

HOLOGIC®

KNOW
THE CAUSE,
Target
THE THERAPY

Mycoplasma genitalium –

A highly prevalent STI you can
now accurately identify.



Aptima® *Mycoplasma genitalium*
Assay

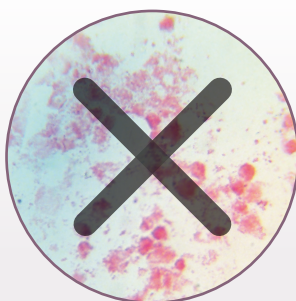
Mycoplasma genitalium is a Highly Prevalent STI

Detection of *Mycoplasma genitalium* (M. gen) Requires Nucleic Acid Amplification Testing



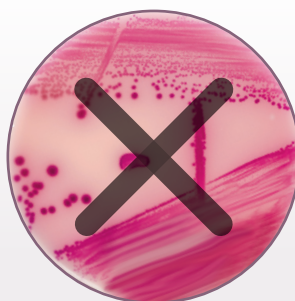
Clinical Presentation

can be similar to other sexually transmitted infections (STIs).²



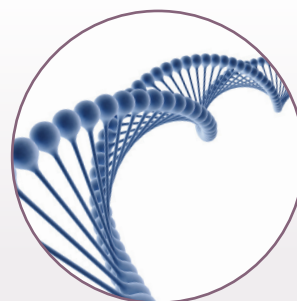
Microscopy

cannot be seen because M. gen has no cell wall.¹



Culture

is not clinically feasible as it may take up to six months.¹



Nucleic Acid Amplification Test (NAAT)

is the recommended method of detection.^{1,3}

Trichomoniasis, Chlamydia, Gonorrhea and M. gen are Associated with Similar Clinical Presentation⁴⁻¹³

	Similar Symptoms					
	Trichomoniasis	Bacterial Vaginosis	Yeast Infection	Chlamydia	Gonorrhea	<i>Mycoplasma genitalium</i>
Abnormal Discharge	✓	✓	✓	✓	✓	✓
Vaginal Odor	✓	✓				
Vaginal Irritation	✓	✓	✓	✓	✓	✓
Pain During Urination/Sex	✓	✓	✓	✓	✓	✓

and the Test You Choose Matters¹



Testing is Recommended for Women with Recurrent Cervicitis and Should Be Considered in Women with PID¹

- ▶ Prevalence of **18.3%**¹⁴
- ▶ Detected in **10%-30%** of women with clinical cervicitis^{1,15}
- ▶ Identified in up to **22%** of pelvic inflammatory disease (PID) cases^{1,15}
- ▶ Untreated PID can lead to adverse pregnancy outcomes^{1,15}



Testing is Recommended for Men with Recurrent Non-gonococcal Urethritis¹

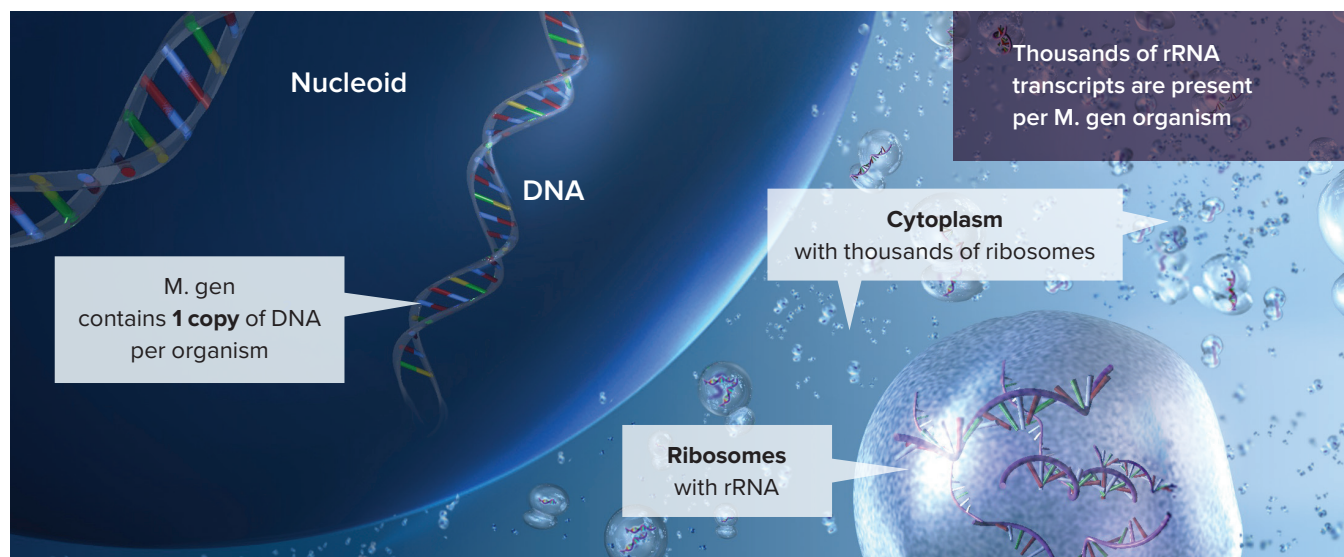
- ▶ Prevalence of **16.5%**¹⁴
- ▶ More likely to exhibit symptoms of *M. gen* infection¹⁵
- ▶ Responsible for **40%** of persistent or recurrent urethritis in men¹

When patients do experience symptoms, they are similar to those associated with other urogenital tract bacterial infections.^{1,18}



May also increase the risk of HIV acquisition and transmission^{1,16-17}

NAAT is Needed to Detect *M. gen* Because the Infection Contains a Very Low Organism Load³



M. gen can be difficult to detect because the bacterial organism load is low compared to other STIs commonly tested for. This means that a highly sensitive rRNA test is needed for accurate diagnosis.³

Proper Diagnosis is Important to Drive the Right Treatment Decisions

Recommended treatments are
organism-specific¹

Trichomoniasis

- ▶ **Metronidazole**
500 mg orally 2x/day for 7 days
(Treatment for women)
- or
- ▶ **Tinidazole**
2g orally single dose
(Treatment for women and/or men)

Gonorrhea

- ▶ **Ceftriaxone**
500 mg* IM in a single dose for
persons weighing <150 kg
- If chlamydial infection has not been
excluded, treat for chlamydia with
Doxycycline 100 mg orally 2x/day
for 7 days
- * For persons weighing ≥150 kg, 1g
Ceftriaxone should be administered.

Chlamydia

- ▶ **Doxycycline**
100 mg orally 2x/day for 7 days

M. gen Treatment Considerations¹

Mycoplasma genitalium

Recommended Regimens if M. gen
Resistance Testing Is Available:

- ▶ If macrolide sensitive: 100 mg orally 2x/
day for 7 days of **Doxycycline**, followed
by 1g orally initial dose of **Azithromycin**,
followed by 500 mg orally 1x/day of
Azithromycin for an additional 3 days
(2.5g total)
- ▶ If macrolide resistant: 100 mg orally 2x/
day for 7 days of **Doxycycline**, followed
by 400 mg orally 1x/daily for 7 days of
Moxifloxacin

Recommended Regimens if M. gen
Resistance Testing Is **NOT** Available:

- ▶ 100 mg orally 2x/day for 7 days of
Doxycycline, followed by 400 mg orally
1x/daily for 7 days of **Moxifloxacin**

The content in this piece is for information purposes only and is not intended to be medical advice. It is the responsibility of the treating provider to determine the appropriate course of action.

A DNA-based test has been shown to **miss up to 40% of infections** compared to an rRNA-based test.¹⁹

Sensitivity of Detection in Patients with M. gen Infections¹⁹⁻²¹



vs.



Aptima® Mycoplasma genitalium assay RNA-based test

DNA-based LDT test



vs.



Aptima® Mycoplasma genitalium assay RNA-based test

DNA test vendor

CDC recommends **NAATs** to detect M. gen.¹



* Sensitivity from Le Roy Study.

† Sensitivity from Unemo Study. Performance in vaginal specimen.

‡ Sensitivity information provided above is specific to patient-collected vaginal swab (PVS) for symptomatic patients. For complete performance characteristics for the Aptima Mycoplasma genitalium assay, please refer to the package insert.

One sample. Multiple results. Maximum Efficiency.

Choose the **FDA-cleared NAAT** for the detection of ribosomal RNA (rRNA) from *M. gen*.

Aptima® Multitest Swab

Detect up to **7 infections** from one vaginal sample.²¹⁻²⁵

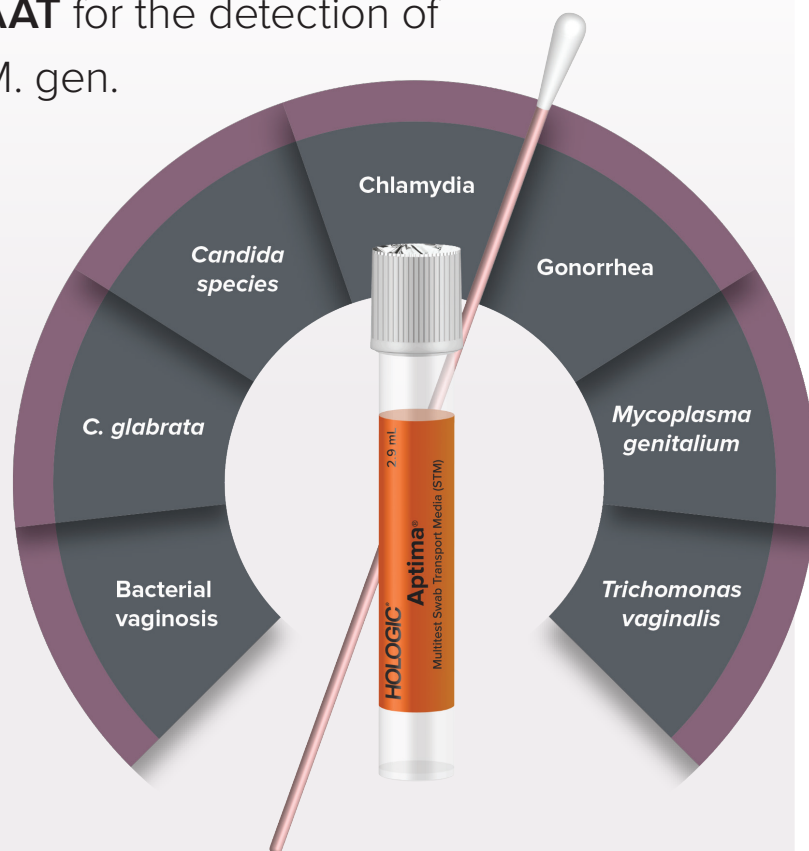
Vaginal swabs are the CDC preferred collection method for *M.gen* testing.¹²



Vaginal Sample



Penile Meatal Sample*



* Penile meatal sample only FDA-cleared for *M. gen*.

Alternative Specimen Collection Also Available

Urine

- ▶ Female urine (first catch)
- ▶ Male urine (first catch)

Unisex Swab

- ▶ Endocervical swabs
- ▶ Male urethral swabs

Visit **HologicWomensHealth.com** for more information.

Refer to the appropriate assay package insert for available specimen types.

References: 1. Workowski, et al. Sexually Transmitted Infections Treatment Guidelines 2021. MMWR Recomm Rep 2021;70:2. Falk L, et al. Signs and symptoms of urethritis and cervicitis among women with or without *Mycoplasma genitalium* or *Chlamydia trachomatis* infection. *Sex Transm Infect.* 2005;81(1):73-78. 3. Frølund M, et al. Urethritis-associated pathogens in urine from men with non-gonococcal urethritis: a case-control study. *Acta Derm Venereol.* 2016;96(5):689-694. 4. Kent H. Epidemiology of vaginitis. *Am J Obstet Gynecol.* 1991;165(4):1168-1176. 5. Manhart LE, Gaydos CA, Taylor SN, Lillis RA, Hook EW 3rd, Klausner JD, Remillard CV, Love M, McKinney B, Getman DK. Characteristics of *Mycoplasma genitalium* Urogenital Infections in a Diverse Patient Sample from the United States: Results from the Aptima *Mycoplasma genitalium* Evaluation Study (AMES). *J Clin Microbiol.* 2020 Jun 24;58(7):e00165-20. doi: 10.1128/JCM.00165-20. PMID: 32321783; PMCID: PMC7315021. 6. Hainer BL, Gibson MV. Vaginitis. *Am Fam Physician.* 2011 Apr 1;83(7):807-15. PMID: 21524046. 7. Bautista CT, Wurapa EK, Saterén WB, Morris SM, Hollingsworth BP, Sanchez JL. Association of Bacterial Vaginosis With Chlamydia and Gonorrhea Among Women in the U.S. Army. *Am J Prev Med.* 2017 May;52(5):632-639. doi: 10.1016/j.amepre.2016.09.016. Epub 2016 Nov 3. PMID: 27816380. 8. CDC. Trichomonas Fact Sheet. Center for Disease Control and Prevention website. Last reviewed February 15, 2023. Accessed February 15, 2023. <https://www.cdc.gov/std/trichomonas/stdfact-trichomoniasis.htm> 9. CDC. Bacterial Vaginosis Fact Sheet. Center for Disease Control and Prevention website. Last reviewed February 15, 2023. Accessed February 15, 2023. <https://www.cdc.gov/std/bacterial-vaginosis/stdfact-bacterial-vaginosis.htm> 10. CDC. Candida Fact Sheet. Center for Disease Control and Prevention website. Last reviewed February 15, 2023. Accessed February 15, 2023. <https://www.cdc.gov/fungal/diseases/candidiasis/genital/index.html> 11. CDC. Chlamydia Fact Sheet. Center for Disease Control and Prevention website. Last reviewed February 15, 2023. Accessed February 15, 2023. <https://www.cdc.gov/std/chlamydia/stdfact-chlamydia.htm> 12. CDC. *Mycoplasma genitalium* – CDC Detailed Fact Sheet. Center for Disease Control and Prevention website. Last reviewed December 5, 2022. Accessed June 1, 2023. <https://www.cdc.gov/std/mgen/stdfact-mgen-detailed.htm> 13. CDC. Gonorrhea – CDC Detailed Fact Sheet. Center for Disease Control and Prevention website. Last reviewed April 11, 2023. Accessed July 11, 2023. <https://www.cdc.gov/std/gonorrhea/stdfact-gonorrhea-detailed.htm> 14. Manhart L, et al. *Mycoplasma genitalium* in the US (MyGeniUS): Surveillance data from 2020-2021. Oral presentation at CDC STD Prevention Conference; Sept 19-22. 15. Jensen et al., *Mycoplasma genitalium*: prevalence, clinical significance, and transmission. *Sex Transm Infect.* 2005;81:458-462. 16. Taylor-Robinson D and Jensen JS. *Mycoplasma genitalium*: from chrysalis to multicolored butterfly. *Clin Microbiol Rev.* 2011;24(3):498-514. 17. Vandepitte J, et al. Association between *Mycoplasma genitalium* infection and HIV acquisition among female sex workers in Uganda: evidence from a nested case-control study. *Sex Transm Infect.* 2014;90(7):545-549. 18. Lis R, et al. *Mycoplasma genitalium* infection and female reproductive tract disease: a meta-analysis. *Clin Infect Dis.* 2015;61(3):418-426. 19. Le Roy C, 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. 20. Unemo 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. 21. Aptima *Mycoplasma genitalium* assay [package insert]. AW-17946, San Diego, CA; Hologic, Inc., 2022. 22. Aptima *Trichomonas vaginalis* Assay [package insert]. AW-25942, San Diego, CA; Hologic, Inc., 2023. 23. Aptima CV/TV assay [package insert]. CVTV: AW-23713, San Diego, CA; Hologic, Inc., 2023. 24. Aptima BV assay [package insert]. BV: AW-23712, San Diego, CA; Hologic, Inc., 2022. 25. Aptima Combo 2 Assay [package insert]. AW-25929, San Diego, CA; Hologic, Inc., 2023.

hologic.com | diagnostic.solutions@hologic.com | +1.888.484.4747

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Aptima® *Mycoplasma genitalium* Assay