MAYO CLINIC LABORATORIES

Test Definition: GCCON

Neisseria gonorrhoeae Confirmation, Nucleic Acid Amplification, Varies

Overview

Useful For
Detecting *Neisseria gonorrhoeae*.

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

Highlights
This test is used to confirm positive *Neisseria gonorrhoeae* results from the Hologic Aptima Combo 2 Assay or another *N gonorrhoeae* molecular assay.

Method Name
Transcription Mediated Amplification

NY State Available
Yes

Specimen

Specimen Type
Varies

Ordering Guidance
This test should be ordered only on prior *Neisseria gonorrhoeae* positive specimens or a new specimen collection from a patient who previously tested positive for *N gonorrhoeae* by the Hologic Aptima Combo 2 assay (eg, CGRNA / *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, Nucleic Acid Amplification, Varies; GCRNA / *Chlamydia trachomatis*, Nucleic Acid Amplification, Varies; MCTGC / *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, Miscellaneous Sites, Nucleic Acid Amplification, Varies; MGRNA / *Neisseria gonorrhoeae*, Miscellaneous Sites, Nucleic Acid Amplification, Varies) or by an alternative *N gonorrhoeae* molecular assay.

Additional Testing Requirements
A prior positive *Neisseria gonorrhoeae* result from the Hologic Aptima Combo 2 assay or another *N gonorrhoeae* molecular assay is required prior to performing this test.

Shipping Instructions
If submitting a previously tested specimen that resulted as positive for *Neisseria gonorrhoeae*, ensure that the sample is tightly capped with a non-penetrable cap on the specimen transport tube. Maintain recommended storage and shipping requirements indicated below.

Necessary Information
Specimen source is required.

Specimen Required

If testing is being performed on a previously tested specimen that resulted as positive, submit that specimen.

If testing is being performed on a newly collected specimen, submit only 1 of the following specimens:

Specimen Type: Ocular (corneal/conjunctiva)
Supplies:
-Aptima Unisex Swab Collection Kit (T583)
-Aptima Multitest Swab Specimen Collection Kit (T584)
Container/Tube: Aptima Multitest Swab or Aptima Collection Unisex Swab
Specimen Volume: 1 Swab
Collection Instructions:
1. Swab site using Aptima Multitest Swab or Aptima Collection Unisex Swab. Specimens must be collected using either of these options.
Note: The white swab provided within the collection kit is a cleaning swab and should not be used for collection. Discard the white cleaning swab.
2. Place collection swab in transport tube provided in collection kit.
3. Snap off swab at score line so it fits into closed tube.
4. Cap tube securely and label tube with patient's entire name and collection date and time.
5. Maintain swab container at 2 to 30 degrees C (refrigerated temperature is preferred) or -20 to -70 degrees C and transport within 14 days of collection.

Specimen Type: Vaginal
Supplies: Aptima Multitest Swab Specimen Collection Kit (T584)
Container/Tube: Aptima Multitest Swab
Specimen Volume: 1 Swab
Collection Instructions:
1. Specimen must be collected using the Aptima Multitest Swab Specimen Collection Kit.
2. Insert swab (pink shaft) about 5 cm past introitus and rotate gently for 30 seconds.
3. Place pink swab into transport tube provided in collection kit.
4. Snap off pink swab at score line so it fits into closed tube.
5. Cap tube securely, and label tube with patient's entire name and collection date and time.
6. Maintain swab container at 2 to 30 degrees C (refrigerated temperature is preferred) or -20 to -70 degrees C and transport within 14 days of collection.

Specimen Type: Urine
Supplies: Aptima Urine Transport Tube (T582)
Container/Tube: Aptima urine specimen transport tube
Specimen Volume: 15 to 20 mL
Collection Instructions:
1. Patient should not have urinated for at least 1 hour prior to specimen collection.
2. Patient should collect first portion of random voided urine (first part of stream) into a sterile, plastic, preservative-free container.

3. Within 24 hours of collection. transfer 2 mL of urine into the urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine transport tube.
4. Place the labels on the transport tube so the black fill lines are still visible for volume confirmation at Mayo Clinic Laboratories.
5. Maintain urine specimen transport tube at 2 to 30 degrees C (refrigerated temperature is preferred) and transport within 30 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for 12 months.

Specimen Type: Oropharynx/Pharynx/Throat
Supplies: Aptima Multitest Swab Collection Kit (T584)
Container/Tube: Aptima Collection Multitest Swab
Specimen Volume: Swab
Collection Instructions:
1. Specimens must be collected using Aptima Multitest Swab Specimen Collection Kit.
2. Swab site using Aptima Collection Multitest Swab (pink shaft).
3. Place pink swab in transport tube provided in collection kit.
4. Snap off pink swab at score line so it fits into closed tube.
5. Cap tube securely and label tube with patient's entire name and collection date and time.
6. Maintain swab container at either 2 to 30 degrees C (refrigerated temperature is preferred) or -20 to -70 degrees C and transport within 14 days of collection.

Specimen Type: Rectal/Anal
Supplies: Aptima Multitest Swab Collection Kit (T584)
Container/Tube: Aptima Multitest Swab
Specimen Volume: Swab
Collection Instructions:
1. Specimens must be collected using Aptima Multitest Swab Specimen Collection Kit.
2. Insert swab into rectum about 3 to 5 cm past anal margin and gently rotate swab for 10 seconds.
3. Place collection swab in transport tube provided in collection kit.
4. Snap off swab at score line so it fits into closed tube.
5. Cap tube securely and label tube with patient's entire name and collection date and time.
6. Maintain swab container at either 4 to 30 degrees C (refrigerated temperature is preferred) or -20 to -70 degrees C and transport within 14 days of collection.

Specimen Minimum Volume

See Specimen Required

Reject Due To

Midstream urine specimen	Reject
Clean catch urine specimen	Reject
Overfilled	Reject

urine transport tubes	
Multiple sources on single tube	Reject
Transport tubes containing a cleaning swab or more than 1 swab	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 treatment as soon as possible and reduces the risk of disease spread. Prompt treatment reduces the risk of infertility in women.

Per CDC guidance, a positive *N gonorrhea* result in a child undergoing evaluation for an STI should be confirmed because of the risk of a false positive result due to the overall low prevalence of STIs in this patient population. An initial positive result should be confirmed by re-testing the sample using an assay targeting an alternative *N gonorrhea* gene region, or by collecting and testing a new specimen.

Reference Values

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

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.

No interference is expected with swab specimens 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.

Testing of urine specimens with this method is not intended to replace cervical exam and endocervical sampling for diagnosis of urogenital infection; infections may result from other causes, or concurrent infections may occur.

Testing urine specimens as the sole test for identifying female patients with chlamydial or gonococcal infections may miss some infected individuals.

This assay has not been shown to cross-react with commensal (nonpathogenic) *Neisseria* species in the oropharynx.

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 tests 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 Aptima Neisseria gonorrhoeae assay is a nucleic acid amplification test (NAAT) that employs target capture, transcription-mediated amplification, and hybridization protection assay technologies. The detection of the ribosomal RNA amplification product sequences (amplicon) is achieved using nucleic acid hybridization. Single-stranded chemiluminescent DNA probes are labeled and combined with amplicon to form stable RNA:DNA hybrids. Light emitted from the labeled RNA:DNA hybrids is measured as photon signals by a luminometer.(Package insert: Aptima Neisseria gonorrhoeae Assay, AW-28505-001. Hologic, Inc; Rev 001, 02/2024)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

1 to 4 days

Specimen Retention Time

7 days

Performing Laboratory Location

Test Definition: GCCON

Neisseria gonorrhoeae Confirmation, Nucleic Acid Amplification, Varies

Mayo Clinic Laboratories - Rochester Superior Drive

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 modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

87591

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
GCCON	N gonorrhoeae Confirm, RNA, Varies	43305-2

Result ID	Test Result Name	Result LOINC® Value
SRC20	SOURCE:	31208-2
623157	N gonorrhoeae Confirm, RNA, Varies	43305-2