
# BD MAX™ Vaginal Panel

Real-time PCR assay

## The need for efficient Vaginitis diagnostic testing

**Vaginitis**, one of the most common gynaecological problems in clinical medicine, accounts for millions of office visits each year.[1,2] However, it is difficult to diagnose due to symptom overlap[3,4] and patient co-infection[5], which may lead to inappropriate treatment, continued troublesome symptoms and serious associated risks.

The three main infectious causes of vaginitis are **bacterial vaginosis (BV), yeast vaginitis (candidiasis) and *T. vaginalis* vaginitis (trichomoniasis).**[2]

## Discover the assay

The **BD MAX™ Vaginal Panel** is the **first microbiome-based PCR assay** simultaneously detecting organisms associated with Bacterial Vaginosis (BV), Vulvovaginal Candidasis (VVC) and Trichomoniasis (TV), **reducing the need for repeat testing.**[5] It is an automated assay including nucleic acid extraction and real-time polymerase chain reaction (PCR) for direct and qualitative detection and differentiation of DNA targets from:

- **Bacterial vaginosis markers** (*Lactobacillus spp.* (*L. crispatus and L. jensenii), Gardnerella vaginalis, Atopobium vaginae*, Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), *Megasphaera-1*)
- **Candida spp.** (*C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis*)
- ***Candida glabrata***
- ***Candida krusei***
- ***Trichomonas vaginalis***

The **BD MAX™ Vaginal Panel** separately calls out the organisms that may require different treatment for Candidiasis due to co-infection which occurs in approximately 20 % of cases.[6]

This assay is also based on a **unique algorithm providing accurate BV results** in line with clinical understanding of BV as a polymicrobial condition.[6]

This test also includes a sample processing control.

## Sample types

Vaginal swab (clinician or patient collected in clinical setting)

## Workflow and time to results

Results obtained in approximately **2.5 hours for 24 specimen**

Less than **1.5 minutes of hands-on time** in sample preparation

**Compatibility to run alongside other BD MAX™ assays** for greater flexibility. To be noted that the **BD MAX™ Vaginal Panel is NOT rack compatible**, meaning that the assay has to be placed on a separate rack of 12 samples. The 2nd rack can be loaded with other types of BD MAX™ assays.

## Scientific evaluation

Read more about the **BD MAX™ Vaginal Panel** from molecular studies and publications.

*Broache et al., Performance of a Vaginal Panel Assay compared with the Clinical Diagnosis of Vaginitis, OBSTETRICS & GYNECOLOGY, December 2021 Volume 138 Number 6.*

## Ready-to-use reagents storable at room temperature

| REF | Contents | Quantity |
|---|---|---|
| 443712 | **BD MAX™ Vaginal Panel - Vaginitis Master Mix (C4)**<br>Dried PCR Master Mix containing Target and Sample Processing Control-specific primers and probes and PCR enzyme | 24 tests<br>(2 x 12 tubes) |
| | **BD MAX™ Vaginal Panel - Vaginosis Master Mix (C5)**<br>Dried PCR Master Mix containing Target and Sample Processing Control-specific primers and probes and PCR enzyme | 24 tests<br>(2 x 12 tubes) |
| | **BD MAX™ Vaginal Panel Reagent Strip**<br>Unitised reagent strip containing wash buffer, elution buffer, and neutralisation buffer reagents, as well as disposable pipette tips necessary for sample processing and DNA extraction | 24 strips |
| | **BD MAX™ Vaginal Panel - Extraction Tube (C6)**<br>Dried Magnetic Affinity Beads, dried lytic enzyme and dried Sample Processing Control | 24 tests<br>(2 x 12 tubes) |
| | **Septum Cap** | 25 |

## Rapid, targeted testing on the BD MAX™ System

The innovation of the BD MAX™ System offers you a **fully integrated, automated real-time PCR platform** with the possibility of running multiple assays simultaneously.* Its automated workflow **reduces manual tasks** to achieve rapid, reliable results and facilitates off-hour testing, helping to **offset molecular testing costs**.** [7,8]

### Snap

Assemble unitised reagent strips with ready-to-use reagents.

### Load

Load Sample Buffer Tubes, Racks and PCR cartridges.

### Go

Come back in an average of 2.5 hours for results.***

**Discover our full assay portfolio and the BD MAX™ System**

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**BD MAX™ Vaginal Panel [IFU 443712], Franklin Lakes, NJ: Becton, Dickinson and Company; 2021.**

**1.** Centers for Disease Control and Prevention, Sexually Transmitted Disease Surveillance 2019, Atlanta: U.S., Department of Health and Human Services; 2015. (http://www.cdc.gov/std/stats14) **2.** Egan ME, Lipsky MS (2000). Diagnosis of Vaginitis. Am Fam Physician 62 (5): 1095–1104 **3.** Hainer BL, Gibson MV. A Fam Phys. 2011;83(7):807-815. **4.** Paladine H, Desai U. A Fam Phys. 2018;97(5);321-329. **5.** Gaydos CA et al. Obstet Gynecol. 2017;130(1):181-189. **6.** Schwebke et al, J Clin Microbiol. 2020; 58(2):e01643-19. **7.** Mortensen JE, et al. Comparison of time-motion analysis of conventional stool culture and the BD MAX Enteric Bacterial Panel (EBP). BMC Clin Pathol. 2015;15:9. **8.** Hirvonen JJ, et al. Comparison of BD Max Cdiff and GenomEra C. difficile molecular assays for detection of toxigenic Clostridium difficile from stools in conventional sample containers and in FecalSwabs. Eur J Clin Microbiol Infect Dis. 2015;34(5):1005-1009.

* BD assays are run & rack compatible – Only MDR-TB and GBS are not run and rack compatible / Vaginal Panel and open systems' assays are only run compatible.
** When compared to culture or immunochromatographic antigen (IA).
*** Time is assay dependent. 4 hours for full results on MDR-TB assay.

**The BD MAX™ System and BD MAX™ Vaginal Panel are in-vitro diagnostic medical devices bearing a CE-mark.**



CE