



URGENT PRODUCT RECALL

January 16, 2017

Product Name	UDI	Catalog No.	Lot No.	Expiration Date
BD Vacutainer® Buffered Sodium Citrate: (9NC) Blood Collection Tube (13 x 75 mm x 4.5 mL)	N/A	369714	6090572	10/31/2017

Dear Customer,

BD is conducting a voluntary recall for a single lot (lot 6090572) of catalog number 369714, BD Vacutainer® Buffered Sodium Citrate: (9NC) Blood Collection Tube 13 x 75 mm x 4.5 mL. After receiving a customer complaint reporting erroneous results, BD confirmed that a limited portion of the referenced lot was manufactured with approximately twice the expected amount of buffered sodium citrate additive, an anticoagulant. Additive overfill in this amount may cause erroneous results which can lead to specimen recollection and potential delay of treatment or misdiagnosis/mismanagement of treatment and serious complications, such as clotting or postponing surgery. No adverse events have been reported for this issue.

The affected lot number can be found on the individual unit label and the shelf pack label. Sample graphics showing the location of the catalog and lot number on the unit and shelf pack labels are included to assist you in identifying if the recalled lot is within your control. BD distributed the affected lot beginning June 22, 2016.

Our records indicate you may have been shipped the above-referenced lot of product.

BD Life Sciences – Preanalytical Systems
1 Becton Drive
Franklin Lakes, NJ 07417
USA

bd.com

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Immediately review your inventory for catalog number 369714, lot number 6090572 and quarantine the product subject to the recall.
2. Complete the Customer Recall Response Form and fax it back to BD at **1-844-388-5534** or email to **bd8872@stericycle.com**.
3. Return all affected products using the enclosed packaging instructions and include the completed Recall Response Form with the product. Upon receipt of the returned product, BD will issue replacement product.


NOTE: Even if you do not have any of the affected lot in your inventory, please complete the Customer Recall Response Form indicating you have zero (0) quantity and fax the completed form back to BD at 1-844-388-5534 or email the completed form to bd8872@stericycle.com.

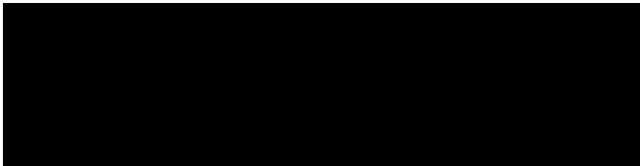
If you have any questions or require assistance with the return of the recalled product and/or availability of replacement product, please contact **1-844-265-7408 between 8AM and 5 PM ET Monday through Friday.**

Any adverse health consequences experienced with the use of this product should be reported to BD and may be reported to the FDA's MedWatch Adverse Event Reporting program at www.fda.gov/medwatch/report.htm.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with the highest quality products. Thank you for your prompt support on this important matter. BD appreciates your cooperation.

Sincerely,

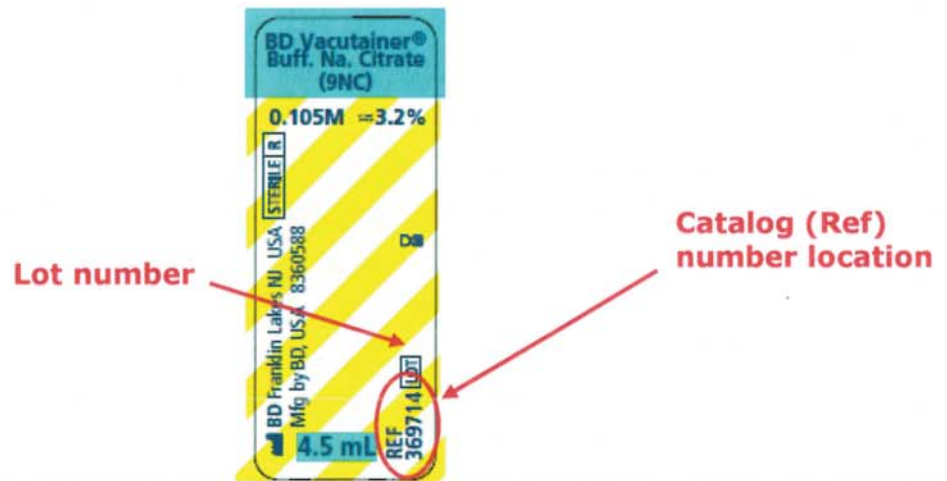

Aparna [Redacted] Cert Hospital
Management, IF CAP
Director Medical Affairs
BD Life Sciences - Preanalytical
Systems


Regulatory Compliance Manager
BD Life Sciences - Preanalytical
Systems

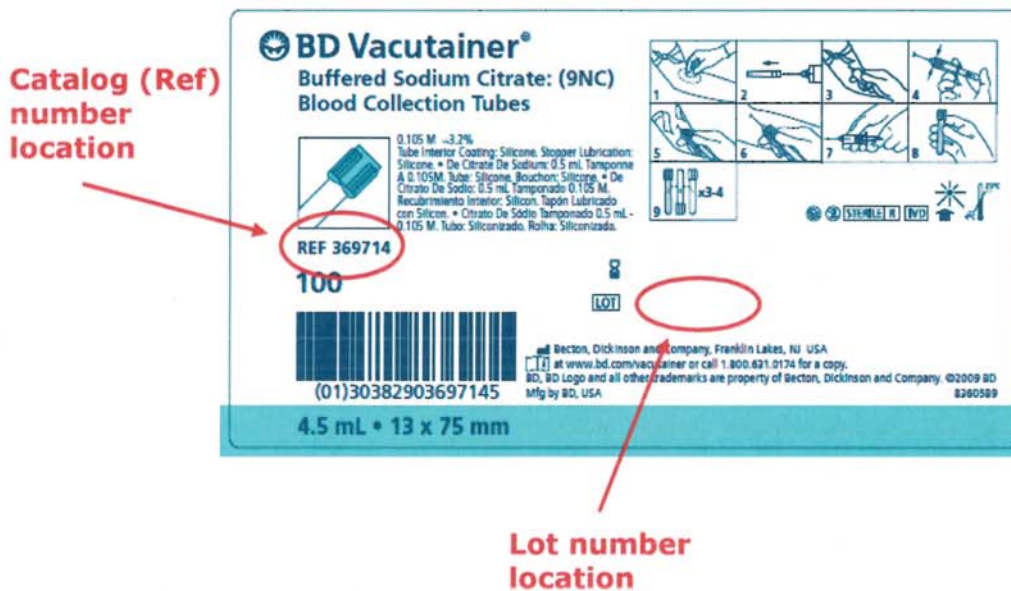
**BD Vacutainer® Buffered Sodium Citrate: (9NC) Blood Collection Tube
(13 x 75 mm x 4.5 mL):
Catalog number 369714, Lot number 6090572**

Recall Catalog (Ref) / Lot Identification Sample

A. Unit (Tube):



B. Shelf:



Customer Recall Response Form

BD Vacutainer® Buffered Sodium Citrate: (9NC) Blood Collection Tube (13 x 75 mm x 4.5 mL)

Catalog (Ref) #	Lot Number
369714	6090572

Check inventory and complete the information below, even if you do not have the affected product. *Failure to complete all sections of this page may result in improper or delayed product replacement.* Fax the completed form to BD at 1-844-388-5534 or email the completed form to bd8872@stericycle.com.

Please return only product from the lot referenced in the recall letter; you will only receive product replacement for recalled product that you return.

Facility: _____
Please use full, current facility name. Do not use initials.

Street Address: _____

City: _____ **State:** _____ **Zip:** _____

Contact Person: _____

Telephone No.: _____ **Email Address:** _____

Fax No.: _____

I have read and understood the attached notice.

Name:	
Title:	
Signature/Date:	

We do not have any of the affected product(s) on hand. (Fill out and return this form to BD at fax or email above)

We have the following units and request replacement(s) (Fill out and return this form to BD at fax or email above and return the product per the packing instruction.)

Product Name	Catalog No.	Lot No.	No. of Units
BD Vacutainer® Buffered Sodium Citrate: (9NC) Blood Collection Tube(13 x 75 mm x 4.5 mL)	369714	6090572	

Please enclose the completed form with the return product shipment.

PACKING INSTRUCTIONS

**BD Vacutainer® Buffered Sodium Citrate: (9NC) Blood Collection Tube
(13 x 75 mm x 4.5 mL) Recall**

Product Return Instructions:

1. Please enclose the complete Recall Response Form with the shipment.
2. The simplest way to return product would be to access the following UPS website: <http://returns.upsrow.com>
login: **bdapi**, Password: **bdapi**

When you access the site, you can select among 3 UPS shipping options. If you select the initial option, "Display Return Label Only", you can give the package to a UPS person who stops at your site or drop it off at a UPS location. If you select either of the remaining two options, a UPS person will stop by your location specifically to pick up the package. You need to enter the returned product reorder number, lot number and quantity on the website.

Note: If you are not returning product, also indicate this on the website.

3. If you do not have access to the internet you can call UPS at 1-800-PICK-UPS (742-5877) and arrange for a pick-up using the following charge number specific to this recall: **0ER739**.

Product should be returned to:
Returns Team, ref. PAS-17-954-FA
BD Distribution Center
DOOR #2
130 Four Oaks Parkway
Four Oaks, NC 27524

For shipments over 150 pounds - utilize UPS Ground Freight. UPS Freight Customer Service can be contacted at 1-800-333-7400. When arranging the pick-up of freight, please specify 3rd party billing as follows:

Returns Team, ref. PAS-17-954-FA
BD c/o Cass Info Systems
PO Box 67
St. Louis, MO 63166-0067

BD Life Sciences – Preanalytical Systems
1 Becton Drive
Franklin Lakes, NJ 07417
USA

bd.com

4. Upon receipt of returned product, BD will provide product replacement. A returned goods authorization is NOT required for this recall return process.

DO NOT SHIP FREIGHT COLLECT
Our warehouse cannot receive products shipped "freight collect".