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FIELD SAFETY NOTICE

Related to BD Phoenix™ E. faecium Susceptible Results

April 2012

<u>Product Name</u>	<u>Cat. Number</u>	<u>Version Numbers</u>
BD Phoenix™ System Software	448035/448046	5.55R, 5.66A, 5.70A, 5.75A, 5.83A, 6.01A
BD Phoenix™ Update Disks (PUD)	441107/448047	4.51R, 4.65G, 4.61A, 4.65A, 4.71A, 4.75A, 4.81A, 4.91A, 5.11A, 5.15A, 5.21A

Dear Valued Customer,

As you are using the BD Phoenix™ Automated Microbiology System for the quantitative determination of antimicrobial susceptibility of Gram Positive bacteria including bacteria belonging to the genus *Enterococcus*, we would like to inform you about the following.

Through customer feedback (mostly from users in the United States) and subsequent investigation by our in-house technical experts, BD has identified an increase in a new type of strains of *E. faecium* that show slower growth patterns than those previously identified. As a result, an increase in false susceptible interpretations for vancomycin can be observed on all BD Phoenix PMIC or PMIC/ID panels for this specific *E. faecium* strain.

Please note that this issue is related only to 'Vancomycin Susceptible' results, and not to other drugs tested. Also all 'Vancomycin Resistant' results for *E. faecium* and all MIC results for organisms other than *E. faecium* continue to be interpreted correctly.

BD is constantly following up on the emergence of such new strains and as a result has already started developing a software update to address these new strains of *E. faecium*. Customers will be contacted by their BD Service Engineer to arrange for the installation of this software update as soon as it is available.

Until this software update is implemented, BD recommends that customers treat vancomycin susceptible results for *E. faecium* with caution to prevent incorrect results from being reported and the possibility of inappropriate therapy prescribed, and to do the following:

1. Confirm all 'Vancomycin Susceptible' *E. faecium* results with an additional test methodology, such as Vancomycin Screen Agar (BD cat number 222204) or Gradient tests. BD will provide you with a number of Vancomycin Screen Agar plates free of charge until the updated software is available.
2. Continue to report 'Vancomycin Resistant' *E. faecium* test results as these results are not effected by this issue

For regulatory purposes, please fill in the attached form so that we may acknowledge your receipt of this notification and reconsolidate quantity. Simply **complete and fax** the form either to your local BD contact or to the BDDS European Regulatory & Quality Management dept at +33 476 68 3292.

It will not be necessary to contact BD by telephone to receive the software update. Your BD Service Engineer will contact you to arrange for the installation of the updated software when it becomes available. However, would you have any further questions upon receipt of this letter, please contact your local BD representative at **XXXXX**.

Please accept our apology for any inconvenience this may cause. BD is committed to providing you with the highest quality products.

Thank you for your continued support.



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**PLEASE RETURN THIS FORM
SO THAT WE MAY ACKNOWLEDGE YOUR RECEIPT OF THIS NOTICE**

From:

Facility:

Street address:

City/Zip

Four horizontal dashed lines for address information.

PRODUCT CONCERNED AND STATUS, AS APPROPRIATE

Product name(s)	Cat.number(s)	Lot number(s) Serial number Soft. version number
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Phoenix Instrument Serial Number(s) _____

With this document, I, _____, _____,
Name Title

certify that I have received the notice from BD for the product(s) mentioned above and have handled these products as instructed in the notice.

Date

Signature

Please return this document to BD

- either to your local BD subsidiary,
- or to the European BD Diagnostics, Diagnostic Systems Regulatory & Quality Management department., fax + 33 (0) 476 68 3292.