MAYO CLINIC LABORATORIES

Test Definition: SCGCV

Neisseria gonorrhoeae, Self-Collect, Amplified RNA, Vaginal

Overview

Useful For

Detecting *Neisseria gonorrhoeae* using vaginal swabs collected by the patient in a healthcare setting

This test is not intended for use in medico-legal applications.

Method Name

Only orderable as part of a profile. For more information see SCCGV / *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, Self-Collect, Amplified RNA, Vaginal.

Transcription Mediated Amplification

NY State Available

Yes

Specimen

Specimen Type

Varies

Specimen Required

Only orderable as part of a profile. For more information see SCCGV / *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, Self-Collect, Amplified RNA, Vaginal.

Specimen Type: Vaginal
Supplies: Aptima Vaginal Swab Self-Collection Kit (T1001)
Container/Tube: Aptima Multitest Swab
Specimen Volume: Swab
Collection Instructions:
1. Specimens must be collected in a healthcare setting by the patient using the Aptima Multitest Swab (provided in T1001 or available separately)**.**
2. Provide patient with the Aptima Vaginal Swab Self-Collection Kit or Aptima Multitest Swab and collection instructions.
3. Instruct patient to collect the specimen following the instructions provided and then return swab to the healthcare professional once complete.
4. Once patient returns the specimen, ensure the tube is securely capped, and label tube with patient's entire name and collection date and time.
5. Maintain swab container at 2 to 30 degrees C (refrigerate temperature is preferred) and transport within 60 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for up to 12 months.

Specimen Minimum Volume

See Specimen Required

Reject Due To

Transport tubes containing a cleaning swab or more than 1 swab	Reject
No swab present in Aptima vial	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated (preferred)		APTIMA VIAL
	Ambient		APTIMA VIAL
	Frozen		APTIMA VIAL

Clinical & Interpretive

Clinical Information

Gonorrhea is caused by the bacterium *Neisseria gonorrhoeae*. It is a very common sexually transmitted infection (STI), with over 677,000 cases of gonorrhea reported to the Centers for Disease Control and Prevention (CDC) in 2020. Like chlamydia, many infections in women are asymptomatic, and the true prevalence of gonorrhea is likely much higher than reported. The organism causes genitourinary infections in women and men and may be associated with dysuria as well as vaginal, urethral, or rectal discharge. Complications include pelvic inflammatory disease in women and gonococcal epididymitis and prostatitis in men. Gonococcal bacteremia, pharyngitis, and arthritis may also occur. Infection in men is typically associated with symptoms that would prompt clinical evaluation. Given the risk for asymptomatic infection in women, screening is recommended for women at increased risk of infection (eg, women with previous gonorrhea or other STIs, inconsistent condom use, new or multiple sex partners, and women in certain demographic groups, such as those in communities with high STI prevalence). The CDC currently recommends dual antibiotic treatment due to emerging antimicrobial resistance.

Culture was previously considered to be the gold standard test for diagnosis of *Chlamydia trachomatis* and *N gonorrhoeae* infections. However, these organisms are labile in vitro; therefore, precise specimen collection, transportation, and processing conditions are required to maintain organism viability, which is necessary for successful culturing. In comparison, nucleic acid amplification testing (NAAT) provides superior sensitivity and specificity and is now considered the reference standard method for diagnosis in most cases. Immunoassays and nonamplification DNA tests are also available for *C trachomatis* and *N gonorrhoeae* detection, but these methods are significantly less sensitive and

less specific than NAAT.

Improved screening rates and increased sensitivity of NAAT have resulted in an increased number of accurately diagnosed cases. Improved detection rates result from improved performance characteristics of the assays and patients' easy acceptance of urine testing. Early identification of infection enables sexual partners to seek testing and/or treatment as soon as possible and reduces the risk of disease spread. Prompt treatment reduces the risk of infertility in women.

Reference Values

Only orderable as part of a profile. For more information see SCCGV / *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, Self-Collect, Amplified RNA, Vaginal.

Negative

Interpretation

A positive result indicates the presence of nucleic acid from *Neisseria gonorrhoeae* and strongly supports the diagnosis of gonorrheal infection.

A negative result indicates the absence of *N gonorrhoeae* nucleic acid. A negative result does not exclude the possibility of infection. If clinical indications strongly suggest gonococcal or chlamydial infection, additional specimens should be collected for testing.

A result of inconclusive indicates that a new specimen should be collected.

The predictive value of an assay depends on the prevalence of the disease in any specific population. In settings with a high prevalence of sexually transmitted infections, positive assay results have a high likelihood of being true-positive results. In settings with a low prevalence of sexually transmitted infections, or in any settings in which a patient's clinical signs and symptoms or risk factors are inconsistent with gonococcal urogenital infection, positive results should be carefully assessed, and the patient retested by other methods (eg, culture for *N gonorrhoeae*) if appropriate.

Cautions

The performance of this assay has not been evaluated in adolescents less than 14 years.

This report is intended for clinical monitoring or management of patients; it is not intended for use in medico-legal applications.

Appropriate specimen collection and handling is necessary for optimal assay performance.

Results should be interpreted in conjunction with other laboratory and clinical information.

A negative test result does not exclude the possibility of infection. Improper specimen collection, concurrent antibiotic therapy, presence of inhibitors, or low numbers of organisms in the specimen (ie, below the sensitivity of the test) may cause false-negative test results.

In low-prevalence populations, positive results must be interpreted carefully, as false-positive results may occur more

frequently than true-positive results in this setting.

In general, this assay should not be used to assess therapeutic success or failure since nucleic acids from these organisms may persist for 3 weeks or more following antimicrobial therapy.

No interference is expected due to:
-Blood
-Lubricants and spermicides

The effects of tampon use, douching, specimen types other than those listed in Specimen Required, and specimen collection variables have not been determined.

Clinical Reference

1. Workowski KA, Bachmann LH, Chan PA, et al. Sexually transmitted infections treatment guidelines, 2021. MMWR Recomm Rep. 2021;70(4):1-187. doi:10.15585/mmwr.rr7004a1
2. Adamson PC, Klausner JD. Diagnostic test for detecting Chlamydia trachomatis and Neisseria gonorrhoeae in rectal and pharyngeal specimens. J Clin Microbiol. 2022;60(4):e0021121. doi:10.1128/JCM.00211-21

Performance

Method Description

The HOLOGIC Aptima Combo 2 Assay combines the technologies of target capture, transcription-mediated amplification, and dual kinetic assay. The detection of the ribosomal RNA amplification product sequences (amplicon) is achieved using nucleic acid hybridization. Single-stranded chemiluminescent DNA probes are labeled and combine with amplicon to form stable RNA:DNA hybrids. Light emitted from the labeled RNA:DNA hybrids is measured as photon signals in a luminometer.(Package insert: Aptima Combo 2 Assay, AW-25929-001. Hologic, Inc; Rev 002, 06/2023)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

1 to 4 days

Specimen Retention Time

7 days

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

Test Definition: SCGCV

Neisseria gonorrhoeae, Self-Collect, Amplified RNA, Vaginal

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

87591

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
SCGCV	N gonor, RNA, SelfCollect, Vagina	43305-2

Result ID	Test Result Name	Result LOINC® Value
621939	Neisseria gonorrhoeae amplified RNA	43305-2