Chlamydia Antigen Rapid Test Cassette (Swab/Urine)

English

For professional and in vitro diagnostic use only.

[INTENDED USE]

The Chlamydia Antigen Rapid Test Cassette is a rapid immunoassay for the qualitative detection of Chlamydia trachomatis antigen in female cervical swab, male urethral swab or male urine specimens. This device aids in the diagnosis of Chlamydial 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. 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.

Chlamydia Antigen Rapid Test Cassette is a simple, visual qualitative test that detects Chlamydia trachomatis antigen directly from female cervical swab, male urethral swab or male urine specimens. The test is based on immunochromatography and can give a result within 15 minutes.

[PRINCIPLE]

The Chlamydia Antigen Rapid Test Cassette is a qualitative membrane strip based immunoassay for the detection of Chlamydia trachomatis antigen directly from cervix swab, penis swab or male urine specimens. In this test procedure, anti-Chlamydia antibody is immobilized in the test line region of the cassette. After a specimen is placed in the specimen well, it reacts with anti-Chlamydia antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized anti-Chlamydia antibody. If the specimen contains Chlamydia antigen, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain Chlamydia antigen, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

[WARNINGS AND PRECAUTIONS]

- For professional *in vitro* diagnostic use only.
- Do not use after 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 all procedures 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.
- Follow standard biosafety guidelines for handling and disposal of potential infective material.
- Humidity and temperature can adversely affect results.

[COMPOSITION]

The test contains a membrane strip coated with anti-Chlamydia antibody on the test line, goat anti-mouse antibody on the control line, and a dye pad which contains colloidal gold coupled with anti-Chlamydia antibody.
The quantity of tests was printed on the labeling.

Materials Provided

- Test cassette
- Sterile swab (For female cervical swab specimen use only)
- Reagent A
- Work station
- Package insert
- Extraction tube
- Reagent B

Materials Required But Not Provided

- Urine cup
- Sterile swab (Used for male urethral swab specimens)
- Timer
- Centrifuge tube

[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch at temperature (4-30℃ or 40-86℉). The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

[SPECIMEN]

To collect ***Female Cervical Swab Specimen:***

- 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 2-4 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.

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 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 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 24-72 hours refrigerated (2-8℃) for 24 hours. Do not freeze. All specimens should be allow to reach the room temperature (15-30℃) before testing.

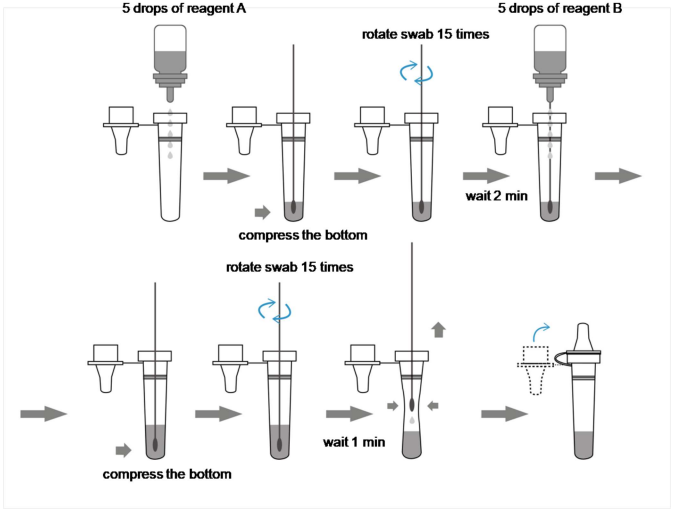
Extraction Procedure: preparation of extracted sample

For Female Cervical or Male Urethral Swab Specimen:

- Hold the reagent A bottle vertically and add 5 drops of reagent A (approx. 300 µL) to the extraction tube. Reagent A is colorless. Immediately insert the swab, compress the bottom of tube and rotate swab 15 times. Let stand for 2 minutes.
- Hold the reagent B bottle vertically and add 5 drops of reagent B (approx. 250 µL) 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. Cover the extraction tube with the connected dropper tip tightly.

For Male Urine Specimens:

- Hold the reagent B bottle vertically and add 5 drops of (approx. 250 µL) reagent B 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 A bottle upright and add 5 drops of (approx. 300 µL) reagent A to the extraction tube. Vertex or tap the bottom of the tube to mix the solution. Let stand for 2 minutes.
- Cover the extraction tube with the connected dropper tip tightly.



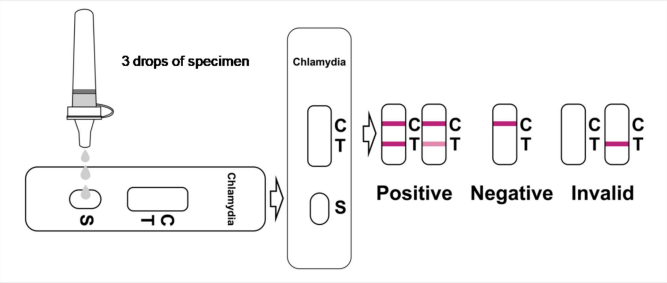
(The picture is for reference only, please refer to the material object.)

[TEST PROCEDURE]

Allow the test device and specimens to equilibrate to temperature (15-30℃

or 59-86℉) prior to testing.

1. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette on a clean and level surface.
3. Reverse the specimen extraction tube, hold the specimen extraction tube upright, transfer 3 drops (approximately 100 µL) to the specimen well (S) of the test cassette, then start the timer. See illustration below.
4. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.



(The picture is for reference only, please refer to the material object.)

[INTERPRETATION OF RESULTS]

Positive: Two lines appear. One colored line should be in the control region (C), and another apparent colored line adjacent should be in the test region (T). This positive result indicates the presence of Chlamydia antigen.
Negative: One colored line appears in the control region (C). No line appears in the test 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 using a new test cassette. If the problem persists, discontinue using the lot immediately and contact your local distributor.

[QUALITY CONTROL]

A procedural control is included in the test. A colored line appearing in the control 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]

- The Chlamydia Antigen Rapid Test Cassette is for *in vitro* diagnostic use only. The test should be used for the detection of Chlamydia trachomatis antigen directly from cervix swab, penis swab or male urine specimens. Neither the quantitative value nor the rate of increase in Chlamydia antigen can be determined by this qualitative test.
- The Chlamydia Antigen Rapid Test Cassette will only indicate the presence of Chlamydia antigen in the specimen and should not be used as the sole criteria for the diagnosis of Chlamydial infection. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Chlamydial infection.

[PERFORMANCE CHARACTERISTICS]

Accuracy

A side-by-side comparison was conducted using the Chlamydia Antigen Rapid Test and commercially available Chlamydia Antigen rapid tests. 1234 clinical specimens from three Professional Point of Care sites were evaluated with the Test and the commercial kit. The following results are tabulated from these clinical studies:

Agreement with Commercial Chlamydia Antigen Rapid Test

		Commercial Chlamydia Antigen Rapid Test		Total
		Positive	Negative	
	Positive	287	19	306
	Negative	6	922	928
Total		293	941	1234

The agreement between these two devices is 97.95% for positive specimens, and 97.98% for negative specimens. This study demonstrated that the Chlamydia Antigen Rapid Test is substantially equivalent to the commercial device.

Cross-Reactivity and Interference

1. Cross-reactivity with following organisms has been studied. The following organisms were found negative when tested with the Chlamydia Antigen Rapid Test: *Acinetobacter baumannii, Bacteroides fragilis, Bordetella pertussis, Candida albicans, Candida glabrata, Cardiobacterium hominis, EikeneUa corrodens, Enterococcus gallinarum, Escherichia coli, Haemophilus phrophlus, Haemophilus influenzae, Haemophilus parainfluenzae, Haemophilus paraphrophilus, Kingella kingae, Klebsiella pneumoniae, Listeria monocytogenes, Moraxella catarrhalis, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus sp. group C, G, F, Streptococcus mutans.*
2. Potentially cross-reactive endogenous substances including common serum components, such as lipids, hemoglobin, bilirubin, were spiked at high concentrations into the Chlamydia Antigen positive and negative specimens and tested, separately. No cross-reactivity or interference was observed to the device.

Analytes	Conc.	Specimens	
		Positive	Negative
Albumin	20 mg/mL	+	-
Bilirubin	10 µg/mL	+	-
Hemoglobin	15 mg/mL	+	-
Glucose	20 mg/mL	+	-
Uric Acid	200 µg/mL	+	-
Lipids	20 mg/mL	+	-

Reproducibility

Reproducibility studies were performed for Chlamydia Antigen Rapid Test at three physician office laboratories (POL). Sixty (60) clinical cervix or penis swab specimens, 20 negative, 20 borderline positive and 20 positive, were used in this study. Each specimen was run in triplicate for three days at each POL. The intra-assay agreements were 100%. The inter-site agreement was 100%.

[BIBLIOGRAPHY]

1. Ryan KJ, Ray CG (editors). Sherris Medical Microbiology (4th ed.). McGraw Hill. pp. 2004; 463–70.
2. J.P. Euzéby. "Chlamydia". List of Prokaryotic names with Standing in Nomenclature. Retrieved 2008-09-11.
3. Darougar S, Jones BR, Kinnison JR, Vaughan-Jackson JD, Dunlop EM. Chlamydial infection. Advances in the diagnostic isolation of Chlamydia, including TRIC agent, from the eye, genital tract, and rectum. Br J Vener Dis 1972; 48 (6): 416–20.

Index of Symbol

Do not reuse	*In vitro* diagnostic medical device
Store between 4-30℃	Consult instructions for use
Caution	Lot number
Use by	Contains sufficient for <n> tests
Keep away from sunlight	Keep dry
Manufacturer	Do not use if package is damaged

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