Vaginitis Screen-Important Information for Clinicians (LTR83220)

Last Approved Time: 04/02/2024 **Revision: 1.10**

Background and Interpretation

- Performance of the assay has not been evaluated in women ≤ 13 years of age.
- Reliable results are dependent on adequate specimen collection, transport, storage, and processing.
- Collection and testing of patient-collected vaginal swab specimens with the assay is not intended to replace clinical examination. Vaginal infections may result from other causes or concurrent infections may occur.
- Interference with the assay was observed in the presence of the following substances:
  - Tioconazole 6.5% Ointment (3% W/V, all analytes)
  - Vaginal Moisturizing Gel (1% W/V, *Candida* spp; 5% W/V, *C. glabrata* 3% W/V, TV)
  - Glacial Acetic Acid (5% V/V, *Candida* spp only)
  - Excessive vaginal mucus
  - The effectiveness of all medication and topical agents has not been exhaustively researched
- Low levels of *C. glabrata* may be masked by high level of *Trichomonas vaginalis*.
- Therapeutic failure or success cannot be determined with the APTIMA molecular vaginitis panel since nucleic acid may persist following appropriate antimicrobial therapy.
- *Candida* species are normal urogenital flora and frequently detected as part of a health microbiome. Correlate *Candida* results with clinical picture. The test performance for each target is as follows (refer to reference or manufacturer):

Organism	Sensitivity	Specificity
Bacterial vaginosis (BV)	95.0%	97.3%
Candida species group	91.7%	94.9%
Candida glabrata target	84.7%	99.1%
Trichomonas vaginalis (TV)	96.5%	95.1%

- Other organisms associated with bacterial vaginosis and similar conditions such as *Prevotella*, *Mobiluncus, Mycoplasma* and *Ureaplasma* are not examined by these assays.
- Invalid results can, and do, occur due to interfering substances.
  - Recollection is recommended if signs and symptoms warrant repeat-testing
  - Invalid rates of 0.7% – 1.7% are expected with this test
- *Candida famata* can produce cross reactivity with the Candida/TV assay component
- *Lactobacillus acidophilus* can produce cross reactivity with the BV assay component