ACL Laboratories Converts Vaginal Pathogens to Hologic® Aptima® Assays

October 2021

Effective Wednesday, October 20, 2021, ACL Laboratories will convert Vaginal Pathogens testing to one standardized platform on the Hologic® Panther® System.

Hologic® Aptima® assays have the most sensitive and specific assay available on the market. They also provide the lowest false positive and false negative rates, assuring more accurate patient management care reducing multiple physician office visits and re-testing. Hologic's increased specificity will support timely diagnosis and effective treatment. The Aptima® assays use the same Aptima® collection devices used for other vaginal health assays; thereby, reducing the amount of collection devices a Provider must keep in their inventory.

Effective Wednesday, October 20, 2021

Vaginal Pathogens (Test Order Code VAGPTH) – consists of Candida species, Gardnerella vaginalis and Trichomonas vaginalis – **will be deactivated.**

The following tests **will replace Vaginal Pathogens (Test Order Code VAGPTH):**

- **SwabOne™ Vaginitis Panel by NAA (Test Order Code LAB9961 / SWOPNL) – 5 results:**
  - Bacterial Vaginosis
  - Candida species
  - Candida glabrata
  - Trichomonas vaginalis
  - Mycoplasma genitalium

- **SwabOne™ Bacterial Vaginosis by NAA (Test Order Code LAB9957 / SWOBV) – 1 result:**
  - Bacterial Vaginosis (detecting presence of *Atopobium vaginae, Gardnerella vaginalis and Lactobacillus spp.*)

- **SwabOne™ Candida/Trichomonas Panel by NAA (Test Order Code LAB9958 / SWOCN) – 3 results:**
  - Candida species (detecting presence of candida *albicans, dubliniensis, tropicalis, parapsilosis)*
  - Candida glabrata
  - Trichomonas vaginalis

- **SwabOne™ Mycoplasma genitalium by NAA (Test Order Code LAB9960 / SWOMG) – 1 result:**
  - Mycoplasma genitalium

Providers may begin ordering any of the above tests now using Aptima® collection device listed below.

ACL Laboratories SwabOne™ testing menu is based on FDA approved TMA reagents from Hologic®. The assays are validated using Aptima® Multi-Test swabs, Aptima® UniSex swabs and Aptima® Urine collection kits. Please see ACL Laboratories Directory of Services (https://acllaboratories.com/providers/test-directory/) for specific collection and source information.

Aptima® Muti-Test swabs are acceptable for all 4 SwabOne™ assays with collection source of vaginal.

Aptima® Unisex swabs are acceptable for all 4 SwabOne™ assays with collection source of vaginal when the Aptima® Multi-Test swab is not available.

Also acceptable for **SWOMG** with **male urethral** collections.

Aptima® Urine collection kits are acceptable only for **SWOMG** for both male and female voided urine collections.

The BD Affirm collection device is ***not*** an acceptable specimen type according to the FDA requirement for the SwabOne™ Vaginal Health assays. As a result, **effective Wednesday, October 20, 2021**, specimens collected using BD Affirm VPIII swab **will be rejected *and* will need to be recollected** using Aptima® collection devices.

If you have questions or need additional information, please contact:
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