LIMING BIO

diagnostics are ASSURED

StrongStep®

Chlamydia trachomatis Antigen Rapid Test

(Dyed latex immunochromatography)

REF : 500010 **Specimen:** Swab

Language: English **Version:** 02

Effective Date: 2011-12

For professional in vitro diagnostic use only.

INTENDED USE

StrongStep® Chlamydia trachomatis Antigen Rapid Test is an immunochromatographic assay for the qualitative presumptive detection of *Chlamydia trachomatis* in female endocervical swab and male urethral swab specimens. This kit is intended to be used as an aid in the diagnosis of Chlamydia infection.

INTRODUCTION

The genus *Chlamydia* includes three species: *Chlamydia trachomatis, Chlamydia pneumoniae*, a primarily human pathogen, and *Chlamydia psittasi*, primarily animal pathogen. *Chlamydia trachomatis* comprise 15 known serovars, is associated with trachomatis and genitourinary infection, and three serovars are associated with lymphogranuloma venereum (LGV). *Chlamydia trachomatis* infections is one of the most common 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 asymtomatic 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 the cases of nongonococcal urethritis are associated with *Chlamydia* infection. 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, long time (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

StrongStep® Chlamydia trachomatis Antigen Rapid Test has been designed to detect *Chlamydia trachomatis* through visual interpretation of color development in the internal strip. The membrane was immobilized with antigenus-specific lipopolysaccharide (LPS) monoclonal antibody on the test region. During the test, the specimen is allowed to react with colored monoclonal anti-Chlamydia antibody colored particals conjugates, which were precoated on the conjugate pad of the test. The mixture then moves on the membrane by capillary action, and interact with reagents on the membrane. If there were enough Chlamydia antigens in specimens, a colored band will form at the test region of the membrane. Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

20 Individually packed test devices	Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions.
1 bottle of Extraction Buffer A - 10ml	Buffer solution containing 0.2 M sodium hydroxide with yellow cap.
1 bottle of Extraction Buffer B - 10ml	Buffer solution containing 0.2 M hydrochloric acid with white cap.
20 Extraction tubes	For specimens preparation use.
1 Workstation	Place for holding buffer vials and tubes.
1 Package insert	For operation instruction.
1 Positive control swab (on request only)	Contain inactived Chlamydia trachomatics and sodium azide. For external control.
1 Negative control swab (on request only)	Not contain Chlamydia trachomatics. For external control.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer	For timing use.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its 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 totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to performing any tests.
- 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 the procedure 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.
- 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 completed, dispose the swabs carefully after autoclaving them at 121°C for at least 20 minutes. Alternatively, they can be treated with 0.5% sodium hypochloride (or house-hold bleach) for one hour before disposal. The used testing materials should be discarded in accordance with local, state and/or federal 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.**
- Cares should be taken to protect components in 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 STORAGE

- The quality of specimen obtained is of extreme importance.

Detection of Chlamydia requires a rigorous and thorough collection technique which provides cellular material rather than just body fluids.

For endocervical specimens:

- Use only Dacron or Rayon tipped sterile swabs with plastic shafts. It is recommened to use the swab supplied by the kits manufacturer(The swab are not contained in this kit, for the ordering information, please contact the manufacturer or local distributor, the catalog numbers are 207000-female swab, 208000-male swab). Swabs from other suppliers have not been validated. Swabs with cotton tips or wooden shafts are not recommended.
- 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 organismn. Firmly rotate the swab for 15 - 20 seconds without contamination with exocervical or vaginal cells.
- Put the swab into the extraction tube, if the test may be run immediately.

For Urethral specimens:

- Standard wire-shafted fiber-tipped swabs should be used for urethral specimen collection. Instruct the patients not to urinate at least two hours prior to specimen collection.
- Insert the swab into the urea about 2-4 cm, rotate for 3-5 seconds and withdraw it, and place it into the extraction tube, if the swab may be tested immediately.
- Do not place the swab in any transport device containing medium since transport medium interferes with the assay and viability of the organisms is not required for the assay. If immediate testing is not possible, the patient samples should be placed in a dry transport tube for storage or transport. The swabs may be stored for 24 hours at room temperature (15-30°C) or 1 week at 4°C or no more than 6 month at -20°C. All specimens should be allowed to reach room temperature of 15-30°C before testing.
- Do not use 0.9% sodium chloride to treat swabs before collecting specimens.

PROCEDURE

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

1. Prepare Endocervical or Urethral swab specimens:

- Place a clean extraction tube in the designated area of the workstation.

Add 8 drops of extraction buffer A into the extraction tube.

- Immerse the patients swab into the extraction tube and extract 2 minutes at room temperature. During extraction, 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.
- At the end of the extraction time, add 8 drops of extraction buffer B into the tube and extract for another 1 minute in the same way. Then squeeze the swab firmly against the tube to expel as much liquid as possible from the swab. Discard the swab following guidelines for handling infectious agents.
- The specimens extracted can retain at room temperature for 60 minutes without affecting the result of the Chlamydia test.

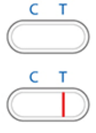
2. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. To obtain a best result, the assay should be performed within one hour.

3. Add 3 drops (approximately 100 µl) of extracted sample from the extraction tube to the sample well on the test cassette. **Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window.**

   As the test begins to work, you will see color move across the membrane.

4. Wait for the colored band(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

POSITIVE RESULT: 	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 RESULT: 	Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).
INVALID RESULT: 	Control band fails to appear. Results from any test which has not produced a control band in 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.

NOTE:

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. But the substances level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered as an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External procedural controls may provided(on request only) in the kits to ensure that the test are functioning properly. Also, the Controls may be used to demonstrate proper performance by the test operator. To perform a positive or negative control test, complete the steps in the Test Procedure section treating the control swab in the same manner as a specimen swab.

LIMITATIONS OF THE TEST

1. *StrongStep*® Chlamydia trachomatis Antigen Rapid Test is for professional *in vitro* diagnostic use, and should be used for the qualitative detection of *Chlamydia trachomatis* only. There is no meaning attributed to line color intensity or width.
2. The Chlamydia Test does not specifically differentiate *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. Women with vaginal discharge should be evaluated for risk factors of cervicitis and pelvic inflammatory disease caused by other organisms including Neisseria gonorrhoeae, Candida albicans, Trichomonas vaginalis or Bacterial vaginosis (These can also be diagnosed by LimingBio's other products: 500020 Neisseria gonorrhoeae antigen rapid test; 500050 Neisseria gonorrhoeae/Chlamydia trachomatis antigen combo rapid test; 500030 Candida albicans antigen rapid test; 500040 Trichomonas vaginalis Antigen Rapid test; 500060 Candida albicans /Trichomonas vaginalis antigen combo rapid test; 500080 Bacterial vaginosis rapid test).
5. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
6. Excessive blood (>50 µL in case of female swabs and >20 µL in case of male swabs) may cause false positive results. Endocervical samples from female patients should not be collected during menstrual period.

PERFORMANCE CHARACTERISTICS

Table: *StrongStep*® Chlamydia trachomatis Antigen Rapid Test vs. Another Branded Chlamydia Test Plus PCR*

Female Endocervical Specimens

Relative Sensitivity: 94.12% (86.80%-98.06%)* **Relative Specificity:** 99.15% (97.85%-99.77%)* **Overall Agreement:** 98.39% (96.96%-99.26%)* ***95% Confidence Interval**			**Another Branded Chlamydia Test Plus PCR** *(Expanded gold standard)*		
			+	-	**Total**
	***StrongStep*® Chlamydia Test**	+	80	4	84
		-	5	469	474
			85	473	558

Male Urethral Specimens

Relative Sensitivity: 94.59% (88.62%-97.99%)* **Relative Specificity:** 99.9% (99.12%-99.99%)* **Overall Agreement:** 98.86% (97.54%-99.58%)* ***95% Confidence Interval**			**Another Branded Chlamydia Test Plus PCR** *(Expanded gold standard)*		
			+	-	**Total**
	***StrongStep*® Chlamydia Test**	+	105	0	105
		-	6	417	423
			111	417	528

*: This clinical study is performed using a famous branded Chlamydia Antigen Rapid Test as the comparison test, of which the discrepant results were confirmed by Real-time PCR.

The antibody used in the Chlamydia test has been shown to detect all 15 Chlamydia serovars. In addition, *Chlamydia psittaci* and *Chlamydia pneumonia* strains have been tested with the test and gave a positive result. Cross reactivity with other organisms has been studied using suspensions of 10^7 CFU/ml. The following organisms were not detected using the test:

Acinetobacter calcoaceticus	*Proteus vulgaris*
Salmonella typhi	*Acinetobacter spp.*
Staphylococcus aureus	*Candida albicans*
Neisseria catarrhalis	*Neisseria gonorrhoea*
Neisseria meningitidis	*Neisseria lactamica*
Escherichia coli	*Gardnerella vaginalis*
Streptococcus faecalis	*Streptococcus faecium*
Pseudomonas aeruginosa	*Trichomonas vaginalis*
Ureaplasma Urealyticum	*Mycoplasma hominis*

LITERATURE REFERENCES

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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
Σ_n	Contains sufficient for <n> tests
	Do not reuse
EC REP	Authorized representative in the European Community
CE	CE marked according to IVD Medical Devices Directive 98/79/EC

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