Introducing the Amplified BD MAX™ Vaginal Panel

March 2019: *Rochester Regional Health Laboratories now offers the BD MAX™ Vaginal Panel, an amplified PCR-based alternative to the BD Affirm™ VPIII Vaginitis test. The BD MAX™ Vaginal Panel is a highly sensitive molecular assay that is intended to aid in the diagnosis of vaginal infections in women with a clinical presentation of bacterial vaginosis, vulvovaginal candidiasis and/or trichomoniasis. Due to a significantly higher cost, this test is not recommended for 1st line testing, but may be a preferred option for recurrent or persistent cases of vaginitis. (See Laboratory Evaluation of Vaginitis Algorithm for further guidance).*

Clinical Background:

Vaginitis is one of the most common problems in women's health. The three main infectious causes include bacterial vaginosis (BV), yeast vaginitis (candidiasis) and *T. vaginalis* vaginitis (trichomoniasis).

Bacterial vaginosis, a common cause of vaginal discomfort, is associated with late-term miscarriages, premature rupture of membranes and preterm birth. BV is strongly linked with an increased acquisition risk of human immunodeficiency virus (HIV) and other sexually transmitted diseases and is associated with a high incidence of endometritis and pelvic inflammatory disease following gynecologic procedures. This laboratory diagnosis of BV can be made by measuring the relative abundance of the vaginal microbiome. Hydrogen-peroxide producing *Lactobacillus* species are important members of the normal vaginal flora and are found in decreased amounts in patients with BV. Additionally, there is an increase in anaerobes such as *Atopobium vaginae* and *Gardnerella vaginalis*. Colonization also occurs with non-cultivable anaerobe organisms such as BVAB-2 and *Megasphaera*-1. Taken together, the relative abundance and diversity of these microorganisms in a vaginal sample are diagnostic for bacterial vaginosis.

Episodes of vulvovaginal candidiasis are most commonly caused by *Candida albicans*, however, up to 30% of cases may be caused by *Candida* species other than *C. albicans.* Among these species, the most frequently reported in cases of vulvovaginal candidiasis are *C. glabrata, C. parapsilosis* and *C. tropicalis.* Importantly, *C. glabrata* and *C. krusei* are the main *Candida* species that can be resistant to fluconazole-based antifungal therapy. Aside from significant vaginal discomfort and discharge, complications of vulvovaginal candidiasis are rare.

Trichomoniasis, caused by *Trichomonas vaginalis*, is one of the most common sexually transmitted infections worldwide with over 170 million cases per year. Trichomoniasis is associated with adverse events such as preterm birth, delivery of a low-birth weight infant and facilitation of sexual transmission of HIV.

Historically, the diagnosis of BV was based on clinical symptoms, scoring by Nugent or Amsel criteria and more recently by the BD Affirm™ VPIII probe-based detection of *Gardnerella.* Vulvovaginal candidiasis can be diagnosed by clinical symptoms and elevated levels of Candida species may be detected using the BD Affirm™ VPIII. Trichomoniasis is detected using wet preps, culture or antigen detection. However, these methods may lack sensitivity, can suffer from observer variation and may provide only limited information on the causes of vaginitis. These limitations may be overcome by using an amplified PCR-based assay with increased sensitivity and the ability to differentiate organisms that are common causes of vaginitis.

About the BD MAX™ Vaginal Panel

The BD MAX™ Vaginal Panel performed on the BD MAX™ System is an automated *in vitro* diagnostic test for the direct detection of DNA targets from bacteria associated with bacterial vaginosis, *Candida* species associated with vulvovaginal candidiasis, and *Trichomonas vaginalis* from vaginal swabs in patients who are symptomatic for vaginitis/vaginosis. This assay provides a more comprehensive analysis of the vaginal microbiota when compared with other diagnostics used for vaginitis. The BD MAX™ Vaginal Panel utilizes real-time polymerase chain reaction (PCR) for the amplification of specific DNA targets and utilizes fluorogenic target-specific hybridization probes to detect and differentiate DNA from:

- **Bacterial Vaginosis Indicator Bacteria** (Individual organisms are not reported):
  - *Lactobacillus* spp. (including *L. crispatus* and *L. jensenii*)
  - *Gardnerella vaginalis*
  - *Atopobium vaginae*
  - Bacterial Vaginosis Associated Bacteria-2 (BVAB-2)
  - *Megasphaera-1*
- **Species associated with vulvovaginal candidiasis:**
  - *Candida* species including *C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis*
  - *Candida glabrata*
  - *Candida krusei*
- ***Trichomonas vaginalis***

Important FAQs about the new BD MAX™ Vaginal Panel:

Q: ***How do I order the new BD MAX™ Vaginal Panel?***

A: The BD MAX™ Vaginal Panel can be ordered in CareConnect by selecting the test "*Vaginal Panel, Amplified (Second Line Testing)".* Providers not using CareConnect can order Test Code 10626 (VGPAA), "Vaginal Panel, Amplified."

Q: ***My office orders the BD Affirm™ VPIII Vaginitis Test. Is there a difference in the collection supply that I will need for the BD MAX™ Vaginal Panel?***

A: ***Yes.*** The BD MAX™ Vaginal Panel requires its own dedicated collection device called the BD MAX™ UVE Specimen Collection Kit. The kit is designed with a collection swab and specialized buffer to stabilize the organisms of the vaginal microbiome. Specimens submitted in any other transport device cannot be used for the BD MAX™ Vaginal Panel.

The BD MAX™ UVE Specimen Collection kit can be provided through your usual Rochester Regional Health Laboratories supply process.
Please note: The BD™ MAX UVE Specimen Collection kit is also supplied with a transfer pipette, which is not used for this collection and should be discarded.

Q: ***What are the major benefits for performing the BD MAX™ Vaginal Panel?***
A: There are several major benefits to performing the BD MAX™ Vaginal Panel, especially in the small percentage of patients who do not respond to therapy based on 1st line testing (eg. recurrent, persistent vaginitis). First, the BD MAX™ Vaginal Panel is significantly more sensitive than the BD Affirm™ VPIII test, especially for trichomoniasis since it is a PCR-based amplification method. Second, the quantification of five members of the vaginal microbiome increases the specificity for diagnosing BV, in comparison to the BD Affirm™ VP III test, which only detects Gardnerella. Finally, the differentiation of Candida krusei (which is intrinsically resistant to fluconazole) and C. glabrata (which may be resistant to fluconazole) from other Candida species can ensure appropriate antifungal therapy is administered.

Q: ***Are there any reasons that I might not want to order the BD MAX™ Vaginal Panel?***
A: Yes, this test is expensive and may not be necessary in most patients. Patients may incur this higher cost as a full or partial out-of-pocket expense if they have a co-pay, have not met their deductible or are self-pay. Even when covered by insurance, this higher test cost impacts total community healthcare spend.

Q: ***Can I still order the BD Affirm™ VPIII Vaginitis Test? What specimen do I collect?***
A: ***Yes.*** The BD Affirm™ VPIII Vaginitis Test is still available and is the preferred first-line testing for vaginitis. Vaginal specimens collected with the Pink Starplex® Swab or the VP Affirm™ ATTS system will be tested with the BD Affirm™ VPIII Vaginitis Test. Any specimen that is collected using the BD MAX™ UVE Specimen Collection Kit can only be tested with the BD MAX™ Vaginal Panel.

Test Information: Vaginal Panel, Amplified (2nd Line Testing)

Alternate Test Name:	Vaginosis, Vaginitis, Vaginal Panel, Amplified
Test Number:	10626
Department:	Microbiology
SPECIMEN COLLECTION REQUIREMENTS	
Collection Container:	BD MAX™ UVE Specimen Collection Kit *(shown here)*  **** Note: The dispensing pipette is NOT used in this collection scheme.**
Collection Notes:	○ Collect swab prior to pelvic, speculum or bimanual exam. ○ **No lubricant** is to be used before or during sample collection. ○ Use only the provided BD MAX™ UVE Specimen collection kit. ○ Gently slide the swab 2 inches (5cm) into the vagina. Avoid the posterior fornix. ○ If the swab does not slide easily, gently rotate the swab as you push. If it is still difficult, do not attempt to continue. ○ Rotate the swab for 10 to 15 seconds. ○ Withdraw the swab **without** touching the skin outside the vagina. ○ Insert the swab into the BD MAX™ UVE Buffer. ○ Break the swab shaft **only** at the pre-scored mark and cap the BD MAX™ UVE Buffer tube tightly. ○ Ensure that the ring of 2-D barcodes at the bottom of the UVE Buffer tube is **not** obscured by any labels.
Transport Temperature:	Room Temperature
Specimen Volume:	Not applicable
Also Acceptable:	Only vaginal specimens collected in the BD MAX™ UVE Specimen Collection Kit may be used.
TECHNICAL SPECIFICATIONS	
Performed:	Monday-Sunday
Reported:	Next day
Methodology:	Polymerase Chain Reaction (PCR)
CPT:	87801, 87661, 87481 (x3)
LOINC:	74635-4, 72481-5, 69563-5, 72389-0, 62461-9
Stability:	Room temperature: 8 days Refrigerated: 14 days
Reference Range:	Trichomonas DNA: Not Detected Candida Group DNA: Not Detected Candida glabrata DNA: Not Detected Candida krusei DNA: Not Detected Bacterial vaginosis: Not Detected
Notes:	The dispensing pipette is NOT used in this collection scheme. Use only the swab provided for sample collection.

Questions regarding the analytical and clinical performance of this testing should be directed to Suzanne E. Dale, PhD, D(ABMM), Director, Microbiology and Molecular Diagnostics, p: (585) 429-2360. All other inquiries for this testing may be directed to Customer Service at Rochester Regional Health Laboratories, p. (585) 922-LABS.

	NEW BD MAX™ Vaginal Panel, 2nd Line Testing (Amplified PCR-Based Assay) ***Recommended Use: Recurrent or Persistent Cases of Vaginitis***		*ADVANTAGES of NEW Panel*	Older BD Affirm™ VPIII Vaginitis Test (Non-Amplified Probe-Based Assay) **Recommended Use: First Line Screening for Etiologies of Vaginitis**	
	Organisms Detected	**Report: Detected / Not Detected**		**Organisms Detected**	**Report: Positive / Negative**
Bacterial Vaginosis	▪ *Lactobacillus* species (*L. crispatus* & *L. jensenii*) ▪ *Gardenerella vaginalis* ▪ *Atopobium vaginae* ▪ Bacterial vaginosis associated bacteria- 2 (BVAD-2) ▪ Megasphaera-1	Bacterial vaginosis DNA	The BD MAX Vaginal provides a more comprehensive analysis of the vaginal microbiome compared to the BD Affirm VPIII Vaginitis Test. Decreases in Lactobacilli and increases in anaerobic flora are associated with BV.	*Gardnerella vaginalis* (Detects increases in Gardnerella vaginalis)	Positive / Negative
Candidiasis	▪ Candida group (*C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis*)	Candida group DNA		Candida species (Detects significant levels of *C. albicans, C. glabrata, C. kefyr, C. krusei, C. parapsilosis, C. tropicalis*)	Positive / Negative
	▪ *C. glabrata*	C. glabrata DNA	Identifies organisms which may be resistant to fluconazole. Azole-based therapies may be ineffective.		
	▪ *C. krusei*	C. krusei DNA	C. krusei is intrinsically resistant to fluconazole.		
Trichomonas vaginalis	▪ *T. vaginalis*	Trichomonas DNA	Uses real-time PCR to amplify DNA from T. vaginalis. Up to 50% more sensitive than the BD Affirm assay for the detection of Trichomonas.	*T. vaginalis* (Detects *Trichomonas vaginalis* DNA with a limit of detection of 5,000 Trichomonads)	Positive / Negative
COST	Insured: Covered by Most Payers Self Pay: $$$$ Please contact RRHL for more information.			Insured: Covered by Most Payers Self Pay: $$$ Please contact RRHL for more information.	