

URGENT MEDICAL DEVICE PRODUCT ADVISORY

Date: April 6, 2018

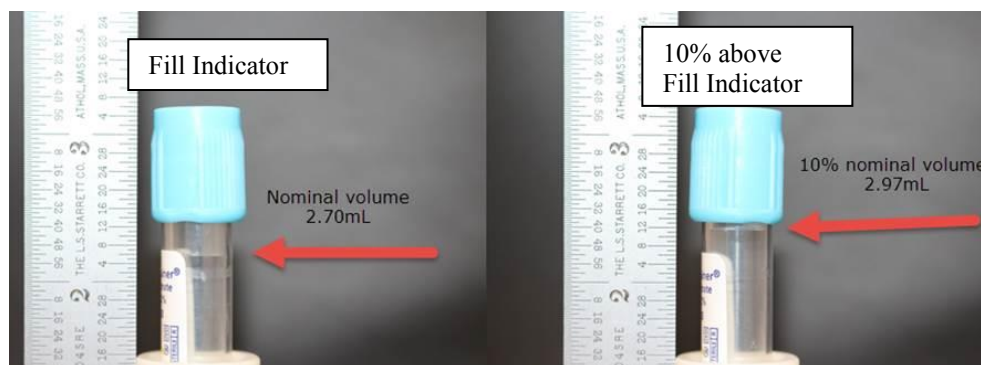
For the Attention of: Medical Device Safety Officer, Lab Manager, Lab Director, Phlebotomy Department

Description of the problem and health hazard(s):

Product Name	Catalog (Ref) No.	Lot No.	Expiration Date
TUBE CIT PLH 13X75 2.7 PLBL L/BL .109	363083	All Lots within Expiry	
TUBE CIT PLH 13X75 2.7 SLBLCE .109	364305		

BD has confirmed that approximately 3.4% of BD Vacutainer Plus Plastic Citrate Blood Collection Tubes (2.7mL) noted above (light blue top tube) will exhibit over fill draw volumes from ~11-14%. The most common use of these tubes is in the evaluation of all aspects of the coagulation cascade. It is also used prior to surgery to assess the risk of bleeding and clotting, and to establish and monitor anticoagulation therapy.

As per BDs Instructions for Use (IFU), the overfilling or under filling of tubes will result in an incorrect blood-to-additive ratio and can lead to incorrect analytic results or poor product performance. The fill indicator line on the tube represents the nominal volume of blood required for appropriate analysis.



BD will continue to ship product with the potential for this over fill draw volume, so as not to impact critical patient care, until the root cause is identified, and corrective actions have been made.

NOTE: Return of product is not required.

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Advise all relevant staff to inspect tubes prior to testing to assure an acceptable fill volume has been achieved. BD recommends that you recollect the sample and/or follow your laboratory protocols if the draw volume exceeds 10% over the fill line on the tube.
2. Share this Product Advisory with all users of the product within your facility to ensure awareness.
3. Simply complete, sign and fax the completed form to your local BD contact / authorized service personnel.

Actions Taken by BD:

BD continues to investigate the root cause of this issue and will apply corrective actions as appropriate. Customers will be notified if any additional actions are required upon completion of the root cause analysis.

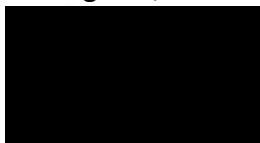
BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

For all other inquiries please contact our BD representative and they will ensure that you are put in contact with the most appropriate individual to address your concerns.

We sincerely regret any inconvenience this may have caused you.

Thank you for your continued support.

Regards,



Joyce Tan
Associate Director, Regulatory Affairs
Greater Asia

CUSTOMER RESPONSE FORM

BD Vacutainer Plus Plastic Citrate Blood Collection Tubes (2.7mL)

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. No Product Return is required.

Name:	
Title:	
Signature/Date:	