1 Becton Drive
Franklin Lakes, NJ 07417
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April 1, 2024

RE: Changes to Product Labeling, IFU, and Shelf-Life Notification for the BD Vacutainer® Fluoride Blood Collection Tubes

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 Indications for Use and electronic Instructions for Use (eIFU) for BD Vacutainer® Fluoride Blood Collection Tubes. These changes do not impact the design, form, or fit of these products.

BD Life Sciences has received clearance from the U.S. Food and Drug Administration (FDA) for an expanded indication for use for our BD Vacutainer® Fluoride Blood Collection Tubes, which now includes the additional claim for Lactate testing for the Sodium Fluoride/KOx tube. For BD Vacutainer® Fluoride Blood Collection Tubes, we completed Glucose and Lactate testing over a variety of test methods and time periods as described in the Analytic Equivalency section below. For the full clinical performance testing that was completed, please review the Analytical Equivalency section of the IFU.

The product codes in scope of this notification are listed in the table below.

Product Catalog Number	Product Description	Status and Changes	Alternate Product Catalog#	Alternate Product Description
367587	BD Vacutainer® Sodium Fluoride: 3 mg Na_2EDTA: 6 mg Blood Collection Tube, 2.0mL	510(k) Cleared Indications for Use Labeling update		
367921	BD Vacutainer® Sodium Fluoride 5 mg Potassium Oxalate 4 mg (FX) Blood Collection Tube, 2.0mL	510(k) Cleared Indications for Use Labeling update		
367922	BD Vacutainer® Sodium Fluoride 10 mg Potassium Oxalate 8 mg (FX) Blood Collection Tube, 4.0mL	510(k) Cleared Indications for Use Labeling update		
367925	BD Vacutainer® Sodium Fluoride 15 mg Potassium Oxalate 12 mg (FX) Blood Collection Tube, 6.0mL	510(k) Cleared Indications for Use Shelf-life change Labeling update		
368587	BD Vacutainer® Sodium Fluoride 10 mg Potassium Oxalate 8 mg (FX) Blood Collection Tube, 4.0mL	Discontinued as of October 1, 2024	367922	BD Vacutainer® Sodium Fluoride 10 mg Potassium Oxalate 8 mg (FX) Blood Collection Tube, 4.0mL
368033	BD Vacutainer® Sodium Fluoride: 10 mg Potassium Oxalate: 8 mg Blood Collection Tube, 4.0mL	Discontinued as of October 1, 2024	367922	BD Vacutainer® Sodium Fluoride 10 mg Potassium Oxalate 8 mg (FX) Blood Collection Tube, 4.0mL
367729	BD Vacutainer® Sodium Fluoride: 30 mg Blood Collection Tube, 7.0mL	Discontinued as of October 1, 2024	367925	BD Vacutainer® Sodium Fluoride 15 mg Potassium Oxalate 12 mg (FX) Blood Collection Tube, 6.0mL

On April 5, 2024, BD Life Sciences will implement a new electronic Instructions for Use (eIFU) for the BD Vacutainer® Fluoride Blood Collection Tubes. Key updates include the following:

Intended Use Statement - The BD Vacutainer® Fluoride Blood Collection Tubes updated intended use will read:

> *BD Vacutainer® Fluoride Blood Collection Tubes are evacuated, sterile, single-use, in vitro diagnostic medical devices available with Sodium Fluoride/Potassium Oxalate or Sodium Fluoride/Na_2EDTA. They are intended to be used by trained healthcare professionals for the*

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collection, containment, preservation, transportation, and centrifugation of venous blood specimens as required for in vitro diagnostic testing. Plastic BD Vacutainer® Fluoride Blood Collection Tubes are used to collect whole blood for the generation of plasma samples.

Blood collected in BD Vacutainer® Fluoride Blood Collection Tubes containing Sodium Fluoride/Potassium Oxalate are used for glucose and lactate determinations. Blood collected in BD Vacutainer® Fluoride Blood Collection Tubes containing Sodium Fluoride/Na_2EDTA are used for glucose determinations.

Analytical Equivalency - The following information has been added to the IFU:

Evaluations of BD Vacutainer® Fluoride Tubes have been performed for selected analytes and instrument platforms. See table below.

Within-tube stability has been demonstrated for Glucose and Lactate in BD Vacutainer® Fluoride tubes. Glucose was tested at 4 hours storage at room temperature and 24 hours refrigerated. Within-tube stability has been demonstrated for Lactate at 45 minutes after being held on ice with the NaF/KOx tube. These studies were performed with tubes centrifuged at 2,000 g/10 minutes. It is recommended to test Lactate as quickly as possible.

To view the table, please go to https://eifu.bd.com/.

Instructions for Use in Electronic Format (eIFU) - BD Life Sciences has transitioned from physical copies of product inserts to electronically available Instructions for Use (eIFUs) for BD Vacutainer® Fluoride Blood Collection Tubes. Moving our product insert 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, as of April 5, 2024, please go to https://eifu.bd.com/.

Additional Updates:

In August 2024, BD Life Sciences will begin implementing the following label changes for the BD Vacutainer® Fluoride Blood Collection Tubes:

Case Label – The eIFU website URL will also be available on the case label for the products.

Product Shelf-Life Change:

BD Life Sciences is also reducing the shelf-life for BD Vacutainer® Fluoride Blood Collection Tube, 6.0mL, catalog number 367925, from 17 months to 15 months. This shelf-life change is based on data available at the time of our 510(k) clearance by the FDA and is not the result of a product performance issue. This change does not impact any BD Vacutainer® Fluoride Blood Collection Tube, 6.0mL, catalog number 367925, manufactured prior to August 1, 2024.

It is recommended to follow your institution's policies and procedures for product validation prior to use.

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Product Discontinuation:

Effective October 2024, we will be fully discontinuing the below BD Vacutainer® Fluoride Blood Collection Tubes. These changes do not impact the design, form, or fit of these products.

Product Catalog Number	Product Description	Status and Changes	Suggested Alternate Product Catalog#*	Suggested Alternate Product Description
368587	BD Vacutainer® Sodium Fluoride 10 mg Potassium Oxalate 8 mg (FX) Blood Collection Tube, 4.0mL	Discontinued as of October 1, 2024	367922	BD Vacutainer® Sodium Fluoride 10 mg Potassium Oxalate 8 mg (FX) Blood Collection Tube, 4.0mL
368033	BD Vacutainer® Sodium Fluoride: 10 mg Potassium Oxalate: 8 mg Blood Collection Tube, 4.0mL	Discontinued as of October 1, 2024	367922	BD Vacutainer® Sodium Fluoride 10 mg Potassium Oxalate 8 mg (FX) Blood Collection Tube, 4.0mL
367729	BD Vacutainer® Sodium Fluoride: 30 mg Blood Collection Tube, 7.0mL	Discontinued as of October 1, 2024	367925	BD Vacutainer® Sodium Fluoride 15 mg Potassium Oxalate 12 mg (FX) Blood Collection Tube, 6.0mL

*The potential alternative products are BD's suggestions based on its own comparison of the form, features, and functions of the discontinued products and the potential alternative products. Depending on a customer's circumstances, clinical requirements and intended use of the proposed alternative product, such product may not be a clinically appropriate alternative to the discontinued product, and any such determination shall be made by the customer.

Moving forward, we will be providing all product updates accessible at https://go.bd.com/vacutainer-product-updates.html as these clearances are received by the FDA and will be available for all BD Vacutainer® tube product families. This website URL has been live since November 2023. It is best to go directly to https://go.bd.com/vacutainer-product-updates.html to get the most updated information. On the website it is recommended that you sign up to receive notifications for future clearances and the most up-to-date product information.

For more information about these changes, 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,

Attiq Amjad

Attiq Amjad
Associate Director, Marketing
BD Life Sciences

Advancing the world of health

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