NDC®

Delivering Efficiency to Healthcare

# FAX COVER

| | |
|---|---|
| **From:** *National Distribution & Contracting, Inc.*<br>*Djana Milliken – Compliance*<br>***URGENT***<br>****This is being faxed/emailed to the "bill to" account for your company. Please distribute to any/all branches.****** | |
| **To:**<br>*Purchasing or Regulations Department* | **Date:**<br>*3/17/2016* |
| **Pages:** *7* *(Including cover page)* | |
| **Regarding:**<br>*BD Urgent Product Correction*<br>*Item # 367716 and 369714* | |

**Comments:**

*Dear Distributor,*
*Attached is a letter we received from BD regarding the field correction of specific lots of item # 367716 and 369714 . Our records indicate that you purchased this product from us. Please read attached letter and check your inventory for any affected product.* ***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 correction.*
*Thanks,*

Djana Milliken

*Djana Milliken*

*407 New Sanford Road, La Vergne, TN 37086*
*compliance@ndc-inc.com / Phone: 615-324-6375 / Fax: 615-229-6801*

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

bd.com

BD

# URGENT PRODUCT CORRECTION

March 16, 2017

| Product Name | UDI | Catalog No. | Lot No. | Expiry Date |
|---|---|---|---|---|
| BD Vacutainer® Buffered Sodium Citrate: (9NC) Blood Collection Tube (13 x 75 mm x 4.5 mL) | N/A* | 367716<br>369714 | See list provided on p. 4 | |

Dear Distributor,

BD is conducting a voluntary correction for specific lots of BD Vacutainer® Buffered Sodium Citrate: (9NC) Blood Collection Tubes with the catalog numbers noted above.

BD has confirmed a limited number of tubes associated with the lots listed (p. 4) and currently in the market may exhibit stopper pullout, where the stopper is withdrawn from the tube as the user removes the needle from the stopper following specimen collection. An example of stopper pullout is demonstrated in Figure 1 below.

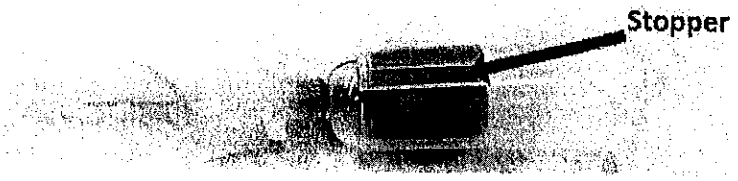


**Figure 1**. Stopper pullout – stopper remains attached to needle

Stopper pullout can result in user exposure to blood resulting from an unstoppered tube as well as the potential for accidental needle sticks, both of which may result in exposure to blood borne pathogens. BD has received a report of a Needle Stick Injury associated with this issue.

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While performing any venipuncture using BD Vacutainer® Glass Citrate tubes associated with the above lots:

- Be sure to follow your local PPE (Personal Protective Equipment) requirements, which include using gloves and impervious lab coats during and after blood collection.

- Review of any additional protective equipment required to ensure safe collection, such as protective face shield usage, should also be considered.

- During collection, it is recommended to hold the tube in place while it is in the holder. If using a BD Vacutainer® Push Button Blood Collection Set (i.e. Wingset) or BD Vacutainer® Safety Lok Blood Collection Set for the venipuncture, the tube should be held while in the holder and in the stopper up position until blood collection is complete. An example of tube positioning is demonstrated in **Figure 2** below.

**Figure 2.** Recommended positioning of tube

Affected lot numbers 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 lots are within your control.

Our records indicate you may have been shipped the above-referenced lots of product. BD distributed the potentially affected lots between December 18, 2015 and December 5, 2016.

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Franklin Lakes, NJ 07417
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bd.com

**PLEASE TAKE THE FOLLOWING ACTIONS:**

1. If you have distributed this product, please identify your customers and notify them immediately of this Product Correction. A copy of the BD Customer Product Correction Letter is included with this communication. This Product Correction is being conducted at the Consumer/User level.

2. 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 Product Correction.

3. Complete the Customer Product Correction Response Form and fax it back to BD at **1-888-965-5976** or email to **bd4555@stericycle.com.** Return of this form will acknowledge your receipt and understanding of this notification.

   **NOTE: Even if you do not have any of the affected lot in your inventory, please complete the Customer Product Correction Response Form indicating you have received the communication and fax the completed form back to BD at 1-888-965-5976 or email the completed form to bd4555@stericycle.com.**

If you have any questions or require assistance with this Product Correction, please contact **1-888-965-5810 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
WW Vice President, Medical Affairs,
BD Life Sciences – Preanalytical Systems

Gail Griffiths
Sr. Director Regulatory Compliance
BD Life Sciences

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## BD Vacutainer® Buffered Sodium Citrate: (9NC) Blood Collection Tubes Catalog Numbers 367716 and 369714

## Affected Lot Numbers

| Catalog Number | Lot Number | Expiry Date |
|---|---|---|
| 367716 | 5251673 | 3/31/2017 |
| 369714 | 5272777 | 4/30/2017 |
| | 5336909 | 6/30/2017 |
| | 5357632 | 7/31/2017 |
| | 6040953 | 9/30/2017 |
| | 6064634 | 9/30/2017 |
| | 6124932 | 11/30/2017 |
| | 6173983 | 12/31/2017 |
| | 6187600 | 1/31/2018 |
| | 6216656* | 2/28/2018 |

*UDI DI (01)30382903697145, PI (17)180228(10)6216656(30)0100

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1 Becton Drive
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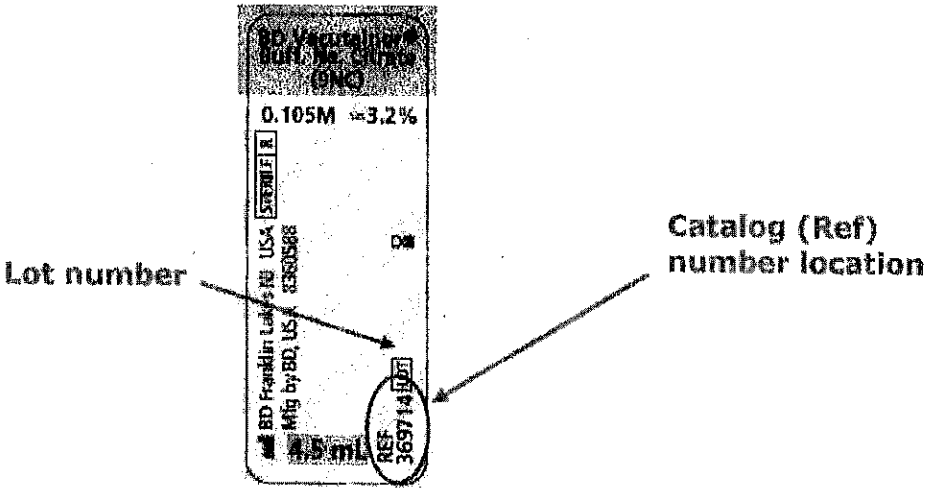
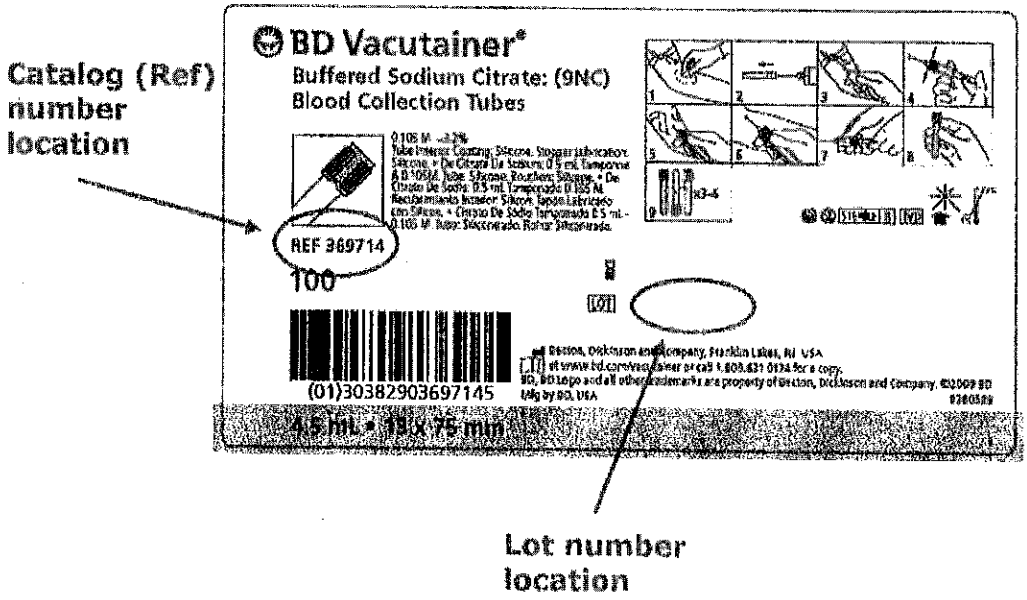
## Product Correction Catalog (Ref) / Lot Identification Sample (Catalog number 369714 provided as an EXAMPLE)

### A. Unit (Tube):




### B. Shelf:






Advancing the world of health

3/17/2017

# BD Urgent Product Correction

**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**

## Acknowledgment of Receipt

***Customer Information***

Account No. _____

Account Name _____

Address _____

City/State/Zip _____

Contact Name _____

Phone No. _____

Fax No. _____

Email _____

***Inventory Information***

| Item number | LOT # | Expiry Date |
|---|---|---|
| 367716 | | |
| 369714 | | |
| | | |
| | | |

☐ 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:***

Djana Milliken
Fax #: 615.229-6801
Email: compliance@ndc-inc.com

*Delivering Efficiency to Healthcare®*

[illegible]