



URGENT MEDICAL DEVICE FSMA

Date

Product Name	Catalog (Ref) No.	Lot No.	Exp. Date
BD Vacutainer® Plus Citrate Plasma Tube	363048	7298982	2018-07

For the Attention of: Medical Device Safety Officer or Lab Manager

Description of the problem and health hazard(s):

BD is conducting a voluntary recall for a single lot of catalog number 363048, BD Vacutainer® Plus Citrate Plasma Tubes. This action is being taken based on confirmation that a limited portion of the referenced lot may not have received the required amount of sodium citrate additive. Additive under fill may cause erroneous results which can lead to specimen recollection and potential delay of treatment.

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 numbers 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 on **DATE**. Our records indicate you may have been shipped the above referenced lot of product.

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

- Immediately review your inventory for catalog number 363048, lot number 7298982 and quarantine the product.
- Please share this notification with all users of the product to ensure they are also aware of this issue.
- Complete the Customer Recall Response Form and **fax** it back to BD at **Contact Information**.

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 Contact Information.

- Discard all affected product and return the completed Recall Response Form. BD will issue replacement product.

Contact Information

If you require further assistance, please contact:

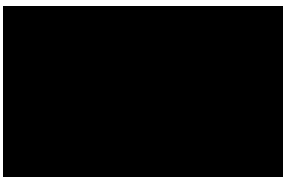
BD Contact	Contact Information	Areas of Support
BD Customer/Technical Support	Contact Information	For recall questions or assistance with replacement product.

Actions Taken by BD:

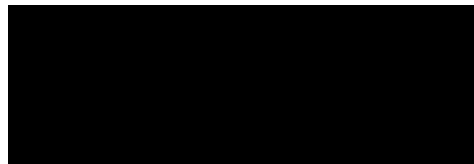
BD will replace the discarded inventory.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with 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

BD Vacutainer Plus Citrate Plasma Tube

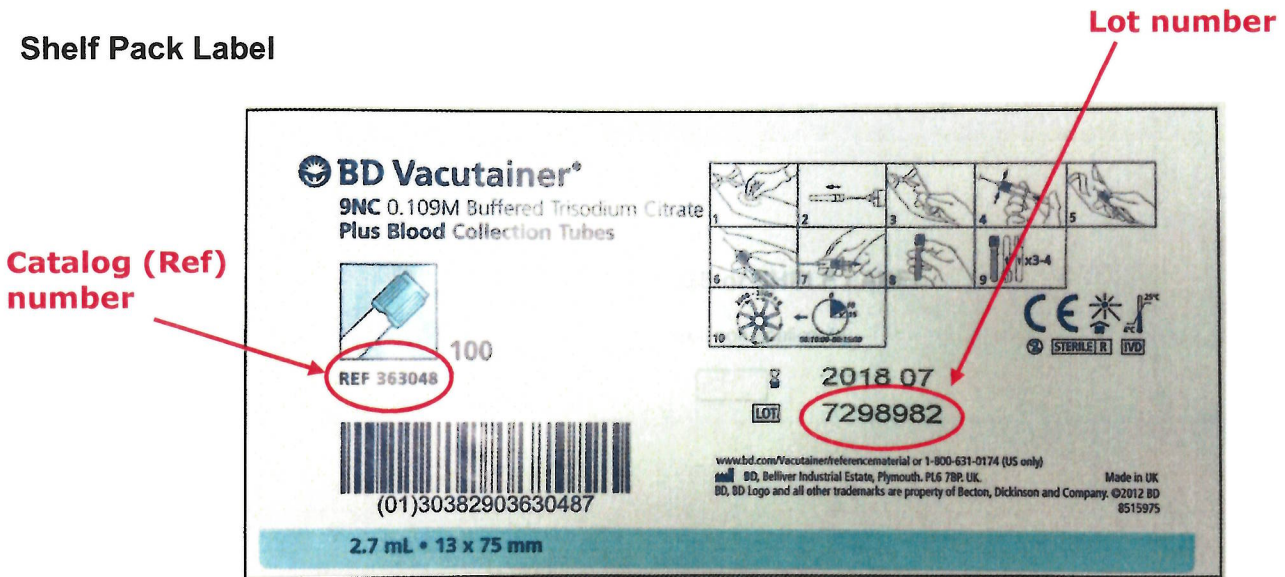
Catalog number 363048, Lot number 7298982

Catalog (REF) / Lot Identification Sample

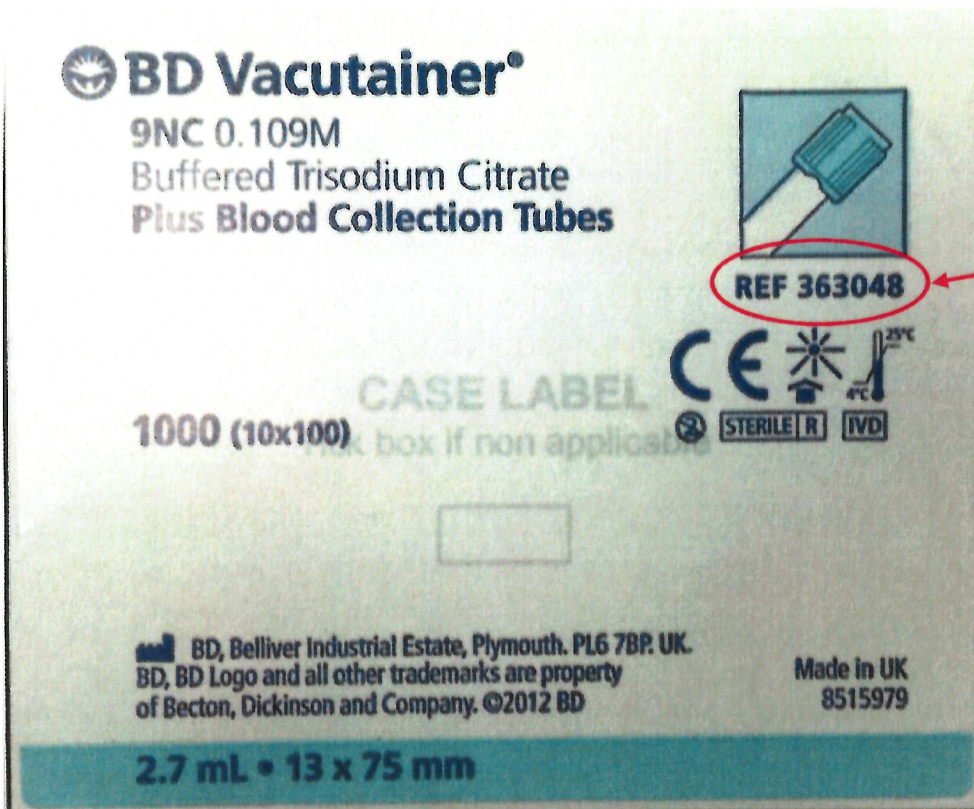
Unit (Tube) Label



Shelf Pack Label



Case Label



Catalog (Ref)
number

Please assist BD by promptly returning this form to:
BD Regulatory Compliance
Fax #: Add contact information
Email: Add contact information

Customer Response Form

BD Vacutainer® Plus Citrate Plasma Tubes

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.
- We do not have any of the affected product(s) on hand.
- We have the following units and request replacement.

Name:	
Title:	
Signature/Date:	

I certify that I have discarded all affected product indicated above as available inventory at the time of receipt of this notification.

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