



November 1, 2023

RE: Changes to Product Labeling, IFU, and Shelf-Life Notification for the BD Vacutainer® EDTA 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 (IFU) for BD Vacutainer® EDTA Blood Collection Tubes. These changes do not impact the design, form, or fit of these products.

Given the time that has passed since our original filing to the U.S. Food and Drug Administration (FDA) for the BD Vacutainer® EDTA Blood Collection Tubes, we have submitted, and recently received, a new 510(k) clearance from FDA in order to demonstrate the continued performance of these products. For BD Vacutainer® EDTA Blood Collection products, we completed hematology parameter testing with representative methods 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
367841	BD Vacutainer® K ₂ E (EDTA) 3.6 mg Blood Collection Tubes, 13x75, 2.0mL
367856	BD Vacutainer® K ₂ E (EDTA) 5.4 mg Blood Collection Tubes, 13x75, 3.0mL
367861	BD Vacutainer® K ₂ E (EDTA) 7.2 mg Blood Collection Tubes, 13x75, 4.0mL
367863	BD Vacutainer® K ₂ E (EDTA) 10.8 mg Blood Collection Tubes, 13x100, 6.0mL
366450	BD Vacutainer® K ₃ E (EDTA) 12 mg Blood Collection Tubes, 13x100, 7.0mL
366643	BD Vacutainer® K ₂ E (EDTA) 18 mg Blood Collection Tubes, 16x100, 10.0mL
367899	BD Vacutainer® K ₂ E (EDTA) 10.8 mg Blood Collection Tubes, 13x100, 6.0mL
367842	BD Vacutainer® K ₂ E (EDTA) 3.6 mg Blood Collection Tubes, 13x75, 2.0mL

On November 1, 2023, BD Life Sciences will implement a new electronic Instructions for Use (eIFU) for the BD Vacutainer® EDTA Blood Collection Tubes. Key updates include the following:

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

BD Vacutainer® EDTA Blood Collection Tubes are evacuated, sterile, single use, in vitro diagnostic medical devices. They are intended to be used by trained



healthcare professionals for the collection, containment, preservation, and transport of human venous blood specimens used for in vitro diagnostic testing.

BD Vacutainer® K₂EDTA and K₃EDTA Blood Collection Tubes are used for testing in hematology such as white blood cells (WBC), red blood cells (RBC), red blood cell distribution width (RDW), hemoglobin (Hgb), hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), platelets, and 5-part white blood cell (WBC) differential counts (neutrophils, lymphocytes, monocytes, eosinophils, basophils).

BD Vacutainer® Plus K₂EDTA Tubes may be used for routine immunohematology testing and blood donor screening. The performance characteristics of these tubes have not been established for immunohematology testing in general; therefore, users must validate the use of these tubes for their specific assay-instrument/reagent system combinations and specimen storage conditions.

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

Evaluations of BD Vacutainer® EDTA Tubes have been performed for analytes listed in Table B using test methods listed in Table C. Within-tube stability has been demonstrated using the BD Vacutainer® EDTA Tubes for the following parameters and conditions in Table B. Analyte stability can be affected by a wide range of factors and should therefore be evaluated for the storage containers and conditions of each laboratory.

To view the tables with data, 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® EDTA 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 November 1, 2023, please go to <https://eifu.bd.com/>.

Additional Updates:

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

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

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 both BD Vacutainer® K₂E (EDTA) 10.8 mg Blood Collection Tube, 6.0mL, catalog numbers 367863 and 367899, 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® K₂E (EDTA) 10.8 mg Blood Collection Tubes, 6.0mL, manufactured prior to February 1, 2024.

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

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 will go live on November 21, 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,

A handwritten signature in black ink, appearing to read "Ryan Tuttle".

Ryan Tuttle
WW Platform Leader
BD Life Sciences, Integrated Diagnostic Solutions

Advancing the world of health