Helping all people live healthy lives

Urgent Field Safety Notice
Device destruction

Product Name	Cat. Number	Unit	Lot Number	Exp. Date
BBL™ Crystal™ Enteric/Nonfermenter ID Kit	245000	Ctn of 24	2086315	February 20, 2013
			2101435	February 20, 2013

February 2013

Dear Valued Customer,

BD has determined through complaint investigation that the above referenced products have the citrate (CIT) and malonic acid (MLO) reagents in the reversed prong/well positions.
This may lead to no-identification or multiple identification choices.

- When No ID is reported, there is no potential hazard as the user has to identify the organism using another method. When multiple identifications are reported, the user is instructed to run test that will differentiate the organisms listed.
- If a misidentification is was reported, a potential hazard may arise. In this case, the antimicrobial therapy could be based on the organism ID and an ineffective drug could be prescribed, or, in the case of a false Salmonella identification from stool, no antimicrobic would be prescribed.

Our records indicate you may have been shipped the above-referenced lot numbers.
Please discontinue use of any of these lot numbers and discard any remaining packages. We will issue replacements for the discarded material.
Please circulate this notice within your organization to other people that may be impacted.

For any question you may have upon receipt of this letter and to organize product replacement, please contact your local BD representative, name, at XXXXX.

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 department at +33 476 68 3292.
Please note that this notice is being notified to the national Regulatory Agency.

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.

Name
Title

Helping all people live healthy lives

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

From:
Facility:
Street address:

City/Zip

PRODUCT CONCERNED AND STATUS, AS APPROPRIATE

Product name(s)	Cat.number(s)	Lot number(s) Serial number Soft. version number	Status	Quantity(ies)
BBL™ Crystal™ Enteric/Nonfermenter ID Kit	245000	2086315	☐ Received	
			☐ Used	
			☐ Destroyed	
		2101435	☐ Received	
			☐ Used	
			☐ Destroyed	

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.