

Setting the standard of excellence as the first fully automated test to receive both FDA and Health Canada approval for diagnostic detection of *Mycoplasma genitalium*.



Sense an elusive threat.

Mycoplasma genitalium (*M. genitalium*) is a sexually transmitted infection (STI) that poses a threat to men's and women's long-term health. The Aptima® Mycoplasma genitalium assay on the Panther® system is the first sample-to-result NAAT test that can be run alone or in conjunction with chlamydia (CT)/gonorrhea (NG) and *Trichomonas vaginalis* assays from the same sample in one run.

Now, *M. genitalium* has nowhere to hide.

Detecting a Prevalent, Overlooked STI

M. genitalium infection is often asymptomatic.³ When patients do experience symptoms, they are similar to those associated with other urogenital tract bacterial infections.⁴

- ▶ Present in up to 12% of men and women.⁵
- ▶ Responsible for 30% of persistent or recurrent urethritis in men.⁶
- ▶ Detected in 10-30% of women with clinical cervicitis.²
- ▶ Identified in up to 22% of pelvic inflammatory disease (PID) cases.²

Left Untreated, the Danger Grows

Accurate diagnosis of a suspected infection is necessary to guide proper treatment and prevent further resistance to antibiotics such as macrolides.²



20%

females or males may become infertile.²



18%

females may experience chronic pelvic pain.



9%

may have a life-threatening tubal pregnancy.

In addition to being associated with elevated risk for PID, *M. genitalium* infections may also increase the risk of HIV acquisition and transmission.^{6,7}

Enhance your STI testing services with the addition of the Aptima[®] Mycoplasma genitalium Assay.

Proven TMA Technology

Targeting RNA vs DNA improves clinical accuracy.⁸

Pinpoint the Danger

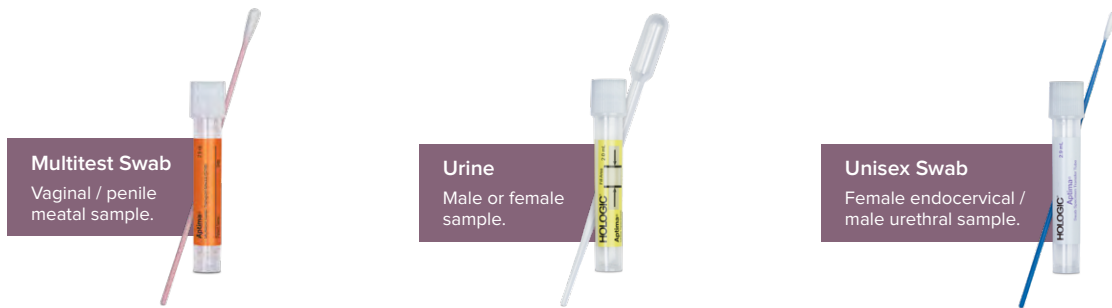
Identify *M. genitalium*, CT, and NG infections to guide effective treatment.²

Sample-to-result Automation

Process Aptima assays on Panther with minimal hands-on interaction.

One Sample, Multiple STI Results

Multiple sample types make it easy for clinicians to test for *M. genitalium*, either alone or from the same sample taken for CT/NG or *Trichomonas vaginalis* testing.*



*Refer to individual assay package inserts for cleared specimen types and performance claims.

Performance Results⁵

Sample Type	Clinician-collected vaginal swab	Patient-collected vaginal swab	Endocervical swab	Female urine	Patient-collected penile meatal swab	Male urethral swab	Male urine
Sensitivity	92.0%	98.9%	81.5%	77.8%	88.4%	98.2%	90.9%
Specificity	98.0%	98.5%	98.3%	99.0%	97.8%	99.6%	99.4%

The addition of the Aptima Mycoplasma genitalium Assay allows you to offer more complete, clinically relevant STI testing and ultimately reduces the RISK of complications related to misdiagnoses. Contact your Hologic representative for more information.

References: 1. Munson E, et al. Clinical Laboratory Assessment of Mycoplasma genitalium Transcription-Mediated Amplification Using Primary Female Urogenital Specimens. *J Clin Microbiol.* 2016;54(2): 432-438. doi:10.1128/JCM.02463-15. 2. CDC. Sexually Transmitted Diseases and Treatment Guidelines: *Mycoplasma genitalium*. <http://www.cdc.gov/std/tg2015/emerging.htm>. Updated June 4, 2015. Accessed January 8, 2019. 3. Haggerty C, et al. *Mycoplasma genitalium*: An Emerging Cause of Pelvic Inflammatory Disease. *Infect Dis Obstet Gynecol.* 2011;2011(959816). doi:10.1155/2011/959816. 4. 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;81:73-78. doi:10.1136/sti.2004.010439. 5. Aptima Mycoplasma Genitalium Assay [package insert] AW-17946, San Diego, CA; Hologic, Inc., 2019. 6. Taylor-Robinson D, et al. *Mycoplasma genitalium*: from chrysalis to multicolored butterfly. *Clin Microbiol Rev.* 2011;24(3):498-514. doi:10.1128/CMR.00006-11. 7. 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):545-9. doi:10.1136/sextrans-2013-051467. 8. Unemo M, et al. 2018. 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.* 24(5):533-539. doi:10.1016/j.cmi.2017.09.006.

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Aptima Mycoplasma genitalium Assay