

SAGINAW COUNTY DEPARTMENT OF PUBLIC HEALTH LABORATORY DIVISION

Chlamydia and N. gonorrhoeae Non-culture

Rev. 1/4/17

Chlamydia and N. gonorrhoeae Non-culture by Amplified RNA Assay

ANALYTES TESTED: Chlamydia trachomatis and Neisseria gonorrhoeae

USE OF TEST: Determination of Infection by Detection of *Chlamydia* and *N. gonorrhoeae* RNA

SPECIMEN COLLECTION AND SUBMISSION GUIDELINES:

Test Request Form

Specimen Collection and Submission Guidelines
Transport Temperature: Ambient temperature

SPECIMEN TYPE:

Specimen Required: Endocervical, urethral, vaginal swab or urine.

Minimum Acceptable Volume: 2 ml for urine.

Container: Unisex swab collection kit for endocervical, and male urethral specimens.

Vaginal swab collection kit for vaginal specimens.

Urine transport tube for urine specimens.

SPECIMEN REJECTION CRITERIA:

- 1. Critical Data Needed For Testing:
 - Patient name
 - Patient date of birth
 - Patient gender
 - Specimen source
 - Date collected
 - Submitting Agency
- 2. For cervical/urethra or vaginal swabs:
 - If the lab receives a swab specimen transport tube with no swab, two swabs, or a swab not supplied by Gen-Probe, the specimen will be rejected.
 - If the specimen container is received leaking, not properly labeled, or the specimen label does not match the test requisition, or the specimen is greater than thirty days old when received, it will not be tested.
- 3. Urine specimens:
 - Any urine specimen transport tube with volumes above or below allowable level will be rejected.
 - If the specimen container is received leaking, not properly labeled, or the specimen label does not match the test requisition, or the specimen is greater than thirty days old when received, it will not be tested.

TEST PERFORMED:

Methodology: GenProbe Aptima RNA Amplification

Turn Around Time: Typically tests are reported within five business days of receipt.

Where/When Performed: Once a week in the SCDPH Laboratory

RESULT INTERPRETATION:

Reference Range: Not detected.



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A positive result indicates that *Chlamydia /N. gonorrhoeae* RNA is present in the sample and strongly supports a diagnosis of Chlamydia/gonorrhoea infection.

FEES:

The current fee is \$77.08 for a *Chlamydia trachomatis* and *N. gonorrhoeae* test (commonly referred to as the Combo Test). Medicaid or private insurance will be billed based on information provided with the requisition. If no billing information is provided, the submitter will be billed.

LIMITATIONS:

Excess mucus should be removed to ensure collection of columnar epithelial cells lining the endocervix. If excess mucus is not removed, sampling of these cells is not ensured.

ADDITIONAL INFORMATION:

- Submit specimens promptly to laboratory to decrease potential for equivocal results.
 Urines must be tested within 30 days of collection. Swabs must be tested within 60 days of collection.
- 2. Assay results should be interpreted in conjunction with other laboratory and clinical data available to the clinician.
- 3. Test-of-cure is not recommended as a routine procedure after therapy for *C. trachomatis* or *N. gonorrhoeae* infections with recommended treatment regimens. Non-culture tests should not be performed <4 weeks after completion of antimicrobial therapy because the presence of nonviable organisms may produce false-positive results. CDC recommends repeat testing of positive patients 3-6 months (up to one year) after treatment to assist in the identification of repeat infections.

ALIASES:

CT and GC Combo