BD MAX™ Vaginal Panel specimen collection procedure

BD MAX™ UVE Specimen Collection Kit

Clinician collection procedure

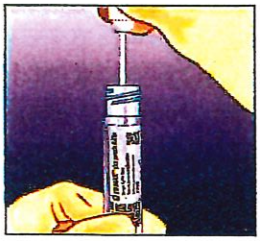
Collect swab prior to pelvic, speculum, or bimanual exam.

No lubricant should be used for the sample collection due to potential molecular inhibition during testing.

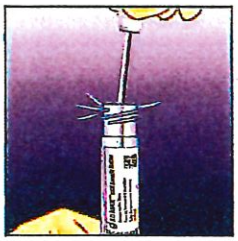
1. Gently slide the swab **2 inches (5 cm)** into the vagina. If the swab does not slide easily, gently rotate the swab as you push. If it is still difficult, do not attempt to continue.
2. Rotate the swab for 10 to 15 seconds.
3. Withdraw the swab without touching the skin outside the vagina.

Swab to Tube Transfer Procedure

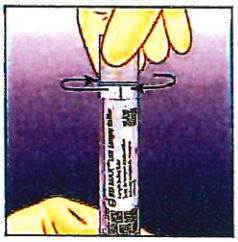
To transfer the sample:



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.

Swab Storage & Transport

Swab sample must be transferred immediately after collection to the **BDMAX™ UVE SAMPLE BUFFER tube** when kept at 2°C to 30°C.

Specimen Type:

Vaginal swab collection for BD MAX Vaginal Panel

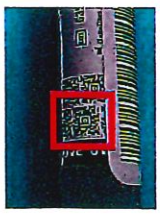
In BDMAX™ UVE SAMPLE BUFFER tube prior to testing

2–30°C	2–8°C
8 days	14 days

BD MAX™ VAGINAL PANEL
LABELING BD MAX™ UVE SAMPLE BUFFER TUBE

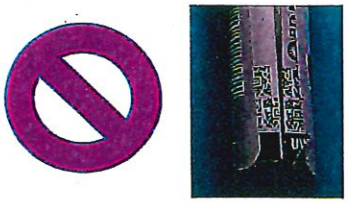
Two rows with multiple, identical QR codes are printed around the bottom of the BD MAX™ UVE SAMPLE BUFFER tube. After labeling one full QR code must be visible.

Correct Labeling



Fully visible QR code

Incorrect Labeling



Full QR code cannot be seen

At least one full QR code must be visible after labeling.

For additional information on the BD MAX™ Vaginal Panel, call 1-877-803-1010

Reference: BD MAX™ Vaginal Panel [package insert]; BD MAX™ UVE Specimen Collection Kit [package insert]

BD Max Vaginal Panel

Test Code: **51665**

First FDA swab approved to detect the most common causes of vaginitis/vaginosis:

***Bacterial vaginosis, Vulvovaginal candidiasis, and* Trichomonas vaginalis** account for millions of physician office visits each year. By testing for all three with one BD Max Vaginal Panel, you can quickly provide an accurate diagnosis in up to 93% of infections vs. 79% with previous testing methodologies.

Quick Facts:

- The BD Max Vaginal Panel is the **first FDA** – cleared nucleic acid amplification test (NAAT:PCR) for bacterial vaginitis/vaginosis
- Applies a unique microbiome algorithm to identify the imbalance of multiple organisms and derive a result for vaginitis
- Generates separate, specific results for Candida glabrata and Candida krusei, which can be resistant to conventional treatment for candida infection
- Improves co-infection detection rates by 29% vs. other testing methodology
- Next day turnaround time

Health Risks for Undiagnosed Patients:

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

Clinical diagnosis and traditional diagnostic techniques can be subjective with variable sensitivity and specificity; as a result 40% of women with vaginitis leave an initial medical visit undiagnosed.[2 3]

	Organisms Detected	Results	
		BD MAX	Other
Bacterial Vaginosis	• *Gardnerella vaginalis* • *Lactobacillus crispatus* • *Lactobacillus jensenii* • *Atopobium vaginae* • *BVAB-2* • *Megasphaera - 1*	Yes, algorithmically detects imbalance of organisms	No, detects GV only
Vulvovaginal Candidiasis	• *Candida albicans* • *Candida parapsilosis* • *Candida tropicalis* • *Candida dubliniensis*	Yes	Yes
	• *Candida glabrata*	Yes	No
	• *Candida krusei*	Yes	No
Trichomonas vaginalis	• *Trichomonas vaginalis*	Yes	Yes

For more information please call 317-803-1010 or contact your Sales Account Manager.

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