

GC AND CHLAMYDIA TRACHOMATIS PROBE COLLECTION

Specimen Collection for Neisseria gonorrhoeae and/or Chlamydia trachomatis

Specimen	Chlamydia trachomatis Probe vs Patient Infected Status		Neisseria gonorrhoeae Probe vs Patient Infected Status	
	Sensitivity (%)	Specificity (%)	Sensitivity (%)	Specificity (%)
Female endocervical swab	94.2	97.6	99.2	98.7
Female urine	94.7	98.9	91.3	99.3
Male urethral swab	95.9	97.5	99.1	97.8
Male urine	97.9	98.5	98.5	99.6
Overall	95.9	98.2	97.8	98.9

CONTAINER

Female Endocervical: Gen-Probe Aptima Unisex Swab Collection Kit, blue shafted swab
Note: For hysterectomy patients, collect urine.

Male Urethral: Gen-Probe Aptima Unisex Swab Collection Kit, blue shafted swab

Male or Female Urine: Gen-Probe Aptima Urine Transport Tube

Unacceptable: No swab, White shaft swab, or Two swabs in swab transport tube
Swab not from Unisex swab collection kit
Urine transport tube not filled to “Fill Area” (above or below – rejected)
Urine not in transport tube
M4 media
Sources (eye, rectal, throat, vaginal, etc) other than female endocervical, male urethral, or urine.

SPECIMEN COLLECTION

Female Endocervical Swab Specimens:

- Remove excess mucus from cervical os and surrounding mucosa using cleaning swab (white shaft swab in package with red printing). **Discard the swab.**
- Insert specimen collection swab (*blue shaft swab* in package with green printing) into endocervical canal.
- Gently rotate swab clockwise for 10 to 30 seconds in endocervical canal to ensure adequate sampling.
- Withdraw swab carefully; avoid any contact with vaginal mucosa.
- Remove cap from swab specimen transport tube and immediately place specimen collection swab into specimen transport tube.
- Carefully break swab shaft at scoreline; use care to avoid splashing contents.
- Re-cap swab specimen transport tube tightly.

Male Urethral Swab Specimens:

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

- a. Insert specimen collection swab (**blue shaft swab** in package with green printing) 2 to 4 cm into urethra.
- b. Gently rotate swab clockwise for 2 to 3 seconds in urethra to ensure adequate sampling.
- c. Withdraw swab carefully.
- d. Remove cap from swab specimen transport tube and immediately place specimen collection swab into specimen transport tube.
- e. Carefully break swab shaft at scoreline; use care to avoid splashing contents.
- f. Re-cap 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.

- a. 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.
- b. 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.***
- c. Re-cap urine specimen transport tube tightly.

TRANSPORT:

Ambient or refrigerated. Swab within 60 days. Urine in transport tube within 30 days.

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.
- After treatment, nucleic acid may persist following appropriate antimicrobial therapy. For test of cure, perform GC or Chlamydia culture.
- 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.
- Positive predictive values decrease when testing populations with low prevalence or individuals with no risk of infection. In low prevalence populations a false positive rate can exceed the true positive rate, so that the predictive value of a positive test is low. Culturing should be considered for confirmation in these cases.