CLINICAL LABS OF HAWAII

Client Communication

April 2023

Mycoplasma genitalium Assay

Effective April 24, 2023, CLH will offer the Hologic Aptima ® *Mycoplasma genitalium* NAAT Assay.

Mycoplasma genitalium (M. gen) is an emerging health concern. Testing for *M. gen* is recommended for all patients with recurrent urethritis, cervicitis and Pelvic Inflammatory Disease (PID)[1]. Both women and men with *M. gen* infections are often asymptomatic and when left untreated, this infection can result in serious health consequences.[1,2]

Because the symptoms from *M. gen* infections are very similar to those caused by *Trichomonas*, *Chlamydia*, and *Gonorrhea*, and treatment varies depending on the organism, it is imperative to accurately diagnose. For this reason, the CDC recommends nucleic acid amplification (NAAT) based assays for the detection of *M. gen*.

Clinical Labs of Hawaii (CLH) is proud to continue to offer our providers state-of-the-art testing as part of our ongoing commitment to the advancement of diagnostic care for men and women. CLH will offer the FDA-approved *M. gen* by Transcription-Mediated Amplification (TMA) technology available with the Hologic Aptima®. This RNA-based assay is proven to be 40% more accurate than DNA-based assays.[3,4,5]

With just one vaginal sample, using the Aptima® Multitest Swab Collection kit, providers can now detect up to 7 infections and disease states: *M. gen*, bacterial vaginosis, *Candida species*, *Candida glabrata*, *Trichomonas vaginalis*, *Chlamydia*, and *Gonorrhea*. Urine is the preferred specimen for men and an acceptable specimen option for women.

Mycoplasma genitalium NAAT (effective 4/24/23)			
Test Code	MGENT (4163)		
Ordering Recommendation	For the qualitative detection of *Mycoplasma genitalium* ribosomal RNA (rRNA) in vaginal or urine specimens.		
Specimen Collection	• Vaginal swab using the Aptima® Multitest Swab Specimen Collection Kit (orange label); either clinician or patient collected (in a clinical setting i.e. at the provider's clinic). *Not recommended for patients under 15 years old.* ***Do not send patients to CLH for collection.*** • First-catch urine (20-30ml). Patients should not have urinated for at least 1 hour prior to collection. Female patients should not cleanse the labial area. Submit to the lab ASAP for processing. 		
Stability after collection	*Vaginal Swab:* 30 days at room temperature or refrigerated *Urine:* 24 hours refrigerated, if submitted in a sterile cup. Submit to the lab ASAP (urine must be processed within 24 hours of collection). If the urine is transferred to an Aptima urine tube (yellow label), it is stable for 30 days room temperature or refrigerated.		
Turn-around Time	Reports in 2-4 days (performed on Mondays and Thursdays)		
Results	Qualitative		
Reference Range	Negative		
Methodology	TMA (transcription-mediated amplification)		
CPT Codes	87563 (Pre-certification/authorization may be required based on the patient's insurance plan)		
Sensitivity and Specificity	**Reported Result:**	**Sensitivity (%)**	**Specificity (%)**
	Vaginal, Client collected	92.0	98.0
	Vaginal, Patient collected	98.9	98.5
	Urine, male	90.9	99.4
	Urine, female	77.8	99.0

References:

1. Workowski, et al. Sexually Transmitted Infections Treatment Guidelines 2021. MMWR Recomm Rep 2021;70.

2. Jensen et al., Mycoplasma genitalium: Prevalence, Clinical Significance, and Transmission. Sex Transm Infect 2005;81:458-462.

https://www.update.com/contents/mycoplasma-genitalium-infection-men-and-women.

4. Kent H.L. Epidemiology of Vaginitis.

5. Frolund M, et al. Urethritis-associated Pathogens in Urine from men with Non-gonococcal Urethritis: A Case-control Study. Acta D.erm Venereol. 2016;96(5):689-694.

If you have any questions, please contact our Client Services Department at 808-677-7998 (Oahu) or 1-866-281-6816 (toll-free).

Thank you for choosing Clinical Labs of Hawaii