Vaginal Pathogens Panel
Implementation – February 17, 2025

To Our Valued Providers & Staff

Salem Health Laboratories is pleased to announce a new test for the qualitative detection of bacteria and yeast associated with bacterial vaginosis/vaginitis (BV) and vulvovaginal candidiasis (VVC) and trichomonal vaginitis (TV). The new test uses PCR-based technology to detect DNA of bacteria and yeast associated with BV, VVC, and TV. This test is intended as an aid in the diagnosis of BV, VVC, and TV. This test will replace the current DNA probe test, Vaginitis/Vaginosis by DNA Hybridization (LAB70640 – BD Affirm). The new test will be called: **Vaginal Pathogens Panel (LAB7147 – Xpert Xpress MVP).**

Specimen Collection

- Swabs can be collected by the health care provider or by patient self-collect.
- The Multiplex Vaginal Panel will require a different sample collection kit from the current Vaginitis/Vaginosis assay. **The new assay is compatible only with vaginal specimens collected with the Xpert Swab Specimen Collection kit (Catalog Number: SWAB/G-50-US).**
- For transport, use the Xpert Swab Transport Reagent tube included in the Xpert Swab Collection kit.
- See attached collection instructions for:
    - Vaginal – Clinician Collection
    - Vaginal – Self-collection

Specimen Acceptability Requirements and Appropriate Transport

Sample Type(s): Vaginal Swab collected using the Xpert Swab Specimen Collection kit
Volume: Single Swab in Xpert Swab Transport Reagent tube
Transport Container: Xpert Swab Transport Reagent tube
Transport: Room temperature or refrigerated 2-28°C
Sample Stability: 42 days
Storage: Room temperature or refrigerated 2-28°C

Specimen Retention

7 days

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How to Order

Test Name: Vaginal Pathogens Panel
Test Code: LAB7147
CPT Code: 81515
Synonyms: MVP, Vaginosis, Vaginitis, Trichomonas, Trichomonas vaginalis

Specimen Rejection Criteria

- Unlabeled specimens
- **Sources other than vaginal** (All other sources will be rejected)
- Use of other swabs other than the one in the kit is **NOT** acceptable
- Transport swabs only in the Xpert Swab Transport Reagent tube (included with collection kit). **Do not transport swabs in saline or any other preservative.**

Test Location and Turn-Around-Time (TAT)

Test Location: Salem Health Priority Lab – Molecular; West Valley Lab – Molecular
Days Performed: Daily
TAT: 75 minutes

Test Methodology

Real-Time Polymerase Chain Reaction (PCR). Qualitative Results Only.

- Bacterial Vaginosis: Detected or Not Detected
- Candida spp: Detected or Not Detected
- Candida glabrata/krusei: Detected or Not Detected
- Trichomonas vaginalis: Detected or Not Detected

Reference Range

- Bacterial Vaginosis: Not Detected
- Candida: Not Detected
- Candida glabrata/krusei: Not Detected
- Trichomonas vaginalis: Not Detected

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Result Interpretation

One major difference between the Vaginal Pathogens Panel and the (LAB7147 – Xpert Xpress MVP) and the Vaginitis/Vaginosis by DNA Hybridization (LAB70640 – BD Affirm) is the detection targets used to determine if a sample is positive for bacterial vaginosis (BV) and vulvovaginal candidiasis (VVC).

First is the *Gardnerella vaginalis* target, which was used to determine if a sample was positive for bacterial vaginosis. The equivalent to this target is the Bacterial Vaginosis target, which uses an algorithm to determine if a sample is positive for bacterial vaginosis. Rather than relying on a single bacterial target, the algorithm used in the Vaginal Pathogens Panel looks for several bacterial targets that are consistent with a diagnosis of bacterial vaginosis.

The other change in detection targets is the *Candida* target. On the BD Affirm test, there was a single *Candida* target. On the new Vaginal Pathogens Panel, there will be two *Candida* targets. These two targets will be the *Candida spp* target and the *Candida glabrata/krusei* target. The *Candida spp* target and the *Candida glabrata/krusei* target will detect several *Candida* species that are associated with VVC (*Candida albicans, C. tropicalis, C. parapsilosis, C. dubliensis, C. glabrata, C. krusei*). Not that the test does not differentiate between the various *Candida* species.

Bacterial Vaginosis*	**Candidiasis**	**Trichomoniasis**
Atopobium spp. *(Atopobium vaginae, Atopobium* novel species *CCUG 55226)* BVAB2 *Megasphaera-1*	*Candida spp.* *(C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis;* species not differentiated) *Candida glabrata/Candida krusei* species not differentiated))	*Trichomonas vaginalis*

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Sensitivity & Specificity

The Vaginal Pathogens Panel has an advantage over the BD Affirm in the detection of bacterial vaginosis (BV), vulvovaginal candidiasis (VVC), and trichomonal vaginitis (TV). The Vaginal Pathogens Panel uses PCR-based technology compared to the DNA-probe technology of the BD Affirm.

In a study published in the Journal of Clinical Microbiology, PCR-based methods detected BV with a sensitivity of 96.9% and specificity of 92.6%. The BD Affirm detected BV with a sensitivity of 90.1% and 67.6% specificity. For VVC, the same study found that PCR-based methods had a 97.7% sensitivity and 93.2% specificity, and that the BD Affirm had a 58.1% sensitivity and 100% specificity. For TV, the study found that PCR-based methods had a sensitivity of 98.1% versus 46.3% for the BD Affirm.

Testing Questions?

Please contact the Salem Health lab for any testing questions at:
Main Campus (Priority Lab) #: (503)-814-3130
West Valley Hospital Lab #: (503)-623-7303
Regional Lab #: (503)-814-1662
Client Services Phone #: (503)-814-5227

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Collection Changes

The Vaginal Pathogens Panel will use a different collection device compared to the BD Affirm assay. See images below for examples of the new collection device for the Vaginal Pathogens Panel, and the old collection device for the BD Affirm assay.

Vaginal Pathogens Panel Collection Device:

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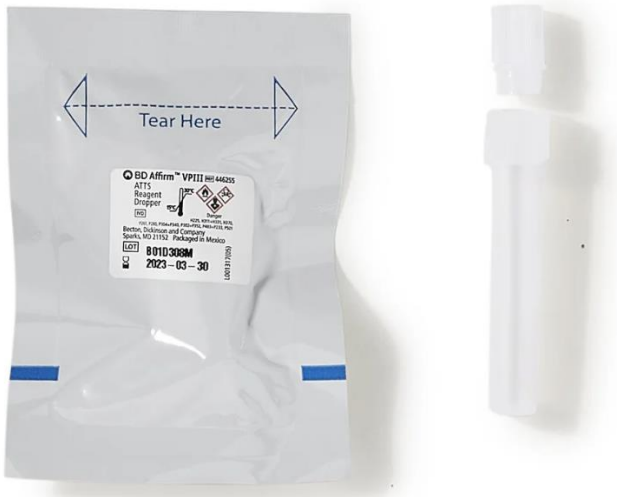
Collection Changes

BD Affirm Collection Device:

This collection device will no longer be in use as the BD Affirm assay will no longer be offered after the switch over to the Vaginal Pathogens Panel.



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