BD MAX™ Vaginal Panel

Elevate the standard of care
What is Vaginitis/Vaginosis?

**BV:** Syndrome with an unhealthy ratio of flora indicating infection

**VVC:** Fungal infection - can include resistant species to azole

**TV:** Protozoan parasite, common STI

All 3 infections require **different treatment.** Accurate detection is critical for **targeted therapy.**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Burden of disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial Vaginosis (BV)</td>
<td>29.2% or 21.4 M cases (prevalence in U.S. women)³</td>
</tr>
<tr>
<td>Vulvovaginal Candidiasis (VVC)</td>
<td>75% of women experience VVC in their lifetime¹</td>
</tr>
<tr>
<td>Trichomoniasis (TV)</td>
<td>Most common, curable STI, 3.7M U.S. infections⁴</td>
</tr>
</tbody>
</table>
Molecular diagnosis of Vaginitis

Traditional testing may result in misdiagnosis or under-diagnosis. There have been efforts over recent years to develop **molecular tests**, that can **provide greater sensitivity** and **specificity**. One of the first tests was the BD Affirm™ VPIII, a direct molecular DNA probe detecting *Candida* species, *Trichomonas vaginalis*, and *Gardnerella vaginalis*.

Molecular **Nucleic Acid Amplification Test (NAAT)** was the next advance, which provided high levels of sensitivity and specificity for Trichomoniasis. NAAT was recommended as a testing method by CDC.

The most recent advance is the **BD MAX™ Vaginal Panel**
- First FDA Market-Authorized
  - Microbiome-based test using a **unique algorithm** that determines the ratio of healthy vs. unhealthy bacteria
  - NAAT (PCR) for *Candida*
BD MAX™ Vaginal Panel

First FDA IVD, microbiome-based, PCR assay detecting DNA targets from:

- Bacteria associated with Bacterial Vaginosis (BV), Candida species associated with Vulvovaginal Candidiasis (VVC), and Trichomonas vaginalis (TV)
- Proprietary algorithm detects bacterial imbalance causing BV

Maximize efficiency

- 1 collection, 1 test for the 3 most common causes of vaginitis and vaginosis
- Utilizes same collection device as BD MAX™ CT/GC/TV

Support antimicrobial stewardship initiatives

- Providing actionable test results for BV, Candida and TV
- No equivocal results
- Reporting Candida krusei and C. glabrata

Photo courtesy of CDC/M. Rein

BV

VVC

TV
# BD MAX™ Vaginal Panel  
**Sources, targets, and reports**

Aid diagnosis in **symptomatic** women using a clinician-collected vaginal swab or a self-collected vaginal swab[^5]

<table>
<thead>
<tr>
<th>Detected targets</th>
<th>Reports (pos. or neg.)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Candidiasis</strong></td>
<td></td>
</tr>
<tr>
<td><em>Candida</em> group</td>
<td><em>Candida</em> group</td>
</tr>
<tr>
<td><em>C. albicans</em>, <em>C. parapsilosis</em>, <em>C. tropicalis</em>, <em>C. dubliniensis</em></td>
<td></td>
</tr>
<tr>
<td><em>C. glabrata</em></td>
<td><em>C. glabrata</em></td>
</tr>
<tr>
<td><em>C. krusei</em></td>
<td><em>C. krusei</em></td>
</tr>
<tr>
<td><strong>Trichomoniasis (TV)</strong></td>
<td><em>Trichomonas vaginalis</em></td>
</tr>
<tr>
<td><em>Trichomonas</em> vaginalis</td>
<td><em>Trichomonas vaginalis</em></td>
</tr>
<tr>
<td><strong>Bacterial Vaginosis (BV)</strong></td>
<td>Bacterial Vaginosis</td>
</tr>
<tr>
<td><em>Lactobacillus</em> species (<em>L. crispatus</em> and <em>L. jensenii</em>)</td>
<td></td>
</tr>
<tr>
<td><em>Gardnerella vaginalis</em></td>
<td></td>
</tr>
<tr>
<td><em>Atopobium vaginae</em></td>
<td></td>
</tr>
<tr>
<td><em>Megasphaera-1</em></td>
<td></td>
</tr>
<tr>
<td><em>BVAB-2</em></td>
<td></td>
</tr>
</tbody>
</table>

[^5]: BD MAX Vaginal Panel Package Insert
Microbial shift occurring in BV

- BV is characterized by 1,000-10,000 fold increase in certain pathogenic bacteria resulting in an unbalanced microbiome.6
- Lactobacilli concentrations decrease several orders of magnitude.7
- BV is associated with many anaerobic bacteria and various ratios of flora.8
Representation of overlap and differences between BD Affirm™ VPIII, BD MAX™ Vaginal Panel, and Nugent reference, for diagnosis of BV

**BD MAX Vaginal Panel**
NAAT molecular method which incorporates the latest advances in vaginal microbiome understanding

**Single BV Result:** Positive or Negative

**Lactobacillus crispatus**
**Lactobacillus jensenii**

**Atopobium vaginae**
**BVAB-2**
**Megasphaera-1**

**Non BV predictive**
**Lactobacillus spp**
**Mobiluncus morphotypes**

**Nugent Score**
Subjective method compounded by inter-user variability and indeterminate results

**BD Affirm VPIII**
DNA probe molecular method detecting **Gardnerella vaginalis** only

**Gardnerella vaginalis**
Candida species

**Candida group**

- *Candida albicans* – responsible for 70-90% of vulvovaginal candidiasis\(^9\)
- Among the other species, the most predominantly described in literature are *C. parapsilosis*, *C. tropicalis*, and *C. dubliniensis*\(^9,12\)

**Candida glabrata**

- *C. glabrata* resistance is acquired – some strains are resistant to azole antifungal agents and the majority are resistant to fluconazole. *C. glabrata* may be treated with Terconazole\(^9,10,11,12\)

**Candida krusei**

- *C. krusei* resistance is intrinsic – this species is resistant to 1st and 2nd line therapies, including fluconazole and other azole drugs. 3rd line agents, such as boric acid, are considered for treatment\(^10,11\)
Collection instructions

Self-collected vaginal swabs

- Do **not** provide a lubricant with the BD MAX UVE Specimen Collection Kit to aid in self-collection.
- Patient should collect their specimen **before** any clinical vaginal exam is performed with a lubricant.
- Patient should provide staff with swab in sheath for transfer process.

Vaginal specimen self-collection for
BD MAX™ Vaginal Panel
BD MAX™ UVE Specimen Collection Kit

For clinician staff

- Do not use a lubricant with the BD MAX UVE Specimen Collection Kit to aid in self-collection.
- Patient must collect their specimen **before** any vaginal exam is performed with a lubricant.
- Patients who will have both tests should receive 2 specimen collection kits and collect 2 vaginal swab samples, placed in each of 2 tubes provided.

Patient instructions for self-collection

Please read all instructions before collecting specimens. If you have any questions about this procedure, please ask your doctor or nurse.

1. Twist the cap to break the seal (Figure 1). Do not use if seal is broken or damaged. Carefully pull the cap with attached swab off the tube. Do not touch the soft tip or lay the swab down. If you touch or drop the swab tip or the swab is laid down, discard the swab and request a new vaginal swab. Check for presence of the swab tip. If the swab has no tip, discard it and request a new vaginal swab.

2. Hold the swab by the cap with one hand so the swab tip is pointing toward you (Figure 2). With your other hand, gently spread the skin outside the vagina. Insert the tip of the swab into the vaginal opening (Figure 2). Point the tip toward your lower back and relax your muscles.

3. Gently slide the swab 2 inches (5 cm) into the vagina (Figure 3). If the swab does not slide easily, gently rotate the swab as you push. If it is still difficult, do not attempt to continue self-collection; consult your clinician at this point.

4. Rotate the swab for 10 to 15 seconds (Figure 4).

5. Withdraw the swab without touching the skin outside the vagina. Place the swab in the tube and cap the tube securely (Figure 5).

- After collection, wash hands with soap and water, rinse, and dry. Return the swab in its tube to the nurse or clinician as instructed.

*Please note: Pipette not needed for collection or transfer (urine only)
Collection instructions
Clinician-collected vaginal swabs

• Do not use a lubricant with the BD MAX UVE Specimen Collection Kit.

• Collect specimen before any speculum or internal vaginal exam is performed with a lubricant.

• Do not collect the specimen at the posterior fornix.

• Swab transfer, storage and transport instructions include patient self-collected swabs.

BD MAX™ Vaginal Panel specimen collection and transfer procedure

BD MAX™ UVE Specimen Collection Kit

Clinician collection procedure
• Collect swab prior to pelvic, speculum, or bimanual exam.
• Do not use a lubricant with the BD MAX UVE Specimen Collection Kit.
• Collect swab prior to pelvic, speculum, or bimanual exam.
• Do not use a lubricant with the BD MAX UVE Specimen Collection Kit.

1. Gently slide the swab 2 inches (5 cm) into the vagina. If the swab does not slide easily, gently rotate the swab as you push. If it is still difficult, do not attempt to continue.
2. Rotate the swab for 10 to 15 seconds.
3. Withdraw the swab without touching the skin outside the vagina.

Swab-to-tube transfer procedure (clinician-collected and self-collected)

To transfer the sample

1. Fully insert the swab into the tube so that the tip is at the bottom.
2. Carefully break the shaft at the score mark. Be careful to avoid splashing.
3. Tightly re-cap the tube.
4. Label tube with patient information, date, and time collected. Be careful not to obscure the bar codes on the tube.

Swab Storage and Transport
When kept at 2°C to 8°C, the swab specimen (post-collection) must be transferred within 2 hours to the BD MAX UVE Sample Buffer Tube.

Specimen Type: Vaginal swab collection for BD MAX Vaginal Panel (not requiring preswarm) to BD MAX UVE Sample Buffer Tube prior to testing.

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal swab</td>
<td>2–8°C</td>
<td>14</td>
</tr>
</tbody>
</table>

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BD Life Sciences, Sparks, MD 21152-0999 USA
800.638.8663
When lubrication must be used

**Lubricant avoidance**
Whenever appropriate, do not use a lubricant (substitute water).
When a lubricant must be used to obtain a specimen, avoid contact between the swab and the lubricant.
See BD MAX™ Vaginal Panel Product Insert for a list of known interfering substances.

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Apply a dime-sized amount of lubricant gel.
Apply only to exterior sides of the speculum, avoiding the tip.
Clinician Resources/Education

For more information about this assay and additional patient instructions please visit:

http://moleculardiagnostics.bd.com/for-clinicians/

Reference:
5. BD MAX Vaginal Panel Package Insert.

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