



<<Date>>

URGENT: FIELD SAFETY NOTICE – PAS-19-1526

BD Microtainer® K2E Tubes

REF: 365975 Lot Numbers: 9017588, 9017590, 9028803 and 9045873

Type of Action: Product Removal

Attention: Clinical Personnel, Risk Managers, Biomedical Personnel

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

Dear valued Customer,

BD is conducting a Field Safety Corrective Action to remove specific lots of the BD Microtainer® K2E tubes due to insufficient K2E additive. According to our distribution records your organisation may have received the impacted tubes.

Description of the Problem

The impacted BD Microtainer® K2E tubes are being removed as they contain insufficient K₂EDTA additive within the reservoir of the tube due to a manufacturing issue between January 2019 and February 2019. Insufficient additive could result in potential erroneous results due to an inappropriate blood-to-additive ratio. Patients may need to be re-sampled, which may lead to a delay in treatment.

This product removal is limited to the product code / lot numbers listed in Table 1 below. No other product codes or lot numbers are affected. Appendix 1 shows the location of the product code/lot number

Product Code (REF)	Lot Number
365975	9017588
	9017590
	9028803
	9045873

Actions for Customers to take:

1. Please inspect your inventory and locate and quarantine any unused product of any of the impacted lot numbers. Destroy all impacted product or return to your BD local representative / distributor to be destroyed.



2. If you have further distributed the product, please identify those users and notify them at once of this product removal.
3. BD recommends discussing the content of this letter with your laboratory director regarding the need to review previous test results associated with these affected lots.
4. Complete the customer response form on page 3 indicating:
 - the quantities destroyed/returned **OR**
 - that your organisation does not have any impacted units left in inventory
5. Return the completed customer response form to BDUKFieldAction@bd.com for replacement product or credit **as soon as possible or no later than 12 July 2019.**

Contact Reference Person

If you have any questions about this, please contact your local BD representative or the local BD office.

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

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

Sincerely,

A handwritten signature in blue ink, appearing to read 'William David'.

William David
Sr. Director, Quality Compliance,
EMEA Quality Compliance
BD Switzerland Sàrl



Customer Response Form - PAS-19-1526

BD Microtainer® K2E Tubes

REF: 365975 Lot Numbers: 9017588, 9017590, 9028803 and 9045873

Please read in conjunction with Field Safety Notice PAS-19-1526 and return completed and signed form to as soon as possible or **no later than the 12 July 2019** to BDUKFieldAction@bd.com.

- **I confirm this notice has been read, understood and that all recommended actions have been implemented as required.**

Tick the appropriate box below

We do not have any of the affected product as listed in Table 1 in our possession.

OR

We have the following units of the affected product as listed in Table 1 in our possession and I confirm that the units have been destroyed/returned (*Please complete the table below with the lot number and the number of units destroyed/returned*)

Lot Number/s:	Units destroyed/returned <i>(insert quantity below)</i>
9017588	
9017590	
9028803	
9045873	

Account/Organisation Name:	
Department (if applicable):	
Address:	
Postcode:	City:
Contact Name:	
Job Title:	
Contact Telephone Number:	Contact E-mail Address:
Signature:	Date:

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



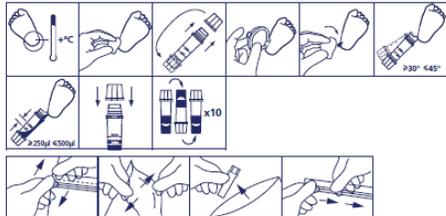
Appendix 1 - Product Code / Lot number Identification

 **BD Microtainer®**
K2E Tubes



REF 365975

50



Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417-1885 USA
Becton, Dickinson and Company, Belliver Industrial Estate, Belliver Way, Roborough,
Plymouth, PL6 7BP United Kingdom 500014441
©2016 BD, BD, the BD Logo and all other trademarks are property of Becton, Dickinson and Company.

Lot Number



(01)30382903659754

Product Code
(REF)

Product Code
(REF)

 **BD Microtainer®**
K2E Tubes



REF 365975

200

YYYY-MM-DD

LOT 8201643



Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417-1885 USA
Becton, Dickinson and Company, Belliver Industrial Estate,
Belliver Way, Roborough, Plymouth, PL6 7BP United Kingdom 500018683
©2016 BD, BD, the BD Logo and all other trademarks are property of Becton, Dickinson and Company.

Shelf Carton Example

Case Carton Example