



Helping all people
live healthy lives

Urgent Field Safety Notice

Device destruction

Product Name	Cat. Number	Unit	Lot Number	Exp. Date
BBL™ DrySlide™ PYR Kit	231747	Carton of 60 tests	2276481	September 30, 2013
BBL™ DrySlide™ Oxidase Kit	231746	Carton of 300 tests	2222008	August 31, 2013

April 22nd, 2013

Dear Valued Customer,

BD has determined through complaint investigation that during the manufacturing process, some components of the test slides in the above mentioned products have been placed into the incorrect product packaging.

This may lead in intermittent Quality Control failures and incorrect results.

- **PYR:**
This test is one of several tests used for the identification of Group A Streptococcus or Enterococcus. Should an incorrect reaction occur with this test, the likelihood of misidentification is remote, as a laboratory is not likely to report a result solely on PYR results.
- **Oxidase:**
Since additional testing is done for full bacterial identification, in the event of this product failure the likelihood of a misidentification resulting in an adverse health outcome is remote.

The issue is limited to only these two lots. This is because a bundle of strips used to produce the slides was shared and switched between these two lots.

Corrective actions have been implemented to prevent this issue of product mix up in future lots.

Our records indicate you may have been shipped the above mentioned 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 organisation to other people that may be impacted.

For any questions you may have upon receipt of this letter and to organise product replacement, please contact your local BD representative, Ruth Craggs, at ruth_craggs@europe.bd.com or (+44) 1865 781 584.

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 myself on fax number (+44) 1865 781 578 or to the BDDS European Regulatory & Quality Management department at +33 476 68 3292. Please note that this Field Safety Notice is being notified to the National Regulatory Agency.

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

Thank you for your continued support.

Ruth CRAGGS

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

From:

Facility:

Street address:

City/Zip

[Green input fields for facility, street address, and 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™ DrySlide™ PYR Kit	231747	2276481	<input type="checkbox"/> Received <input type="checkbox"/> Used <input type="checkbox"/> Destroyed	
BBL™ DrySlide™ Oxidase Kit	231746	2222008	<input type="checkbox"/> Received <input type="checkbox"/> Used <input type="checkbox"/> 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.