Associated Pathologists/PathGroup Labs is now offering the BD Affirm VPIII test for Vaginitis/Vaginosis. This test is available for samples collected using BD Affirm Ambient Temperature transport swabs and ThinPrep collected specimens.

Vaginitis, one of the most common problems in clinical medicine, accounts for more than 10 million office visits each year. The three main categories of vaginitis are bacterial vaginosis (BV), yeast vaginitis (candidiasis) and T. vaginalis vaginitis (trichomoniasis). BV is the most common vaginal infection, and accounts for 15 to 50% of vaginitis/vaginosis depending upon the patient population. The complications of BV can be especially significant in pregnant women, resulting in increased risk of adverse pregnancy outcome, including pre-term labor and birth. Vaginal candidiasis is the second most common form of vaginal infection seen in varied clinical settings. Three quarters of all adult women will experience at least one episode of vaginal candidiasis during their lifetime, with 40 to 50% experiencing a second episode. Approximately 5% of the adult female population suffers from recurrent, often intractable yeast infection. Trichomoniasis, a non-reportable sexually transmitted disease, has been estimated to affect 180 million annually worldwide. In the United States, an estimated 3 million women contract trichomoniasis each year. Pregnant women positive for T. vaginalis are more likely to have pre-term rupture of membranes, as well as pre-term labor and birth. T. vaginalis is a risk factor for the development of post-surgical gynecologic infections.

The BD Affirm VPIII Vaginitis/Vaginosis Panel detects the presence of Candida species (C. albicans, C. glabrata, C. kefyr, C. krusei, C. parapsilosis, C. tropicalis), Trichomonas vaginalis and Gardnerella vaginalis. Simultaneous infection by more than one organism is common.

This panel is available for specimens collected using BD Affirm Ambient Temperature Transport Swabs or ThinPrep™ cytology collection system. BD Affirm Ambient Temperature Transport Swabs will provide the highest sensitivity, specificity and predictive values. The panel has been validated for ThinPrep™ collected specimens by PathGroup Labs.
Clinical Utility

- Diagnostic screening for the presence of *Candida* sp., *T. vaginalis* and *G. vaginalis* when consistent with clinical signs and symptoms.

**Methodology:** BD Affirm VP III (DNA probe hybridization)

**Test Codes:** AVP

**CPT Codes:** 87480 (*Candida* species), 87660 (*Trichomatis vaginalis*), 87510 (*Gardnerella vaginalis*)

**Specimen Collection:** BD Affirm Ambient Temperature Transport Swabs or ThinPrep™ collected cytology specimens.

**Ordering the Tests(s):** On the bottom of an Associated Pathologists Cytology requisition, on the lines above the word, “Confidential”, write boldly in all caps, “DO VAGINITIS PANEL.” (If entire panel is not wanted request individual test(s) by writing boldly in all caps, “TEST FOR CANDIDA, TRICH, and/or GARDNERELLA”.)

**Shipping and Handling:** Room temperature storage and transport. BD Affirm Ambient Temperature Transport Swabs must be received within 72 hours of collection.

**Reference Ranges:** Not detected for all organisms

**Analytic Performance:** From the BD Affirm Package Insert (FDA-cleared):

- **Candida sp.**: Sensitivity 80.6%, Specificity 98.2%, compared to culture
- **G. Vaginalis**: Sensitivity 83.8%, Specificity 100%, compared to gram stain
  - Sensitivity 89.0%, Specificity 99.1%, compared to culture
- **T. vaginalis**: Sensitivity 92.8%, Specificity 99.9%, compared to wet mount
  - Sensitivity 89.6%, Specificity 99.9% compared to culture

**Turnaround Time:** Next Day

**References**