



❖ **GC AND CHLAMYDIA DNA PCR TEST CHANGES**

Effective 9/19/05, Allina Medical Laboratories will change to the Gen-Probe Aptima Combo 2 Assay for detection of *Neisseria gonorrhoeae* and *Chlamydia trachomatis*. This assay is a target amplification nucleic acid probe test based on target capture, Transcription-Mediated Amplification, and Dual Kinetic assay.

Advantages include:

- Female urines may be tested in addition to male urines. Improved sensitivity of urine testing.
- Improved specificity for *Neisseria gonorrhoeae*. No cross reactions with other *Neisseria* species.
- One collection kit for both male and female swabs.
- Transport at ambient temperature or refrigerated.
- Longer specimen stability (60 days for swabs and 30 days for urine in the transport containers)
- Blood and lubricants do NOT interfere with the test.

<i>Chlamydia trachomatis</i> Probe vs Patient Infected Status		
Specimen	Sensitivity (%)	Specificity (%)
Female endocervical swab	94.2	97.6
Female urine	94.7	98.9
Male urethral swab	95.9	97.5
Male urine	97.9	98.5
Overall	95.9	98.2

<i>Neisseria gonorrhoeae</i> Probe vs Patient Infected Status		
Specimen	Sensitivity (%)	Specificity (%)
Female endocervical swab	99.2	98.7
Female urine	91.3	99.3
Male urethral swab	99.1	97.8
Male urine	98.5	99.6
Overall	97.8	98.9

Test Names **GC Chlamydia trach. Probe (6746/GCC)**
Chlamydia trach. Probe (6744/CHP)
GC Probe (6745/GCP)
Test numbers and CPT codes remain the same.

Specimen Types Female endocervical swab
Male urethral swab
Female and male urine

Containers *Swab:* Gen-Probe Aptima Unisex Swab Specimen Collection Kit
Urine: Gen-Probe Aptima Combo 2 Assay Urine Specimen Collection Kit
Note: Begin collection of specimens in the new containers on 9/19/05.

Unacceptable No swab in swab transport tube
Two swabs in transport tube
Swab not from Unisex swab collection kit
M4 Media
Urine transport tube not filled to "Fill Area" (above or below – rejected)
Urine not in transport tube

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

Collection The following instructions are provided on the kit package.

Female Endocervical Swab Specimens:

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

- 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. Female patients should not cleanse labial area prior to providing specimen.
- b. Remove cap from urine specimen transport tube and transfer 2ml of urine into urine specimen transport tube using disposable pipet 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.

For your convenience, two references have been included at the end of this edition of the Update newsletter:

- A revised GC/Chlamydia flowsheet reflecting these changes
- Instruction sheet for collection/handling specimens for use with the new Aptima Unisex Swab, or Urine kits

Please order a supply of these new kits to place into use on September 19, 2005. If you have any questions about this transition, or for collection posters, please contact your AML Account Representative.