Overview

Useful For
Rapid, sensitive, and specific identification of *Mycoplasma genitalium* from genitourinary and reproductive sources

This test is not intended for medicolegal use.

Method Name
Real-Time Polymerase Chain Reaction (PCR) using LightCycler and Fluorescent Resonance Energy Transfer (FRET)

NY State Available
Yes

Specimen

Specimen Type
Varies

Shipping Instructions
Ship specimen refrigerated.

Necessary Information
Specimen source is required.

Specimen Required
The high sensitivity of amplification by polymerase chain reaction (PCR) requires the specimen to be processed in an environment in which contamination of the specimen by *Mycoplasma genitalium* DNA is not likely.

Submit only 1 of the following specimens:

Specimen Type: Swab

Supplies:
- Culturette (BBL Culture Swab) (T092)
- BD Eswab (T853)

Sources: Cervix, urethra, urogenital, vaginal

Container/Tube:

Preferred: Culture swab transport system (Dacron or rayon swab with aluminum or plastic shaft with either Stuart or Amies liquid medium)

Acceptable: Swab in transport media: M4, M4-RT, M5, M6, universal transport medium, or Eswab
Specimen Volume: One swab

Collection Instructions:
1. Vaginal: Collect specimen by swabbing back and forth over mucosa surface to maximize recovery of cells.
2. Urethra or cervical: Collect specimen by inserting swab 1 to 3 cm and rotating 360 degrees.
3. Place swab back into swab cylinder.

Specimen Type: Fluid

Sources: Amniotic, pelvic, peritoneal, prostatic secretion, reproductive drainage, semen

Container/Tube:

Preferred: Sterile container

Acceptable: Container with 3 mL of transport media: M4, M4-RT, M5, M6 or universal transport media

Specimen Volume: 1-2 mL

Specimen Type: Urine-first void, kidney/bladder stone, ureter

Container/Tube: Sterile container

Specimen Volume: 10 mL or entire specimen

Collection instructions: Urine first void: Specimen can be collected at any time during the day. The patient should not have urinated for at least 1 hour prior to specimen collection. The first voided portion is the initial 20-30 mL of the urine stream obtained without cleaning the external urethra.

Specimen Type: Tissue

Sources: Placenta, products of conception, genitourinary

Container/Tube: Sterile container

Specimen Volume: 5 mm(3)

Collection Instructions:
1. Collect fresh tissue specimen.
2. Submit fresh tissue only, do not add fluid to tissue
3. Refrigerate or freeze specimen.

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

Fluid: 1 mL  
Urine, first void: 2 mL  
Swab: 1 swab  
Tissue: 5 mm(3)

**Reject Due To**

Cotton or calcium alginate-tipped swab, wooden shaft swab, transport swab containing gel or charcoal  
Formalin-fixed and/or paraffin-embedded tissues  
Port-a-Cul tube  
Anaerobic fluid vials  
Dry swab (no pledget or sponge)

**Specimen Stability Information**

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Varies</td>
<td>Refrigerated (preferred)</td>
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**Clinical and Interpretive**

**Clinical Information**

*Mycoplasmoïdes genitalium*, previously *Mycoplasma genitalium*, causes acute and chronic nongonococcal urethritis, cervicitis, and pelvic inflammatory disease. Culture isolation is technically challenging; polymerase chain reaction (PCR) is the diagnostic test of choice.

**Reference Values**

Not applicable

**Interpretation**

A positive PCR result for the presence of a specific sequence found within the *Mycoplasmoïdes genitalium tuf* gene indicates the presence of *M genitalium* DNA in the specimen.

A negative PCR result indicates the absence of detectable *M genitalium* DNA in the specimen, it but does not rule-out infection as false-negative results may occur due to the following: inhibition of PCR, sequence variability underlying the primers or probes, or the presence of *M genitalium* in quantities below the limit of detection of the assay.

**Cautions**

Interfering substances may affect the accuracy of this assay; results should always be interpreted in conjunction with clinical and epidemiological findings.

This test does not detect other *Mycoplasmoïdes* or ureaplasmas.

**Supportive Data**
This assay was clinically validated in a blinded fashion using 399 archived specimens submitted for Mycoplasmoides hominis or Ureaplasma culture, 383 of which were in M4, M5, M6, or universal transport medium (UTM). The specimens consisted of 349 genitourinary and 50 reproductive fluids or tissues. The results were compared to polymerase chain reaction (PCR) results obtained using the method described by Jurstrand et al.(1) Compared to the method by Jurstrand et al, the Mayo Clinic PCR assay had 100% sensitivity and 100% specificity; however, only 1 positive specimen, a vaginal swab, was included in the analysis. That specimen was also tested by PCR by Dr. Kathleen A. Stellrecht at the Albany Medical Center(2) and found to be positive. The limit of detection of the assay is 100 targets/mL for all validated sources. Additional spiking studies (at the limit of detection of the assay) were performed using 30 or more of each of the following: genitourinary swabs, genitourinary fluid, and reproductive tissue or fluid. All results (except for 2) were as expected.

Clinical Reference

Performance

Method Description
This polymerase chain reaction (PCR) method employs a target-specific detection system including primers, as well as fluorescent resonance energy transfer (FRET) hybridization probes designed for the tuf gene of Mycoplasmoides genitalium. The LightCycler instrument amplifies and monitors target nucleic acid sequences by fluorescence during PCR cycling. This is an automated PCR system that can rapidly detect amplified product development. The detection of amplified products is based on the FRET principle. For FRET product detection, a hybridization probe with a donor fluorophore, fluorescein, on the 3' end is excited by an external light source, which emits light that is absorbed by a second hybridization probe with an acceptor fluorophore, LC-Red 640, on the 5' end. The acceptor fluorophore then emits light of a different wavelength that is measured with a signal that is proportional to the amount of specific PCR product. The process is completed in a closed-tube system.(Unpublished Mayo method)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday

Analytic Time
3 days

Maximum Laboratory Time
4 days

Specimen Retention Time
7 days
Performing Laboratory Location
Rochester

Fees and 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 was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
87563

LOINC® Information

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