A rapid test for the qualitative detection of Chlamydia antigen in female cervical swab, male urethral swab and male urine specimen to aid in the diagnosis of Chlamydia infection.

[EXPERIMENTAL DESIGN]

Chlamydia trachomatis is the most common cause of sexually transmitted venereal infection in the world. It is comprised of elementary bodies (the infectious form) and reticulate inclusion bodies (the replicating form). It can cause serious reproductive and ocular infection, with frequent serious complications in both women and neonates. Complications of Chlamydia infection in women include pelvic inflammatory disease, ectopic pregnancy, premature rupture of membranes, and induction of labor. In neonates, the incidence of conjunctivitis and pneumonia is high. Vertical transmission of the disease during parturition to newborn infants can result in serious neonatal conjunctivitis and pneumonia in men, of Chlamydia includes urethritis and epididymitis. At least 40% of the nongonococcal urethritis cases are associated with Chlamydia infection. Approximately 70% of women with Chlamydia infections and 40% of men with urethritis infections are asymptomatic. Traditionally, Chlamydia infection has been diagnosed by detection of Chlamydia inclusion bodies in the cervical cells by the most sensitive specific laboratory method, but it is labor intensive, expensive, long (18-20 hours) and not routinely available in most hospitals.

The Chlamydia Rapid Test Cassette (Swab/Urine) is a rapid test to qualitatively detect the Chlamydia antigen from the specimen. The antibody used in the Chlamydia Rapid Test Cassette (Swab/Urine) has a high specificity relative to PCR.

[METHODS & MATERIALS]

- **Test Cassette**
- **Extraction reagent 1 (0.25M NaOH)**
- **Extraction reagent 2 (0.2 M HC3)**
- **Package insert**
- **Materials Required But Not Provided**
  - Urine cup (For male urine specimens only)
  - Centrifuge tube (For male urine specimens only)

**EXTRACTION & DETECTION**

- **For Female Cervical Swab Specimen**
  - Hold the reagent bottle vertically and add 6 drops of reagent 1 (approx. 300ul) to the extraction tube. Reagent 1 is colorless. Immediately insert the swab, compress the bottom of tube and rotate 15 times. Let stand for 2 minutes.
  - Hold the reagent bottle vertically and add 6 drops of reagent 2 (approx. 250ul) to the extraction tube. The solution will turn turbid. Compress the bottle of tube and rotate 15 times until the suspension is homogenous.
  - Transfer the solution in the extraction tube to the centrifuge tube. Let stand for 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.

- **For Male Urine Specimens**
  - For Male Urine Specimens:
    - 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.

- **For Male Urethral Swab Specimen**
  - Place the test cassette on a clean and level surface. Add 3 full drops of the extraction solution (approx. 100ul) to the specimen well of the test cassette, then start the timer. Avoid trapping air bubbles in the wells. If the test is to be conducted immediately, treat the urine pellet according to the extraction protocol. If the test is to be conducted immediately, put the swab into the extraction tube. If the test is to be conducted immediately, treat swabs before collection swab.

- **Storage and Stability**
  - Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable in the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use past the expiration date.

**SPECIMEN COLLECTION AND PREPARATION**

- The Chlamydia Rapid Test Cassette (Swab/Urine) can be performed using female cervical swab, male urethral swab and male urine specimen.

- **The quality of specimens obtained is of extreme importance. Detection of Chlamydia requires a viable Chlamydia organism.**

- **To Collect Female Cervical Specimens**
  - Use cotton swab spiral (5x7cm) or any plastic shaft swab may be used.
  - Before specimen collection, remove excess mucous from the endocervical area with a cotton ball and discard.
  - The female urethra may be punctured, the squamous fornix, the cervical os, the endocervical canal, etc. until the tip of the tube is no longer visible. This will permit acquisition of columnar or cuboidal epithelial cells, which are more susceptible to the Chlamydia organism. A female swab is inserted 1-3cm (clockwise or counterclockwise) in the cervix, let stand for 15 seconds, then withdraw the swab while squeezing the tube. Keep as much liquid in the tube as possible.

- **To Collect Male Urethral Swab Specimens**
  - Male Urethral swabs should be used for urethral specimen collection. Instruct patients not to urinate for at least 1 hour prior to specimen collection.
  - Insert the swab into the urethral about 2-4cm, 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.

- **To Collect Male Urine Specimens**
  - Use the screw caps of clean, or previously used, morning urine in a sterile urine cup. First morning urine specimens are preferred to achieve the highest concentrations of Chlamydia antigen.
  - Mix the urine specimens by pipetting for 10 seconds, then transfer 5ml of the urine specimen into a centrifuge tube, add 10ml distilled water and centrifuge at 3,000 rpm for 15 minutes.
  - Carefully discard the supernatant.
  - If the test is to be conducted immediately, put the swab into the extraction tube.

**INTERPRETATION OF RESULTS**

- **Positive:** Two lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T). A positive result indicates that Chlamydia was detected in the specimen. The presence of this colored line in the test line region (T) will vary depending on the concentration of Chlamydia present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive. The intensity of the color in the test line region (T) will vary depending on the concentration of Chlamydia present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

- **Negative:** One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that Chlamydia antigen is not present in the specimen, or is present in levels below the detection limit of this test. The absence of a colored line in the test line region (T) indicates an invalid test result.

- **Invalid/Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques may interfere with the test result. The presence of Chlamydia trachomatis cannot be determined from the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**Sensitivity and Specificity**

- **Sensitivity:** 99.7% (95% confidence interval: 99.5-100%)
- **Specificity:** 99.9% (95% confidence interval: 99.7-100%)

**Boston Health Care for the Homeless**

**REFERENCES**


**BIBLIOGRAPHY**


**INDEX OF SYMBOLS**

- **IVD**
- **Use by**
- **Number**
- **Catalog #**

**AUTHOR**