JAY INSLEE
Governor

JOHN R. BATISTE
Chief

STATE OF WASHINGTON
WASHINGTON STATE PATROL
WASHINGTON STATE TOXICOLOGY LABORATORY
2203 Airport Way South, Suite 360 • Seattle, Washington 98134-2027 • (206) 262-6100 • FAX (206) 262-6145

October 31, 2022

Subject: BD Product Advisory September 15, 2022

On October 3, 2022 the Washington State Patrol Toxicology Laboratory Division received notification from manufacturer BD regarding the presence of a compound in blood collection tubes that demonstrated potential interference with methanol reporting from gas chromatography methods. The notice dated September 15, 2022 is attached.

Methanol testing performed by the Washington State Patrol Toxicology Laboratory utilizes headspace gas chromatography with flame ionization detection. Consistent with Forensic Toxicology practices, positive reporting of methanol by the Laboratory requires two tests, utilizing two different gas chromatograph columns, mitigating impacts of false reporting caused by interfering substances.

The aforementioned testing and reporting protocols employed by the Laboratory also meet the recommended actions included in BD's notification dated September 15, 2022 in response to this issue.

Please contact the Laboratory at 206-262-6100 or toxlab@wsp.wa.gov with any questions.

Sincerely,

Eric Lo
Toxicology Laboratory Division
Laboratory Manager

EL:ab/eg/el

BD Life Sciences – Integrated Diagnostic Solutions
1 Becton Drive
Franklin Lakes, NJ 07417
USA
bd.com

URGENT MEDICAL DEVICE PRODUCT ADVISORY

BD Vacutainer® Tube Sodium Fluoride: 100 mg, Potassium Oxalate: 20 mg

September 15, 2022

Product Name	UDI	Catalog (Ref) Number	Lot Number(s)
BD Vacutainer® Tube Sodium Fluoride: 100 mg, Potassium Oxalate: 20 mg	Case: 50382903670012 Shelf: 30382903670018 Each: 00382903670017	367001	All lots impacted

For the Attention of: **Lab Manager/Risk Manager**

BD is conducting a voluntary product advisory for the BD Vacutainer® Tube Sodium Fluoride: 100 mg, Potassium Oxalate: 20 mg listed in the table above.

Description of the problem and health hazard(s):

The affected product REF 367001, BD Vacutainer® Tube Sodium Fluoride: 100 mg, Potassium Oxalate: 20 mg, Gray Top, 10 mL contains isobutylene (also known as isobutene or 2-methylpropene) which in a recent publication[1] demonstrated potential interference in determination of methanol by gas chromatography (GC) methods. Other non-GC methods are not impacted.

This potential interference may lead to an erroneous test result for methanol (false positive or falsely elevated), due to the incorrect identification of isobutylene as methanol. The reported interference does not impact determination of ethanol or other analytes.

This interference was reported on a dual-column headspace GC system with flame ionization detection (FID), where the isobutylene peak retention time matched that of methanol on one column, but not on the second column. In the publication, the dual-column system worked as intended to identify the interference, and the isobutylene was not reported as methanol. There is a risk of erroneous results with single-column GC systems, where confirmation from a second column is not available. This risk can be mitigated by robust method validation including using the tube as a blank/control, to identify potential interference and ensure the system is set to prevent co-elution.

Potential interference from isobutylene is due to outgassing from the rubber stopper in the blood collection tube, and is therefore inherent in all production lots. BD has received three (3) complaints in the past three years (June 2019 – July 2022) believed to be related to this issue. One complaint upon further evaluation, did not involve methanol interference. The other two complaints were from the author of the cited publication. There have been no adverse events of death or serious injury reported due to potential interference of isobutylene.

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[1] Kosecki PA, Autret A, Abbott L, Keller-Brooke K. Isobutylene contamination of blood collected in 10-ml evacuated blood collection tubes with gray conventional rubber stoppers. J Forensic Sci. 2021 Nov;66(6):2484-2492

PLEASE TAKE THE FOLLOWING ACTIONS:

1. Inspect your inventory for the specific catalog number listed above.

2. Ensure the contents of this Product Advisory are read, understood and shared with laboratory management staff having oversight over gas chromatography testing for methanol. Review internal method validations, and if applicable, adjust test practices or settings to avoid potential interference (e.g., implementing the tube as a blank/control, adjustment of GC column and/or operational settings to prevent co-elution, or conversion to dual-column system).

3. If the potential interference cannot be mitigated, stop using the BD Vacutainer® Tube Sodium Fluoride: 100 mg, Potassium Oxalate: 20 mg. Product may be returned for credit.

4. Complete the attached Customer Response Form and return to the BD contact noted on the form whether or not you have any of the impacted material so that BD may acknowledge your receipt of this notification per FDA requirements.

5. 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 via:

   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

Actions Taken by BD:

1. Corrective and preventive action was initiated to investigate root cause and identify actions.

2. The product Instructions for Use (IFU) will be updated to address the potential risk of interference from rubber stopper outgassing in gas chromatography methods.

If you require further assistance, please contact:

BD Contact	US Contact Information	Areas of Support
North American Regional Complaint Center	**Phone:** 1-844-8BD-LIFE (1-844-823-5433) Say "Recall" when prompted Mon–Fri 8:00am and 5:00pm CT **or** **Email:** productcomplaints@bd.com	Product Advisory, Recall questions, Product Complaints, Technical Questions

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,

Jeffrey Andrews

Jeffrey Andrews, M.D.
WW VP Medical Affairs

Larry Perruzza
Sr. Director, Post Market Quality

Advancing the world of health

CUSTOMER RESPONSE FORM

IDS-22-4525-FA

BD Vacutainer® Tube Sodium Fluoride: 100 mg, Potassium Oxalate: 20 mg

Please assist BD by promptly returning this form to BD:
Website: https://bdx.force.com/CC360/s/impactedproducts?rn=IDS-22-4525
Email: BDRC9@bd.com
Fax: 312-949-0236

Street Address: _____

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

Customer Response Form Completed By:	
Name:	
Title:	
Telephone No.	
Fax No.	
Email Address	

Please check all that apply:

☐ I have read and understood the attached notice and taken appropriate actions.

Please assist BD with assuring these communications are delivered to the appropriate person/function within your facility if that is not you.

Person/function responsible for the receipt and management of product advisory and recalls at your facility:

Name: _____

Phone: _____

Email: _____

Fax #: _____