Chlamydia Rapid Test is a qualitative, lateral flow immunoassay for the detection of chlamydia antigen from female cervical, male urethral and male urine. In the test, antibodies specific to the chlamydia antigen are 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 coloured line in the test region. The presence of this coloured line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

[REAGENTS]
The test contains chlamydia antibody coated particles and chlamydia 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.

[SPECIMEN COLLECTION AND PREPARATION]
- The Chlamydia Rapid Test can be performed using female cervical swab, male urethral swab or 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 just body fluids.
- **To collect female cervical swab specimens:**
  - 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 specimen collection.
  - 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 it stand for 10 seconds, then withdraw. Do not use 0.9% sodium chloride to treat swabs before specimen collection.
  - If the test is to be conducted immediately, put the swab into the extraction tube.
- **To collect male urine specimens:**
  - Collect 15-30ml 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 container. Transfer 10ml of the urine specimen into a centrifuge tube, add 10ml 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 the tube by blotting onto absorbent pad.
  - 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 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 (0.2M HCl)
- Extraction tubes
- Sterile female cervical swabs
- Workstation
- Dropper tips
- Package insert

Materials Required But Not Provided

- Urine cup (for male Urine specimens only)
- Centrifuge tube (for male urine specimens only)
- Sterile male urethral swab
- Positive control
- Negative control
- Timer

[DIRECTIONS FOR USE]
Allow the test, reagents, specimen, and/or controls to reach room temperature (15- 30°C) prior to testing.
1. 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.

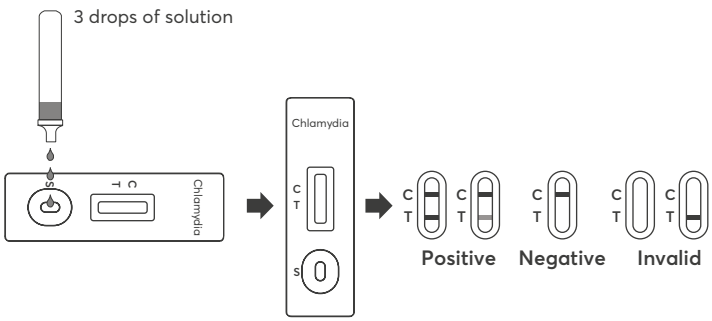
2. Extract the chlamydia antigen according to the specimen type.

- **For female cervical or male urethral swab specimens:**
  - Hold the reagent 1 bottle vertically and add 5 drops of reagent 1 (approx. 300µl) to the extraction tube. Reagent 1 is colourless. Immediately insert the swab, compress the bottom of the tube and rotate swab 15 times. Let it stand for 2 minutes.
  - Hold the reagent 2 bottle vertically add 6 drops of reagent 2 (approx. 250µl) to the extraction tube. The solution would turn turbid. Compress the bottle of tube and rotate the swab 15 times until the solution turns clear with a slight green or blue tint. If the swab is bloody, the colour will turn yellow or brown. Let it 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:**
  - Hold the reagent 2 bottle vertically and add 6 drops of (approx. 250µl) reagent 2 to the urine pellet in the centrifuge tube, then shake the tube vigorously until the suspension is homogeneous.
  - Transfer all the solution in the centrifuge tube to an extraction tube. Let it stand for 1 minute. Hold the reagent 1 bottle upright and add 5 drops of (approx. 300µl) reagent 1 to the extraction tube. Vertex or tap the bottom of the tube to mix the solution. Let it stand for 2 minutes.
  - Fit the dropper tip on top of the extraction tube.

3. Place the test cassette on a clean and level surface. Add 3 full drops of the extracted solution (approx. 100µl) to the specimen well ofv the test cassette (S), then start the timer. Avoid trapping air bubbles in the specimen well.

4. Wait for the colour to appear. Read the result at 10 minutes, do not interpret the result after 20 minutes. Note: It is suggested not to use the extraction reagent, beyond 6 months after opening the vial.



INTERPRETATION OF RESULTS
(Please refer to the illustration above)
POSITIVE:* Two coloured lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T). A positive result indicates that chlamydia was detected in the specimen.
***NOTE:** The intensity of the colour in the test line region (T) will vary depending on the concentration of chlamydia
ecimen. Therefore, any shade of colour in the test line region (T) should be considered positive.

coloured line appears in the control line region (C). No line appears in the test line region
sult indicates that chlamydia antigen is not present in the specimen, or is present below the
f the test.
l 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]
An internal procedural control is included in the test. A coloured 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 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 or 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 chlamydia Performance with specimens other than female cervical swabs, male urethral swabs and male urine 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 repeated to between 20% and 30%. In a low-risk population such as those patients attending obstetrics and gynaecology 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]

Sensitivity

The Chlamydia Rapid Test has been evaluated with specimens obtained from patients of STD clinics. PCR is used as the reference method for the Chlamydia Rapid Test. 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 has a high sensitivity relative to PCR.

Specificity

The Chlamydia Rapid Test ses an antibody that is highly specific for chlamydia antigen in female cervical swab, male urethral swab or male urine specimens. The results show that the Chlamydia Rapid Test has a high specificity relative to PCR.

For Female Cervical Swab Specimens

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

Relative Sensitivity: 93.3% (81.7%-98.6%)*
Relative Specificity: 97.5% (93.7%-99.3%)*
Overall Accuracy: 96.6% (93.1%-98.6%)* *95%Confidence Intervals

For Male Urethral Swab Specimens

Method		PCR		Total Results
Chlamydia Rapid Test Cassette (Swab/Urine)	Results	Positive	Negative	
	Positive	50	5	55
	Negative	8	115	123
Total Results		58	120	178

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

For Male Urine Specimens

Method		PCR		Total Results
Chlamydia Rapid Test Cassette (Swab/Urine)	Results	Positive	Negative	
	Positive	35	0	35
	Negative	2	60	62
Total Results		37	60	97

Relative Sensitivity: 94.6% (81.8%-99.3%)*
Relative Specificity: >99.9% (95.1%-100%)*
Overall Accuracy: 97.9% (92.7%-99.7%)* *95% Confidence Interval

[CROSS REACTIVITY]
The antibody used in the Chlamydia Rapid Test has been shown to detect all known chlamydia serovars. chlamydia psittaci and chlamydia pneumoniae strains have been tested with the Chlamydia Rapid Test and were shown to cross react when tested in suspensions of 109 colony forming units (CFU)/ml. Cross reactivity with other organisms has been studied using suspensions of 109 CFU/ml. The following organisms were found negative when tested with the Chlamydia Rapid Test:

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

[BIBLIOGRAPHY]
1. Sanders J.W. et al Evaluation of an Enzyme Immunoassay for Detection of Chlamydia trachomatis in Urine of Asymptomatic Men. J.Clinical Microbiology, (1994) 32, 24-27.
2. 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, (1993) 31,1209-1212.
3. Schachter, J Sexually transmitted Chlamydia trachomatis infection. Postgraduate Medicine,(1982) 72, 60-69.

Index of Symbols

	Consult instructions for use		Tests per kit	EC REP	Authorised Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalogue #
	Do not use if package is damaged		Consult Instructions for Use		Manufacturer

CE 0123

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