

DRG® Chlamydia Ag Rapid Test (RAP-4722)

As of 31 Jan. 2008

RUO in the USA**THIS KIT IS INTENDED FOR RESEARCH USE ONLY.****NOT FOR USE IN DIAGNOSTIC PROCEDURES.****INTENDED USE**

The Chlamydia test card is a rapid chromatographic immunoassay for detection of *Chlamydia trachomatis* in female cervical swab, male urethral swab and male urine specimens to aid in the detection of Chlamydia infection.

PRINCIPLE

The Chlamydia test card is a qualitative, lateral flow immunoassay for the detection of Chlamydia antigen from female cervical swab, male urethral swab and male urine specimens. In this test, antibody specific to the Chlamydia antigen 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 generate a colored line in the test line 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.

REAGENTS

The test device contains Chlamydia antibody coated particles and Chlamydia antibody coated on the membrane.

PRECAUTIONS

- For professional research use only in the United States.
- Do not use after expiration date.
- The test device must remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Humidity and temperature can adversely affect results.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Use only **sterile**, **Dacron** swabs to obtain endocervical specimens.

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STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use.

- Do not freeze.
- Do not use beyond the expiration date.

MATERIALS**1.1 MATERIALS PROVIDED**

- Chlamydia Test Cards
- Test tubes
- Dropper tips
- Sterile female cervical swabs (h 0086)
- Reagent A (0.2M NaOH)
- Reagent B (0.2N HCl)
- Quantitative pipette
- Workstation
- Package insert

1.2 MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Urine cup (for male urine specimens only)
- Centrifuge tube (for male urine specimens only)
- Sterile male urethral swabs
- Positive control
- Negative control

SPECIMEN COLLECTION AND PREPARATION

The Chlamydia test card can be performed using female cervical swab, male urethral swab and male urine specimens.

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.

To collect **Female Cervical Swab Specimens**:

- Use the swab provided in the kit. Alternatively, any plastic-shaft Dacron swab may be used.

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- 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 cuboidal epithelial cells, which are the main reservoir of the Chlamydia organism. Firmly rotate the swab 360° in one direction (clockwise or counterclockwise), let stand for 15 seconds, then withdraw the swab. Avoid contamination from exocervical or vaginal cells. Do **not** use 0.9% sodium chloride to treat swabs before collecting samples.
- 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 persons giving samples not to urinate for at least one hour prior to specimen collection.
- Insert the swab into the urethra about 2-4 cm, 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 collecting samples.
- If the test is to be conducted immediately, put 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 3000 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.

It is recommended that specimens be processed as soon as possible after collection. If immediate testing is not possible, the swab specimens should be placed in a dry transport tube for storage or transport. The swabs may be stored for 4-6 hours at room temperature (15-30°C) or 24-72 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 room temperature (15-30°C) before testing.

DIRECTIONS FOR USE

Allow the test device, specimen, reagents, and/or controls to reach room temperature (15-30°C) 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.
- 3.

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RUO in the USA**For Female Cervical or Male Urethral Swab Specimens:**

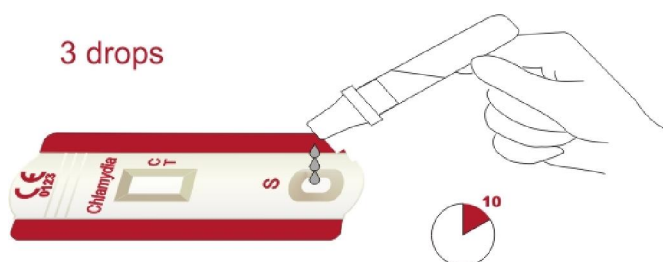
- Hold the Reagent A bottle vertically and **add 5 full drops of Reagent A** (approximately 300 µL) to the extraction tube. Reagent A is colorless. Immediately insert the swab, compress the bottom of the tube and rotate the swab 15 times. Let stand for 2 minutes.
- Fill the quantitative pipette for Reagent B up to the marked line (approximately 220 µL) then **add the Reagent B** to the extraction tube. The solution will turn cloudy. Compress the bottom of tube and **rotate the swab 15 times** until the solution turns to a clear color with a slight green or blue tint. If the swab is bloody, the color will turn yellow or brown. Let stand for 1 minute.
- Press the swab against the side of the tube and withdraw the swab while squeezing the tube. Keep as much liquid in the tube as possible. Fit the dropper tip on top of the extraction tube.

For Male Urine Specimens:

- Fill the quantitative pipette for **Reagent B** to the marked line (approximately 220 µL) then **add the Reagent B** 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 1 minute.** Hold the **Reagent A** bottle upright and **add 5 full drops of Reagent A** (approximately 300 µL) to the extraction tube. Vortex or tap the bottom of the tube to mix the solution. **Let stand for 2 minutes.**
- Fit the dropper tip on top of the extraction tube.

Place the test device on a clean and level surface. **Add 3 full drops of the extracted solution** (approximately 100 µL) to the specimen well (S) of the test device, then start the timer. Avoid trapping air bubbles in the specimen well (S).

Wait for the colored line(s) to appear. **Read the result at 10 minutes.** Do not interpret the result after more than 20 minutes.

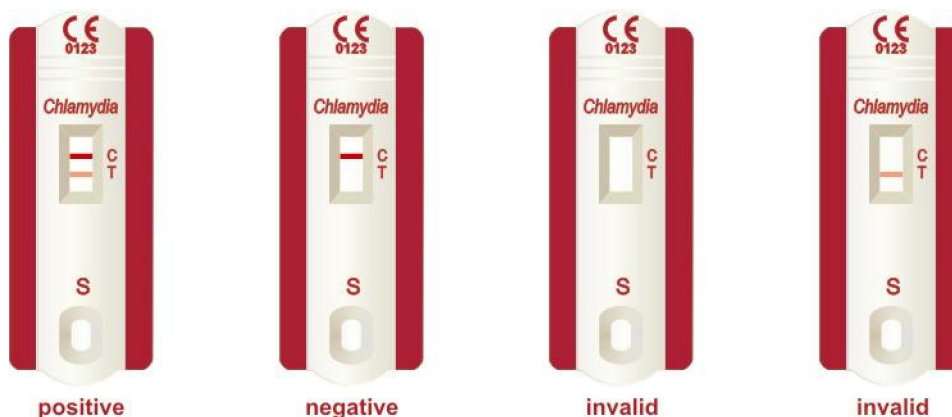


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INTERPRETATION OF RESULTS

- Negative:** One colored line appears in the control line region (C). No apparent colored line appears in the test line region (T).
- Positive:*** Two distinct colored lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).
- Invalid:** Control line (C) fails to appear. Insufficient sample 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 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.

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 sufficient specimen volume, adequate membrane wicking and correct procedural technique. 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.

1.3 Cross-Reactivity

The antibody used in the Chlamydia test card has been shown to detect all known Chlamydia serovars. *Chlamydia psittaci* and *Chlamydia pneumoniae* strains have not yet been tested with the Chlamydia test card.

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Cross reactivity with other organisms has been studied using suspensions of 109 Colony Forming Units (CFU)/mL. The following organisms were found negative when tested with the Chlamydia test card:

<i>Acinetobacter calcoaceticus</i>	<i>Pseudomona aeruginosa</i>	<i>Proteus mirabilis</i>	<i>Acinetobacter spp</i>
<i>Neisseria meningitides</i>	<i>Neisseria gonnorhea</i>	<i>Enterococcus faecalis</i>	<i>Salmonella choleraesius</i>
<i>Group B/C Streptococcus</i>	<i>Enterococcus faecium</i>	<i>Candida albicans</i>	<i>Hemophilus influenzae</i>
<i>Staphylococcus aureus</i>	<i>Proteus vulgaris</i>	<i>Branhamella catarrhalis</i>	<i>Klebsiella pneumoniae</i>
<i>Gardnerella vaginalis</i>			