CE 0483

QuickStripe™ Chlamydia Ag

A rapid test device for the qualitative detection of Chlamydia trachomatis antigen in female cervical swab, male urethral swab and male urine specimens.

Instruction Manual

Test kit for 20 tests individually pouched
REF 41101

For *In Vitro* Diagnostic Use
For professional use
Store at 2-30°C. ***Do Not Freeze***

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Intended Use

The *QuickStripe*™ Chlamydia Ag 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

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 asymptomatic.
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 labor 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.

Principle

The *QuickStripe*™ Chlamydia Ag 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.

Reagents

The *QuickStripe*™ Chlamydia Ag 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.
The QuickStripe™ Chlamydia Ag test consists of a reagent strip mounted in a plastic housing. The amount of Chlamydia trachomatis antibody coated on the test regions is less than 0.001mg, the amount of streptavidin coated on the control region is about 0.0003mg.The conjugate pad contains 0.002 mg Chlamydia trachomatis antibody coupled with red latex particles.
Reagent A contains 0.2M NaOH;
Reagent B contains 0.2M HCl.

Materials

Materials Provided

- Individually packed Test devices with desiccant
- Extraction tubes & tips
- Reagent A
- Reagent B
- Sterilized swabs, Puritan, CE MDD 0086
- Workstation
- Package Insert (upon request)

Materials Required but Not Provided

- Timer

Precautions

- For professional in vitro diagnostic use only.
- 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.
- It is recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).

- 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.

Storage and Stability

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- 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 equipment, containers or reagents can lead to false results.

Specimen Collection and storage

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.

Do not use 0.9% sodium chloride to treat swabs before collecting specimens.

To collect **Female Cervical Swab Specimens**:

- Use the swab provided in the kit.
- 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 cubical epithelial cells, which are the main reservoir of the Chlamydia organism. Firmly rotate the swab in one direction (clockwise or counterclockwise) for 15-20 seconds without contamination with exocervical or vaginal cells.
- 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 Dacron swabs should be used for urethral specimen collection. Instruct patients not to urinate for 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.

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 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.
- Carefully discard the supernatant, keep the tube inverted and remove any supernatant from the rim of tube by blotting onto absorbent paper.
- If the test is to be conducted immediately, treat the urine pellet according to the Directions for Use.
- 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). The urine specimens can be stored refrigerated (2-8°C) for 24 hours. Do not freeze.
- All specimens should be allowed to reach a room temperature of 15-30°C before testing.

Procedure

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

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 antigen according to the specimen type.

For Endocervical or Male Urethral Swab Specimens:

- Place a clean extraction tube in the workstation. Hold the Reagent A bottle vertically and add 8 full drops of Reagent A to the extraction tube. Immediately insert the patient swab, compress the swab against the side of the tube and rotate the swab for 2 minutes so that the liquid is expressed from the swab and can reabsorb.
- Add 8 drops of reagent B. Compress 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. Fit the dropper tip on top of the extraction tube.
- The extracted specimen can remain at room temperature for 60 minutes without affecting the test result.

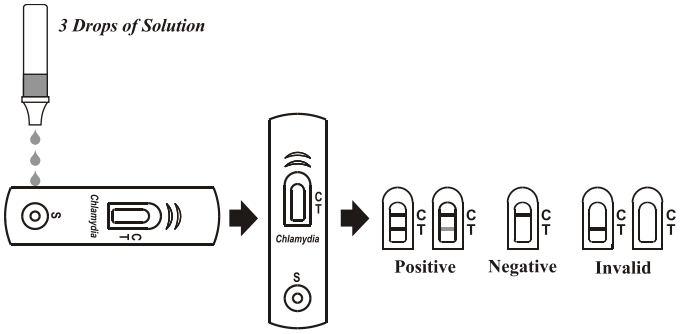
For Male Urine Specimens:

- Add 8 drops of reagents A 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 2 minutes. Hold the Reagent B bottle upright and add 8 drops of Reagent B to the extraction tube. Vortex or tap the bottom of the tube to mix the solution. Let stand for 1 minute.
- Fit the dropper tip on top of the extraction tube.

3. Place the test device on a clean and level surface. **Add 3 drops** (approximately 100µL) **of the extracted solution** to the specimen well (S) of the test device, and start the timer. ***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 line(s) to appear. **Read results at 10 minutes.** If no line appears after 10 minutes, please read again at 20 minutes.



Interpretation of Results

(Please refer to the illustration above)

POSITIVE: Two distinct colored lines appear on the membrane. One band line appears in the control region (C) and another line appears be in the test line region (T).

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line region (T).

INVALID: Control line fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Note: The shade of color in the test line region (T) may vary, but it should be considered positive whenever there is even a faint colored line.
Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure

Quality Control

Internal procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control, confirming sufficient specimen volume, adequate membrane wicking and correct procedural technique.
External Control is 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 of the Test

1. The QuickStripe™ *Chlamydia Ag* is for professional *in vitro* diagnostic use only. This test should be used for the qualitative detection of Chlamydia trachomatis antigen. 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 chlamydia 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.

Performance Characteristics

Table: QuickStripe™ Chlamydia Ag test vs. INSTALERT™ Chlamydia Test Device

Female Cervical Specimens

Relative Sensitivity:
97.0%(93.7%-98.6%)*
Relative Specificity:
98.3%(96.3%-99.2%)*
Overall Agreement:
97.8% (96.2%-98.7%)*
***95% Confidence Interval**

		INSTALERT™ +	INSTALERT™ -	Total
QuickStripe™	+	197	6	203
Chlamydia Ag	-	6	342	348
		203	348	551

Male Urethral Specimens

Relative Sensitivity:
97.7%(94.3%-99.1%)*
Relative Specificity:
96.7%(93.4%-98.4%)*
Overall Agreement:
97.1%(95.0%-98.4%)*
***95% Confidence Interval**

		INSTALERT™ +	INSTALERT™ -	Total
QuickStripe™	+	172	7	179
Chlamydia Ag	-	4	207	211
		176	214	390

Male Urine Specimens

Relative Sensitivity:
98.5%(92.1%-99.7%)*
Relative Specificity:
94.2% (86.2%-97.8%)*
Overall Agreement:
96.4% (91.8%-98.4%)*
***95% Confidence Interval**

		INSTALERT™ +	INSTALERT™ -	Total
QuickStripe™	+	67	4	71
Chlamydia Ag	-	1	66	67
		68	70	138

Sensitivity

The analytical sensitivity of the QuickStripe™ Chlamydia Ag test is $1.0e^5$ org/test Chlamydia EB.

Cross-Reactivity

The antibody used in the QuickStripe™ Chlamydia Ag test has been shown to detect all known fifteen Chlamydia serovars. Chlamydia psittaci and Chlamydia pneumoniae strains have not been tested with the Chlamydia Rapid Test Device (Swab/Urine).
Cross reactivity with other organisms has been studied using suspensions of 10^7 CFU/swab. The following organisms were found negative when tested with the QuickStripe™ Chlamydia Ag test:

Acinetobacter calcoaceticus	*Gardnerella vaginalis*	*Neisseria meningitides*
Acinetobacter spp	*Group B Streptococcus*	*Proteus mirabilis*
Branhamella catarrhalis	*Group C Streptococcus*	*Proteus vulagris*
Candida albicans	*Hemophilus influenzae*	*Pseudomonas aeruginosa*
Enterococcus faecalis	*Klebsiella pneumoniae*	*Salmonella choleraesius*
Enterococcus faecium	*Neisseria gonorrhea*	*Staphylococcus aureus*

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Glossary of Symbols

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community
STERILE EO	Sterilized using ethylene oxide		
CE	CE marking according to IVD Medical Devices Directive 98/79/EC		

CE 0483

EC REP

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