BD
1 Becton Drive
Franklin Lakes, NJ 07417
USA

bd.com

AMENDED URGENT MEDICAL DEVICE RECALL

BD Vacutainer® Fluoride Tubes for Blood Alcohol Determinations

June 12, 2019

Product	Catalog Number	Lot Number	UDI (GTIN, DI + PI)	Exp. Date
BD Vacutainer® Fluoride Tubes for Blood Alcohol Determinations	**367001**	**8187663**	**(01)30382903670018(17)200731 (10)8187663(30)0100**	**2020/7/31**

For the Attention of: Lab Director/Recall Coordinator

Description of the problem and health hazard(s):

You may have received a recall communication from BD on, May 30, 2019, that incorrectly identified the name of the product subject to the recall. Although the catalog and lot number for the one affected lot of product was correct, the product name was incorrect. This notice replaces the initially distributed notice dated May 30, 2019.

BD is conducting a voluntary medical device recall for the catalog and lot number shown above for the BD Vacutainer® Fluoride Tubes for Blood Alcohol Determinations. A small portion of this lot has been confirmed to have no additive within the tube.

As per good clinical practice, in 95% of the cases, missing additive would be detected when a visual inspection of the BD Vacutainer® Fluoride Tubes for Blood Alcohol Determinations prior to blood collection.[1] However, once blood is collected in the tubes, the clinician will be unable to determine if the tube contains additive or not. If no additive is present in the tube the sample may clot and should be rejected and recollected as per good clinical practice.

Based on publicly available scientific literature, in cases where the sample is processed without the preservative (additive) in the tube, testing has yielded reliable results if the samples were stored at room temperature for no longer than two days. If the sample was stored for more than 2 days, the result for blood alcohol determination might not be accurate (either falsely low or falsely high).[2]

The root cause was related to a manufacturing error and has been corrected.

Distribution of the affected lot began on August 31, 2018 and our records indicate you may have received the affected product.

Please Take the Following Actions:

1. Immediately review your inventory for the specific catalog and lot number listed above. 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 in your facility to ensure that they are also aware of this recall.

3. Complete the attached Customer Response/Certificate of Destruction Form 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.

[1] 1CLSI. Collection of Diagnostic Venous Blood Specimens. 7th. Ed. CLSI standard GP41-page15, section 2.9.1 Supplies Are Gathered. Wayne, PA: Clinical and Laboratory Standards Institute; 2017. [2] Wu, A. H. (2006). Tietz clinical guide to laboratory tests. St. Louis, MO: Saunders/Elsevier. Section IV- Therapeutic Drugs and Drugs of Abuse pg 1345

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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 20852-978

Actions Taken by BD:

1. Corrective actions have been initiated to prevent recurrence of the identified root cause.

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-19-1461-FA

BD Vacutainer® Fluoride Tubes for Blood Alcohol Determinations

Please assist BD by promptly returning this form to: BD Regulatory Compliance
Email: BDRC2@bd.com or
Fax No.: Fax 312-949-0227
Facility: _____

Please use full, current facility name. Do not use initials

Street Address: _____

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

Contact Person: _____

Telephone No.: _____**Fax 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 Vacutainer® Fluoride Tubes for Blood Alcohol Determinations	**367001**	**8187663**	

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 _____