



URGENT PRODUCT CORRECTION

June 2016

Product Name	Catalog No.	Lot No.	Expiration Date
BD Trucount™ Absolute Counting Tubes (IVD)	340334	6083708	28 February 2018

Dear BD Trucount Customer:

BD has recently confirmed that the pouches in the above listed kit may not be sealed properly.

Our records indicate you may have been shipped the above-referenced lot of product. Please inspect the pouches that you may have in inventory for pouch seal integrity and desiccant color per the package insert instructions. The pouches contained in the kit can be identified with the Lot No.16040 and are embossed with “17 02 16 T3” or “16 02 16 T3”. If the pouch seal is intact and the desiccant included in the pouch is blue, the product may be used. If the pouch seal integrity is compromised and/or the desiccant has turned from blue to lavender, discard the tubes, because exposure to the ambient environment can rapidly degrade the performance of the product. BD will replace the discarded inventory. See Figures 1 through 4.

Figure 1: Kit Box Label

Figure 2: Pouch Label

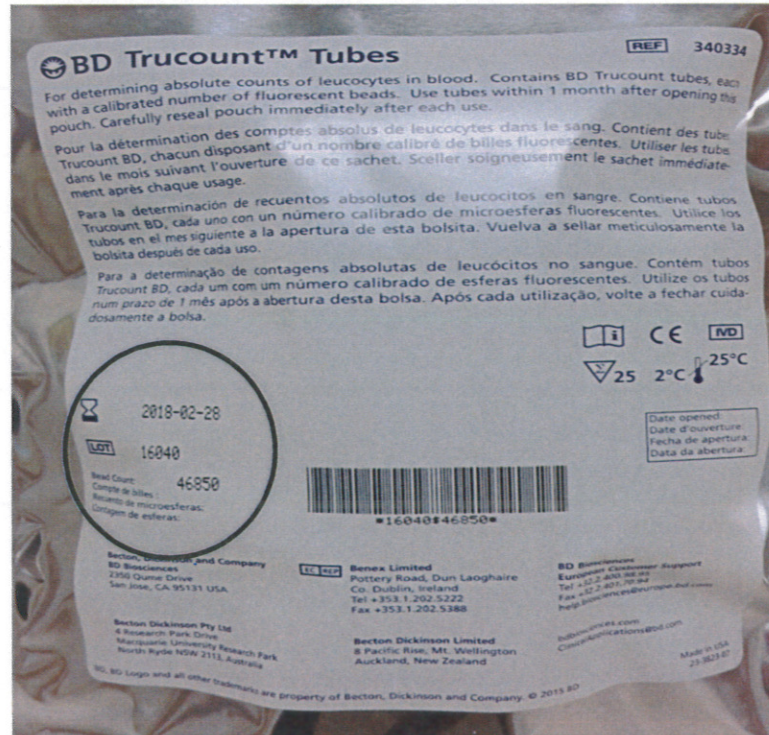


Figure 3: Emboss Code "17 02 16 T3"

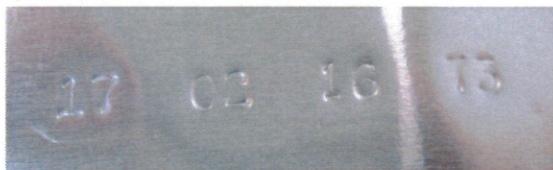


Figure 4: Emboss Code "16 02 16 T3"



BD would like to reinforce the need to visually inspect the desiccant contained in each pouch. Please review the following statements, taken directly from the package insert:

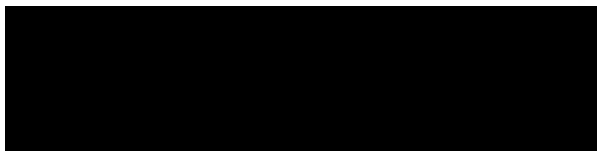
- *Examine the desiccant each time you open the pouch. If the desiccant has turned from blue to lavender, discard the remaining tubes.*

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

Please complete the attached form **whether or not you have any inventory remaining** so that we may acknowledge your receipt of this notification and process your product replacement.

If you require further assistance, please contact BD Customer Support at 855.236.2772 (prompt 3) in the United States. For customers outside the US, contact your local BD Biosciences representative or distributor.

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.



Melissa Quinn
Manager, Regulatory Compliance



Tracy Lopes
Head of Clinical Solutions Global Platforms, Marketing

Fax or Email to: BD Regulatory Compliance
Fax No.: 408-577-1409
Email: BDBRC@bd.com

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

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.:** _____

I have read and understood the attached notice.

Name:	
Title:	
Signature/Date:	

We do not have any of the affected product(s) on hand.

We have the following units and request replacement(s):

Product Name	Catalog No.	Lot No.	No. of Units
BD Trucount™ Absolute Counting Tubes (IVD)	340334	6083708	