

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

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**URGENT FIELD SAFETY NOTICE - EXPANSION**

August 18, 2017

<b>Product Name</b>	<b>Catalog Number</b>
BD MAX™ Vaginal Panel	443710
BD MAX™ UVE Specimen Collection Kit	443376
BD MAX™ CT/GC/TV	442970
BD MAX™ CT/GC	442969

Dear BD MAX Customer,

BD recently notified customers in July 2017 regarding an increased rate of unresolved (UNR) and indeterminate (IND) results for the BD MAX™ Vaginal Panel, experienced by some customers. A non-reportable result may lead to repeat of the test and/or re-collection of a specimen.

Based on additional investigation conducted, BD is expanding the scope of the previous Field Action to include the BD MAX™ CT/GC and BD MAX™ CT/GC/TV assays and providing additional details regarding specimen collection.

Data suggests that this issue is related to the following factors: incorrect specimen collection practices, inappropriate use of lubricants and possibly, in some cases, interfering substances (including creams, gels, foams inserted in the vagina by the patient). The following information is intended to provide clinicians and patients with supplemental information 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 investigation has identified the specific root cause(s) for this issue impacting the BD MAX Vaginal Panel, the BD MAX CT/GC assay and the BD MAX CT/GC/TV assay, BD will provide an updated customer communication and revise product labeling as appropriate.

This Field Action has been mailed to all customers that have ordered the BD MAX Vaginal Panel, BD MAX CT/GC, BD MAX CT/GC/TV and/or the BD MAX UVE Specimen Collection Kits through BD.

Product returns or discards are not required.

The following information from the Instructions For Use of BD MAX™ UVE Specimen Collection Kit, BD MAX™ Vaginal Panel, BD MAX™ CT/GC assay and BD MAX™ CT/GC/TV assay has been refined to provide concise instructions for the clinicians and their patients.

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**Patient Education:**

If the following recommendations are not given or followed, the clinician should still proceed with the collection of vaginal and/or endocervical swabs. If possible, patients should be counseled to refrain from using intravaginal medication, vaginal lubricants, douching, using tampons, or having sexual intercourse for at least 48 hours before the collection of swab specimens. They should also avoid scheduling their appointment during heavy menstrual bleeding.

**Sample Collection Instructions:**

**For all assays:** Do not collect specimen at the posterior fornix.

**For clinician-collected vaginal swabs for MAX Vaginal Panel:**

- Collect swab prior to pelvic, speculum or bimanual exam
- After parting the labia, gently slide the dry swab no more than 2 inches into the vagina, with gentle rotation, making sure the swab touches the walls of the vagina so that moisture is absorbed by the swab.
- Rotate the swab gently for 10–15 seconds; withdraw the swab without touching the skin.
- No lubricant is used for the sample technique.
- Do not collect specimen at the posterior fornix.

**For clinician-collected endocervical swabs for MAX CT/GC/TV:**

- When using a speculum
  - Lukewarm water may be used to warm and lubricate the speculum.
  - If lubricant must be used, it should be used sparingly and applied only to the exterior sides of the speculum blades, avoiding contact with the tip of the speculum
- Avoid contact between the swab and speculum or lubricant.
- Insert the collection swab into the endocervical canal and rotate gently for 10–15 seconds; withdraw the swab without touching the speculum.
- Do not collect specimen at the posterior fornix.

**For clinician-collected swabs for MAX CT/GC/TV and MAX Vaginal Panel for the same patient:**

- Use 2 specimen collection kits and collect 1 vaginal swab sample, and 1 endocervical swab sample, each placed in each of 2 tubes provided.
- ***Preferred collection method***
  - Collect the MAX Vaginal Panel vaginal swab first, following the instruction above for MAX Vaginal Panel.
  - Collect the MAX CT/GC/TV assay endocervical swab second, following the instruction above for CT/GC/TV.
- ***Optional collection method, if a speculum has been inserted prior to collecting the Vaginal Panel swab***

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- Lukewarm water may be used to warm and lubricate the speculum.
  - If lubricant must be used, it should be used sparingly and applied only to the exterior sides of the speculum blades, avoiding contact with the tip of the speculum
- Avoid contact between the 2 swabs and the speculum or lubricant.
- Insert the MAX Vaginal Panel collection swab to contact the vaginal sidewall, at least 2 inches within the vagina, rotate gently for 10-15 seconds; withdraw the swab without touching the speculum.
- Insert the MAX CT/GC/TV collection swab into the endocervical canal and rotate gently for 10–15 seconds; withdraw the swab without touching the speculum.

**Patient self-collected vaginal swabs for MAX CT/GC/TV and MAX Vaginal Panel**

- 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.
- 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 self-collected vaginal swabs may be used for MAX Vaginal Panel testing and/or MAX CT/GC/TV assay testing.

**Footnote:** Avoid use of lubricants that contain carbomer (or carbopol polymers).

**Please share this Field Safety Notice with all users** of the product to ensure they are also aware of this issue.

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

If you have 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.

Yours Sincerely,

Laury Michels  
Regulatory Affairs Specialist  
BD Life Sciences



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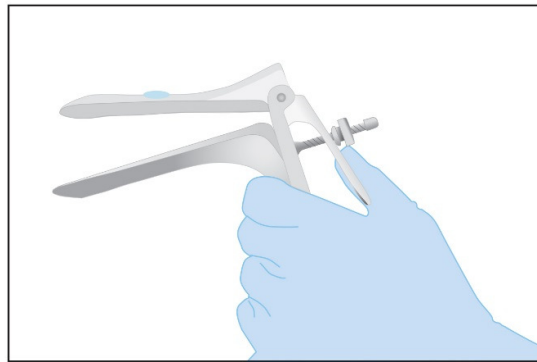
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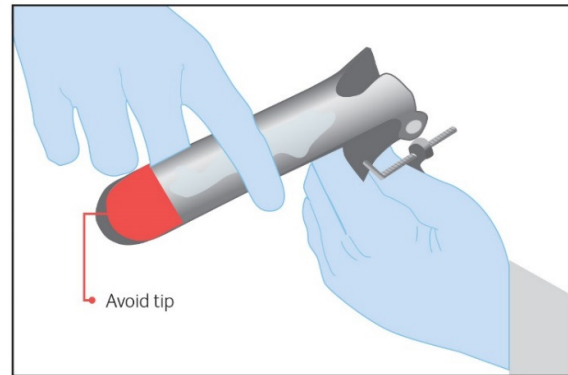
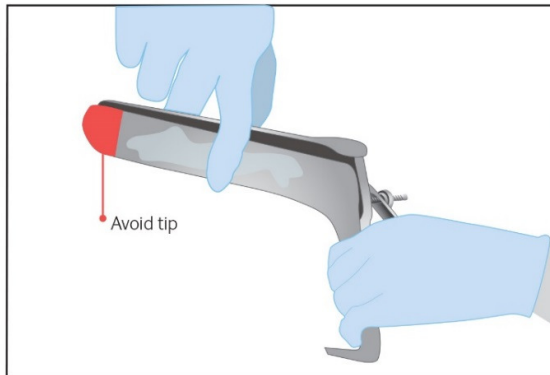
**Appendix 1**

**How to Use a Lubricant for the Collection of Vaginal or Endocervical Swabs**

- Be sparingly if lubricant is applied 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.

## Customer Response Form

### BD MAX Vaginal Panel & BD MAX CT/GC/TV Assays

**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:	

Product Name	Catalog Number(s)
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BD MAX™ UVE Specimen Collection Kit	443376
BD MAX™ CT/GC/TV	442970
BD MAX™ CT/GC	442969