

KNOW THE CAUSE,  
*Target*  
THE THERAPY

**Mycoplasma genitalium** –

A highly prevalent STI you can now accurately identify.

**Aptima® Mycoplasma genitalium Assay**

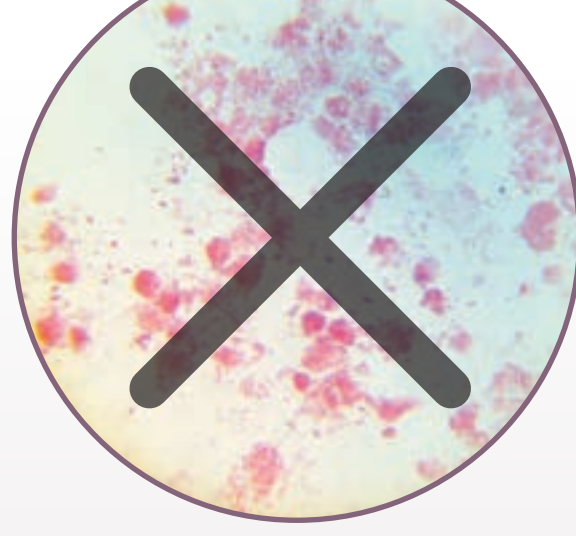
**Mycoplasma genitalium is a Highly Prevalent STI and the Test You Choose Matters<sup>1</sup>**

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



**Clinical Presentation**

can be similar to other sexually transmitted infections (STIs).<sup>2</sup>



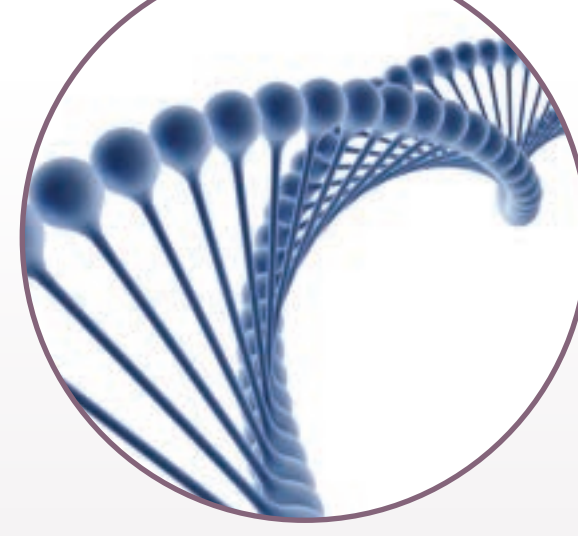
**Microscopy**

cannot be seen because M. gen has no cell wall.<sup>1</sup>



**Culture**

is not clinically feasible as it may take up to six months.<sup>1</sup>



**Nucleic Acid Amplification Test (NAAT)**

is the recommended method of detection.<sup>1,3</sup>

Trichomoniasis, Chlamydia, Gonorrhea and M. gen are Associated with Similar Clinical Presentation<sup>4-13</sup>

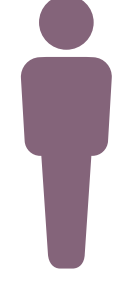
	Similar Symptoms					
	Trichomoniasis	Bacterial Vaginosis	Yeast Infection	Chlamydia	Gonorrhea	<i>Mycoplasma genitalium</i>
Abnormal Discharge	✓	✓	✓	✓	✓	✓
Vaginal Odor	✓	✓		✓	✓	✓
Vaginal Irritation	✓	✓	✓	✓	✓	✓
Pain During Urination/Sex	✓	✓	✓	✓	✓	✓

**Testing is Recommended for Women with Recurrent Cervicitis and Should Be Considered in Women with PID<sup>1</sup>**



- ▶ Prevalence of **18.3%**<sup>14</sup>
- ▶ Detected in **10%-30%** of women with clinical cervicitis<sup>15</sup>
- ▶ Identified in up to **22%** of pelvic inflammatory disease (PID) cases<sup>11,15</sup>
- ▶ Untreated PID can lead to adverse pregnancy outcomes<sup>11,15</sup>

**Testing is Recommended for Men with Recurrent Non-gonococcal Urethritis<sup>1</sup>**



- ▶ Prevalence of **16.5%**<sup>14</sup>
- ▶ More likely to exhibit symptoms of M. gen infection<sup>15</sup>
- ▶ Responsible for **40%** of persistent or recurrent urethritis in men<sup>1</sup>



May also increase the risk of HIV acquisition and transmission<sup>16,17</sup>

When patients do experience symptoms, they are similar to those associated with other urogenital tract bacterial infections.<sup>1,18</sup>

**NAAT is Needed to Detect M. gen Because the Infection Contains a Very Low Organism Load<sup>3</sup>**

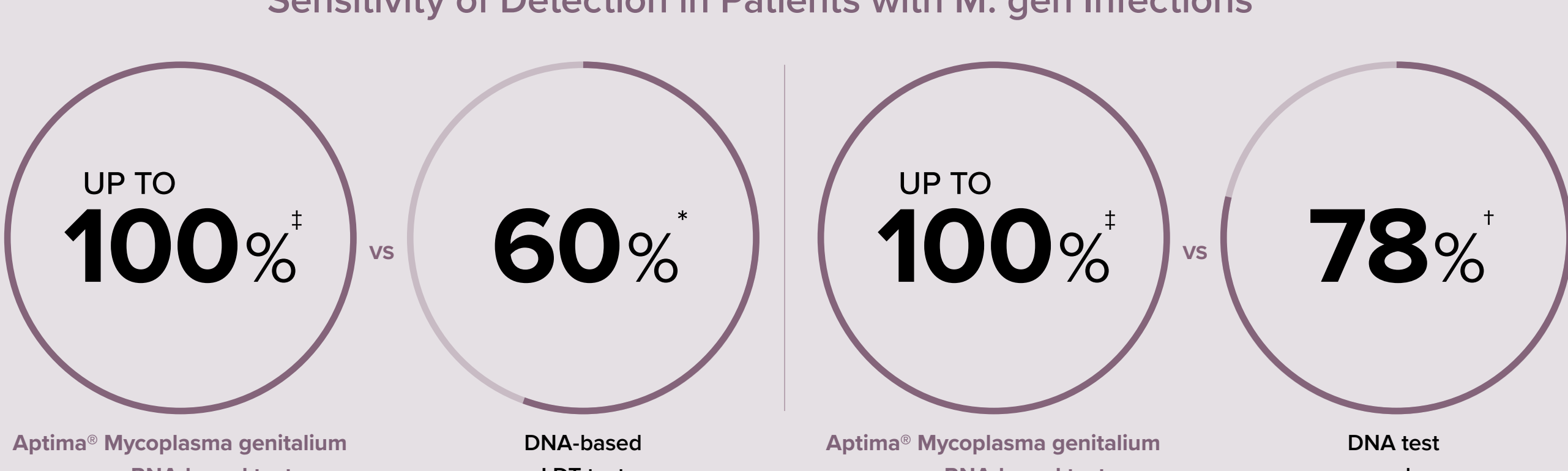
**Thousands of rRNA transcripts are present per M. gen organism**

**M. gen contains 1 copy of DNA per organism**

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

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

**Sensitivity of Detection in Patients with M. gen Infections<sup>19-21</sup>**



CDC recommends **NAATs** to detect M. gen.<sup>1</sup>

\* 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.

**Proper Diagnosis is Important to Drive the Right Treatment Decisions**

**Recommended treatments are organism-specific<sup>1</sup>**

**Trichomoniasis**

- ▶ **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

\*For persons weighing >150 kg, Ig Ceftriaxone should be administered

If chlamydial infection has not been excluded, treat for chlamydia with **Doxycycline 100 mg orally 2x/day for 7 days**

**Chlamydia**

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

**M. gen Treatment Considerations<sup>1</sup>**

**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**

**One sample. Multiple results. Maximum Efficiency.**

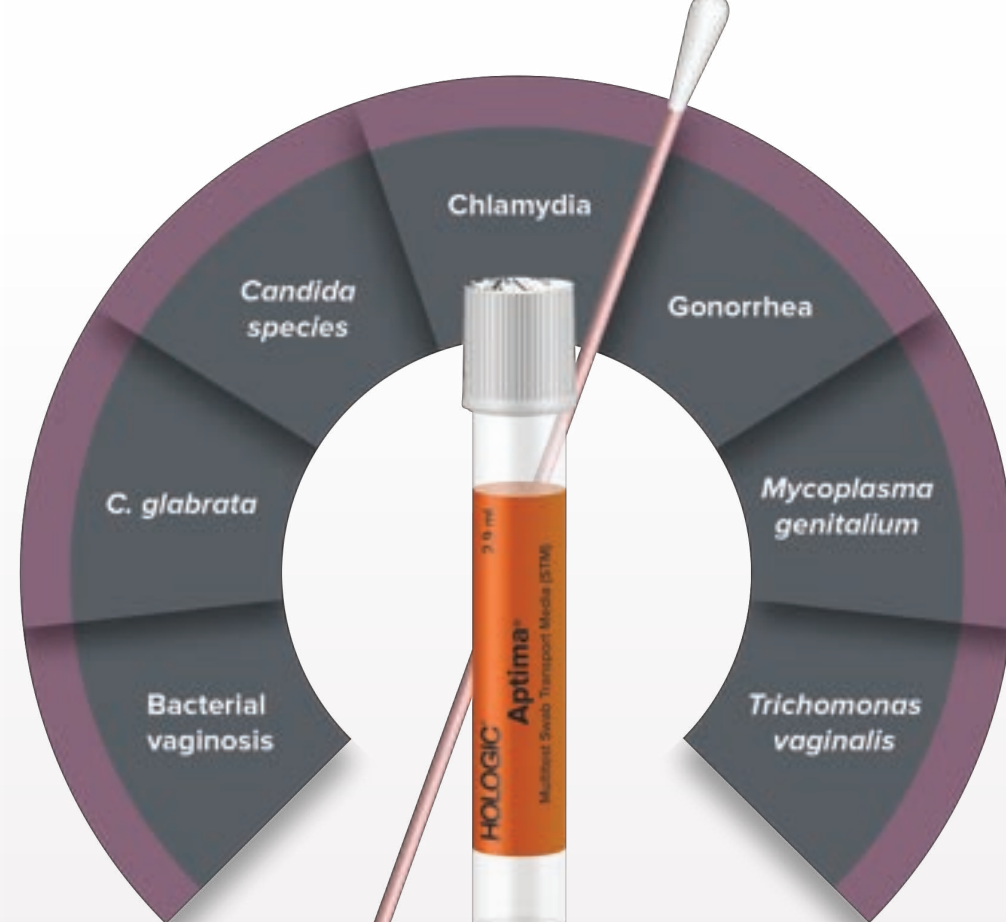
Choose the **FDA-cleared NAAT** for the detection of ribosomal RNA (rRNA) from M. gen.

**Aptima® Multitest Swab**

Detect up to **7 infections** from one sample.<sup>21-25</sup>

Vaginal swabs are the CDC preferred collection method for M.gen testing.<sup>12</sup>

- ▶ Vaginal Sample
- ▶ Penile Meatal Sample\*



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

**Specimen Alternative Collection Also Available**

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

- ▶ **Endocervical Swab**
- ▶ Endocervical swabs
- ▶ Male urethral swabs

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

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

**References:** 1. Workowski, et al. Sexually Transmitted Infections Treatment Guidelines 2021. 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(7):73-78. 3. Friuland 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 18;83(7):807-15. PMID: 21524046. 7. Bautista CT, Wurapa EK, Sateren 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/bv/stdfact-bacterial-vaginosis.htm 10. CDC. Chlamydia 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):499-514. 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.