BD
1 Becton Drive
Franklin Lakes, NJ 07417
USA

bd.com

URGENT MEDICAL DEVICE RECALL

BD Microtainer® Tubes w/ BD Microgard™ Closure, K_2EDTA additive

June 3, 2019

PRODUCT DESCRIPTION	CAT #	Lot Number	UDI (GTIN, DI + PI)	Exp. Date
BD Microtainer® Tube w/ BD Microgard™ Closure. K_2EDTA additive. Lavender closure 250-500uL fill volume.	365974	**9017591**	(01)30382903659747 (17)200630(10)9017591(30)50 (01)50382903659741 (17)200630(10)9017591(30)200	**2020-06-30**
		9017593	(01)30382903659747 (17)200630(10)9017593(30)50 (01)50382903659741 (17)200630(10)9017593(30)200	**2020-06-30**
		9052823	(01)30382903659747 (17)200731(10)9052823(30)50 (01)50382903659741 (17)200731(10)9052823(30)200	**2020-07-31**

For the Attention of: Lab Director/Recall Coordinator

Description of the problem and health hazard(s):

BD is conducting a voluntary medical device recall for BD Microtainer® Tubes w/ BD Microgard™ Closure, K_2EDTA additive, Catalog# 365974. The above-referenced lots have been confirmed to have reduced or no additive within the tube reservoir. The lot numbers impacted by this issue are identified on page 2 below.

Based on the reduced or no additive situation, the BD Microtainer® Tubes w/ BD Microgard™ Closure, K_2EDTA additive may develop visible clots within the tube samples or micro clots that are not easily detected during visual inspection of the tubes. A clotted sample may lead to recollection of samples or, retesting of patients, resulting in delayed reporting of test results and patient treatment. Additionally, if a micro clot is undetected, it may contribute to inaccurate cell counts including platelet, and hemoglobin levels which could potentially produce erroneous results that impact patient treatment.

Distribution of the affected lots began on February 4, 2019 and our records indicate you may have received the affected product.

Please Take the Following Actions:

1. Immediately review your inventory for Catalog# 365974 with the lot numbers listed below. Destroy all product subject to the recall in accordance with your institution's process for destruction.

2. Share this Urgent Medical Device Recall notification with all users of the product within your facility to ensure that they are also aware of this action.

3. Complete the attached Customer Response/Certificate of Destruction Forms and return to the BD contact noted on the form regardless of whether you have any affected material or not so that BD may acknowledge your receipt of this notification and process your product replacement, if applicable.

4. Report any adverse health consequences experienced with the use of this product to BD. Events may also be reported to the FDA's MedWatch Adverse Event Reporting program.
   Web: MedWatch website at www.fda.gov/medwatch **Phone**: 1-800-FDA-1088 (1-800-332-1088)
   Mail: MedWatch, HF-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-9787

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Actions Taken by BD:

BD's root cause investigation has confirmed that the reduced or no additive was related to an equipment malfunction. The equipment malfunction has been corrected.

Contact Information:

Please use the contact information provided below for complaints, adverse event reports, or questions regarding this recall.

BD Contact	US Contact Information
Customer Quality	888-237-2762 OPT **3**, OPT **2** Monday – Friday 8:00am and 5:00pm (CT)

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,

Aparna Jha Ahuja,MD
PG cert Hosp Management, DCH&FW, IF CAP
WW Vice President Medical Affairs, PAS

Gail Griffiths
Sr. Director, Corporate Regulatory Compliance
BD US Region

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CUSTOMER RESPONSE/DESTRUCTION FORM

PAS-19-1526-FA

BD Microtainer® Tubes w/ BD Microgard ™ Closure, K_2EDTA additive

Please assist BD by promptly returning this form to: BD Regulatory Compliance
Email: BDRC1@bd.com or
Fax No.: 410-316-4258

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

Street Address: _____

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

Contact Person: _____

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

Check all that apply:

☐ I have read and understood the attached notice.

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

☐ I certify that I have destroyed all affected product and request replacements for the quantity shown below

Product Name	Cat. No. (Ref)	Lot No.	Units (Qty.)
BD Microtainer® Tubes w/ BD Microgard ™ Closure, K_2EDTA additive	**365974**		

Name:	
Title:	
Signature/Date:	

To further assist BD in ensuring that these notices are delivered correctly to individuals in your facility, please indicate if there is a centralized function who is responsible for managing recalls.

☐ **No**, there is no centralized function responsible for managing recalls

☐ **Yes**, there is a centralized function responsible for managing recalls
Function/Department Name _____
Contact Person _____
Telephone # _____ Email Address _____