



Becton Dickinson Benelux NV

Customer Service

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RPR Gent (Afdeling Dendermonde)

bd.com

URGENT FIELD SAFETY NOTICE
BDDS-18-1286

Date: October 10, 2018

Product Name	Product Catalog No.	Serial No.	Manufacturing Date
BD MAX System	441916	See Attached List	Various

For the Attention of:

Microbiology Manager/Supervisor

Description of the problem and health hazard(s):

Based on customer complaint investigations, BD has confirmed that a limited number of BD MAX™ Systems were manufactured with purchased optical filters that have shown a potential to produce a false positive result for *Candida glabrata* when processing samples positive for *Trichomonas vaginalis* during testing with the BD MAX™ Vaginal Panel. If the BD MAX Vaginal Panel was successfully verified/validated using the contrived ZeptoMetrix Vaginal Panel Control Panel, the risk of reporting a clinical false positive *C. glabrata* result is low. The reported *C. glabrata* false positive results were all identified by customers when using the control material.

The likelihood of occurrence of harm is improbable. If a *C. glabrata* false positive were to occur, it is expected that the patient would be correctly treated for a true *T. vaginalis* infection, regardless of whether the patient is also unnecessarily treated for a *C. glabrata* infection. The *C. glabrata* false positive result may prompt unnecessary treatment with an intravaginal antifungal agent or pH adjuster; however, the potential health hazards of receiving these treatments when they are not clinically needed are generally mild and transient.

To prevent any potential future occurrence BD will be replacing all impacted readers.

Our records indicate you may have one or more BD MAX Systems with impacted BD MAX readers in your facility.



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Please Take the Following Actions:

1. Complete the attached Customer Response Form and return to the BD contact noted on the form whether or not you have any of the impacted instruments so that BD may acknowledge your receipt of this notification.
2. Await notification from BD Service to schedule replacements.
3. Share this Advisory with all users of the BD MAX instrument within your facility to ensure awareness.
4. If a patient's specimen is positive for both *T. vaginalis* and *C. glabrata*, the *C. glabrata* result should be confirmed using an alternate testing method prior to reporting.

Actions Taken by BD:

BD Service will contact you to schedule a Service visit that is convenient to your facility to inspect and replace any affected readers.

Contact Information

BD Contact	Contact Information
BD Customer/Technical Support	Please contact your local BD representative

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,

Laury Michels
Regulatory Affairs Specialist
BD Life Sciences



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Affected Product List:

Catalog Number	Serial Number
441916	CM0019
	CM0064
	CM0066
	CT0138
	CT0184
	CT0190
	CT0205
	CT0233
	CT0255
	CT0264
	CT0265
	CT0269
	CT0272
	CT0292
	CT0298
	CT0303
	CT0308
	CT0338
	CT0428
	CT0454
	CT0479
	CT0489
	CT0493
	CT0505
	CT0519
	CT0542
	CT0575
	CT0614
	CT0644
	CT0663
	CT0673
	CT0683
	CT0691
	CT0704
	CT0725
	CT0779
	CT0781
	CT0790
	CT0795
	CT0797
	CT0800
	CT0852
	CT0860

Catalog Number	Serial Number
441916	CT0880
	CT0883
	CT0918
	CT0924
	CT0930
	CT1001
	CT1132
	CT1165
	CT1205
	CT1206
	CT1207
	CT1211
	CT1212
	CT1213
	CT1215
	CT1217
	CT1220
	CT1221
	CT1229
	CT1230
	CT1232
	CT1234
	CT1235
	CT1236
	CT1237
	CT1241
	CT1247
	CT1249
	CT1250
	CT1251
	CT1252
	CT1254
	CT1257
	CT1258
	CT1261
	CT1268
	CT1270
	CT1271
	CT1275
	CT1276
	CT1279
	CT1280



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CUSTOMER RESPONSE FORM BD Max System (BDDS-18-1286)

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 shared this notice with the appropriate personnel within my organization.

Our facility uses the BD MAX™ Vaginal Panel: Yes No

Product Name	Catalog No.	Serial No(s).
BD MAX System	441916	

Name:	
Title:	
Signature/Date:	