1 Becton Drive
Franklin Lakes, NJ 07417
USA
bd.com

August 18, 2025

RE: Changes to Product Labeling and IFU for the BD Vacutainer® Citrate 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 and electronic Instructions for Use (eIFU) for BD Vacutainer® Citrate Blood Collection Tubes. These changes do not impact the design, form, or fit of these products.

BD has submitted and recently received 510(k) clearance from the FDA for the BD Vacutainer® Citrate Blood Collection Tubes. BD completed coagulation parameter testing with representative methods as described in the Analytic Performance section below. For the full clinical equivalence testing that was completed, please review the Analytic Performance and Clinical Equivalence sections of the IFU.

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

Product Catalog Number	Product Description
363080	BD Vacutainer® Citrate Blood Collection Tubes, 13x75, 1.8mL
363083	BD Vacutainer® Citrate Blood Collection Tubes, 13x75, 2.7mL
366560	BD Vacutainer® Citrate Blood Collection Tubes, 13x75, 2.7mL

On October 31, 2025, BD Life Sciences will implement new electronic Instructions for Use (eIFU) for the BD Vacutainer® Citrate Blood Collection Tubes. Key updates include the following:

Intended Use Statement - The BD Vacutainer® Citrate Blood Collection Tubes updated Intended Use Statement will read:

> *The BD Vacutainer® Citrate Blood Collection Tube (0.109M buffered Sodium Citrate) is a sterile, single-use tube used for the collection, containment, transport, and centrifugation of venous blood specimens to obtain plasma for in vitro diagnostic testing. It is used in settings where a venous blood sample is collected by a healthcare worker. The BD Vacutainer® blood Collection tube is used for clinical laboratory testing in coagulation.*

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

> *Evaluations of BD Vacutainer® Citrate Blood Collection Tubes have been performed for parameters listed in Table B using test methods listed in Table C. Within-tube stability has been demonstrated using the BD Vacutainer® Citrate Blood Collection*

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Tubes for the following parameters and conditions in Table B at room temperature (15-25° C). Parameter stability can be affected by a wide range of factors and should therefore be evaluated for the storage containers and conditions of each laboratory.

Table B: Within Tube Stability

Analyte	Temp: RT 4 hours	Temp: RT 8 Hours	Temp: RT 16 hours	Temp: RT 24 hours
PT (Prothrombin Time)	Pass	Pass	Pass	Pass
INR (International Normalized Ratio)	Pass	Pass	Pass	Pass
aPTT (Activated Thromboplastin Time)	Pass	Pass	–	–
D-Dimer	Pass	Pass	Pass	–
Anti-Factor Xa	Pass	Pass	–	–

Table C

Study Objective	Instrument	Test Method	Analytes tested
Clinical Equivalence	Diagnostica Stago, STA R Max	Mechanical	PT/INR
	Instrumentation Laboratory ACL TOP 750	Photo-Optical	aPTT D-Dimer Anti-Factor Xa
Within-Tube Stability	Diagnostica Stago, STA Compact (or comparable)	Mechanical	PT/INR
	Instrumentation Laboratory ACL TOP 550	Photo-Optical	aPTT D-Dimer Anti-Factor Xa
	Sysmex CS-2500	Optical	

For complete information, 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® Citrate Blood Collection Tubes. Moving our product information online will ensure our customers always have the most up-to-date product information available.

To ensure all updates are reviewed, please read the entire eIFU.

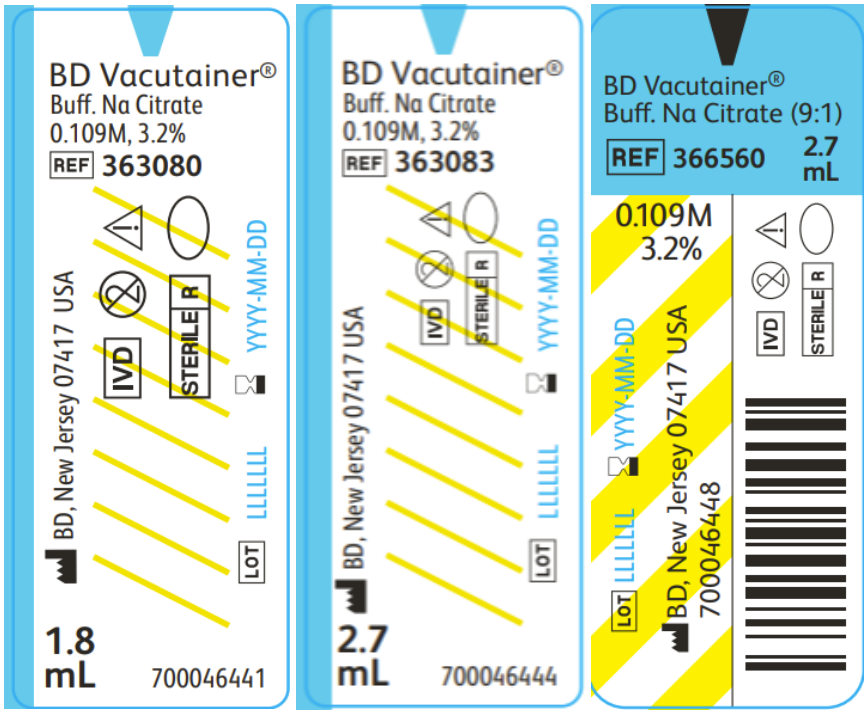
To access the eIFU, as of October 31, 2025, please go to https://eifu.bd.com/.

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Additional Updates:
In October 2025, BD Life Sciences will begin implementing the following label changes for the BD Vacutainer® Citrate Blood Collection Tubes:

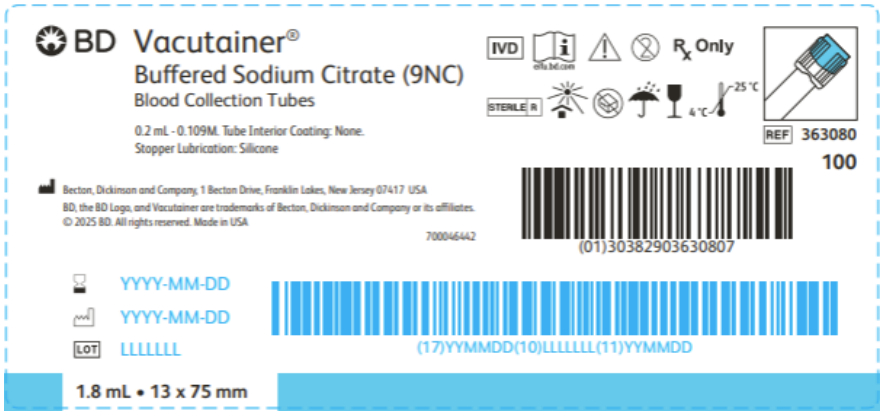
Unit Label:

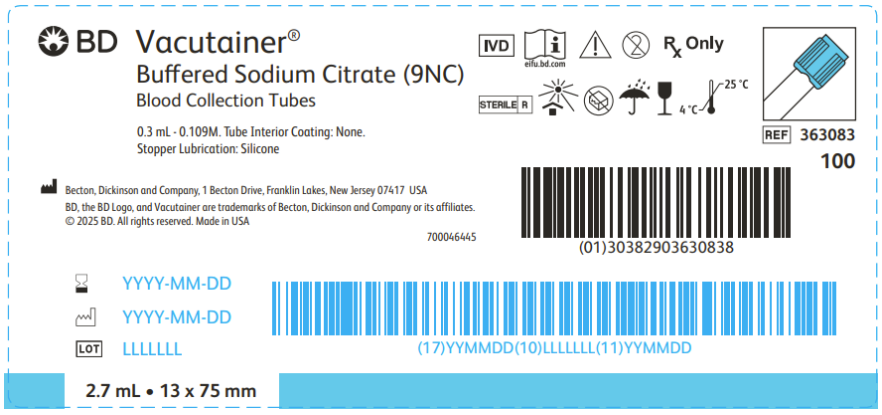


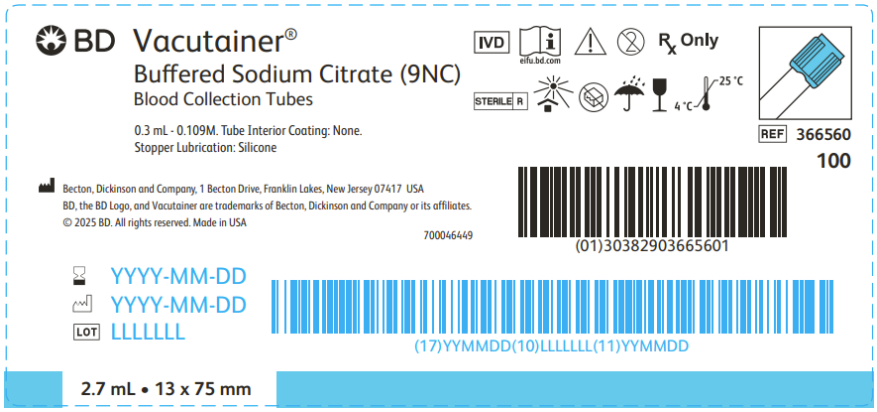
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Shelf pack Label:



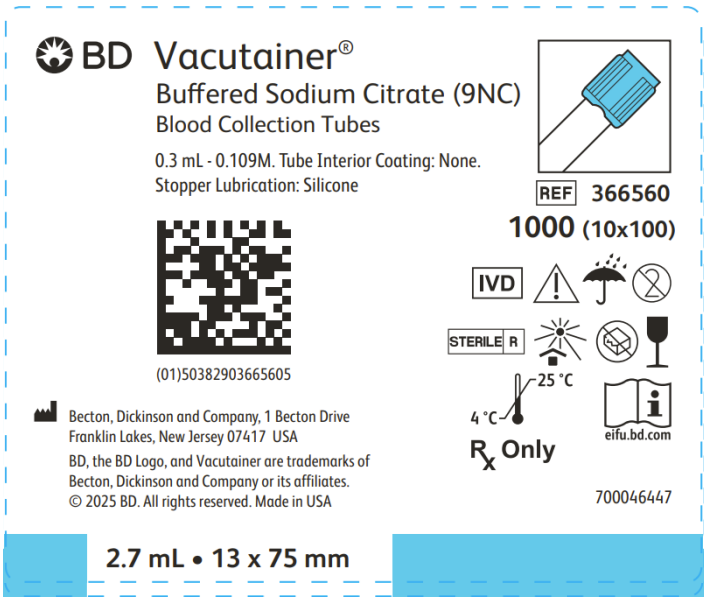


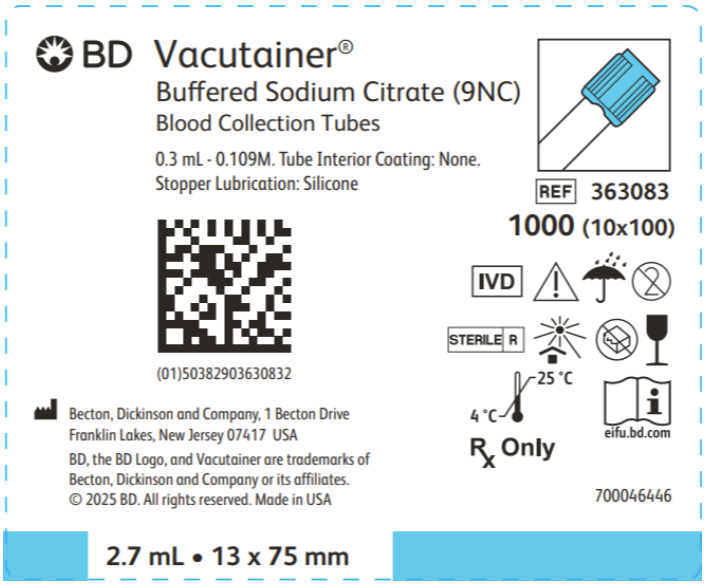


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Case Label:





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

Please 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. You can sign up to receive notifications for future clearances and the most up-to-date product information on the website.

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,

Erin N. Balkema

Erin Balkema
Sr. Director, WW Lab Specimen Management
BD Life Sciences, Integrated Diagnostic Solutions

Advancing the world of health

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