



Becton Dickinson Benelux NV

Customer Service

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RPR Gent (Afdeling Dendermonde)

bd.com

URGENT FIELD SAFETY NOTICE - UPDATE

Date: March 7, 2018

Product Name	Catalog Number(s)	KEY-CODE
BD MAX™ Vaginal Panel	443712 443710 (product now sold as PCN 443712)	443712
BD MAX™ UVE Specimen Collection Kit	443376	443376
BD MAX™ CT/GC/TV	442970	442970
BD MAX™ CT/GC	442969	442969

Dear BD MAX Customer,

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

Based on the investigation, it has been determined that this issue is related to the following factors:

- Specimen collection practices and
- Inappropriate use of lubricants and possibly, in some cases, interfering substances (including creams, gels, foams inserted in the vagina by the patient).

BD would like to inform you that the package inserts for the impacted products have been revised in order to provide concise instructions for laboratorians, clinicians, and their patients regarding collection practices and interfering substances. Although new package inserts will begin transition into manufactured product kits shortly, customers may immediately retrieve the updated package insert by accessing the following site:



www.bd.com/e-labeling

KEY-CODE: (refer to the table above)

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Please share this Field Safety Notice with all users of the product at your facility to ensure they are also aware of the updated information.

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

If you have questions or require further assistance, 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 continued support on this important matter. BD appreciates your cooperation.

Sincerely,

Laury Michels
Regulatory Affairs Specialist
BD Life Sciences



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CUSTOMER RESPONSE FORM
BD MAX Vaginal Panel & BD Max CT/GC/TV Assays

Please assist BD by promptly returning this form to:

Name:

Email:

Fax No.:

Facility: _____
Please use full, current facility name. Do not use initials.

Street Address: _____

City: _____ **Zip:** _____ **Country:** _____

Contact Person: _____

Telephone No.: _____ **Fax No.:** _____

Email address: _____

I have read and understood the attached notice.

I have shared this notice with the appropriate personnel within my organization.

Name:	
Title:	
Signature/Date:	