



FAX COVER

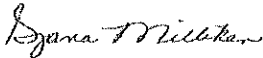
From: National Distribution & Contracting, Inc.
 Djana Milliken – Compliance
 URGENT
 This is being faxed/emailed to the "bill to" account for your company. Please distribute to any/all branches.

To: Purchasing or Regulations
 Department

Date: 1/19/2017

Pages: 5 (Including cover page)

Regarding:
 BD Vacutainer Buffered Sodium Citrate
 Blood collection Tube (13 X 75 mm X 4.5 ml)

Comments:
 Dear Distributor,
 Attached is a letter we received from BD regarding the recall on item # 369714. Our records indicate that you purchased this product from us. Please read attached letter and check your inventory for any affected product with listed lot number. If you have any of this product in stock please fill out attached "Request for return" form, so that we can issue you a RGA for return. **Also, please make note that no credit will be issued without an RGA. If you have any questions please feel free to contact me. It is very important that we receive a response, a record of receipt is very important in documentation of these types of notices.** Additionally, if you have distributed these products to your customers, please advise them of the recall, and have return any affected product to you.
 Thanks,

 Djana Milliken

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

bd.com



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 Distributor,

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 between June 22, 2016 and September 19, 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. Immediately discontinue shipment of the affected product.
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 with the completed Recall Response Form following the instruction on the enclosed packing instruction. Upon receipt of the returned product, BD will issue a credit.
4. If you have distributed this product, please identify your customers and notify them immediately of this product recall. A copy of the BD Customer Recall Letter is included with this communication.
5. If you would like BD to conduct the notification to your customers, please email your customer list within 3 business days to **Matthew.Kelleher@bd.com**. Please include the contact name, address, phone number, email address, and/or fax numbers for each customer. BD will notify these customers of the recall.


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.

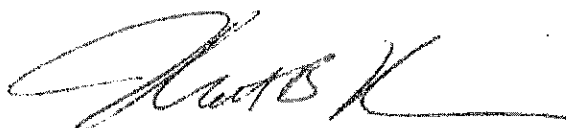
If you have any questions or require assistance with the return of the recalled product and/or availability of credit, please contact **1-844-265-7408 between 8AM and 5 PM ET Monday through Friday.**

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 Ahuja, MD, PG cert Hospital
Management, IF CAP
Director Medical Affairs
BD Life Sciences - Preanalytical
Systems


Matthew Kelleher
Regulatory Compliance Manager
BD Life Sciences - Preanalytical
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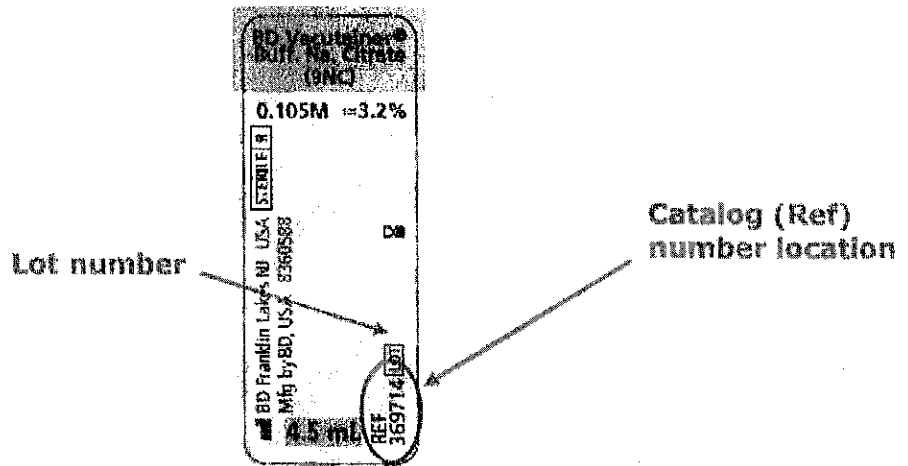
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**BD Vacutainer® Buffered Sodium Citrate: (9NC) Blood Collection Tube
(13 x 75 mm x 4.5 mL):**

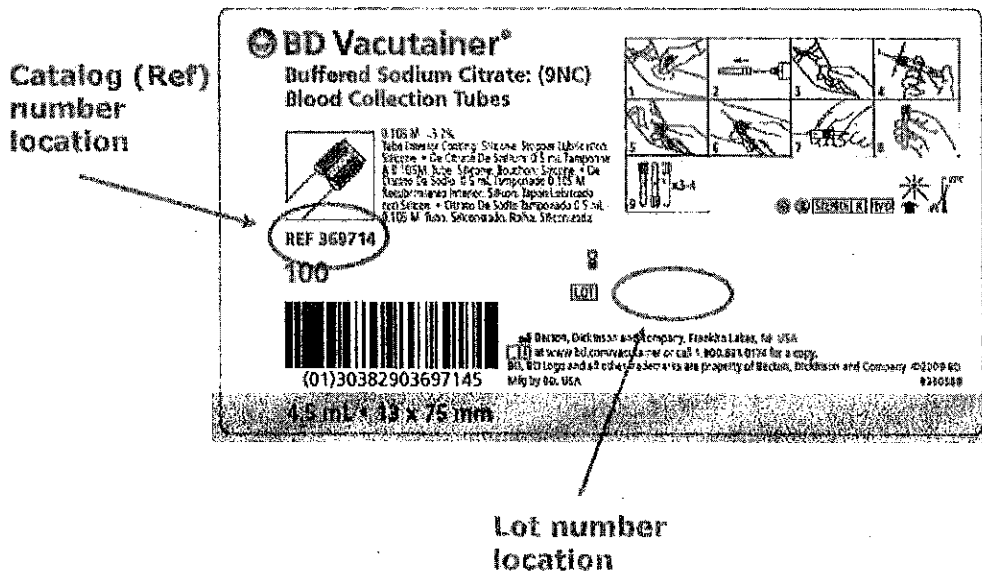
Catalog number 369714, Lot number 6090572

Recall Catalog (Ref) / Lot Identification Sample

A. Unit (Tube):



B. Shelf:





1/19/2017

BD Vacutainer Buffered Sodium Citrate: Blood Collection Tube

Please fill out and fax/email this distributor form within 10 business days, even if you do not have the recalled product.

Please complete and fax to: 615-229-6801 or email to: compliance@ndc-inc.com

REQUEST FOR RETURN FORM

Customer Information

Account No. _____

Account Name _____

Address _____

City/State/Zip _____

Contact Name _____

Phone No. _____

Fax No. _____

Email _____

Inventory Information

Item number	Lot number	Expiration date	Quantity to return

- I have read and understood the information within the accompanying notification. All relevant customers/ personnel have been informed of its contents, any necessary actions taken and records retained as part of our documentation.
- We have inspected our inventory and have no product related to this recall

Completed by: (Print Name /Signature/Date) _____

Returned Completed form to:

Fax #:
Email:

Djana Milliken
615.229-6801
compliance@ndc-inc.com

Delivering Efficiency to Healthcare®

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www.ndc-inc.com | 615-229-6800