Test Definition: AMGEN

Mycoplasma genitalium, Transcription-Mediated Amplification, Urine or Urogenital Swab

Overview

Useful For

Detecting *Mycoplasma genitalium* in cases of suspected infection

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

Highlights

This test is approved by the US Food and Drug Administration for performance on vaginal swabs, endocervical swabs, female/male urine, male urethral swabs, and penile/meatal swabs.

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:

Swab specimen must be collected using an Aptima Collection Unisex Swab or Aptima Collection Multitest Swab based on the corresponding source. These swabs are contained in the Aptima Collection Kit.

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 the blue shaft swab into transport tube provided in collection kit.
6. Snap off 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) within 60 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for an additional 90 days.

Specimen Type: Vaginal
Supplies: Aptima Multitest Swab Collection Kit (T584)
Container/Tube: Aptima Multitest Swab
Specimen Volume: 1 Swab
Collection Instructions:
1. **Specimens must be collected using the Aptima Multitest Swab 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 is preferred temperature) within 60 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for an additional 90 days.

Specimen Type: Urethra (Male patients only)
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. 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 swab gently at least 1 full rotation using sufficient pressure to ensure swab comes in contact with all urethral surfaces. Allow 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 is preferred temperature) within 60 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for an additional 90 days.

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 Aptima 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 container at 2 to 30 degrees C (refrigerate is preferred temperature) within 30 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C up to an additional 90 days.

Specimen Type: Penile/meatal
Supplies: Aptima Multitest Swab Collection Kit (T584)
Container/Tube: Aptima Multitest Swab
Specimen Volume: 1 Swab
Collection Instructions:
1. **Specimens must be collected using the Aptima Multitest Swab Collection Kit.**
2. Roll the swab (pink shaft) just at the tip or outside the opening to the penis. Be sure to roll the swab completely around the opening to get the best sample.
3. Immediately place the pink swab into the collection tube.
4. Carefully break the pink swab shaft at the score line and recap the 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 is preferred temperature) within 60 days of collection. If longer storage is needed, freeze at -20 to -70 degrees C for an additional 90 days.

Forms

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

Specimen Minimum Volume

Urine-first void: 2 mL; Swabs (endocervical, urethral, vaginal, penile/ meatal): See Specimen Required

Reject Due To

Midstream urine specimen Clean catch urine specimen Overfilled or underfilled urine transport tubes Specimen collected into a	Reject

SurePath Prep device or ThinPrep vial Transport tubes containing a cleaning swab or more than 1 swab Multiple sources on single tube	

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Varies		APTIMA VIAL

Clinical & Interpretive

Clinical Information

Mycoplasma genitalium, an under-recognized sexually transmitted infection (STI), causes acute and chronic non-gonococcal urethritis, cervicitis, and pelvic inflammatory disease. Due to its growing prevalence, *M genitalium* was cited as an emerging public health threat by the Centers for Disease Control and Prevention (CDC) in 2015. In high-risk populations, prevalence has been reported as high as 9% to 24% in male patients and 11% to 16% in female patients. *M genitalium* is commonly misdiagnosed as other STIs (eg, *Chlamydia trachomatis* or gonorrhea), which can lead to improper treatment of the underlying cause and an increase in duration of infection. In 2021, the CDC updated their STI guidelines to recommend that men with recurrent non-gonococcal urethritis and women with recurrent cervicitis or pelvic inflammatory disease should be tested for *M genitalium*.

Reference Values

Negative

Interpretation

A positive result indicates the presence of nucleic acid from *Mycoplasma genitalium* and strongly supports the diagnosis of a *M genitalium* infection.

A negative result indicates that nucleic acid from *M genitalium* was not detected in the specimen.

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 a specific population. In settings with a high

prevalence of sexually transmitted infections, positive assay results have a high likelihood of being truly positive. In settings with a low prevalence of sexually transmitted infections, or in any setting in which a patient's clinical signs and symptoms or risk factors are inconsistent with urogenital infection, positive results should be carefully assessed, and if appropriate, the patient retested by other methods.

Cautions

Care must be taken to avoid cross-contamination during handling of specimens.

This test does not detect other *Mycoplasma* or *Ureaplasma* species.

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

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

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

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 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.

Interference in assay results was observed when mucus at a final concentration of 0.3% weight/volume was added to clinical specimen matrix. Interference was not observed when mucus at a final concentration of 0.03% weight/volume was added to clinical specimen matrix.

Performance of the assay has not been evaluated in individuals younger than 15 years.

Clinical Reference

Waites KB, Crabb DM, Ratliff AE, Geisler WM, Atkinson TP, Xiao L. Latest advances in laboratory detection of mycoplasma genitalium. J Clin Microbiol. 2023;61(3):e0079021. doi:10.1128/jcm.00790-21

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 Mycoplasma genitalium Assay. AW-17946 Hologic, Inc; Rev 004, 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
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 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
87563

MAYO CLINIC LABORATORIES

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LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
AMGEN	Mycoplasma genitalium, TMA, Varies	100706-1

Result ID	Test Result Name	Result LOINC® Value
616592	Mycoplasma genitalium Result	100706-1
AMGES	Specimen Source:	31208-2