► BD MAX™ Vaginal Panel

How can you achieve

IMPACT?

"Tests that take hours as opposed to days ... will have a positive patient impact."

Scientific Director of the Esoteric Testing/R&D Department Tampa General Hospital

Expand your lab's molecular testing potential

- **Workflow efficiency** for timely patient management[1]
- Diagnostic **speed and accuracy** to aid in fast, appropriate treatment[1]
- Testing **versatility** for a wide range of patients[1]

Visit moleculardiagnostics.bd.com to find out how

BD MAX™ System

BD

Elevate the standard of care Introducing the BD MAX™ Vaginal Panel

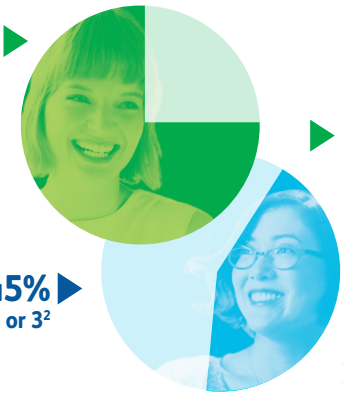
The first microbiome-based, polymerase chain reaction (PCR) assay that directly detects the 3 most common infectious causes of vaginitis[1]

- Bacterial vaginosis, vulvovaginal candidiasis, and *Trichomonas vaginalis*[1]
- Maximize efficiency with 1 collection, 1 test for the 3 most common infectious causes of vaginitis
- Supports antimicrobial resistance initiatives by reporting *Candida krusei* and *C. glabrata*

Why change?

Traditional diagnostics leave up to 40% of women with vaginitis undiagnosed after an initial clinical visit.[2] The BD MAX™ Vaginal Panel provides more complete, accurate detection,[1] to help more patients.

Significant prevalence. Severe complications.



Up to 75% of women experience at least one case of VVC*, TV** or BV† in their lifetime[3]

40% to 45% will have 2 or 3[2]

These Infections Result in

Approximately **10 Million** Office visits per year[4]

*VVC = vulvovaginal candidiasis.
**TV = Trichomonas vaginalis.
†BV = bacterial vaginosis.

Why now?

Health risks include

- Preterm or low birth-weight babies
- Late-term miscarriage
- Increased risk of sexually transmitted infections such as HIV and pelvic inflammatory disease[1]

A need for improved testing

Clinical diagnosis and traditional diagnostic techniques tend to be subjective with variable sensitivity and specificity[3]

40% of women with vaginitis leave an initial medical visit undiagnosed[2]

This potentially leads to:

- Continued symptoms
- Repeat visits
- Inappropriate treatment
- Poor antimicrobial stewardship
- Unnecessary associated healthcare system costs[2,3,5]

Overall performance compared to patient infection status[1]

	Clinician-Collected		Self-Collected		Contrived Samples[d]	
	Sens*	Spec**	Sens	Spec	PPA[2]	NPA[3]
Bacterial Vaginosis	90.5%	85.7%	90.7%	84.5%		
Candida group [1]	90.9%	94.1%	92.2%	91.9%		
Candida glabrata [a]	75.9%	99.7%	86.7%	99.6%	100%	100%
Candida krusei [b]	No Data	99.8%	No Data	100%	100%	100%
Trichomonas vaginalis [c]	93.1%	99.3%	93.2%	99.3%		

* Sensitivity **Specificity
[1] *Candida* group includes *C. albicans, C. dubliniensis, C. parapsilosis* and/or *C. tropicalis*
[2] Positive Percent Agreement
[3] Negative Percent Agreement
[a] Out of 7 *C. glabrata* false negative results, 6 showed chromagar results consistent with low *C. glabrata* load (1+ to 2+ growth level) and 1 showed chromagar result consistent with high *C. glabrata* load (3+ growth level).
[b] No *C. krusei* positive specimens were identified in the study by the Reference Method.
[c] 9 false-negative results were recorded. Of those, 7 were found negative with an FDA-cleared molecular method.
[d] For rare analytes, an evaluation of contrived specimens was performed to supplement data collected in the study. Half of the positive contrived specimens were at ≥1 and <2 LoD.

Why BD? Accurate treatment begins with an accurate diagnosis. BD MAX Vaginal Panel is the first FDA-authorized, microbiome-based assay that detects the 3 most common infectious causes of vaginitis,[3] with the efficiency of 1 swab. Consistent, accurate results that surpass traditional methods for vaginitis detection.[1]

References: 1. Package Insert/Clinical Trial Data. 2. Carr PL et al. "Shotgun" versus sequential testing. Cost-effectiveness of diagnostic strategies for vaginitis. *JGIM*. 2005;793-799. 3. Hainer BL et al. Vaginitis: diagnosis and treatment. *Am Fam Phys.* 2011;83:807-815. 4. Kent HL. Epidemiology of vaginitis. *Am J Obstet Gynecol.* 1991;165:1168-1176. 5. Powell K. Vaginal thrush: quality of life and treatments. *Br J Nurs.* 2010;19:1107-1111.

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