

TEST OBSOLETE

NOTIFICATION DATE: August 20, 2012 **EFFECTIVE DATE:** November 16, 2012

Chlamydia trachomatis and Neisseria gonorrhoeae by Nucleic Acid Amplification

Test ID: CGDNA Secondary ID: 84465

EXPLANATION: Mayo Medical Laboratories will begin moving to a new testing platform for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* on September 17th, 2012. New test information is included in this notice. This current test code, CGDNA, will become obsolete on November 16, 2012.

NOTE: Supply item T504 NAT Swab Specimen Collection System, currently used for *C. trachomatis* and *N. gonorrhoeae* testing, will NOT be acceptable for the new test. Please replace this supply item in all locations of your facility by November 16, 2012.

RECOMMENDED ALTERNATIVE TEST:

Chlamydia trachomatis and Neisseria gonorrhoeae by Nucleic Acid Amplification (GEN-PROBE)

Test ID: CGRNA

USEFUL FOR: Diagnosing *Chlamydia trachomatis* or *Neisseria gonorrhoeae* infections.

METHODOLOGY: Transcription Mediated Amplification

PROFILE INFORMATION:

Test ID	Reporting Name	Available Separately	Always Performed
CTRNA	C. Trachomatis Amplified RNA	Yes	Yes
GCRNA	N. Gonorrhoeae Amplified RNA	Yes	Yes

REFERENCE VALUES: Chlamydia trachomatis: Negative Neisseria gonorrhoeae: Negative

SPECIMEN REQUIREMENTS: Specific specimen source is required. Submit only 1 of the following specimens:

NOTE: Swab specimen must be collected using an APTIMA Collection Unisex Swab or APTIMA Collection Vaginal Swab. These swabs are contained in the APTIMA Collection Kit. Specimens sent with no swab, two swabs, or non Gen-Probe swabs will not be accepted. For endocervical specimens, cervical mucous should first be removed using a cleaning swab. The endocervical sample is then obtained using the sample swab. Specimens sent with only the cleaning swab will not be accepted.

Specimen Type: Endocervix (Females Only)

Container/Tube: APTIMA Unisex Swab Specimen Collection System (Supply T583)

Specimen Volume: Swab

Specimen Type: Vaginal (Females Only)

Container/Tube: APTIMA Vaginal Swab Specimen Collection System (Supply T584)

Specimen Volume: Swab

This is the most appropriate swab supply item for female vaginal collections.

Specimen Type: Urethra (Males Only)

Container/Tube: APTIMA Unisex Swab Specimen Collection System (Supply T583)

Specimen Volume: Swab

Specimen Type: Urine (Males and Females)

Container/Tube: APTIMA Urine Specimen Collection Kit (Supply T582)

Specimen Volume: 30 mL

Specimen must be transferred to APTIMA Urine Specimen Collection Kit within 24 hours of collection. Collection must be first void (first catch, first portion). Midstream, clean catch and catheter collections are not acceptable. Collect 30 mLs of urine and aliquot 2 mLs of urine into the APTIMA Urine Specimen Collection Kit tube using the disposable pipette provided in the kit.

Specimen Type: ThinPrep Specimen (Endocervix, Females Only)

Container/Tube: APTIMA Specimen Transfer Kit

Specimen Volume: 1 mL

Note: Aliquot ThinPrep specimen for Chlamydia and/or Neisseria testing before processing for

Pap smear.

CAUTIONS: The presence of mucous does not interfere with this assay. However, for endocervical samples, this test requires endocervical cells which may not be present in adequate numbers if the endocervical mucus is not first removed.

No interference is expected due to:

- -Blood (urine and swab) specimens
- -Lubricants and spermicides (swab)

This assay DOES detect plasmid-free variants of *Chlamydia trachomatis*. This assay does NOT detect *Chlamydia pneumoniae*.

FEE: Please contact your Regional Manager for your account's fee information.

CPT CODE: 87491-*Chlamydia trachomatis* 87591-*Neisseria gonorrhoeae*

DAY(S) SET UP: Monday through Sunday **ANALYTIC TIME:** 1 day

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager or Kim J. Baker, MML Laboratory Technologist Resource Coordinator Telephone: 800-533-1710