CERTIFICATE OF COMPLIANCE

BD Diagnostics
Preanalytical Systems
150 South 1st Avenue
Broken Bow NE 68822-2203 US

Product Name : TUBE GLU GC 16X100 10.0 PLBL GR NAF/KOX
Catalog Number : 367001 **Manufacture Date**: 2018/08/11
Batch Number : 8187663
Expiration Date : 2020/07/31

CERTIFICATION OF COMPLIANCE

This material number is a (TUBE GLU GC 16x100 10.0 PLBL GR NAF/KOX) BD Diagnostics Preanalytical Systems Blood Collection Tube reorder #367001. Manufacturing specification for this tube requires the following amounts of powdered additives in each tube.

Potassium Oxalate 18.0mg. to 23.0mg. (Nominal 20.0mg.)
Sodium Fluoride 90.0mg. to 115.0mg. (Nominal 100.0mg.)

This tube is manufactured specifically for blood alcohol determination. The chemicals added to this tube will not disturb the integrity of the blood sample relative to the alcohol content.

Vacuum in the tube is set to draw 9.3mL to 10.7mL (Nominal 10.0mL). Using a specific gravity for blood of 1.057 grams the following would be the minimum and maximum percent of additive to blood.

Potassium Oxalate 0.16% to 0.23% (Nominal 0.19%)
Sodium Fluoride 0.80% to 1.17% (Nominal 0.95%)

Sterility Claim:
All products which are labeled as either "Sterile" or "Sterile Interior" and released for sale by BD Diagnostics Preanalytical Systems are certified to be sterile as long as the product package or product is unopened and undamaged. For those products labeled "Sterile Interior" only the product interior is sterile.

Manufacturing Claim:
BD Diagnostics Preanalytical Systems products are manufactured in accordance with the medical device regulations (21CFR820) and comply with Medical Device Reporting (MDR) Regulations (21CFR803). All products and manufacturing facilities comply with FDA registration and listing requirements (21CFR807). The released products satify BD Diagnostics Preanalytical Systems finished product specifications. The Broken Bow facility is also ISO 13485:2003 certified.

Broken Bow Quality Assurance
Release date:2018/08/22
Name:Erlinda Larsen

This certificate is produced and controlled electronically and is valid without handwritten signatures.

Creation Date: 2018/08/22 13:43:02

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

BD
1 Becton Drive
Franklin Lakes, NJ 07417
USA

bd.com

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

BD
1 Becton Drive
Franklin Lakes, NJ 07417
USA

bd.com

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 _____

June 21, 2019

BD Statement on Voluntary Recall of BD Vacutainer® Fluoride Tubes for Blood Alcohol Determinations

Ensuring the safety and quality of our products is our top priority at BD. As part of this commitment to quality, BD recently issued a voluntary recall for one lot of BD Vacutainer® Fluoride Tubes for Blood Alcohol Determinations because a small portion of the lot was confirmed to have no additive within the tube. BD determined that this issue only impacts 300 tubes within the lot and has recovered 199 of those tubes. The manufacturing issue, identified as the root cause, was immediately corrected.

Any tube without additive should be detected when the clinician conducts a visual inspection of the tube prior to blood collection as per good clinical practice. Additionally, if blood is collected in a tube with no additive, the sample may clot and should be rejected and recollected as per good clinical practice.

Based on publicly available scientific literature, in cases where a sample is processed without the 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 two days, the result for blood alcohol determination might not be accurate (either falsely low or falsely high).[1]

# # #

About BD

BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 65,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit bd.com.

[1] 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

TRITECHFORENSICS
identify. collect. preserve.

21 June 2019

RE: BD Vacutainer® Flouride Tubes for Blood Alcohol Determinations

Dear Valued Customer:

As we have recently communicated to you, BD is conducting a voluntary recall on a specific Lot of BD Vacutainer® Tubes for Blood Alcohol Determinations ("BD Tubes"). As further specified in the attached letter from BD, the voluntary recall is limited to BD Catalog Number 367001 with Lot Number 8187663 and due to the possibility, that a small number of BD Tubes may not have contained the preservative (additive) within the tube.

Tri-Tech Forensics, Inc. ("TTF") has been assembling evidentiary specimen collection kits for over 35 years and we are committed to providing our customers with exceptional quality and service. Given this communication from BD, TTF has conducted an internal review and identified the TTF specimen collection kits containing such BD Tubes. As part of our commitment to excellence, we are contacting those limited number of customers who have received such BD Tubes to the take steps necessary to retrofit such kits containing BD Tubes as specified above. Although the BD letter states that missing additive would be detected upon visual inspection of the BD Tubes prior to blood collection, TTF would like to be proactive in its approach to the BD voluntary recall and offer the replacement of such BD Tubes in the impacted kits if desired.

If you have any questions or concerns, please do not hesitate to contact me.

Bobby Dameron
Director of Sales
910-457-6600
rdameron@tritechusa.com