



September 17, 2023

RE: Changes to Product Labeling, IFU, and Product Array for BD Vacutainer® Trace Element 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 Intended Use Statement, new electronic Instructions for Use, labeling, and launch of a newly offered alternative 3.0 mL tube for BD Vacutainer® Trace Element Blood Collection Tubes.

Given the time that has passed since our original filing to the U.S. Food and Drug Administration (FDA) for the BD Vacutainer® Trace Element Blood Collection Tubes, we have submitted, and recently received, a new 510(k) clearance from FDA in order to demonstrate the continued performance of the 6.0 mL products and substantiate the equivalence of a newly offered 3.0 mL tube. Clinical performance testing was completed as described in the Analytic Equivalency section below.

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

Product Catalog#	Product Description	Shelf-Life	Status
368380	BD Vacutainer® Trace Element Serum Blood Collection Tube, 13X100mm, 6.0mL, Royal Blue Closure	12 months	510(k) Cleared
368381	BD Vacutainer® Trace Element K ₂ EDTA (K2E) 10.8mg Blood Collection Tube, 13X100mm, 6.0mL, Royal Blue Closure	12 months	510(k) Cleared
367777	BD Vacutainer® Trace Element K ₂ EDTA (K2E) 5.4 mg Blood Collection Tube, 13X100mm, 3.0mL, Royal Blue Closure	10 months	510(k) Cleared New Product Catalog# Available for order as of January 2024
367855	BD Vacutainer® K ₂ E (EDTA) 5.4 mg Blood Collection Tube, 13x75mm, 3.0mL, Tan Closure	12 months	Discontinued as of July 1, 2024

On September 17, 2023, BD Life Sciences will implement a new electronic Instructions for Use (eIFU) for the BD Vacutainer® Trace Element Blood Collection Tubes. Key updates include the following for product catalog numbers 368380 and 368381:

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

BD Vacutainer® Trace Element Serum Tubes and BD Vacutainer® Trace Element K₂EDTA Tubes are plastic, evacuated, sterile, single use, in vitro diagnostic medical devices. They are intended to be used in settings where venous blood specimens are collected by trained healthcare professionals for the collection, transportation, and processing of blood in a closed tube. Blood collected in the BD Vacutainer® Trace Element Serum Tubes and BD Vacutainer® Trace Element K₂EDTA Tubes are used for trace element testing (e.g., Arsenic, Cadmium, Chromium, Copper, Lead, Manganese, Mercury, Selenium, and Zinc).

There has been a change to remove Calcium, Iron, and Magnesium from the trace element indications, as they are generally tested with chemistry tubes.

Precautions – The following precaution has been added:

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Examine tubes prior to use. Do not use if the additive is missing, discolored, or if foreign matter or precipitate is present.

- *Spray coated K₂EDTA additive is visible in the tube and should appear as clear or colorless dots. It may have a white to slightly yellow appearance. This coloration does not affect the performance of the additive.*
- *Spray coated clot activator additive is visible in the tube and should appear as white dots. It may have a slightly cloudy appearance. A cloudy appearance does not affect the performance of the additive.*

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

Transportation studies have been performed for selected analytes (As, Cd, Cr, Cu, Hg, Pb, Mn, Se) and support the claim for shipping of the specimens within non-centrifuged BD Vacutainer® Trace Element K₂EDTA or Serum Blood Collection Tubes at room temperature.

Within-tube stability has been evaluated for select elements (As, Cd, Cr, Cu, Hg, Pb, Mn, Se, Zn) in BD Vacutainer® Trace Element K₂EDTA or Serum Blood Collection Tubes. Within-tube stability was demonstrated for As, Cd, Cr, Cu, Hg, Pb, Mn, Se at 24 hours and Zn at 4 hours storage at room temperature using ICP-MS.

Published studies have demonstrated that serum / plasma zinc levels increase with increasing delay to centrifugation due to prolonged contact with red cells.¹⁻² Therefore, it is recommended that samples for serum/plasma zinc determinations be separated soon after collection (and clotting for serum samples) to minimize artefactual increase in zinc.

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 additional tables with data, please go to <https://eifu.bd.com/>.

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® Trace Element Blood Collection Tubes. 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, as of September 17, 2023, please go to <https://eifu.bd.com/>.

Additional Updates:

In January 2024, BD Life Sciences will begin implementing the following label changes for the BD Vacutainer® Trace Element 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 Launch and Discontinuation:

In January 2024, BD Life Sciences will begin implementing the new BD Vacutainer® Trace Element Blood Collection Tube, 3.0mL (Catalog#: 367777 | Closure Color: Royal Blue), aligned to the labeling of 368380 and 368381.

Effective July 1, 2024, we will be fully discontinuing the BD Vacutainer® Blood Collection Tube for Lead Testing, 3.0mL (Catalog#: 367855 | Closure Color: Tan) and replace it with a Trace Element Tube, 3.0mL of equivalent size for multiple element testing (Catalog#: 367777 | Closure Color: Royal Blue), also listed in the chart below.

Discontinued Product Catalog#	Product Description	Alternative Product Catalog#	Product Description	Shelf-Life
367855	BD Vacutainer® K ₂ E (EDTA) 5.4 mg Blood Collection Tube, 13x75mm, 3.0mL, Tan Closure	367777	BD Vacutainer® Trace Element K ₂ EDTA (K2E) 5.4 mg Blood Collection Tube, 13X100mm, 3.0mL, Royal Blue Closure	10 months

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

For more information about these changes or to obtain a copy of BD’s scientific documentation to support the product transition, 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,

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

Zinc Stability:

- English JL, Hambidge KM. Plasma and serum zinc concentrations: effect of time between collection and separation. Clin Chim Acta. 1988 Jul 29;175(3):211-5.
- Leger M, Despinasse Q, Faure P, Arnaud J, Ravelet C, Chovelon B. Influence of delayed separation of plasma from whole blood and centrifugation protocol on Zn plasma concentration. Clin Chem Lab Med. 2020 Oct 25;58(11):e279-e281.

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