Chlamydia Rapid Test Cassette (Swab/Urine)

Package Insert

A Rapid test for the qualitative detection of Chlamydia antigen in female cervical swab, male urethral swab and male urine specimens. For professional in vitro diagnostic use only.

【INTENDED USE】
The Chlamydia Rapid Test Cassette is a rapid chromatographic immunassay 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】
Chlamydia trachomatis is the most common cause of sexually transmitted venereal infection in the world. It is composed of elementary bodies (the infectious form) and reticulate or inclusion bodies (the replicating form). Chlamydia trachomatis 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 cervicitis, urethritis, endometritis, pelvic inflammatory disease (PID) and increased incidence of ectopic pregnancy and infertility. Vertical transmission of the disease during parturition from to neonate can result in inclusion conjunctivitis or pneumonia. In men, complication of Chlamydia includes urethritis and epididymitis. At least 40% of the nongonococcal urethritis cases are associated with Chlamydia infection. Approximately 70% of women with endocervical infections and up to 50% of men with urethral infections are asymptomatic. Traditionally, Chlamydia infection has been diagnosed by 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 (18-72 hours) and not routinely available in most situations.

The Chlamydia Rapid Test Cassette (Swab/Urine) is a rapid test to qualitatively detect the Chlamydia antigen from female cervical swab, male urethral swab and male urine specimens.

【PRINCIPLE】
The Chlamydia Rapid Test Cassette (Swab/Urine) is a qualitative, lateral flow immunoassay for the detection of Chlamydia antigen from female cervical, male urethral and male urine. In the test, antibody specific to the Chlamydia antigens is coated on the test line region of the test. During testing, the extracted antigen solution reacts with an antibody to Chlamydia that is coated onto particles. The mixture migrates up to react with the antibody to Chlamydia on the membrane and generates a color line in the test region. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENT】
The test contains Chlamydia antibody coated particles, Chlamydia antibodies coated on the membrane and buffer with 0.02% NaNS.

【PRECAUTIONS】
1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. 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.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. The used tests, specimens and potentially contaminated materials should be discarded according to the local regulations.
6. Humidity and temperature can adversly affect results.
7. Do not use test if pouch is damaged.

【STORAGE AND STABILITY】
Store as packaged in the sealed pouch at room temperature or refrigerated (15-30°C) before testing.

【MATERIALS】

- **Test Cassette**
- **Extraction reagent 1 (0.15M NaOH)**
- **Sterile female cervical swabs**
- **Extraction reagent 2 (0.2N HCl)**
- **Workstation 0.02% NaNS, 37mg/ml MOPSO sodium salt**
- **Package insert**
- **Dropper tip**

【DIRECTIONS FOR USE】
Allow the test, reagents, swab specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Open the test cassette from the package. Assemble the test cassette and use within one hour. Best result 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 Female Cervical or Male Urethral Swab Specimen:
- Hold the reagent 1 bottle vertically and add 5 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 the swab for 15 seconds. Let stand for 2 minutes.
- Hold the reagent 2 bottle vertically and 6 drops of reagent 2 (approx. 250ul) to the extraction tube. The solution would turn turbid. Compress the bottle of tube and rotate the swab 15 times until the solution turn clear with a slight green or blue tint. If the swab is bloody, the color will turn yellow or brown. Let stand 1 minute.
- Press the swab against the side of tube and avoid squeezing the swab. Keep as much liquid in the tube as possible. Fit the dropper tip on top of extraction tube.

For Male Urine Specimens:
- Hold the reagent 2 bottle vertically and add 6 drops of (approx. 250ul) reagent 2 to the urine pellet in the centrifuge tube, then shake the tube vigorously until the suspension is homogeneous.
- Transfer all the solution in the centrifuge tube to an extraction tube. Let stand for 1 minute. Hold the reagent 1 bottle upright and add 5 drops of (approx. 300ul) reagent 1 to the extraction tube. Vertex or tap the bottom of the tube to mix the solution. Let stand for 2 minutes.
- Fit the dropper tip on top of extraction tube.
- Place the test cassette on a clean and level surface. Add 3 full drops of the extracted solution (approx. 120ul) to the specimen well of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well.
- Wait for the color to appear. Read the result at 10 minutes; do not interpret the result after 20 minutes.
For Female Cervical or Male Urethral Swab Specimen:

1. Add solution to hole on test strip.
2. Allow to react for 5 minutes.
3. Examine the test strip.

For Male Urine Specimen:

1. Add solution to hole on test strip.
2. Allow to react for 5 minutes.
3. Examine the test strip.

[INTERPRETATION OF RESULTS]

(Refer to the illustration above)

**POSITIVE**: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). A positive result indicates that Chlamydia was detected in the specimen.

**NOTE**: 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 it is present below the detectable level of the test.

**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.

**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 adequate membrane wicking. Control standards 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.

**LIMITATIONS**

1. The Chlamydia Rapid Test Cassette (Swab/Urine) is for in vitro diagnostic use only. This test should be used for the detection of Chlamydia antigen from female cervical swab, male urethral swab and male urine specimens. Neither the quantitative value nor the rate of increase in Chlamydia antigen concentration can be determined by this qualitative test.

2. This test will only indicate the presence of Chlamydia antigen in specimens from both viable and non-viable Chlamydia. Performance with specimens other than female cervical swabs, male urethral swabs and male urine has not been assessed.

3. Detection of Chlamydia is dependent on the number of organisms present in the specimen. This can be affected by specimen collection methods and patient factors such as age, history of Sexually Transmitted Diseases (STDs), presence of symptoms, etc. The minimum detection level of this test may vary according to serovar. Therefore, the test results should be interpreted in conjunction with other laboratory and clinical data available to the physician.

4. Therapeutic failure or success cannot be determined as antigen may persist following appropriate antimicrobial therapy.

5. Excessive blood on the swab may cause false positive results.

**EXPECTED VALUES**

For women attending STD clinics and other high-risk populations, the prevalence of Chlamydia infection has been repeated to be between 20% and 30%. In a low-risk population such as those patients attending obstetrics and gynecology clinics, the prevalence is approximately 5% or less. Reports show that for men attending STD clinics, the prevalence of Chlamydia infection is approximately 8% in asymptomatic men and 11% in symptomatic men. Normal carriage rates of Chlamydia in asymptomatic men are less than 5%.

**[PERFORMANCE CHARACTERISTICS]**

**Sensitivity**

The Chlamydia Rapid Test Cassette (Swab/Urine) has been evaluated with specimens obtained from patients of STD clinics. PCR is used as the reference method for the Chlamydia Rapid Test Cassette (Swab/Urine).

**Specificity**

The Chlamydia Rapid Test Cassette (Swab/Urine) uses an antibody that is highly specific for Chlamydia antigen in female cervical swab, male urethral swab and male urine specimens. The results show that the Chlamydia Rapid Test Cassette (Swab/Urine) has a high specificity relative to PCR.

**CONFIDENCE INTERVALS**

For Female Cervical Swab Specimens

**Method**

<table>
<thead>
<tr>
<th>Chlamydia Rapid Test Cassette</th>
<th>Positive</th>
<th>Negative</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>36</td>
<td>4</td>
<td>40</td>
</tr>
<tr>
<td>Negative</td>
<td>4</td>
<td>110</td>
<td>114</td>
</tr>
<tr>
<td>Total Results</td>
<td>40</td>
<td>114</td>
<td>154</td>
</tr>
</tbody>
</table>

Relative Sensitivity: 90% (76.3%-97.2%)*
Relative Specificity: 96.5% (91.3%-99.0%)*
Relative accuracy: 94.8% (90.0%-97.8%)*

For Male Urethral Swab Specimens

**Method**

<table>
<thead>
<tr>
<th>Chlamydia Rapid Test Cassette</th>
<th>Positive</th>
<th>Negative</th>
<th>Total Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCR</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Positive</td>
<td>24</td>
<td>0</td>
<td>24</td>
</tr>
<tr>
<td>Negative</td>
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<td>45</td>
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</tr>
<tr>
<td>Total Results</td>
<td>26</td>
<td>45</td>
<td>71</td>
</tr>
</tbody>
</table>

Relative Sensitivity: 92.3% (74.9%-99.1%)*
Relative Specificity: 99.6% (93.6%-100%)*
Relative Accuracy: 97.2% (90.2%-99.7%)*

**[BIBLIOGRAPHY]**

