ACM Medical Laboratory

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Technical Bulletin

Detailed information concerning methodology, specimen requirements, and reference ranges on new and specialized tests.

Test Names and Numbers:	**1) Neisseria gonorrhoeae Amplification (6840)** **2) Chlamydia trachomatis Amplification (6841)** **3) Neisseria gonorrhoeae and Chlamydia trachomatis Amplification (6842)**
CPT codes:	**87491, 87591**
Department:	Molecular Diagnostics (476)
Testing Schedule:	Monday to Friday
Specimen Requirement:	Endocervical, vaginal, urethral, rectal or oropharyngeal swabs in Roche PCR Transport media, Male and Female Urine (first void), PreservCyt (ThinPrep) Pap
Reference Range:	Not Detected
Methodology:	Real-time PCR

Test Information

ACM Medical Laboratory has transitioned all Neisseria gonorrhoeae (NG) and Chlamydia trachomatis (CT) amplified testing to the Roche cobas® 4800 platform. This platform has been extensively validated for the following sources: endocervical, vaginal, urethral, rectal, oropharyngeal, PservCyt (ThinPrep) Pap specimens and male and female urines. The CT/NG test performed on the Roche cobas® 4800 platform is FDA-approved for CT/NG screening in symptomatic and asymptomatic patients. The assay exhibits an analytical sensitivity of 10-300 EB/ml and 0.2-3 CFU/ml for CT and NG, respectively, depending on sample type. The assay also incorporates uracil *N*-glycosylase to prevent potential false positive results and multiple primers and probes to detect potential CT and NG mutants that otherwise may be missed.

Laboratory Results

Results for the Roche cobas® 4800 CT/NG assay are reported as follows:

Result:	Interpretation:
Not Detected	No Chlamydia trachomatis or Neisseria gonorrhoeae DNA detected.
Detected	Chlamydia trachomatis or Neisseria gonorrhoeae DNA detected.
Invalid	A result for Chlamydia trachomatis or Neisseria gonorrhoeae could not be reliably determined. Please submit another sample.

Clinical Information

Amplified testing for Neisseria gonorrhoeae and Chlamydia trachomatis is the recommended method for screening symptomatic and asymptomatic patients from all sites of infection. Providers should follow the collection instructions provided by the Roche cobas® swab and urine collection kits. When urine is used, *first void* urine specimens should be obtained to maximize the sensitivity of the assay. The clinical performance characteristics of the Roche cobas 4800 CT/NG assay were established in the Vagina, Endocervical and Urine Screening (VENUS) trial which enrolled > 6000 patients from high prevalence and low prevalence settings (STD clinics and Ob/Gyn practices). The overall sensitivity and specificity for all sample types ranged from 94% to 100%.

Questions? Call (585) 429-2300 (Client Services) or Dr. Suzanne E. Dale, Director of Microbiology and Molecular Diagnostics, (585) 429-2360. Additional copies of this Technical Bulletin are available at: www.acmlab.com.