MAYO CLINIC LABORATORIES

Test Definition: AMGEN

Mycoplasma genitalium,
Transcription-Mediated Amplification, Varies

Overview

Useful For

Detection of *Mycoplasma genitalium* in cases of suspected infection

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

Highlights

This test performs analysis on both FDA-approved and non-FDA-approved sources.
FDA-approved sources include vaginal, endocervical, female/male urine, male urethral, and penile/meatal swabs (genital). Non-FDA-approved sources include prostatic secretion/post-prostatic massage urine (VBIII) and peritoneal fluid (pelvic wash, cul-de-sac fluid).

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. These swabs are contained in the Aptima Collection Kit.

Supplies: Swab, Aptima Male/Female Collection (T583)
Specimen Type: Endocervix
Container/Tube: Aptima Collection Unisex Swab
Specimen Volume: Swab
Collection Instructions:
1. Use cleaning swab (white shaft) to remove excess mucus from endocervix and discard.
2. 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.
3. Place second swab into transport tube provided in collection kit. Snap off swab at score line so swab fits into closed tube.
4. Cap tube securely, and label tube with patient's entire name, and date and time of collection.
5. Transport and store 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.

Supplies: Swab, Aptima Multitest Swab Specimen Collection Kit (T584)
Specimen Type: Vaginal, genital
Container/Tube: Aptima Collection Multitest Swab
Specimen Volume: Swab
Collection Instructions:
1. Insert swab (pink shaft) about 5 cm past introitus and rotate gently for 30 seconds.
2. Place swab into transport tube provided in collection kit. Snap off swab at score line so swab fits into closed tube.
3. Cap tube securely, and label tube with patient's entire name, and date and time of collection.
4. Transport and store 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.

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

Supplies: Aptima Urine Transport Tube (T582)
Specimen Type: Urine (Male and female patients) and post-prostatic massage urine (VBIII)
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. Transfer 2 mL of urine into the Aptima Urine Specimen Transport Tube using the disposable pipette provided within 24 hours of collection. The correct volume of urine has been added when the fluid level is between the black fill lines on

the urine transport tube. Place the labels on the transport tube so the black fill lines are still visible for volume confirmation at Mayo Clinic Laboratories.
4. Transport and store urine or post-prostatic massage urine (VBIII) specimen transport container at 2 to 30 degrees C (refrigerate is preferred temperature) within 30 days of collection. If longer storage is needed for urine specimens other than VBIII, freeze at -20 to -70 degrees C an additional 90 days. **VBII cannot be sent frozen**.

Supplies: Aptima Specimen Transport Tube (T652)
Specimen Type: Peritoneal fluid (pelvic wash or cul-de-sac fluid)
Container/Tube: Aptima Specimen Transfer Tube
Specimen Volume: 1 mL
Collection Instructions:
1. After collection, peritoneal fluid can be stored at 2 to 30 degrees C for up to 24 hours.
2. Transfer specimen into the Aptima Specimen Transfer Tube within 24 hours of collection.
3. Cap tube securely and label tube with patient's entire name and collection date and time.
4. Transport and store specimen container at 2 to 30 degrees C (refrigerate is preferred temperature) within 30 days of collection. **Specimen cannot be sent frozen**.

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

Specimen Minimum Volume
Urine: 2 mL
Swabs (endocervical, urethral, vaginal): See Specimen Required

Reject Due To

Midstream urine specimen Overfilled or underfilled urine transport tubes Specimen collected into a SurePath Prep device or ThinPrep vial Transport tubes containing a cleaning swab or more than 1 swab	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Varies (preferred)	0 hours	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 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 and 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 and/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*.

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

The predictive value of an assay depends on the prevalence of the disease in any particular 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* spp.

This test is intended for use in 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 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 use of tampons, 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% w/v was added to clinical specimen matrix. Interference was not observed when mucus at a final concentration of 0.03% w/v was added to clinical specimen matrix.
Performance of the assay has not been evaluated in individuals < 15 years of age

Clinical Reference

1. Shipitsyna E, Unemo M: *Mycoplasma genitalium* assay (Hologic) and key priorities in the management of *M. genitalium* infections. Expert Rev Mol Diagn. 2020 Nov;20(11):1063-1074
2. Daley GM, Russell DB, Tabrizi SN, McBride J: *Mycoplasma genitalium*: a review. Int J STD AIDS. 2014 Jun;25(7):475-487

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 Mycoplasma genitalium Assay. AW-1794 Hologic, Inc; Rev 002, 04/2019)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

1 to 4 days

Specimen Retention Time

7 days

Performing Laboratory Location

Rochester

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 Regional Manager. 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

87563

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
AMGEN	Mycoplasma genitalium, TMA, Varies	88226-6

Result ID	Test Result Name	Result LOINC® Value
616592	Mycoplasma genitalium Result	88226-6
AMGES	Specimen Source:	31208-2