Sonora Quest Laboratories™
A Subsidiary of Laboratory Sciences of Arizona

Mycoplasma genitalium (M-Gen), TMA

Test Code: 907271

Specimen Requirements: Females: 1 room-temperature vaginal swab in an Aptima® Multitest Transport Tube or endocervical swab in an Aptima Unisex Transport Tube following the instructions in the collection kit. Alternatively, submit 2 mL room-temperature urine in an Aptima Urine Specimen Collection Transport Tube following the instructions in the collection kit.

Males: 1 room-temperature urethral or meatal swab in an Aptima Unisex Transport Tube following the instructions in the collection kit. Alternatively, submit 2 mL room-temperature urine in an Aptima Urine Specimen Collection Transport Tube following the instructions in the collection kit.

CPT Code:* 87563

CLINICAL USE

- Diagnose *Mycoplasma genitalium* infection

CLINICAL BACKGROUND

M genitalium is increasingly recognized as an important sexually transmitted infection (STI),[1] with an estimated prevalence of 1.7% in the general population.[2] Populations of people who engage in high-risk sexual behaviors may have a much higher prevalence (up to 24% among men and 16% among women), comparable to that of chlamydia.[3] Although many infections are asymptomatic, *M genitalium* accounts for a substantial proportion of urethritis, cervicitis, and pelvic inflammatory disease (PID) cases **(Table 1)**.[1,3] Urethritis, cervicitis, and PID can also be caused by other STIs including *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*. Symptoms are not specific to the causative pathogen, and treatment for *M genitalium* differs from treatment for other STIs.[1] Thus, laboratory testing is needed to diagnose *M genitalium* infection and initiate appropriate treatment.

M genitalium is rapidly acquiring antibiotic resistance. Azithromycin, a macrolide used as empiric therapy for urethritis and cervicitis,[1] has a declining cure rate for *M genitalium* infections.[4,5] Empiric treatment of STIs with azithromycin selects for mutations associated with macrolide resistance in *M genitalium* and has likely contributed to these mutations becoming widespread.[1]

Table 1. Proportion of Urogenital Syndrome Cases Caused by *Mycoplasma genitalium*[1]

	Syndrome	Proportion, %
Women	Cervicitis	10-30
	PID	4-22
Men	Urethritis	
	Nongonococcal (NGU)	15-20
	Nonchlamydial nongonococcal (NCNGU)	20-25
	Persistent urethritis	40

Moxitloxacin, a tluoroquinolone, in combination with doxycycline is recommended to treat *M genitalium* infections in the United States.[1] However, the cure rate of moxifloxacin for *M genitalium* infections is also declining.[6] Two recent studies found mutations associated with tluoroquinolone resistance in 11% to 40% of isolates from people in high-risk populations in the United States, and many also had mutations associated with macrolide resistance.[7,8] Identifying *M genitalium* and treating it specifically may help combat the growing problem of antibiotic resistance.[1]

Guidelines from the Centers for Disease Control and Prevention recommend testing people with recurrent or persistent nongonococcal urethritis or cervicitis for *M genitalium*.[1] Testing may also be considered for people with cervicitis, before it becomes persistent or recurrent, or PID.[1] Sex partners of people with *M genitalium* infection may also be tested.[1]

Nucleic acid amplification tests (NAATs) are recommended for detecting *M genitalium* because this pathogen cannot be visualized under a microscope and is prohibitively difficult to culture.[1] Among NAATs, transcription-mediated amplification (TMA) is more sensitive than polymerase chain reaction for *M genitalium*.[9,10] This TMA test has high overall sensitivity (78% to 99%) and specificity (≥98%), though its performance varies by specimen type **(Table 2)**.[3] Vaginal swab is the preferred specimen type for women, as it has the highest sensitivity among all female specimen types (>90%).[3]

INDIVIDUALS SUITABLE FOR TESTING

- Individuals with urethritis, cervicitis, or PID
- Sex partners of people with confirmed *M genitalium* infection

Sonora Quest Laboratories™
A Subsidiary of Laboratory Sciences of Arizona

Table 2. Clinical Sensitivity and Specificity of the *M genitalium*, rRNA, TMA Test[3]

Specimen type	Sensitivity (95% CI), %	Specificity (95% CI), %
Vaginal swab (clinician-collected)	92.0 (86.9-95.1)	98.0 (97.2-98.6)
Vaginal swab (self-collected)	98.9 (95.9-99.7)	98.5 (97.7-99.0)
Endocervical swab	81.5 (75.1-86.6)	98.3 (97.5-98.8)
Female urine	77.8 (71.1-83.3)	99.0 (98.3-99.4)
Urethral swab	98.2 (94.8-99.4)	99.6 (99.1-99.8)
Penile meatal swab	88.4 (82.6-92.5)	97.8 (96.9-98.5)
Male urine	90.9 (85.5-94.4)	99.4 (98.8-99.7)

METHOD

- Qualitative TMA with chemiluminescent detection
- Analytical sensitivity: 0.3 to 0.16 genome equivalents/mL (depending on specimen type)
- Analytical sensitivity: no interference from other urogenital tract pathogens or flora identified

REFERENCE RANGE

Not detected

INTERPRETIVE INFORMATION

A "detected" result is consistent with *M genitalium* infection. False-positive results may be obtained if a specimen is collected too soon after treatment, as NAATs can detect genetic material from nonviable organisms.[3]

A "not detected" result is consistent with no *M genitalium* infection. False-negative results may be obtained if there are too few organisms in the specimen.[3] False-negative results are more likely from female specimen types that are not vaginal swabs.[3] Retesting using a vaginal swab may be appropriate if the clinical suspicion of *M genitalium* infection is high.[3]

When the number of *M genitalium* organisms in a specimen is low, *Mycoplasma pneumoniae*, if present, can interfere with the assay and cause false-negative results.[3] However, such cross-reactivity is rare, as *M pneumoniae* is normally found in the respiratory tract. Mucus at concentrations as low as 0.3% w/v may also interfere with the assay.[3]

References

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. Torrone E, Kruszon-Moran D, Philips C, et al. Prevalence of urogenital *Mycoplasma genitalium* infection, United States, 2017-2018. *Sex Transm Dis.* Published online February 9, 2021. doi:10.1097/OLQ.0000000000001394
3. *Aptima Mycoplasma genitalium* Assay. Package insert. Hologic Inc; 2019.
4. Lau A. Bradshaw CS, Lewis D, et al. The efficacy of azithromycin for the treatment of genital *Mycoplasma genitalium*: a systematic review and meta-analysis. *Clin Infect Dis.* 2015;61(9):1389-1399. doi:10.1093/cid/civ644
5. Manhart LE, Gillespie CW, Lowens MS, et al. Standard treatment regimens for nongonococcal urethritis have similar but declining cure rates: a randomized controlled trial. *Clin Infect Dis.* 2013;56(7):934-942. doi:10.1093/cid/cis1022
6. Li Y, Le WY, Li S, et al. Meta-analysis of the efficacy of moxifloxacin in treating *Mycoplasma genitalium* infection. *Int J STD AIDS.* 2017;28(11):1106-1114. doi:10.1177/0956462416688562
7. Dionne-Odom J, Geisler WM, Aaron KJ, et al. High prevalence of multidrug-resistant *Mycoplasma genitalium* in human immunodeficiency virus-infected men who have sex with men in Alabama. *Clin Infect Dis.* 2018;66(5):796-798. doi:10.1093/cid/ cix853
8. Xiao L, Waites KB, Van Der Pol B, et al. *Mycoplasma genitalium* infections with macrolide and fluoroquinolone resistance associated mutations in heterosexual African American couples in Alabama. *Sex Transm Dis.* 2019;46(1):18-24. doi:10.1097/ OLQ.0000000000000891
9. Le Roy C, Pereyre S, Hénin N, et al. French prospective clinical evaluation of the Aptima *Mycoplasma genitalium* CE-IVD assay and macrolide resistance detection using three distinct assays. *J Clin Microbiol.* 2017;55(11):3194-3200. doi:10.1128/JCM.00579-17
10. Unemo M, Salado-Rasmussen K, Hansen M, et al. Clinical and analytical evaluation of the new Aptima *Mycoplasma genitalium* assay, with data on *M. genitalium prevalence* and antimicrobial resistance in *M. genitalium* in Denmark, Norway and Sweden in 2016. *Clin Microbiol Infect.* 2018;24(5):533-539. doi:10.1016/j.cmi.2017.09.006

*The CPT code provided is based on AMA guidelines and is for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.