Test Definition: MGRNA

Neisseria gonorrhoeae, Miscellaneous Sites, Nucleic Acid Amplification, Varies

Overview

Useful For

Detecting *Neisseria gonorrhoeae* in non-US Food and Drug Administration-approved specimen types

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

Method Name

Transcription Mediated Amplification

NY State Available

Yes

Specimen

Specimen Type

Varies

Ordering Guidance

This test is used for specimens that **are not** US Food and Drug Administration (FDA) approved for this assay. Acceptable non-FDA-approved specimen types are ocular swabs and peritoneal fluid.

For FDA-approved specimen types, order GCRNA / *Neisseria gonorrhoeae*, Nucleic Acid Amplification, Varies.

Necessary Information

Specimen source is required.

Specimen Required

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 (refrigerate temperature is preferred), transport within 60 days of collection.

Specimen Type: Peritoneal fluid (pelvic wash, cul-de-sac fluid)
Supplies: Aptima Specimen Transfer Kit (T652)
Container/Tube: Aptima specimen transfer tube
Specimen Volume: 1 mL
Collection Instructions:
1. Transfer 1 mL of peritoneal fluid directly into the Aptima specimen transfer tube within 24 hours of collection.
2. Cap tube securely and label tube with patient's entire name and collection date and time.
3. Maintain Aptima specimen transfer tube at 2 to 30 degrees C (refrigerate temperature is preferred), transport within 30 days of collection.

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

Specimen Minimum Volume
See Specimen Required

Reject Due To

Multiple sources on single tube	Reject
Fluid collected in ThinPrep vial prior to aliquot into Aptima Transfer 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 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 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

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 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 combined 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 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
MGRNA	N. gonorr, Misc, Amplified RNA	43305-2

Result ID	Test Result Name	Result LOINC® Value
34508	N. gonorr, Misc, Amplified RNA	43305-2
SRC22	SOURCE:	31208-2