**GC and Chlamydia trachomatis Probe Collection**

*Specimen Collection for Neisseria gonorrhoeae and/or Chlamydia trachomatis*

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### Sensitivity and Specificity

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Chlamydia trachomatis Probe versus Patient Infected Status</th>
<th>Neisseria gonorrhoeae Probe versus Patient Infected Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sensitivity (%)</td>
<td>Specificity (%)</td>
</tr>
<tr>
<td>Female endocervical swab</td>
<td>94.2</td>
<td>97.6</td>
</tr>
<tr>
<td>Female urine</td>
<td>94.7</td>
<td>98.9</td>
</tr>
<tr>
<td>Female vaginal</td>
<td>97.2</td>
<td>94.9</td>
</tr>
<tr>
<td>Male urethral swab</td>
<td>95.9</td>
<td>97.5</td>
</tr>
<tr>
<td>Male urine</td>
<td>97.9</td>
<td>98.5</td>
</tr>
<tr>
<td>Overall</td>
<td>95.9</td>
<td>98.2</td>
</tr>
</tbody>
</table>

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**SPECIMENS AND CONTAINERS:**

**Specimens tested at Allina Health Laboratory:**

**Vaginal:** Aptima Vaginal Swab Specimen Collection Kit (pink-shafted swab)

**Endocervical:** Aptima Unisex Swab Specimen Collection Kit (blue-shafted swab)

**Male Urethral:** Aptima Unisex Swab Specimen Collection Kit (blue-shafted swab)

**Male/ Female Urine:** Aptima Urine Specimen Collection Kit

**Hysterectomy patients:** Collect vaginal or urine specimen.

**Specimens referred to Mayo Medical Laboratories (MML):**

**Eye, Rectal:** Collect MAYO Aptima Unisex Swab, refrigerated. Order Chlamydia trachomatis & GC - Eye/Rectal (8274/GCR).

**Ocular, Oral, Mouth, Throat:** Collect MAYO Aptima Unisex Swab, refrigerated. Order Chlamydia trachomatis-Other Sources (8270/CTO). Order Neisseria gonorrhoeae, Miscellaneous Sites (994/MSO).

**Peritoneal Fluid (Pelvic Wash, Cul de Sac Fluid):** Collect MAYO Aptima Unisex Swab, refrigerated. Order Neisseria gonorrhoeae, Miscellaneous Sites (994/MSO).

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**Unacceptable:**

- No swab, white swab, or two swabs in Aptima swab transport tube
- Swab not from Aptima Unisex swab collection kit
- Pink-shafted swab for cervical, endocervical, or urethral source
- Blue-shafted swab for vaginal source
- Collection from vaginal cuff
- Urine transport tube not filled to “Fill Area” (above or below – rejected)
- **Urine not in Aptima transport tube** (Client may transfer urine to Transport Tube within 24 hr. of collection. Due to nucleic acid cross-contamination issues, this must be done at the client site and will not be done at Allina Health Laboratory. If the urine has not been opened in the lab, it may be returned to the client to be transferred to the transport tube; otherwise, recollect.)
- Frozen specimens
- Sources other than female endocervical, vaginal, male urethral, or voided urine, or sources acceptable at Mayo (see above).

**TRANSPORT:**

Ambient or refrigerated.

Swab in transport within 60 days; Urine in transport tube within 30 days.

**SPECIMEN COLLECTION**

*The following instructions are provided on the kit packages.*

**Female Endocervical Swab Specimens:**

*Use Aptima Unisex Swab Specimen Collection Kit. Specimen will be rejected if collected with Aptima Vaginal Swab Specimen Collection Kit.*

1. Remove excess mucus from cervical os and surrounding mucosa using cleaning swab (white shaft swab in package with red printing). **Discard the white swab.**
2. Insert specimen collection swab (blue shaft swab in package with green printing) into endocervical canal.
3. Gently rotate swab clockwise for 10 to 30 seconds in endocervical canal to ensure adequate sampling.
4. Withdraw swab carefully; avoid any contact with vaginal mucosa.
5. Remove cap from swab specimen transport tube and immediately place specimen collection swab into specimen transport tube.
6. Carefully break swab shaft at score line and discard the top portion of the swab shaft; use care to avoid splashing contents.
7. Re-cap swab specimen transport tube tightly.
Female Vaginal Specimens

Option when a pelvic exam is not otherwise indicated for clinician or patient-collected specimen. Not for home use. Patient collection is limited to health care facilities where support/counseling is available to explain procedures and precautions.

Use Aptima Vaginal Swab Specimen Collection Kit. Specimen will be rejected if collected with Aptima Unisex Swab Specimen Collection Kit.

1. Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima Vaginal Swab Specimen Collection Kit.
2. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
3. Carefully insert the swab into the vagina about 2 inches past the introitus and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin.
4. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Vaginal swab Specimen Collection Kit.
5. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
6. Carefully break the swab shaft at the score line against the side of the tube.
7. Immediately discard the top portion of the swab shaft.
8. Tightly screw the cap onto the tube.

Male Urethral Swab Specimens:

Patient should not have urinated for at least 1 hour prior to specimen collection.

1. Insert specimen collection swab (blue shaft swab in package with green printing) 2 to 4 cm into urethra.
2. Gently rotate swab clockwise for 2 to 3 seconds in urethra to ensure adequate sampling. Withdraw swab carefully.
3. Remove cap from swab specimen transport tube and immediately place specimen collection swab into specimen transport tube.
4. Carefully break swab shaft at score line and discard the top portion of the swab shaft; use care to avoid splashing contents.
5. Re-cap the swab specimen transport tube tightly.
Male and Female Urine Specimens:

Patient should not have urinated for at least 1hr prior to specimen collection. Female patients should not cleanse labial area prior to providing the specimen.

1. Direct patient to provide first-catch urine (approximately 20 to 30 ml of initial urine stream) into urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity.
2. Remove cap from urine specimen transport tube and transfer 2ml of urine into urine specimen transport tube using disposable pipette provided. The correct volume of urine has been added when fluid level is between black fill lines on urine specimen transport tube label.
3. If refrigerated, urine may be transferred to the transport tube at the collection site within 24 hr.
4. Re-cap urine specimen transport tube tightly.

METHOD LIMITATIONS

- Mucus should be removed before collection of endocervical specimens to ensure collection of endocervical epithelial cells infected with C. trachomatis.
- Blood, lubricants, spermicides do NOT interfere with the test.
- Vaginal swab sampling is not designed to replace cervical exams and endocervical specimens for diagnosis of urogenital infections and pelvic inflammatory disease, as these may be caused by other organisms.
- The performance of vaginal swab specimens has not been evaluated in pregnant women or females less than 16 years of age.
- After treatment, nucleic acid may persist following appropriate antimicrobial therapy. Except in pregnant women, GC and Chlamydia test-of-cure (i.e. repeat testing 3-4 weeks after completing therapy) is not recommended for persons treated with the recommended or alternative regimens, unless therapeutic compliance is in question, symptoms persist, or reinfection is suspected. If symptoms persist after treatment in cases of gonorrhea, evaluate with GC culture.
- Repeat DNA probe testing for Chlamydia and Neisseria gonorrhoeae is recommended by CDC approximately 3 months after treatment to detect reinfection. This is distinct from retesting for test-of-cure to detect therapeutic failure, which is not recommended by CDC.
- Detection is dependent on the quantity of organisms present in the specimen. This is influenced by patient factors, stage of infection, organism strain, and adequate specimen collection.