Chlamydia cassette

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For professional *in vitro* diagnostic use only			

Chlamydia

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

ONE STEP

PRINCIPLE

The *Linear Chlamydia cassette* (Swab/Urine) is a rapid visual immunoassay for the qualitative presumptive detection of Chlamydia trachomatis in female cervical swab and male urethral swab specimens. This kit is intended for use as an aid in the diagnosis of Chlamydia infection.
The *Linear Chlamydia Test Device (Swab/Urine)* detects Chlamydia trachomatis through visual interpretation of color development on the internal strip. Antigen-specific lipopolysaccharide (LPS) monoclonal antibody is immobilized on the test region of the membrane. During testing, the specimen reacts with monoclonal anti-Chlamydia antibodies conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient chlamydia antigen in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENT COMPOSITION

An antibody specific to the *Chlamydia* antigen is coated on the test line region of the cassette.

PACKAGING CONTENTS

REF 4240220 20 test cassettes

- 20 Test Devices
- 20 Sterile female cervical swabs
- 20 Extraction tubes & tips
- 1 Workstation
- 1 Reagent A (0.2M NaOH)
- 1 Reagent B (0.2N HCl)

STORAGE AND STABILITY

Store at 2-30ºC. The test is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.
Care should be taken to protect the components of this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND PREPARATION

The quality of specimen obtained is of extreme importance. Detection of chlamydia requires a vigorous and thorough collection technique which provides cellular material rather than just body fluids. **Do not use 0.9% sodium chloride to treat swabs before collecting specimens.**

For female cervical specimens:

- Use the swab provided with the kit.
- Before specimen collection, remove excess mucus from the endocervical area with a separate swab or 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 chlamydia organisms. Firmly rotate the swab for 15 - 20 seconds without contamination with exocervical or vaginal cells.
- If the swab may be tested immediately, replace the swab into the extraction tube.

For male urethral specimens:

- Standard wire-shafted fiber-tipped swabs or cytology brushes (not provided) should be used for urethral specimen collection. Instruct the patients not to urinate at least one hour prior to specimen collection.
- Insert the swab 2-4 cm into the urea, rotate for 3-5 seconds and withdraw it. If the swab may be tested immediately, replace the swab into the extraction tube.

Do not place the swab in any transport device containing medium. Transport medium interferes with the assay, and viability of organisms is not required for the assay. If immediate testing is not possible, patient samples should be placed in a dry transport tube for storage or transport. The swabs may be stored for 4 hours at room temperature (15-30°C) or 24 hours refrigerated (2-8°C). Do not freeze. All specimens should be allowed to reach a room temperature of 15-30°C before testing.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Positive and negative controls
- Centrifuge tube (for urine specimens)
- Urine cup (for urine specimens)
- Sterile male urethral swabs

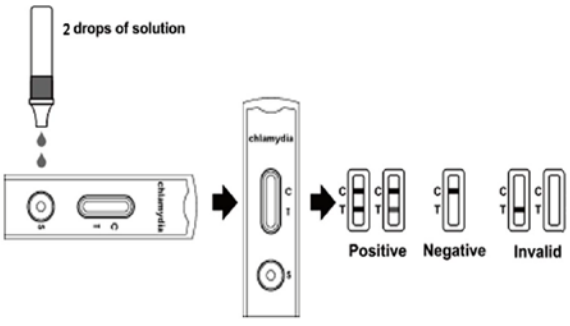
PROCEDURE

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

1. **Prepare endocervical or urethral swab specimens:**
   - Place a clean extraction tube in the workstation. Add 8 drops of reagent A to the extraction tube.
   - Immerse the patient swab into the extraction tube and wait 2 minutes. While waiting, use a circular motion to roll the swab against the side of the extraction tube so that the liquid is expressed from the swab and can reabsorb.
   - Add 8 drops of reagent B. Squeeze the swab firmly against the tube to expel as much liquid as possible from the swab for 1 minute. Discard the swab following guidelines for handling infectious agents.
   - The extracted specimen can remain at room temperature for 60 minutes without affecting the test result.
2. Remove the test from the sealed pouch and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
3. Add **2 drops** (approximately 100 µL) of extracted specimen from the extraction tube to the specimen well (S) of the test cassette.

   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result window.

   As the test begins to work, color will migrate across the membrane.
4. Wait for the colored band(s) to appear. The result should be read at **10 minutes**. Do not interpret the result after 20 minutes.



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

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 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.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test, and cannot determine the concentrations of analytes in specimens.
2. Insufficient specimen volume, incorrect operation procedure or expired tests are the most likely reasons for control band failure.

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 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.

CLINICAL SIGNIFICANCE

The genus Chlamydia includes three species: Chlamydia trachomatis, the recently described Chlamydia pneumoniae, primarily associated with humans, and Chlamydia psittasi, primarily associated with animals. Chlamydia trachomatis comprises 15 known serovars, is associated with trachomatis and gentourinary infection, and three serovars are associated with lymphogranuloma venereum (LGV). Chlamydia trachomatis infections are the most common bacterial sexually transmitted diseases. Approximately 4 million new cases occur each year in the United States, primarily cervicitis and nongonococcal urethritis. This organism also causes conjunctivitis and infant pneumonia. Chlamydia trachomatis infection 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 cervictis, urethritis, endometritis, pelvic inflammatory diseases (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 and pneumonia. In men, at least 40% of cases of nongonococcal urethritis are associated with chlamydia infection and epididymitis. Approximately 70% of women with endocervical infections and up to 50% of men with urethral infections are symptomatic.
Chlamydia psittasi infection is associated with respiratory disease in individuals exposed to infected birds and is not transmitted from human to human. Chlamydia pneumonia, first isolated in 1983, is associated with respiratory infections and pneumonia. Traditionally, chlamydia infection has been diagnosed by the detection of chlamydia inclusions in tissue culture cells. Culture method is the most sensitive and specific laboratory method, but it is labour intensive, expensive, lengthy (2-3 days) and not routinely available in most institutions. Direct tests such as immunofluorescence assay (IFA) require specialized equipment and a skilled operator to read the result.

ANALYTICAL PERFORMANCE

Table: Chlamydia Rapid Test vs. PCR

Female Cervical Specimens

Relative Sensitivity:
90.2% (76.9%-96.5%)*
Relative Specificity:
96.0% (91.2%-99.4%)*
Overall Agreement:
94.0% (89.4%-97.6%)*
***95% Confidence Interval**

		Chlamydia Rapid Test +	Chlamydia Rapid Test -	Total
PCR	+	46	5	51
	-	4	95	99
		50	100	150

Male Urethral Specimens

Relative Sensitivity:
77.8% (66.7%-88.2%)*
Relative Specificity:
92.1% (86.4%-96.9%)*
Overall Agreement:
93.0% (82.1%-92.3%)*
***95% Confidence Interval**

		Chlamydia Rapid Test +	Chlamydia Rapid Test -	Total
PCR	+	42	12	54
	-	9	105	114
		51	117	168

Specificity:
The antibody used in the Chlamydia Rapid Test Device (Swab) has been shown to detect all 15 Chlamydia serovars. In addition, *Chlamydia psittaci* and *Chlamydia pneumonia strains have* been tested and gave positive results. Cross reactivity with other organisms has been studied using suspensions of 10^7 CFU/ml. The following organisms produced negative results with the test:

Acinetobacter calcoaceticus	*Proteus vulgaris*	*Streptococcus faecalis*
Salmonella typhi	*Acinetobacter spp.*	*Streptococcus faecium*
Staphylococcus aureus	*Candida albicans*	*Trichomonas vaginalis*
Neisseria catarrhalis	*Neisseria gonorrhoea*	*Pseudomonas aeruginosa*
Neisseria meningitides	*Neiiseria lactamica*	*Gardnerella vaginalis*
Escherichia coli		

PRECAUTIONS

- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new extraction tube for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in any area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
- Humidity and temperature can adversely affect results.
- When the assay procedure is complete, dispose of swabs carefully after autoclaving them at 121°C for at least 20 minutes. Alternatively, swabs can be treated with 0.5% sodium hypochlorite (i.e., household bleach) for one hour before disposal.
- Used testing materials should be discarded according to local regulations.
- Do not use cytology brushes with pregnant patients.

LIMITATIONS OF THE TEST

1. The *Linear Chlamydia Test Device* is for professional in vitro diagnostic use, and should only be used for the qualitative detection of Chlamydia trachomatis. No meaning should be inferred from the color intensity or width of any apparent bands.
2. The test does not differentiate between C. trachomatis, C. pneumonia or C. psittaci.
3. Detection of chlamydia is dependent on the number of organisms present in the specimen. This may be affected by specimen collection methods and patient factors such as age, history of STD, presence of symptoms, etc. The minimum detection level of this test may vary according to serovar.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

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