



March 2024

RE: Changes to Product Labeling, IFU, and Product Array Notification for the BD Vacutainer® Serum Separator (SST™) 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, new electronic Instructions for Use (IFU), labeling, and launch of a newly offered alternative 10.0mL tube for BD Vacutainer® SST™ 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® SST™ 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® SST™ Blood Collection products, it is used for clinical laboratory testing in chemistry and for the monitoring of certain therapeutic drugs. 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
367977	BD Vacutainer® SST™ Blood Collection Tube, 13x100mm, 4.0mL, Paper Label	510(k) Cleared
367983	BD Vacutainer® SST™ Blood Collection Tube, 13x75mm, 3.5mL, Paper Label	510(k) Cleared
367986	BD Vacutainer® SST™ Blood Collection Tube, 13x100mm, 5.0mL, Paper Label	510(k) Cleared
367988	BD Vacutainer® SST™ Blood Collection Tube, 16x100mm, 8.5mL, Paper Label	510(k) Cleared
367989	BD Vacutainer® SST™ Blood Collection Tube, 13x100mm, 5.0mL, Mylar Label	510(k) Cleared
368013	BD Vacutainer® SST™ Blood Collection Tube, 13x100mm, 5.0mL, Barcode Label	510(k) Cleared
368015	BD Vacutainer® SST™ Blood Collection Tube, 13x75mm, 3.5mL, Barcode Label	510(k) Cleared
368016	BD Vacutainer® SST™ Blood Collection Tube, 16x100mm, 8.5mL, Barcode Label	510(k) Cleared
367990	BD Vacutainer® SST™ Blood Collection Tube, 16x125mm, 10.0mL, Paper Label	510(k) Cleared New Product Catalog# Available for order as of September 2024
367985	BD Vacutainer® SST™ Blood Collection Tube, 16x125mm, 10.0mL, Paper Label	Discontinued as of November 2024

On February 20, 2024, BD Life Sciences will implement a new electronic Instructions for Use (eIFU) for the BD Vacutainer® SST™ Blood Collection Tubes. Key updates include the following:



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

The BD Vacutainer® Serum Separator (SST™) Blood Collection Tube is a sterile, single-use tube used for the collection, containment, transport, and centrifugation of venous blood specimens to obtain and store serum for in vitro diagnostic testing. It is used in settings where a venous blood specimen is collected by a trained healthcare professional. The BD Vacutainer® Serum Separator (SST™) Blood Collection Tube is used for clinical laboratory testing in chemistry and for the monitoring of certain therapeutic drugs.

The BD Vacutainer® Serum Separator (SST™) Blood Collection Tube may be used for routine blood donor screening and diagnostic testing of serum for infectious disease. The performance characteristics of these tubes have not been established for infectious disease 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® SST™ Tubes have been performed for selected analytes on certain instrument platforms. See list of analytes and instruments in Table B in the eIFU.

Whenever changing any manufacturer's blood collection tube, type, size, handling, processing or storage conditions for a particular laboratory assay, the laboratory personnel should review the tube manufacturer's data, the assay manufacturer's data and their own data to establish/verify the reference range for a specific instrument/reagent system. Based on such information, the laboratory can then decide if changes are appropriate.

To view the tables, 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® SST™ 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 March 15, 2024, please go to <https://eifu.bd.com/>.

Additional Updates:

In September 2024, BD Life Sciences will begin implementing the following label changes for the BD Vacutainer® SST™ 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.

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

Product Launch and Discontinuation:



In September 2024, BD Life Sciences will begin implementing the new BD Vacutainer® SST™ Blood Collection Tube, 10.0mL (Catalog#: 367990 | Closure Color: Red/Gray), aligned to the labeling of the rest of the BD Vacutainer® SST™ Blood Collection Tubes mentioned above.

Effective November 2024, we will be fully discontinuing the BD Vacutainer® SST™ Blood Collection Tube, 10.0mL (Catalog#: 367985 | Closure Color: Red/Gray) and replace it with a BD Vacutainer® SST™ Blood Collection Tube, 10.0mL (Catalog#: 367990 | Closure Color: Red/Gray), also listed in the chart below. These changes do not impact the design, form, or fit of these products.

Discontinued Product Catalog#	Product Description	Alternative Product Catalog#	Product Description
367985	BD Vacutainer® SST™ Blood Collection Tube, 16x125mm, 10.0mL, Paper Label	367990	BD Vacutainer® SST™ Blood Collection Tube, 16x125mm, 10.0mL, Paper Label

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. 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
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BD Life Sciences

Advancing the world of health