Test Definition: GCRNA

Neisseria gonorrhoeae, Nucleic Acid Amplification, Varies

Overview

Useful For

Detecting *Neisseria gonorrhoeae*

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

Method Name

Transcription Mediated Amplification

NY State Available

Yes

Specimen

Specimen Type

Varies

Necessary Information

Specimen source is required.

Specimen Required

Submit only 1 of the following specimens:

Specimen Type: Endocervix/Cervix
Supplies: Aptima Unisex Swab Collection Kit (T583)
Container/Tube: Aptima Unisex Swab
Specimen Volume: 1 Swab
Collection Instructions:
1. Specimens must be collected using the Aptima Unisex Swab Collection Kit.
2. Use cleaning swab (white shaft) to remove excess mucus from endocervix/cervix.
3. Discard the cleaning swab.
4. Insert second swab (blue shaft) 1 to 1.5 cm into endocervical canal and rotate swab gently for 30 seconds. Avoid touching vaginal wall when removing swab.
5. Place blue swab into transport tube provided in collection kit.
6. Snap off blue swab at score line so it fits into closed tube.
7. Cap tube securely, and label tube with patient's entire name and collection date and time.
8. 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 12 months.

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 (refrigerate temperature is preferred) and transport within 60 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for 12 months.

Specimen Type: Urethra (Males Only)
Supplies: Swab, Aptima Unisex Swab Collection Kit (T583)
Container/Tube: Aptima Unisex Swab
Specimen Volume: Swab
Collection Instructions:
1. Specimen must be collected using the Aptima Unisex Swab Collection Kit.
2. Patient should not have urinated for at least 1 hour prior to collection.
3. With a rotating movement, insert swab (blue shaft) 2 to 4 cm into urethra.
4. Once inserted, rotate blue swab gently at least 1 full rotation using sufficient pressure to ensure swab comes into contact with all urethral surfaces. Allow blue swab to remain inserted for 2 to 3 seconds.
5. Place blue swab in transport tube provided in collection kit.
6. Snap off blue swab at score line so it fits into closed tube.
7. Cap tube securely, and label tube with patient's entire name and collection date and time.
8. 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 12 months.

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 (refrigerate 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: ThinPrep Specimen (Endocervix/Cervix)
Supplies: Aptima Specimen Transfer Kit (T652)
Container/Tube: Aptima specimen transfer tube
Specimen Volume: 1 mL
Collection Instructions:
1. Collect ThinPrep sample as per normal collection process.
2. **ThinPrep specimen must be aliquoted (as outlined below) before it is processed for Papanicolaou testing (Pap smear).**
3. Vortex ThinPrep/PreservCyt vial 3 to 10 seconds.
4. Within 1 minute of vortexing:
a. Transfer 1 mL of specimen into the Aptima specimen transport tube using a disposable transfer pipette or a pipette tip containing a filter (aerosol barrier or hydrophobic plug).
b. Process only 1 ThinPrep and transfer tube set at a time.
c. Recap Aptima Specimen Transfer Tube tightly and gently invert 3 times to mix.
5. Label Aptima specimen transfer tube with appropriate label.
6. Use remainder of ThinPrep specimen for Pap testing.
7. Maintain specimen transport tube at 2 to 8 degrees C (refrigerate temperature is preferred) and transport within 30 days of collection, or within 14 days if stored at 15 to 30 degrees C. 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 4 to 30 degrees C (refrigerate temperature is preferred) or -20 to -70 degrees C, and transport within 60 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 (refrigerate temperature is preferred) or -20 to -70 degrees C, and transport within 60 days of collection.

Forms

If not ordering electronically, complete, print, and send a Microbiology Test Request (T244) with the specimen.

Specimen Minimum Volume

Urine: 2 mL; Endocervix/Cervix in PreservCyt or Swab specimens: See Specimen Required

Reject Due To

Midstream urine specimen Clean catch urine specimen Overfilled or underfilled urine transport tubes Specimen collected into a SurePath device Transport tubes containing a cleaning swab or more than 1 swab Multiple sources on single tube	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 testing 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.

Reference Values

Negative

Interpretation

A positive result indicates the presence of nucleic acid from *Neisseria gonorrhoeae* and supports a diagnosis of gonorrhea.

A negative result indicates that nucleic acid from *N gonorrhoeae* was not detected. A negative result does not exclude the possibility of infection. If clinical indications strongly suggest gonococcal 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

Care must be taken to avoid cross-contamination during handling of PreservCyt solution liquid Papanicolaou (Pap) specimens. If testing PreservCyt specimens processed with the ThinPrep 2000 processor, it is important to follow procedures to reduce the risk for cross-contamination during Pap processing, such as bleaching of the PreservCyt filter cap and changing gloves between each sample. Refer to the ThinPrep 2000 Processor Operator's Manual and the Aptima specimen for more guidance.

The performance of endocervical, vaginal, and male urethral swab specimens, urine specimens, and PreservCyt solution liquid Pap specimens has not been evaluated in adolescents less than 14 years. The performance of vaginal swab specimens has not been evaluated in pregnant women.

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.

The presence of mucous does not interfere with this assay. However, this test requires endocervical cells, and if excess mucous is not removed prior to collection, adequate numbers of these cells may not be obtained.

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 gonococcal infections may miss some infected individuals.

Performance estimates for urine specimens are based on evaluation of urine obtained from the first part of the urine

stream; performance on midstream collections has not been determined.

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 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

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 Definition: GCRNA

Neisseria gonorrhoeae, Nucleic Acid Amplification, Varies

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
GCRNA	Neisseria gonorrhoeae Amplified RNA	43305-2

Result ID	Test Result Name	Result LOINC® Value
SRC17	SOURCE:	31208-2
34875	Neisseria gonorrhoeae amplified RNA	43305-2