

**Becton Dickinson France S.A.S.**

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[bd.com](http://bd.com)

**URGENT PRODUCT ADVISORY NOTICE**

July 19, 2017

<b>Product Name</b>	<b>Catalog Number</b>
BD MAX™ Vaginal Panel	443710
BD MAX™ UVE Specimen Collection Kit	443376

Dear BD MAX Customer,

BD is currently conducting an investigation into customer complaints regarding an increased rate of unresolved (UNR) and indeterminate (IND) results for the BD MAX™ Vaginal Panel. A non-reportable result may lead to repeat of the test and/or re-collection of a specimen.

Data from the investigation suggest that this issue is related to certain specimen collection practices, including the use of lubricants. The following information is intended to provide clinicians and patients with precautions in relation to current Instructions For Use (IFU) included with BD MAX™ UVE Specimen Collection Kits. Appendix 1 includes additional information to be communicated to your collection sites. Once the investigation has identified the specific root cause(s) for this issue impacting the BD MAX Vaginal Panel, BD will provide an updated customer notification and revise product labeling as appropriate.

This product notification has been mailed to all customers that have ordered the BD MAX Vaginal Panel and/or the BD MAX UVE Specimen Collection Kits through BD. Please note that the use of lubricants during specimen collection has only been observed to impact the UNR/IND rate associated with Vaginal Panel testing.

Product returns or discards are not required.

**Patient Education:**

Patients should be counseled to refrain from intercourse for at least 24 hours before the collection of swab specimens and to refrain from douching, using tampons, or using intravaginal medication for at least 48 hours before the collection of swab specimens. They should also avoid scheduling their appointment during heavy menstrual bleeding. However, if those recommendations are not given or followed, you may still proceed with the collection of vaginal swabs.

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**Sample Collection Options:**

- Whenever possible, do not use lubricant for the collection of the vaginal swab.
- Lukewarm Water: If necessary, lukewarm water may be used to warm and lubricate the speculum.
- Lubricant Gels: If lubricant must be used, lubricant should be used sparingly and applied only to the exterior sides of the speculum blades, avoiding contact with the tip of the speculum.

**For clinician-collected swabs:**

- If a lubricant is used with a speculum for the collection of the vaginal swab, avoid touching the lubricant with the collection device (swab) during the collection.
- If a vaginal exam in addition to the swab collection needs to be performed with a commercial lubricant (e.g. bimanual exam), collect the vaginal swab before that exam.

**For self-collected swabs:**

- Do not provide 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.

**Please share this product notification with all users** of the product to ensure they are also aware of this product notification.

**Please complete the attached Customer Response Form** so that BD may acknowledge your receipt of this notification.

If you have additional questions regarding BD MAX, please contact your local BD Diagnostic Systems Representative.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. Thank you for your prompt support on this important matter. BD appreciates your cooperation.

Sincerely,

Mieke Vleugels  
Manager RA Post-market & Industry  
BD Life Sciences



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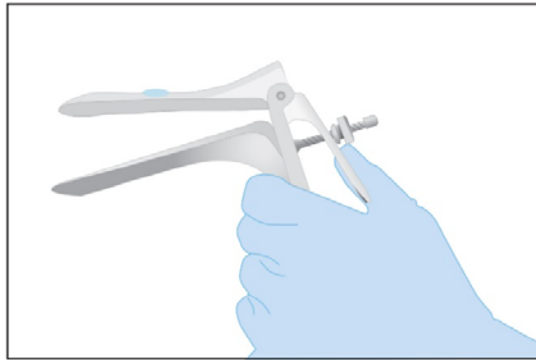
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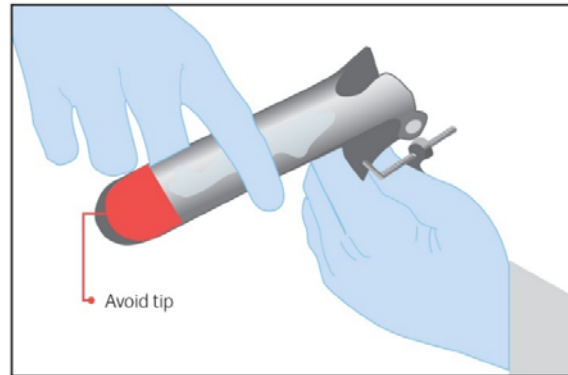
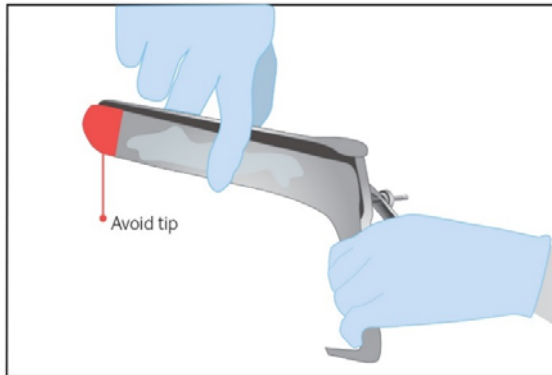
**Appendix 1**

**How to Use a Lubricant for the Collection of Vaginal Swabs  
(BD MAX™ Vaginal Panel)**

- Apply a dime-sized amount of lubricant on the speculum



- Apply only to exterior sides of the speculum, avoiding the tip





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Please assist BD by promptly returning this form to: **XXXXXX**

Fax #: **XXXXXX**

Email: **XXXXXX@bd.com**

## Customer Response Form BD MAX Vaginal Panel

Facility: \_\_\_\_\_

**Please use full, current facility name. Do not use initials.**

Street Address: \_\_\_\_\_

Postal Code or Zip: \_\_\_\_\_ City: \_\_\_\_\_

Country: \_\_\_\_\_

Contact Person: \_\_\_\_\_

Telephone No.: \_\_\_\_\_ Email Address: \_\_\_\_\_

Fax No.: \_\_\_\_\_

I have read and understood the attached notice.

Name:	
Title:	
Signature/Date:	

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BD MAX™ UVE Specimen Collection Kit	443376