

**BD Diagnostic Systems**  
 7 Loveton Circle  
 Sparks, MD 21152  
 tele: 410-316-4000  
 fax: 410-316-4066  
 www.bd.com

**URGENT PRODUCT RECALL**



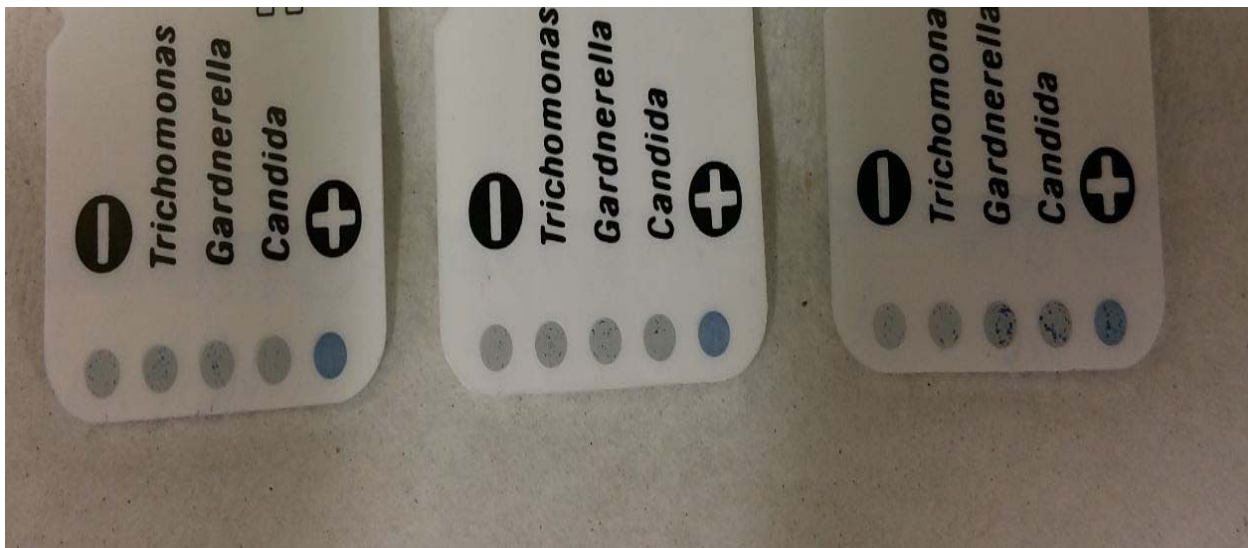
Helping all people  
 live healthy lives

AUGUST 2015

Product Name	Cat. Number	Unit	Lot Number	Exp. Date
BD Affirm VPIII Microbial Identification Tests	446257	120 test kit	5148857	February 19, 2016
			5173648	February 24, 2016
			5141655	February 19, 2016
			5156873	February 24, 2016
BD Affirm VPIII Microbial Identification Tests	446252	24 test kit	5126980	February 9, 2016
			5135673	February 9, 2016
			5138774	February 9, 2016
			5140625	February 19, 2016
			5142767	February 19, 2016
			5153674	February 19, 2016
			5153675	February 24, 2016

Dear Valued BD Customer,

BD has confirmed reports that a portion of tests associated with the above referenced lots of product may exhibit blue speckles or fibers on the beads and cards, as shown below. This issue would result in an invalid test, as described in the package insert.



BD has identified the root cause to be associated with a manufacturing error. The blue discoloration occurs during testing and is not detectable prior to use.

Our records indicate you may have been shipped the above-referenced lot number(s) of product after May 27, 2015. Please discontinue the use of these lot numbers and discard any remaining

packages. We will issue replacements for the discarded material. Newly released lots are not affected.

Please complete the attached form **whether or not you have any inventory remaining** so that we may acknowledge your receipt of this notification. It is not necessary to contact BD by telephone to receive replacements. Simply complete and fax the form to: Attention: Regulatory Compliance, Fax: 410-316-4258 or Email: [BDRC2@bd.com](mailto:BDRC2@bd.com).

Any adverse health consequences experienced with the use of this product should be reported to BD and may be reported to the FDA's MedWatch Adverse Event Reporting program at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm).

If further assistance is needed regarding replacements, please contact BD Customer Service Department at 1-800-675-0908. For all other inquiries, please contact BD Technical Services Department at 1-800-638-8663.

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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Megan LeJeune  
WW Marketing Manager

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Gail Griffiths  
Regulatory Compliance Director

Fax or Email to: BD Regulatory Compliance  
 Fax #: 410-316-4258  
 Email: BDRC2@bd.com

**PLEASE RETURN THIS FORM SO THAT WE MAY ACKNOWLEDGE YOUR RECEIPT OF THIS NOTIFICATION (MC 640)**

Please do not send multiple forms.

**Facility:** \_\_\_\_\_  
 Please use full, current facility name. Do not use initials.

**Street Address:** \_\_\_\_\_

**City:** \_\_\_\_\_ **State:** \_\_\_\_\_ **Zip:** \_\_\_\_\_

**Contact Person:** \_\_\_\_\_

**Telephone No.:** \_\_\_\_\_ **Fax No.:** \_\_\_\_\_

**Total number of affected kits on hand needing replacement:**

Product Name	Cat. Number	Unit	Lot Number	Kits Discarded
BD Affirm VPIII Microbial Identification Tests	446257	120 test kit	5148857	
			5173648	
			5141655	
			5156873	
BD Affirm VPIII Microbial Identification Tests	446252	24 test kit	5126980	
			5135673	
			5138774	
			5140625	
			5142767	
			5153674	
			5153675	

FOR BD USE ONLY			
BILL TO ACC'T NO. 403111	ORDER REASON 517	DELIVERY P.O. NO.	
SHIP TO ACC'T NO.	JUSTIFICATION CODE	INVOICE P.O. NO.	