Chlamydia Trachomatis Antigen Rapid Test

20 Tests

REF GCCHL-502a CE 0197

INTENDED USE

The Chlamydia Trachomatis Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Chlamydia in female cervical swab, male urethral swab and male urine specimens. The product can detect the Chlamydia serovars (D,E,F,H,I,K,G,J) and intended as a screening test and as an aid in the diagnosis of Chlamydia infection.

INTRODUCTION

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 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 Trachomatis infection in women include cervicitis, urethritis, ndometritis, pelvic inflammatory disease (PID) and increased incidence of ectopic pregnancy and infertility.[1] Vertical transmission of the disease during parturition from mother to neonate can result in inclusion conjunctivitis or pneumonia.

In men, complications of Chlamydia Trachomatis infection include urethritis and epididymitis. At least 40% of the nongonococcal urethritis cases are associated with Chlamydia Trachomatis 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 Trachomatis 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.

In 2006 a new variant of Chlamydia trachomatis (nvCT) was discovered in Sweden, it belongs to serovar E.[7,8]

The Chlamydia Trachomatis Antigen Rapid Test 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 Trachomatis to selectively detect Chlamydia Trachomatis antigen from female cervical swab male urethral swab and male urine specimens.

PRINCIPLE

The Chlamydia Trachomatis Antigen Rapid Test is a qualitative, lateral flow immunoassay for the detection of Chlamydia Trachomatis antigen from female cervical swab, male urethral swab and male urine specimens. In this test, antibody specific to the Chlamydia Trachomatis 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 generate 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.

REAGENTS

1 test strip included; latex Conjugates (as main component): Mouse anti Chlamydia antibody (Conjugation) (0.04± 0.01 μg) and Rabbit IgG (0.04± 0.01 μg), Test Line (as main component): Mouse anti Chlamydia antibody (Coating) (0.24±0.08 μg), Control Line (as main component): Goat anti-Mouse IgG (0.6 μg) and Goat anti-Rabbit IgG (0.2 μg).

MATERIALS PROVIDED

1. Test Device: 20 individually pouched devices. A desiccant is included in each pouch;
2. Specimens extraction tube: 20;
3. 1 Package insert;
4. Female Swab: 20 Puritan Sterile Female Swab CE0086 MDD 93/42/EEC

5. 1 Extraction buffer A (Contain 0.2M NaOH): 8.0 ml.		Warning Causes skin irritation. Causes serious eye irritation. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection. If skin irritation occurs; Get medical advice/attention. If eye irritation persists, Get medical advice/attention Take off contaminated clothing and wash before reuse.
6. 1 Extraction buffer B (Contain 0.2M HCl): 8.0 ml.		

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer 2. To collect Male Uretral Uretral swab specimens: sterile male uretral swabs
3. To collect Male Urine specimens:
   - sterile urine cup
   - centrifuge tube

PRECAUTIONS

1. For professional in vitro diagnostic use only. Do not use after expiration date. The test must remain in the sealed pouch until use.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use test if pouch is damaged.
4. 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.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
6. The used test should be discarded according to local regulations.
7. Humidity and temperature can adversely affect results.
8. Use only sterile 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 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 STORAGE

- The Chlamydia Trachomatis Antigen Rapid Test 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 just body fluids.
- To collect Female Cervical Swab Specimens:
  1. Use the sterile swab provided in the kit. Alternatively, any plastic-shaft sterile swab may be used.
  2. 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 collecting specimens.
  3. If the test is to be conducted immediately, put the swab into the extraction tube.
- To collect Male Urethral Swab Specimens:
  1. Standard plastic- or wire-shaft sterile swabs should be used for urethral specimen collection. Instruct patients not to urinate for at least one hour prior to specimen collection.
  2. 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, then withdraw. Do not use 0.9% sodium chloride to treat swabs before collecting specimens.
  3. If the test is to be conducted immediately, put the swab into the extraction tube.
- To collect Male Urine Specimens:
  1. 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.
  2. 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.
  3. Carefully discard the supernatant, keep the tube inverted and remove any supernatant from the rim of tube by blotting onto absorbent paper.
  4. If the test is to be conducted immediately, treat the urine pellet according to the Directions for Use.
  5. To collection Male urine specimens, customer also need a sterile urine cup and acentrifuge tube.
- 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.

TEST PROCEDURE

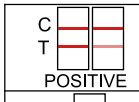
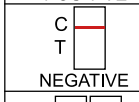
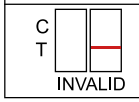
Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.
1. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Extract the Chlamydia Trachomatis antigen according to the specimen type.

For Female Cervical or Male Urethral Swab Specimens:
- Hold the Reagent A bottle vertically and add 5 drops of Reagent A 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.
- Add 6 drops of 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:
- Add 6 drops of 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 drops of Reagent A 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 drops of the extracted solution (approximately 100 μL) to the specimen well (S) of the test device, then start the timer. Avoid trapping air bubbles in the specimen well (S).
4. Wait for the colored line(s) to appear. Read the result at 10 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

 POSITIVE	Two colored bands appear on the membrane. One band appears in the control region(C) and another band appears in the test region(T).
 NEGATIVE	Only one colored band appears in the control region(C).No apparent colored band appears in the test region(T).
 INVALID	Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the 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 Trachomatis Antigen Rapid Test is used for in vitro diagnostic use only. This test should be used for the detection of Chlamydia Trachomatis antigen from female cervical swab, male urethral swab and male urine specimens.
Neither the quantitative value nor the rate of increase in Chlamydia Trachomatis antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Chlamydia Trachomatis 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 Trachomatis 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.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy
The Chlamydia Trachomatis Antigen Rapid Test has been evaluated with specimens obtained from patients of STD clinics and tested by commercial PCR kit. Commercial Chlamydia Trachomatis Antigen Rapid Test (company A) and PCR kit were used as the reference method. The results show that the Chlamydia Trachomatis Antigen Rapid Test has a high overall relative accuracy.

Table 1: The Chlamydia Trachomatis Antigen Rapid Test vs Commercial Chlamydia Trachomatis Antigen Rapid Test (company A)

		Commercial Rapid test		Total Results
		Positive	Negative	
Orient Gene Rapid test	Positive	106	11	117
	Negative	19	226	245
Total Results		125	237	362

Relative Sensitivity：84.8% (77.28%-90.58%)*
Relative Specificity：95.4% (91.86%-97.66%)*
Accuracy：91.7% (88.36%-94.35%)* *95% Confidence interval

Table 2: The Chlamydia Trachomatis Antigen Rapid Test vs PCR kit

		PCR kit		Total Results
		Positive	Negative	
Orient Gene Rapid test	Positive	109	8	117
	Negative	16	229	245
Total Results		125	237	362

Relative Sensitivity：87.2 % (80.05%-92.50%)*
Relative Specificity：96.6% (93.44%-98.53%)*
Accuracy：93.4 % (90.32%-95.70%)* *95% Confidence interval

Analytical Sensitivity
The analytical sensitivity of the Chlamydia Trachomatis Antigen Rapid Test was determined by testing serial dilutions of cultures of known infectivity. The Chlamydia trachomatis serovar E were 4.8×10^3 IFU/mL Chlamydia trachomatis.

Interfering substances
No interference was observed by any of the substances at the concentration tested. Each substance was spiked into negative (1×10^3 IFU/mL) and positive (8×10^3 IFU/mL) samples and then tested in duplicate on three lots of Chlamydia Trachomatis Antigen Rapid Test.

Human mucin (0.1 mg/test)	Metronidazole suppository (5 mg/test)
Tinidazole Vaginal Effervescent Tablets (5 mg/test)	Miconazole nitrate suppository (5 mg/ test)
Bifonazole ointment (5 mg/test)	Kangfute suppository (5 mg/ test)
Nystatin effervescent vaginal tablets (5 mg/ test)	Fuyinjie Lotion (20 μl/ test)
Jieeryin Lotion (10 μl/ test)	Vaginal Moisturizing Gel (10 μl/ test)
Nonoxinol Pellicles (5 mg/ test)	Povidone iodine Lotion (20 μl/ test)

Cross-Reactivity
Chlamydia psittaci and Chlamydia pneumoniae strains have been tested with the Chlamydia Trachomatis Antigen Rapid Test and shown to cross react.

The antibodies used in the Chlamydia Trachomatis Antigen Rapid Test have cross-reactivity with the following micro-organisms below 5%（from the product specification sheets of supplier）.

A. lwoffi	*A. baumanii*	*B. fragilis*	*C. freundii*
C. xerosis	*E. aerogenes*	*E. coli*	*Fusobacterium*
L. acidophilus	*M. hominis*	*M. smegmatis*	*Peptococcus*
Peptostreptococcus	*Propionebacterium*	*R. aeruginosa*	*S. cerevisiae*
S. marcescens	*S. pyogenes*	*T. globrata*	*U. urealyticum*

Cross reactivity with other organisms has been studied using suspensions of 1×10^9 CFU/mL. The following organisms were found negative result when tested with the Chlamydia Trachomatis Antigen Rapid Test.

Acinetobacter calcoaceticus	*Candida albicans*	*Pseudomonas aeruginosa*
Streptococcus faecium	*Neisseria gonorrhoeae*	*Gardnerella vaginalis*
Staphylococcus aureus	*Proteus vulgaris*	*Group A streptococci*
Salmonella minnesota	*Vaginal bacteria Gardiner*	*Group C streptococci*
Klebsiella pneumoniae	*Proteus mirabilis*	

REFERRENCE

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4. Helen Papadogeorgakis. et al. Chlamydia trachomatis Serovar Distribution and Neisseria gonorrhoeae Coinfection in Male Patients with Urethritis in Greece. JOURNAL OF CLINICAL MICROBIOLOGY, June 2010, p. 2231–2234.
5. Antonella Marangoni. et al. Chlamydia trachomatis serovar distribution and other sexually transmitted coinfections in subjects attending an STD outpatients clinic in Italy. NEW MICROBIOLOGICA, 35, 215-219, 2012.
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7. Magnus Unemo. et al. The Swedish new variant of Chlamydia trachomatis: genome sequence, morphology, cell tropism and phenotypic characterization. Microbiology (2010), 156, 1394–1404.
8. Björn Herrmann. et al. Emergence and Spread of Chlamydia trachomatis Variant, Sweden. Emerging Infectious Diseases. • www.cdc.gov/eid • Vol. 14, No. 9, September 2008.

ORDERING INFORMATION

Cat. No.	Product Name	Specimen	Format	Quantity
GCCHL-502a	Chlamydia Trachomatis Antigen Rapid Test	Swab/Urine	Cassette	20 Tests

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized 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	Catalog#
	Warning				

Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue,
Dipu Street, Anji 313300,Huzhou,Zhejiang,China.

EC REP QARAD b.v.b.a.
Cipalstraat 3, B-2440 Geel, Belgium

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