



URGENT PRODUCT REMOVAL RECALL

August 25, 2017

Product Name	UDI	Cat No.	Lot No.	Exp Date
BD Vacutainer® K2 EDTA (K2E) 3.6mg Blood Collection Tube (13 x 75 mm x 2.0 mL)	DI (01)30382903678410 PI (17)180131(10)6279849(30)0100	367841	6279849	1/31/2018

Dear Customer,

BD is conducting a voluntary recall for a single lot of BD Vacutainer® K2 EDTA (K2E) 3.6mg Blood Collection Tube (13 x 75 mm x 2.0 mL) referenced in the table above. BD has confirmed that a limited portion of the lot was manufactured with less than the required amount of K2EDTA additive, an anticoagulant, which may cause erroneous results that could lead to specimen recollection and potential delay of treatment or misdiagnosis/mismanagement of treatment and serious complications, such as failure to detect thrombocytosis or postponing surgery. No adverse events have been reported for this issue at this time.

The affected lot number can be found on the individual unit label, the shelf pack label and case label. Sample graphics showing the location of the catalog and lot number on the labels are included to assist you in identifying if the recalled lot is within your control. BD distributed the affected lot beginning December 16, 2016. This recall letter is being mailed to all distributors and end users of the affected product.

Our records indicate you may have been shipped the above-referenced lot of product.

PLEASE TAKE THE FOLLOWING ACTIONS:

1. Immediately review your inventory for catalog number 367841, lot number 6279849 and quarantine the product subject to the recall.
2. Complete the Customer Recall Response Form and fax it back to BD at **1-866-629-6186** or email to **BD8283@stericycle.com**.

3. Return all affected products using the enclosed packaging instructions and include the completed Recall Response Form with the product. Upon receipt of the returned product, BD will issue replacement product.

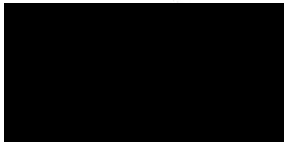
NOTE: Even if you do not have any of the affected lot in your inventory, please complete the Customer Recall Response Form indicating you have zero (0) quantity and fax the completed form back to BD at 1-866-629-6186 or email the completed form to BD8283@stericycle.com.

If you have any questions or require assistance with the return of the recalled product and/or availability of replacement product, please contact **1-855-215-4992 between 8AM and 5 PM ET Monday through Friday.**

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.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with the highest quality products. Thank you for your prompt support on this important matter. BD appreciates your cooperation.

Sincerely,



Aparna Ahuja, MD, PG cert Hospital Management, IF CAP
WW Vice President, Medical Affairs
BD Life Sciences - Preanalytical Systems



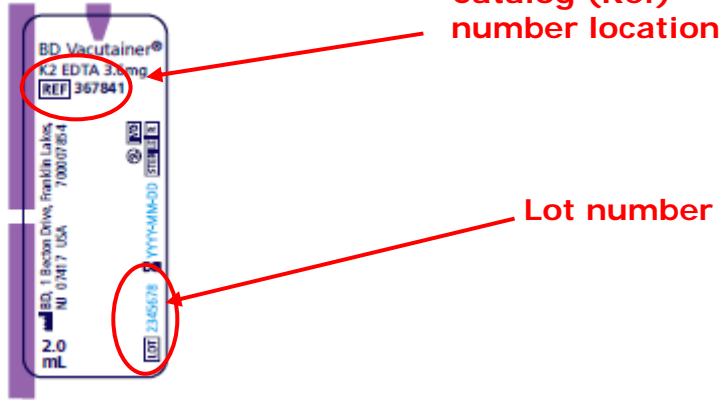
Gail Griffiths
Sr. Director Regulatory Compliance
BD Life Sciences

**BD Vacutainer® K2 EDTA (K2E) 3.6mg Blood Collection Tube
(13 x 75 mm x 2.0 mL)**

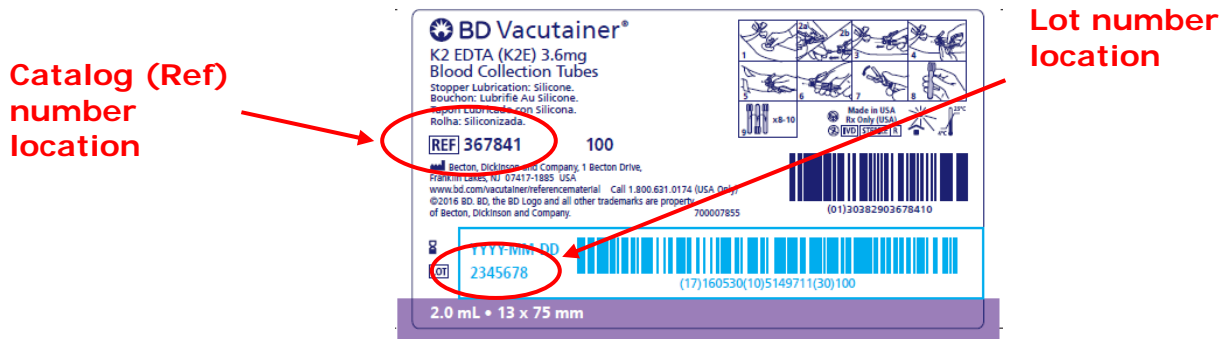
Catalog number 367841, Lot number 6279849

Recall Catalog (Ref) / Lot Identification Sample

A. Unit (Tube):



B. Shelf:



C. Case:



Customer Recall Response Form

BD Vacutainer® K2 EDTA (K2E) 3.6mg Blood Collection Tube

(13 x 75 mm x 2.0 mL)

Catalog (Ref) #	Lot Number
367841	6279849

Check inventory and complete the information below, even if you do not have the affected product. Fax the completed form to BD at 1-866-629-6186 or email the completed form to BD8283@stericycle.com.

Failure to complete all sections of this page may result in improper or delayed product replacement.

Please return only product from the lot referenced in the recall letter; you will only receive product replacement for recalled product that you return.

Facility: _____
Please use full, current facility name. Do not use initials.

Street Address: _____

City: _____ **State:** _____ **Zip:** _____

Contact Person: _____

Telephone No.: _____ **Email Address:** _____

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. (Fill out and return this form to BD at fax or email above)

We have the following units and request replacement(s) (Fill out and return this form to BD at fax or email above and return the product per the packing instruction.)

Product Name	Catalog No.	Lot No.	No. of Units
BD Vacutainer® K2 EDTA (K2E) 3.6mg Blood Collection Tube (13 x 75 mm x 2.0 mL)	367841	6279849	

Please enclose the completed form with the return product shipment.

PACKING INSTRUCTIONS

**BD Vacutainer® K2 EDTA (K2E) 3.6mg Blood Collection Tube
(13 x 75 mm x 2.0 mL)**

Product Return Instructions:

1. Please enclose the complete Recall Response Form with the shipment.
2. The simplest way to return product would be to access the following UPS website:
<http://returns.upsrow.com>
login: **bdapi**, Password: **bdapi**

When you access the site, you can select among 3 UPS shipping options. If you select the initial option, "Display Return Label Only", you can give the package to a UPS person who stops at your site or drop it off at a UPS location. If you select either of the remaining two options, a UPS person will stop by your location specifically to pick up the package. You need to enter the returned product reorder number, lot number and quantity on the website.

Note: If you are not returning product, also indicate this on the website.

3. If you do not have access to the internet you can call UPS at 1-800-PICK-UPS (742-5877) and arrange for a pick-up using the following charge number specific to this recall: **OER739**.

Product should be returned to:

**Returns Team, ref. PAS-17-1057-FA
BD Distribution Center
DOOR #2**

130 Four Oaks Parkway
Four Oaks, NC 27524

For shipments over 150 pounds - utilize UPS Ground Freight. UPS Freight Customer Service can be contacted at 1-800-333-7400. When arranging the pick-up of freight, please specify 3rd party billing as follows:

**Returns Team, ref. PAS-17-1057-FA
BD c/o Cass Info Systems**

PO Box 67
St. Louis, MO 63166-0067

4. Upon receipt of returned product, BD will provide product replacement. A returned goods authorization is NOT required for this recall return process.

**DO NOT SHIP FREIGHT COLLECT
Our warehouse cannot receive products shipped "freight collect".**