

Neisseria gonorrhoeae Confirmation, Nucleic Acid Amplification, Varies

Test ID: GCCON

Useful for:

Detecting *Neisseria gonorrhoeae*.

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

Methods:

Transcription Mediated Amplification

Reference Values:

Negative

Specimen Requirements:

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 (refrigerate temperature is preferred), transport within 60 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 (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: 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.

Specimen Stability Information:

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

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.

CPT Code:

87591

Day(s) Performed: Monday through Sunday

Report Available: 1 to 4 days

Note:

The following referral test code(s) will become obsolete.

Test Name	Test ID	Referral Lab Code	Referral Lab
<i>Neisseria gonorrhoeae</i> , TMA (Alternate Target), Urogenital	ZW51	15033	Quest Diagnostics
<i>Neisseria gonorrhoeae</i> , TMA (Alternate Target), Rectal	ZW51	90990	Quest Diagnostics

Questions

Contact Rebekah Walsh, Laboratory Resource Coordinator at 800-533-1710.