



Get her vaginitis diagnosis right the first time with the BD Vaginal Panel.¹⁻⁵

Demand a new standard of care for you and your patients.



The BD Vaginal Panel for use with the BD MAX™ System and the BD COR™ System:

A clear vaginitis diagnosis in one test

By identifying the root cause of your patient's vaginitis symptoms, you can help avoid recurrence.

Clear diagnosis of bacterial vaginosis (BV), vulvovaginal candidiasis (VVC), and *Trichomonas vaginalis* (TV) is critical to:



Ensure

- Informed treatment decisions²
- Appropriate patient management²



Decrease

- The risk of complications⁵
- The risk of contracting STIs⁵
- The risk of resistance to treatment²
- Health resource utilization⁵



The BD Vaginal Panel provides precision and clarity.

In the diagnosis of vaginitis:



- **Distinct diagnosis** of bacterial vaginosis (BV), vulvovaginal candidiasis (VVC) and *Trichomonas vaginalis* (TV)¹
- The only FDA-cleared test on the market to provide **separate results for *C. glabrata* and *C. krusei***, two *Candida* species that are clinically indistinguishable and can be hard to treat as they have inherent and/or acquired resistance to azoles.^{1,12-14}

In the identification of vaginitis and STI co-infection:



- The same sample can also be tested for ***Chlamydia trachomatis* and *Neisseria gonorrhoeae*** by using the BD CTGCTV2 assay.¹⁶

What if you could get her vaginitis diagnosis right, from the start?

Only a clear diagnosis can stop the cycle of repeat visits.

Traditional diagnostic techniques are often subjective, and their sensitivity is low.⁵⁻⁷



4 out of 10 women with vaginitis symptoms **don't** receive appropriate diagnosis and treatment.⁴



As a result, up to **42%** of women with vaginitis go back to their doctors for persistent symptoms.⁴



More than **1 out of 4** women with vaginitis symptoms have multiple infections, which makes accurate diagnosis and treatment challenging.⁷



Almost **7 out of 10** women report depression or anxiety during acute vaginitis episodes.^{8,9}

Vaginitis is complex and has considerable impact on a woman's quality of life. You want **a diagnostic tool that provides actionable and objective results** to make informed clinical decisions.^{2-5,10,11}

Two points that differentiate the BD Vaginal Panel: it provides clinical information that other assays don't.

1. BD Vaginal Panel is the **only FDA-cleared test on the market to provide separate results for *C. glabrata* and *C. krusei***, two *Candida* species that are clinically indistinguishable, require different treatments and can be hard to treat as they have inherent and/or acquired resistance to azoles.^{1,12-14}

2. BD Vaginal Panel is the **first FDA-cleared microbiome-based, PCR assay that directly detects bacterial vaginosis, vulvovaginal candidiasis and *Trichomonas vaginalis***, the 3 most common infectious causes of vaginitis, in one test, with one swab.^{1,7,10}

What precision does BD Vaginal Panel provide that traditional methods can't?

BD Vaginal Panel vs traditional methods:

A significantly higher sensitivity and comparable specificity to traditional tests.¹⁰

Condition	Diagnostic method	Sensitivity	Specificity
BV*	BD Vaginal Panel	92.7%	91.5%
	Clinician diagnosis	77.3% ^a	92.3% ^b
	Amsel's criteria	75.6% ^a	94.1% ^b
VVC*	BD Vaginal Panel	90.7%	93.6%
	Clinician diagnosis	56.8% ^a	89.2% ^c
	Potassium hydroxide wet mount	57.5% ^a	89.4% ^c
TV	BD Vaginal Panel	96.7%	99.1%
	Clinician diagnosis	68.9% ^a	99.1% ^b
	Wet mount	69.7% ^a	99.5% ^b

* Note: All methods compared to Nugent 0–3 and 7–10 sub-populations as part of study. ^aP<0.0001 compared to the investigational test. ^bP>0.05 compared to the investigational test. ^cP<0.0005 compared to the investigational test.

The greater sensitivity you require to detect co-infections.¹⁰

Diagnostic method	BV + VVC	BV + TV	VVC + TV	BV + VVC + TV
BD Vaginal Panel	73.5%	92.4%	72.0%	80.0%
Clinician diagnosis	17.8% ^a	21.2% ^a	20.0% ^b	10.0% ^b

^aP<0.0001 compared to the investigational test. ^bP<0.0005 compared to the investigational test.

The BD Vaginal Panel provides a more accurate vaginitis diagnosis as compared to traditional methods, including an improved detection of co-infections which occur in 1 out of 4 women.^{6,7,10}

A more accurate diagnosis means improved patient management and informed downstream treatment recommendations.¹⁰

The BD Vaginal Panel detects a broader range of pathogens responsible for vaginitis.^{1,13-15}

BD Vaginal Panel vs other molecular tests on the market:

		BD Vaginal Panel	Hologic Aptima® BV and CT/TV Assays ^{13,15}	Cepheid Xpert® Xpress MVP ¹⁴
Bacterial vaginosis (BV)	<i>Gardnerella vaginalis</i>	✓	✓	✗
	<i>Lactobacillus</i> spp.	✓ <i>L. crispatus</i> and <i>L. jensenii</i>	✓ <i>L. crispatus</i> , <i>L. jensenii</i> , <i>L. gasseri</i>	✗
	<i>Atopobium vaginae</i>	✓	✓	✓
	BVAB-2	✓	✗	✓
	<i>Megasphaera-1</i>	✓	✗	✓
Reported as		BV	BV	BV
Reportable results		POS NEG	POS NEG	POS NEG
Vulvovaginal candidiasis (VVC) / <i>Trichomonas vaginalis</i> (TV)	<i>Candida albicans</i>	✓	✓	✓
	<i>Candida tropicalis</i>	✓	✓	✓
	<i>Candida parapsilosis</i>	✓	✓	✓
	<i>Candida dubliniensis</i>	✓	✓	✓
	<i>Candida glabrata</i>	✓	✓	✓
	<i>Candida krusei</i>	✓	✗	✓
	<i>Trichomonas vaginalis</i>	✓	✓	✓
Reported as		<i>Candida</i> group <i>C. glabrata</i> <i>C. krusei</i> <i>T. vaginalis</i>	<i>Candida</i> species group <i>C. glabrata</i> <i>T. vaginalis</i>	<i>Candida</i> spp. <i>C. glabrata</i> / <i>C. krusei</i> <i>T. vaginalis</i>
Reportable results		POS NEG	POS NEG	DETECTED NOT DETECTED
Recommended CPT® Code 81514 [†]		✓	✗	✗

* *Atopobium* spp. (*Atopobium vaginae*, *Atopobium* novel species CCUG 55226)

With the BD Vaginal Panel, achieve a clear vaginitis diagnosis in a single test.^{1,7}

[†]Disclaimer: Health economic and reimbursement information provided by BD is gathered from third-party sources and is subject to change without notice. The information contained in this reference is presented for information purposes only and does not constitute reimbursement or legal advice. It is always the provider's responsibility to determine medical necessity and to submit appropriate codes and changes for services that are rendered. BD recommends that you consult with your payers, reimbursement specialist and/or legal counsel regarding coverage, coding, and payment matters. CPT five-digit codes, description, two-digit modifiers and other data are copyright © 2022 American Medical Association. All rights reserved. The codes referenced here are not all-inclusive and are not intended to represent all coding options options.

The right treatment starts with the right diagnosis: Ask for the BD Vaginal Panel

- ✓ **FDA-cleared** to detect DNA from organisms associated with **BV, VVC and TV** from a single swab.¹
- ✓ Designed with a proprietary, microbiome-based algorithm for BV that **determines a definitive positive or negative BV result** for each patient.
- ✓ Provides **separate results for *C. glabrata* and *C. krusei***, two *Candida* species that may not respond to traditional therapeutics.^{1,12}
- ✓ Utilizes the **highly sensitive** and CDC-recommended diagnostic technology, **NAAT, for TV detection**.^{10,17}
- ✓ Approved for **clinician-collected and patient-collected samples**.^{*1}
- ✓ Available on the BD MAX™ System for low to mid volume laboratories and the BD COR™ System for high volume laboratories.



Did you know?

You can use the same sample to test for vaginitis and the 3 most prevalent non-viral STIs in symptomatic women if you use the BD Vaginal Panel together with the BD CTGCTV2 assay.^{1,16,18}

Ask your BD Representative for more information.

Let's shape the future of women's health. Together and now.

BD Vaginal Panel - BD CTGCTV2 Assay -
BD Onclarity™ HPV Assay - BD MAX™ GBS Assay
**For more information about the BD comprehensive diagnostic
Women's Health portfolio, please scan the QR code.**



*Patient collection takes place in a healthcare setting.

BV, bacterial vaginosis; FDA, Food and Drug Administration; NAAT, nucleic acid amplification test; NEG, negative; POS, positive; TV, Trichomonas vaginalis; VVC, vulvovaginal candidiasis.

References: 1. BD MAX™ Vaginal Panel Package Insert (P0258) and BD Vaginal Panel for use with the BD COR™ System (L012454). 2. Broache M et al. *Obstet Gynecol.* 2021;138(6):853–9. 3. Miller JM et al. *Clin Infect Dis.* 2018;67(6):e1–e94. 4. Hillier SL et al. *Clin Infect Dis.* 2021;72(9):1538–43. 5. Brown H and Drexler M. *Popul Health Manag.* 2020;23(S1):S3–S12. 6. Schwabke JR et al. *J Clin Microbiol.* 2020;58(2):e01643–19. 7. Gaydos CA et al. *Obstet Gynecol.* 2017;130(1):181–9. 8. Bilardi JE et al. *PLoS One.* 2013;8(9):e74378. 9. Aballéa et al. *Health and Quality of Life Outcomes.* 2013;11:169–81. 10. Schwabke JR et al. *J Clin Microbiol.* 2018;56(6):e00252–18. 11. Van Der Pol B et al. *Sex Transm Dis.* 2021;48(2):134–40. 12. Thompson A et al. *Eur J Clin Microbiol Infect Dis.* 2020;39(1):39–44. 13. Hologic Aptima® CV/TV Assay Package Insert. 14. Cepheid Xpert® Xpress MVP Instructions for Use. 15. Hologic Aptima® BV Assay Package Insert. 16. BD CTGCTV2 for BD MAX™ System Package Insert (P0237). 17. Workowski KA et al. *MMWR Recomm Rep.* 2021;70(4):1–187. 18. Center for Disease Control and Prevention. *Sexually Transmitted Infections Prevalence, Incidence, and Cost Estimates in the United States*, CDC. <https://www.cdc.gov/std/statistics/prevalence-2020-at-a-glance.htm>. Accessed Dec 20, 2022.

BD Life Sciences, 7 Loveton Circle, Sparks, MD 21152-0999, U.S.
800.638.8663

womens-health-solutions.bd.com

BD, the BD Logo, BD COR, BD MAX and Onclarity are trademarks of Becton, Dickinson and Company or its affiliates. All other trademarks are the property of their respective owners. © 2023 BD. All rights reserved.
(BD-93616 2190-US-0523 December 2023)

