URGENT: FIELD SAFETY NOTICE – PAS-016-745-FA

BD Vacutainer® Plus Heparin Tubes
Catalogue Number: 367885, Lot Number: 5084266

14th December 2015

Attention: Medical Device Safety Officer, Risk Manager, Laboratory Director, Head of Supply Chain, Phlebotomy Manager, Clinical Studies Director, Researchers, Clinical Pathologists.

This letter contains important information which requires your **immediate** attention.

Details of affected devices and description of the problem:

BD Life Sciences – Preanalytical Systems is issuing a recall for product code 367885, BD Vacutainer® Plus Heparin Tube, lot number 5084266.

Through customer feedback, BD has become aware that the lot number in Table 1 does not perform as intended. It is estimated that 300 tubes out of a lot size of 202,000 contain sodium fluoride/potassium oxalate, an inhibitor of the glycolytic pathway, instead of the specified lithium heparin additive.

Table 1 – Affected product details

Catalogue Number	Product Description	Lot number	Expiry date
367885	BD Vacutainer® LH 102 I.U. Plus Blood Collection Tubes (6 mL)	5084266	2016 - 08

This Field Safety Notice only affects the catalogue and lot number in Table 1. To locate the catalogue and lot number refer to Attachment 1.

The sodium fluoride/potassium oxalate can also be identified by the presence of a white powder (Attachment 2).

The presence of the sodium fluoride/potassium oxalate additive can lead to erroneous patient results for potassium and sodium due to their inclusion in the additive. Further this may impact other analytes; one single customer complaint indicated that the tube was used for troponin measurement and produced an incorrect result.

Advice on action to be taken:

- Stop use of the affected product immediately and quarantine all stock.
- Inform appropriate personnel in your organisation to discontinue the use of the affected lots.
- Return or destroy affected product following the instructions on the acknowledgement form and credit destruction form, in exchange for replacement product or credit.

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- Review whether there is a need to examine patient test results conducted from 25th May 2015 *(regions, please change this depending on the first dispatch date)* with this impacted product.

- Complete the acknowledgement form (page 5) as soon as possible or **no later than the 15th of January 2016.**

Transmission of this Field Safety Notice

Please maintain awareness of this notice in your organisation for an appropriate period to ensure effectiveness of the corrective action.

Contact Reference Person

If you have any questions about the product please contact your local BD representative or the BD office on (01865) 781666 or BDUK_customerservice@bd.com.

BD Life Sciences – Preanalytical Systems is committed to providing quality products to our customers and we have undertaken appropriate internal corrective actions. We apologise for the inconvenience this situation may cause.

We confirm that the appropriate regulatory agency have been informed of these actions.

Yours sincerely,

Lorna Darrock
European Regulatory Affairs Manager
BD Life Sciences - Preanalytical Systems

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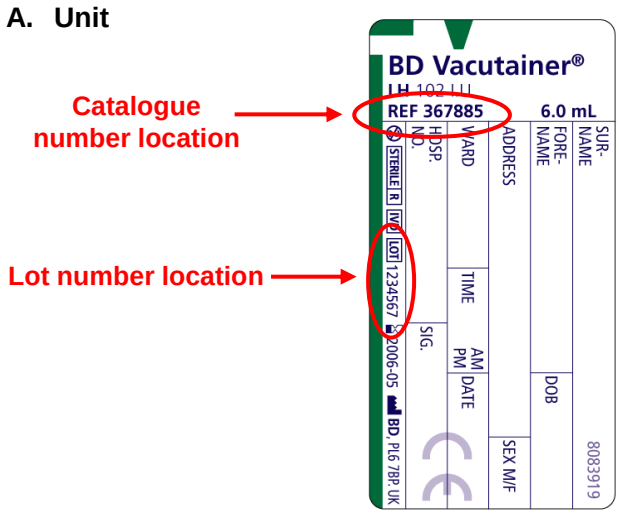
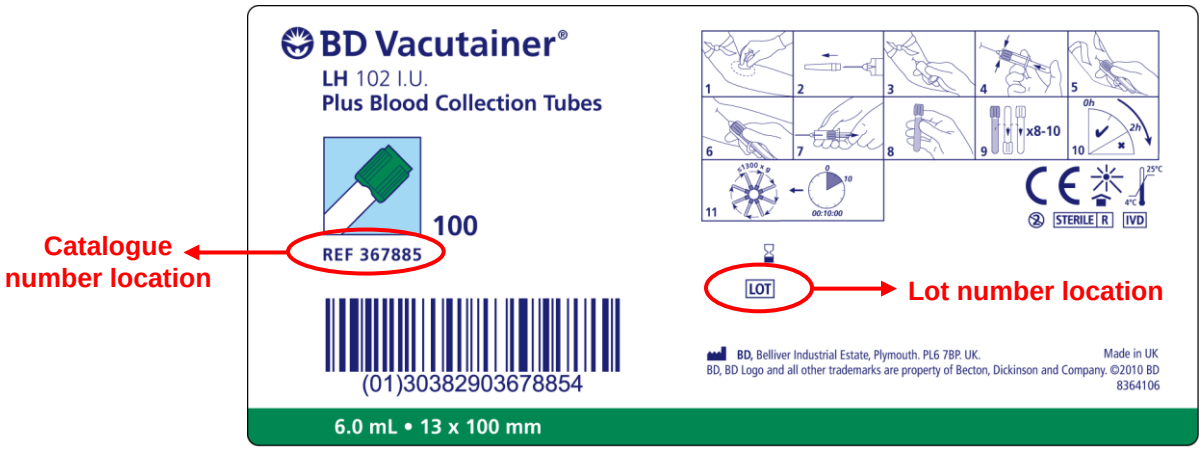
Attachment 1: Guidance on the location of Lot Number and Catalogue Number

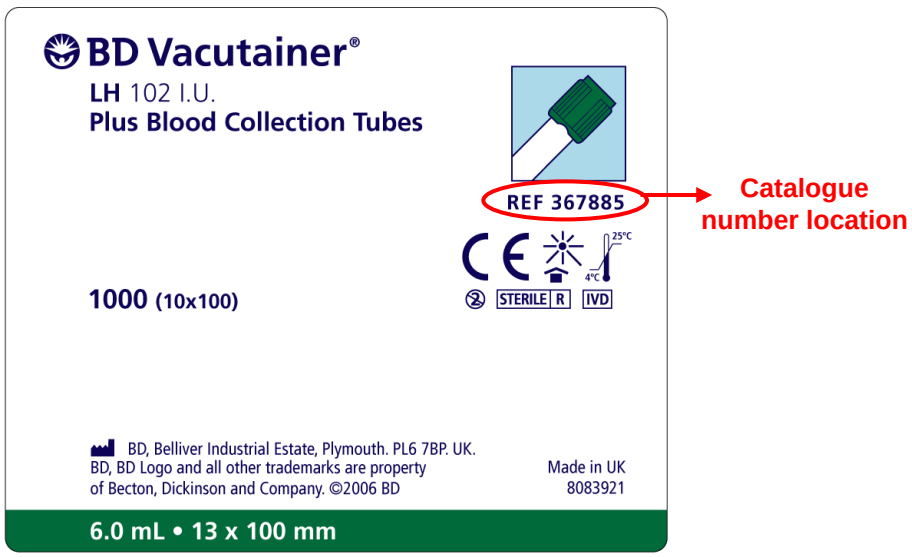
A. Unit



B. Shelf



C. Case



Attachment 2: Impacted tubes can also be identified by the presence of a white powder

The above image shows the presence of sodium fluoride/potassium oxalate in lithium heparin tubes.

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ACKNOWLEDGEMENT FORM

Please read in conjunction with Field Safety Notice PAS-016-745-FA and return form to BDUK_customerservice@bd.com or by fax to: (01865) 781528 / 717313 as soon as possible or **no later than the 15th of January 2016**.

Option 1 ☐

- **YES**, I have affected product in inventory and will return in exchange for replacement product or credit (tick appropriate box below).
- This notice has been read and understood and distributed to all appropriate personnel. *(Fill out and return this form to BD at fax/e-mail above and return the product with a copy of this form to FAO Returns Team, ref. PAS-016-745-FA, BD, DC3, Laagstraat 57, B- 9140 Temse, Belgium)*

Option 2 ☐

- **YES**, I have affected product in inventory and I confirm that this has been destroyed on site in exchange for replacement product or credit (tick appropriate box below).
- This notice has been read and understood and distributed to all appropriate personnel. *(Fill out and return this form along with the Certificate of Destruction form, **and provide evidence of destruction**, to BD at fax/e-mail above)*

Option 3 ☐

- I have **NO** affected product left in inventory.
- This notice has been read and understood and distributed to all appropriate personnel. *(Fill out and return this form to BD at fax/e-mail above*)

Organisation / Hospital / Clinic :	
Department (if applicable) :	
Address :	
Postcode :	City :
Contact Name :	
Job Title :	
Contact Telephone Number :	
Contact E-mail Address :	
Quantity Returned / Destroyed :	☐ Credit ☐ Replacement
Signature :	Date :

This form must be returned to BD PAS before this action can be considered closed for your account

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CERTIFICATE OF DESTRUCTION

If you choose to destroy impacted product, you are requested to complete and return this form to BDUK_customerservice@bd.com or by fax to: (01865) 781528 / 717313 as soon as possible or **no later than the 15th of January 2016**.

Dependent on your choice, replacement product or credit processes will be initiated.

Date of Destruction :
Lot number :
Quantity :
Photographic evidence attached :
Signature : Date :

This form, along with photographic evidence, must be returned to BD PAS in order for replacement product or issue of credit processes to be initiated.

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