# One-Step Chlamydia Antigen Swab Test

**For in vitro Diagnostic Use only**

## INTENDED USE

The One-Step Chlamydia Test is intended for in vitro diagnostic use in the rapid, qualitative detection of Chlamydia trachomatis directly from female endocervical swab and male urethral swab, in addition to ocular specimens from symptomatic patients. The test is intended for use as an aid in the diagnosis of Chlamydia infections.

## SUMMARY

Chlamydia includes three species: Chlamydia trachomatis, Chlamydia pneumonia and Chlamydia psittasi.

Chlamydia trachomatis, a human pathogen, is subdivided into 15 known serovars; 3 are associated with Lymphogra-nuloma Venereum and the remaining 12 with trachomatis and genitourinary infection. Common complications of women infected with Chlamydia include cercicitis, urethritis, endometritis, pelvic inflammatory disease and increased incidence of ectopic pregnancy and infertility, and of men include urethritis and epididymitis. Chlamydia trachomatis infection has a high prevalence and asympomatic carriage rate. Approximately 70% of women with endocervical infections and up to 50% of men with urethral infections are asymptomatic.

Chlamydia psittasi, mainly an animal pathogen, is associated with respiratory disease caused by exposure to infected birds and not transmitted through human interaction.

Chlamydia pneumonia, first isolated in 1983, is a human pathogen and is associated with respiratory infections and pneumonia.

Traditionally, Chlamydia infection is diagnosed by detection of Chlamydia inclusions in tissue culture cells. Although this method is the most sensitive and specific laboratory method, it is costly, labor intensive, time consuming (48-72 hours) and not routinely available in most institutions. Direct immunofluorescence assay requires specialized equipment and a skilled operator to interpret results. The One-Step Chlamydia Test, utilizing the gold particle based immunoassay, provides a simple, rapid, specific yet highly sensitive method of detection of Chlamydia antigen.

## PRINCIPLE

The One-Step Chlamydia Test is a rapid qualitative immunoassay based on the immune-chromatographic principle. (In the assay procedure, a clinical specimen is obtained and placed into an extraction tube containing Extraction Solution A. After two minutes. Extraction Solution B is added to the tube. 3 drops (approximately 150μ l) of extracted sample is added to the sample well). The membrane is pre-coated with anti-genus specific lipopolysaccharide (LPS) monoclonal antibody on the test band (T) region and goat anti-mouse antibody on the control band(C) region. During testing, the sample is allowed to react with the colloidal gold particles which have been coated with monoclonal anti-chlamydia antibody, and then migrates laterally across the membrane by capillary action. If the sample contains Chlamydia antigen, a colored band with a specific antibody- Chlamydia antibody-colloidal gold particle complex will form on the membrane in the test band (T) region. If Chlamydia antigen is not present, a pink line will only form on control band (C) region. To serve as a procedural control, a colored band at the control band (C) region will always appear regardless of the presence of Chlamydia antigen.

## MATERIALS SUPPLIED

- 20 Test Cassettes.
- Extraction Solution A: contain 0.2M sodium hydroxide (7.5 ml).
- Extraction Solution B: contain 0.2M hydrochloric acid (7.5ml).
- Sterile Tip Swabs: 20.
- Extraction Tubes: 20.
- One Package Insert.

## MATERIALS REQUIRED BUT NOT SUPPLIED

- Specimen collection container
- Timer

## STORAGE AND STABILITY

Store the test kit at temperature (4-30˚C) in the sealed pouch out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. Do not freeze.

## PRECAUTIONS

- *FOR PROFESSIONAL AND IN VITRO DIAGNOSTIC USE ONLY.*
- Do not use any of the kit contents after the expiration date. Do not mix kit components from different lots. Do not mix reagent bottle caps.
- Use appropriate precautions in the collection, handing, storage and disposal of specimens and used kit contents. All specimens, reagents and controls should be handled as if they contain infectious agents. When the assay procedure is completed, dispose of used swabs carefully after autoclaving them at 121℃ for over 20 minutes or pretreating them with 0.5%-1% sodium hypochlorite (or household bleach) for an hour.
- Extraction Solution A contains sodium hydroxide (a basic solution) and Extraction Solution B contains hydrochloric acid (an acid solution). If either of the solutions contacts the skin or eye, flush with plenty of water.
- Positive and Negative Controls contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these solutions, always flush with plenty of water to prevent azide buildup.
- Do not eat, drink or smoke in the area where specimens and kit reagent are handled. Wear protective clothing such as laboratory coats and disposable gloves while collecting and assaying samples.
- As with all diagnostic tests, a decisive clinical diagnosis should not be based on the result of a single test, but should only be made by a physician after all clinical and laboratory findings have been evaluated.

## SPECIMEN COLLECTION AND HANDLING

- 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.
- For Female endocervical specimens:
- Before specimen collection, use a swab or cotton ball to remove excess mucus from the endocervical area and discard.
- Use the swab provided with the kit or any shafted swabs with rayon of dacron tips. 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 organism. Firmly rotate the swab for 15-20 second and withdraw without contamination of exocervical or vaginal cells.
- Alternatively, endocervical specimens can be collected with a cytology brush (Not provided. Caution; do not use cytology brushes with pregnant patients). Insert the cytology brush

into the endocervical canal past the squamocolumnar junction. Leave in place two to three seconds. Rotate the cytology brush two full turns, and then withdraw the brush without touching any vaginal surface.

- Place the swab in the extraction tube, if the test is to be conducted immediately.

### For Male Urethral Specimens:

- Use standard wire-shafted fiber-tipped swabs (not provided) for urethral specimen collection. Instruct the patients not to urinate at least one hour prior to specimen collection.
- Insert the swab into the urethra about 2-4cm, rotate for 3-5 seconds and withdraw it.
- Place the swab to the extraction tube, if the test is to be conducted immediately.
- Do not place the swab in any transport device containing medium since transport medium interferes with the assay.
- If immediate testing is not possible, the patient sample should be placed in a dry transport tube for storage or transport. The swabs may be stored for 4 hours at room temperature (10-30℃) or 24 hours at refrigerated (4-8℃). Do not freeze. All specimens should be allowed to reach a room temperature of 10-30℃ before testing.

## TEST PROCEDURE

- Read the “Specimen Collection and Handling” instructions. Do not open pouches until ready to perform the assay. Test reagents, test cassettes, clinical specimens and extraction solution should be brought to room temperature before testing.
- To avoid cross contamination, do not allow the tip of the reagent bottle to come in contact with sample swabs or extraction tubes.

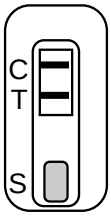
**A. Preparation of Endocervical or Urethral swab specimens:**

- Place a new extraction tube in the designated area of the workstation. Add 6 drops of extraction solution A to the extraction tube.
- Immerse the patient’s swab into the extraction tube, and extract for 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 reabsorbed.
- At the end of the extraction time, add 6 drops of extraction solution B and mix. 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 extracted specimen can remain at room temperature for 60 minutes without affecting the result of the Chlamydia Test.

**B. Test Procedure:**

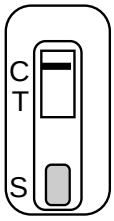
- Follow the instructions for specimen collection and extraction.
- Remove the Chlamydia Antigen Test device from its protective pouch and place it on a clean, dry, and level surface. Label the device with patient or control identification.
- Place the cap on the extraction tube. Add 3 drops (approximately 150µl) of extracted sample from extraction tube to the sample well on the test cassette.
- Wait for test band(T) to appear. The test results should be read in 10 minutes after adding the extracted specimen to the sample well. Depending on the amount of Chlamydia antigen on the swab, a positive result may be visible as soon as 1 minute. To confirm a negative result, a complete reaction time of 15 minutes is required. **Do not interpret results after 15 minutes.**

## INTERPRETATION OF RESULTS



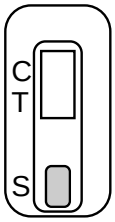

**Positive**

**Two** colored lines should be observed in the viewing window. The line in the test region **(T)** is the probe line; the line in the control region **(C)** is the control line, which is used to indicate proper performance of the device. **The color intensity of the test line may be weaker or stronger than that of the control line.**




**Negative**

The control line(C) appears in the test window, but the test line (T) is not visible.




**Invalid**

No line appears in the control region. Under no circumstances should a positive sample be identified until the control line(C) forms in the viewing area. If the control line does not form, the test result is inconclusive and the assay should be repeated.

## LIMITATION OF PROCEDURE

One-Step Chlamydia Test does not specifically differentiate C. trachomatis, C. Pneumonia or C. Psittaci. Detection of Chlamydia is depended 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 Sexually Transmitted Disease, presence of symptoms, etc.

## QUALITY CONTROL

One-Step Chlamydia Test includes a procedural control. A red colored band appearing in the control band (C) region of the membrane indicates proper performance and reactive reagents.

## PERFORMANCE CHARACTERISTICS

### Specificity

- The antibody used in One-Step Chlamydia Test has been shown to detect all 15 Chlamydia serovars. In addition, Chlamydia psittaci and Chlamydia pneumonia strains have been tested with the Chlamydia Antigen Test and gave a positive result.
- Cross reactivity with other organisms has been studied using suspensions of $10^6$CFU/ml. The following organisms were not detected using this Chlamydia Test:

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|---|---|
| Acinetobacter alcoaceticus | Proteus vulgaris |
| Salmonella typhi | Acinetobacter spp |
| Staphylococcus aureus | Candida albicans |
| Neisseria gonorrheae | Escherichia coli |
| Neisseria catarrhalis | Gardnerella vaginalis |
| Neisseria meningitides | Streptococcus faecalis |
| Neisseria lactamica | Streptococdus faectium |
| Pseudomonas aeruginosa | Trichomonas vaginalis |

## MANUFACTURER

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Revised Jul.05, 2016