URGENT: FIELD SAFETY NOTICE – PAS-16-732-FA

BD Vacutainer® EDTA Blood Collection Tubes
Catalogue number 367862

xxth December 2015

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

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

Details on affected devices and description of the problem:

BD Life Sciences – Preanalytical Systems is issuing a recall for product code 367862, BD Vacutainer® K_2 EDTA Blood Collection Tube.

Based upon internal BD investigations it has been found that the lot numbers listed in Table 1 do not perform as intended, since the affected product contains low or no K_2 EDTA additive.

Table 1 – List of affected lot numbers

Catalogue Number	Product Description	Lot number
367862	BD Vacutainer® K_2 EDTA (K_2E) Plus Blood Collection Tubes (4 mL)	5089771
		5187753

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

Inadequate EDTA additive can lead to:

1. Platelet clumping
   This can lead to a false reduction of platelet counts, a phenomenon known as pseudothrombocytopenia. There are two possible consequences:

   a. Erroneous results
      If the false reduction in platelet counts is not recognised and reported, the issued results would be erroneous.

   b. Specimen rejection
      If platelet clumping is detected as the reason for erroneous results, that specimen will be rejected and there will be a need to recollect the specimen.

2. Blood clotting
   If very low amount of additive is present in the tube, blood may clot and it may not be possible to perform the required laboratory testing. This, too, will lead to specimen rejection and the need to recollect the specimen.

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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, in exchange for replacement product or credit.
- Review whether there is a need to examine patient haematology test results conducted from *25th August 2015 or insert customer specific shipping date – to be checked and entered by the country)* with a specific emphasis on platelet counts.
- Complete the acknowledgement form (page 4) as soon as possible or **no later than the 7th 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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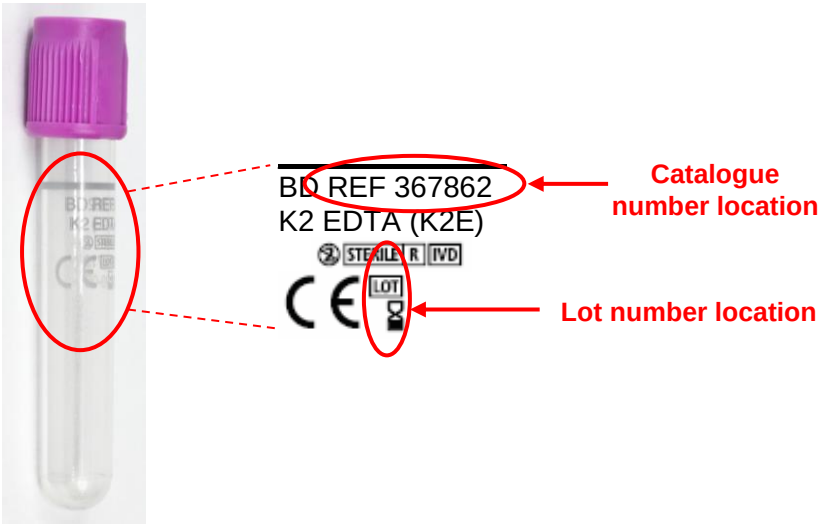
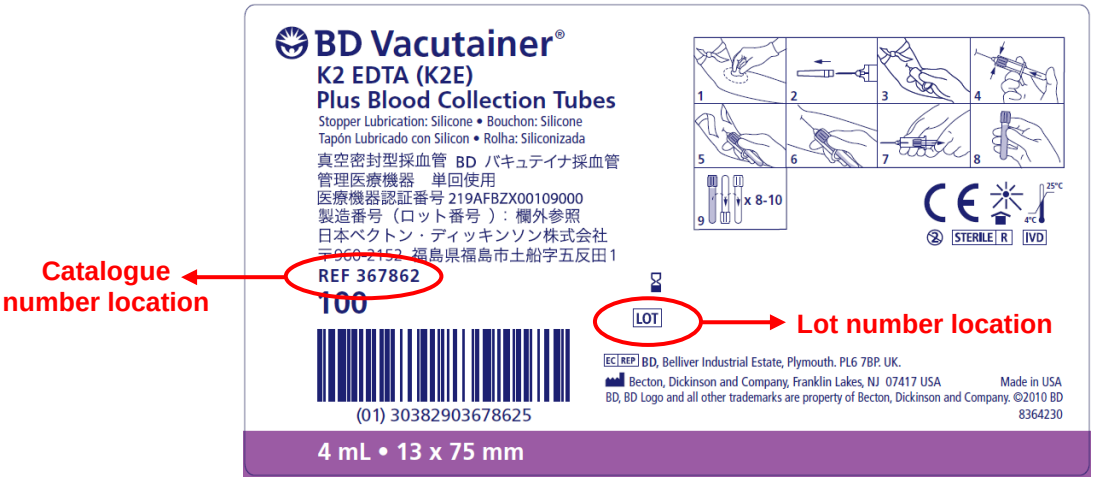
Attachment 1: Guidance on the location of Lot Number and Catalogue Number

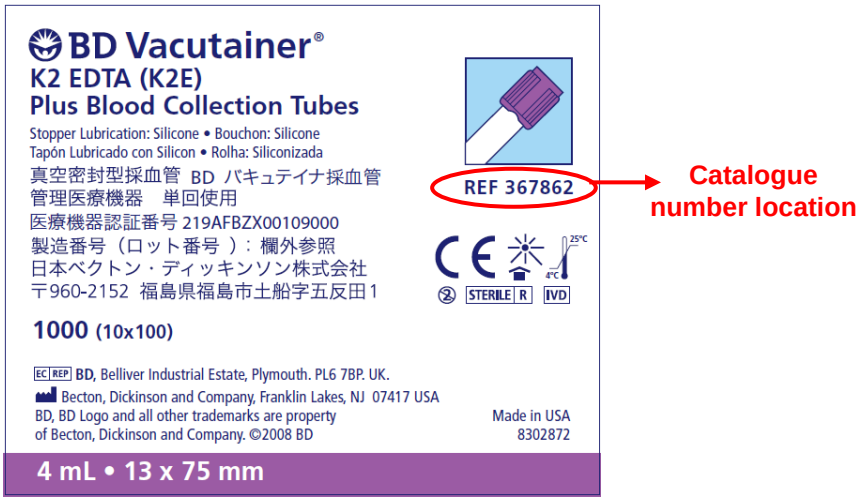
A. Unit



B. Shelf



C. Case



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ACKNOWLEDGEMENT FORM

Please read in conjunction with Field Safety Notice PAS-016-732-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 7th 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-016-732-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, **and provide evidence of destruction**, to BD at fax/e-mail above and return the product with a copy of this form to FAO Returns Team, ref. PAS-016-732-FA, BD, DC3, Laagstraat 57, B- 9140 Temse, Belgium)*

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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