

MARY ALDOUS
First Assistant



RAETHELLA JONES
Chief - Civil Division

VICKI KRAEMER
Chief Investigator

JERI YENNE
CRIMINAL DISTRICT ATTORNEY
BRAZORIA COUNTY

June 26, 2019

Honorable Members of Brazoria County Bar Association

RE: Issues Concerning Gray Top Test Tubes Used for Forensic Blood Collection

Dear Sir/Madam:

My office was recently advised that there are issues with certain gray top test tubes used for forensic blood collection. Please find attached an Amended Medical Device Recall notification from BD. The recall only applies to BD Vacutainer Fluoride Tubes for Blood Alcohol Determinations starting August 31, 2018 as it pertains to lot number 8187663 with an expiration date of 7/31/2020.

The Brazoria County Sheriff's Office Crime Laboratory will be conducting a review of the forensic blood samples submitted to the lab from August 31, 2018 on to the present date to identify any potential samples from the affected lot. Appropriate notifications will be made in those criminal cases involving blood tubes from the affected lot. Brazoria County law enforcement agencies have been notified to discard any unused blood tubes from the affected lot. We will provide you an update when the review is complete. Individual notifications are being sent to each Bar Association member.

Sincerely,

A handwritten signature in blue ink that reads "Jeri Yenne".

JERI YENNE

JY:me

COUNTY COURTHOUSE, 111 E. LOCUST, SUITE 408A, ANGLETON, TEXAS 77515

Angleton Area
(979) 864-1230

Brazosport Area
(979) 388-1230

Houston Area
(281) 756-1230

Fax-Criminal Division
(979) 864-1525

Fax-Civil Division
(979) 864-1712

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 ICLSI. 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



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