



September 1, 2023

RE: Instructions for Use, new Electronic IFU, and Labeling Change Notification for BD Vacutainer® Blood Alcohol Determinations Tube (Sodium Fluoride 100mg, Potassium Oxalate 20mg)

Dear Valued Customer:

BD Life Sciences is committed to providing the best possible product experience to our customers. This communication contains important information concerning changes to the Intended Use Statement (i.e., For Forensic Use Only), new electronic Instructions for Use, and labeling change for the BD Vacutainer® Blood Alcohol Determinations Tube (Sodium Fluoride 100mg, Potassium Oxalate 20mg).

The product code being updated is listed in the table below.

Catalog Number	Product Description
367001	BD Vacutainer® Blood Alcohol Determinations Tube, (Sodium Fluoride 100mg, Potassium Oxalate: 20 mg, Gray Top, 10 mL)

On September 1, 2023, BD Life Sciences will begin implementing the product labeling changes listed below for the BD Vacutainer® Blood Alcohol Determinations Tube.

Changes to Instructions for Use

The Instructions for Use has been updated. Key updates include the following:

Intended Use Statement Change - The BD Vacutainer® Blood Alcohol Determinations Tube will now be labeled as "For Forensic Use Only." The updated intended use will read:

The BD Vacutainer® Blood Alcohol Determinations Tube is an evacuated, sterile, single-use product intended for the collection of venous blood for testing of blood alcohol for the purposes of law enforcement. For Forensic Use Only.

Precautions - The following precaution has been added:

The BD Vacutainer® Blood Alcohol Determinations Tube contains compounds that can leach or outgas into blood specimens that may potentially interfere with chromatographic methods. Laboratories should conduct appropriate validations of chromatography-based assays to ensure these compounds do not interfere.¹

Fill Indicator – A fill indicator has been added to the tube label, and is described in the Instructions for Use.

Instructions for Use in Electronic Format (eIFU) - BD Life Sciences has transitioned from physical paper copies of product inserts to the new updated electronically available



Instructions for Use for the BD Vacutainer® Blood Alcohol Determinations Tube (Sodium Fluoride 100mg, Potassium Oxalate 20mg). Moving our IFU information online will ensure our customers always have the most up-to-date product information available.

To ensure all updates are reviewed, it is recommended to read the entire eIFU.

To access the eIFU, please go to <https://eifu.bd.com/>. This website URL will also be available on the case label for the product.

In Appendix A, attached at the end of this letter, you will find the "Distribution Verification Form" that must be completed and sent back to BD before you may order this product. By completing the Form, you certify that you understand this product is intended For Forensic Use Only and that you will not use the product in a manner inconsistent with labeling. Please scan and email the completed Form to IDS-FUO-Verification-Forms@bd.com.

For more information about these changes, or if you are not performing forensic testing, please contact our BD Technical Services Team at 1.800.638.8663, option 3, or email us at Technical_Services@bd.com. For all other questions, please contact BD customer service at 1.844.823.5433.

Sincerely,

Brent Ashton
Vice-President / General Manager
BD Life Sciences, Integrated Diagnostic Solutions

1. Chromatography Interferences: 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;66:2484–2492

Advancing the world of health



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Franklin Lakes, NJ 07417
bd.com

Ship to Customer # (Completed by BD)	1001041061 1002228124
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BD maintains a process to ensure our products are sold to appropriate users. Receipt of this Form indicates your Company/Institution listed below intends to purchase product 367001, BD Vacutainer® Blood Alcohol Determinations Tube, (Sodium Fluoride 100mg, Potassium Oxalate: 20 mg, Gray Top, 10 mL) which is labeled as and limited to For Forensic Use Only. Please review the description of Forensic Use Only below:

***Forensic Use Only (FUO)** products are intended for use only in drugs of abuse testing for criminal justice or law enforcement purposes. Appropriate users of such products include but are not limited to, court systems, police departments, probation/parole offices, juvenile detention centers, prisons, jails, correction centers and other similar law enforcement entities, laboratories or other establishments performing forensic testing on behalf of these entities. FUO products are neither tested in nor labeled for use in other settings, such as hospitals, physician offices or the like. As such, they cannot be used for diagnostic purposes.*

To order and receive Forensic Use Only (FUO) product from BD, please have a duly authorized representative complete the following information and sign below certifying that your Company/Institution listed below understands product 367001, BD Vacutainer® Blood Alcohol Determinations Tube, (Sodium Fluoride 100mg, Potassium Oxalate: 20 mg, Gray Top, 10 mL) is intended for Forensic Use Only and that your Company/Institution listed below will not use the product in a manner inconsistent with labeling.

Printed Name	Signature
Title	Date Signed
Telephone Number	Email address
Company/Institution Name GBF Inc.	Address 2427 Penny Rd, High Point, NC, 27265

Please scan and email the completed document to IDS-FUO-Verification-Forms@bd.com.

Thank you for your understanding and support.

Appendix A