CLINICAL LABS OF HAWAII

Client Communication

April 2023

Vaginitis Testing

Effective April 24, 2023, CLH will offer the Hologic Aptima ® Vaginitis Panel.

Vaginitis is the leading cause for OBGYN visits with the vast majority (90%) caused by bacterial vaginosis (BV), candida vaginitis (CV), and *Trichomonas vaginalis* (TV), either individually or in combination.[1,2] Untreated BV and TV infections can lead to increased risk for complications associated with acquisition of sexually transmitted infections (including *Chlamydia trachomatis,CT*, *Neisseria gonorrhea,NG*, *Mycoplasma genitalium*, HPV and HIV), Pelvic Inflammatory Disease, cervicitis, and pregnancy-related concerns such as premature delivery and low birth weight.[3]

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 women. CLH will offer the FDA-approved Vaginitis Panel by Transcription-Mediated Amplification (TMA) technology available with the Hologic Aptima®.

Benefits:

- **Nucleic Acid Amplification Test (NAAT) technology recommended by the CDC and ACOG for the diagnosis of TV and BV[3,4]**
- **Excellent sensitivity and specificity with state-of-the-art amplified probe technology**
- **One simple collection- one swab to test for BV, *Candida species*, *C. glabrata* and TV**
- **The Aptima® Multitest Swab Specimen Collection Kit is also approved for CTNG and *Mycoplasma genitalium* collection and testing (which presents similarly to other STIs and are frequently reported as coinfections[6])**
- **An objective, comprehensive and qualitative method for diagnosing the cause of vaginitis**
- **Approved for clinician collection or self-collection (in a clinical setting i.e. at the provider's clinic)**
- **Longer sample stability, 30 days, should re-testing be necessary**

Test information

Vaginitis Panel NAAT (effective 4/24/23)	
Test Code	VAGPAN (4391)
Ordering Recommendation	For the qualitative detection of BV, *Candida species*, *Candida glabrata*, and TV ribosomal RNA (rRNA) in vaginal specimens.
Specimen Collection	 Vaginal swab using the Aptima® Multitest Swab Specimen Collection Kit (orange label); either clinician or patient collected (in a clinical setting ie at the provider's clinic). Not recommended for patients under 14 years old. ***Do not send patients to CLH for collection.***

Stability after collection	30 days at room temperature or refrigerated
Turn-around Time	Reports in 1-2 days (performed Monday to Friday)
Results	Qualitative
Reference Range	Negative
Methodology	TMA (transcription-mediated amplification)
CPT Codes	81513, 87481x2, 87661
Vaginitis Panel test information	➢ **Bacterial vaginosis** ▪ *targets Lactobacillus (L. gasseri, L. crispatus, L. jensenii), Gardnerella vaginalis, and Atopobium vaginae** **A. vaginae is highly specific for BV and rarely occurs in the absence of G. vaginalis suggesting synergism between these microorganisms. Women with G. vaginalis and A. vaginae have higher rates of recurrent BV than women with G. vaginalis alone.*[5] ➢ ***Candida species*** ▪ *targets C. albicans, C. tropicalis, C. parapsilosis, and C. dubliniensis* ➢ ***C. glabrata*** ▪ *reported separately because it could be azole-resistant and may require alternative treatment* ➢ ***Trichomonas vaginalis***

Sensitivity and Specificity	**Reported Result:**	**Sensitivity (%)**	**Specificity (%)**
	BV (clinician collected)	95.0	89.6
	BV (patient collected)	97.3	85.8
	Candida species (clinician collected)	91.7	94.9
	Candida species (patient collected)	92.9	91.0
	Candida glabrata (clinician collected)	84.7	99.1
	Candida glabrata (patient collected)	86.2	98.7
	TV (clinician collected)	96.5	95.1
	TV(patient collected)	97.1	98.9

Reference methods: BV: Nugent score and Amsel criteria. CV: culture and bi-directional sequencing. TV: FDA-cleared NAAT and Inpouch culture.

CLH will discontinue the BD Affirm test code (XAFFIR) for vaginitis testing on April 24, 2023 and the Affirm kits will no longer be accepted. Please contact your CLH representative to request the Aptima® Multitest Swab Specimen Collection Kit as soon as possible.

References:

1. Aptima BV Assay [package insert]. AW-18811, San Diego, CA; Hologic, Inc., 2020
2. Aptima CV/TV Assay [package insert]. AW-18812, San Diego, CA; Hologic, Inc., 2020
3. Workowski, et al. Sexually Transmitted Infections Treatment Guidelines 2021. MMWR Recomm Rep 2021;70.
4. Committee on Practice Bulletins- Gynecology. Vaginitis in Nonpregnant Patients: ACOG Practice Bulletin, Num 215. Obstet Gynecol. 2020;135(1):e1-e17.
5. Muzny CA, et al. An Updated Conceptual Model on the Pathogenesis of Bacterial Vaginosis. J Infect Dis. 2019 Sep 26;220(9):1399-1405. doi:10.1093/infdis/jiz342
6. Gaydos C., et al. Molecular Testing for Mycoplasma genitalium in the United States: Results from the AMES Prospective Multicenter Clinical Study. J Clin Microbiol. 2019;57(11): e01125-19. Published 2019 Oct 23. doi:10. 1128/JCM.01125-19.

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.