Chlamydia Rapid Test Cassette (Swab/Urine)
Package Insert

REF ICH-502	English

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 Cassette 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 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, complication of Chlamydia includes 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 Cassette (Swab/Urine) is a rapid test to qualitatively detect the Chlamydia antigen from female cervical swab, male urethral swab and male urine specimens.

PRINCIPLE

The Chlamydia Rapid Test Cassette (Swab/Urine) is a qualitative, lateral flow immunoassay for the detection of Chlamydia antigen from female cervical, male urethral and male urine. In the 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 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.

REAGENT

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 Cassette (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 just body fluids.
- To collect **Female Cervical Swab Specimens**:
  - 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 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 2-4cm, 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.
- 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 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℃) or refrigerated (2-8℃) for 24 hours. Do not freeze. All specimens should be allow to reach the room temperature (15-30℃) before testing.

MATERIALS

Materials Provided

- Test Cassettes
- Extraction Reagent 1 (0.2M NaOH)
- Extraction Reagent 2 (0.2M HCl)
- Package Insert
- Extraction Tubes
- Sterile Female Cervical Swab
- Workstation
- Dropper Tip

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

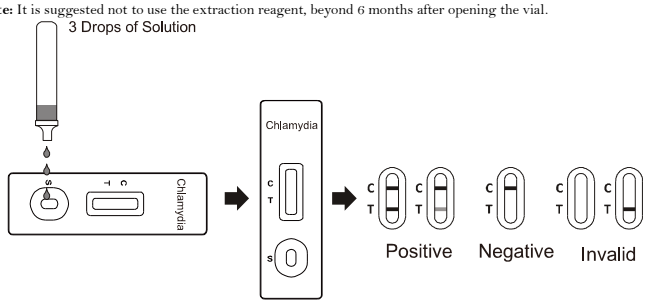
Allow the test, reagents, swab specimen, and/or controls to reach room temperature (15-30℃) prior to testing.

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. 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.
- **For Male Urine Specimens:**
- Hold the reagent 2 bottle vertically and add **6 drops of (approx. 250ul) 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 stand for 1 minute. Hold the reagent 1 bottle upright and add **5 drops of (approx. 300ul) reagent 1** to the extraction tube. Vertex 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 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 (S), 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 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 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 Chlamydia was detected in the specimen.
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Chlamydia 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 Chlamydia 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.

QUALITY CONTROL

An internal 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 Cassette (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 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 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

Sensitivity

The Chlamydia Rapid Test Cassette (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 Cassette (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 Cassette (Swab/Urine) has a high sensitivity relative to PCR.

Specificity

The Chlamydia Rapid Test Cassette (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 Cassette (Swab/Urine) 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 Intervals

Cross Reactivity

The antibody used in the Chlamydia Rapid Test Cassette (Swab/Urine) has been shown to detect all known Chlamydia serovars. Chlamydia psittasi and Chlamydia pneumoniae strains have been tested with the Chlamydia Rapid Test Cassette (Swab/Urine), 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 Cassette (Swab/Urine):

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

BIBLIOGRAPHY

1. Sanders J.W. et al Evaluation of an Enzyme Immunoassay for Detection of Chlamydia trachmatis 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

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

ACRO BIOTECH, Inc.
9500 Seventh Street,
Unit M, Rancho Cucamonga,
CA 91730, U.S.A.

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