URGENT: FIELD SAFETY NOTICE – PAS-14-408-FA

BD Vacutainer® CPT™ (Cell Preparation Tube)

7th July 2014

Attention: Risk Manager, Laboratory Director, Head of Supply Chain, Phlebotomy Manager, Clinical Studies Director, Researchers

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

Details of affected devices & description of the problem:

BD Diagnostics – Preanalytical Systems has identified through customer feedback that the catalogue and lot numbers of BD Vacutainer® CPT listed below in Table 1, have the potential for poor separation, resulting in a reduced number of recovered mononuclear cells. Having an insufficient number of isolated mononuclear cells may lead to possible specimen recollection, potential delay of treatment, and in remote cases it could lead to erroneous results.

Table 1

Catalogue Number	Lot Number	Expiry Date
362780	4063420	03/15
	4090242	04/15
	4063455	03/15
	4090241	04/15
362781	4063421	03/15
362782	4063422	03/15
	4063423	03/15
	4090244	04/15
	4090246	04/15

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

Advice on action to be taken by the user:

For Clinicians using the BD Vacutainer® CPT™ for diagnostic use:

The following actions are required of you:

- Stop use of the product immediately and quarantine the affected lots;
- Inform appropriate personnel in your organisation to discontinue the use of the affected lots;
- Review patient test results from all affected tests conducted from April 2014 onwards;
- Complete the acknowledgement form (page 5) as soon as possible or **no later than the 28th of July 2014**;
- Return all the affected lot numbers or destroy on site, following the instructions on the acknowledgment form in exchange for replacement product.

For Customers using the BD Vacutainer® CPT™ for research studies:

The following actions are required of you:

- Based on the data below in Table 2, collected from BD internal testing of the affected lots, review studies to assess whether the low cell yield will impact your research study;

Table 2

	AVG	SD	CV	Range
% Recovery Affected Lots (Na Heparin)	36.4	7.9	21.7	28.0 - 49.5
% Recovery Product Insert (Na Heparin)	63.0	11.7	18.6	-
% Recovery Affected Lots (Na Citrate)	58.5	28.1	48.0	13.1 – 100.1
% Recovery Product Insert (Na Citrate)	71.7	10.5	14.7	-

*** Footnote:**
Recovery – # of recovered mononuclear cells expressed as a % of the # contained in the original whole blood sample.
AVG – Mean Number **SD** – Standard Deviation **CV** – Coefficient of Variation

- If your assessment concludes that the expected % cell recovery **does not impact** your research studies:
  - you may continue to use the product and complete the acknowledgement form on page 5 as soon as possible or **no later than the 28th of July 2014.**

  or
  - you may also return or destroy the product, completing and following the instructions on the acknowledgement form in exchange for replacement product.

- If your assessment concludes that the expected % cell recovery **does impact** your research:
  - Stop use of the product immediately and quarantine the affected lots;
  - Inform appropriate personnel in your organisation to discontinue the use of the affected lots;
  - Complete the acknowledgement form (page 5) as soon as possible or **no later than the 28th of July 2014;**
  - Return or destroy all the affected lot numbers, following the instructions on the acknowledgment form in exchange for replacement product.

Please maintain awareness of this notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

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

BD Diagnostics is committed to providing quality products to our customers and we are undertaking appropriate internal corrective actions. We apologise for the inconvenience this situation may cause.

Becton, Dickinson U.K.Limited,
Registered in England: 00852702
Registered Office: The Danby Building, Edmund Halley Road, Oxford Science Park, Oxford, Oxfordshire OX4 4DQ

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

Yours sincerely,

Lorna Darrock
European Regulatory Affairs Manager
BD Diagnostics Preanalytical Systems

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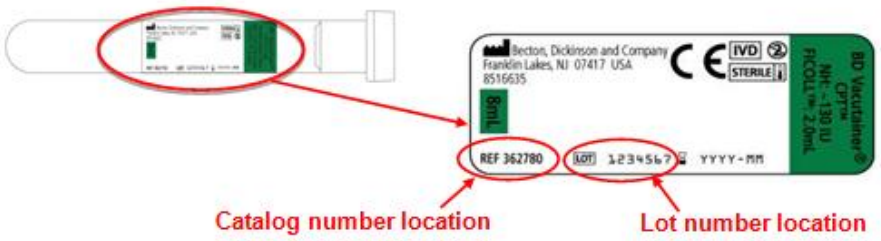
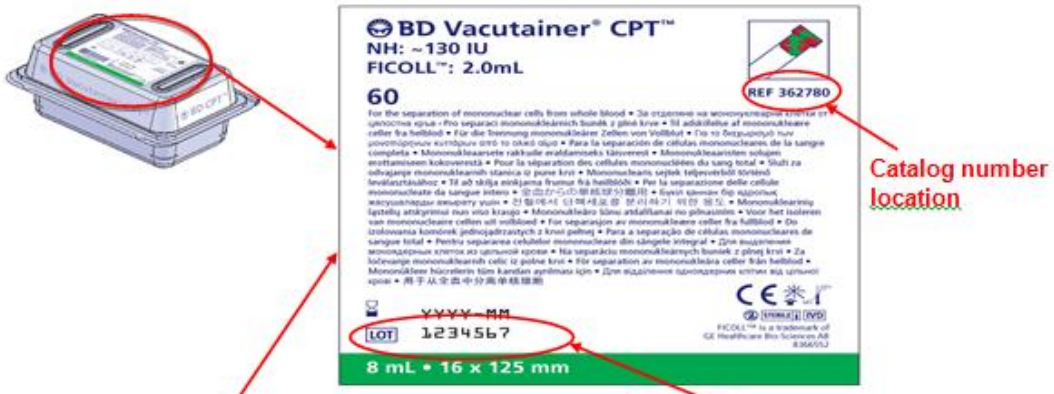
Attachment 1: Guidance on the location of Lot Number and Catalogue Number

Label Enclosure



Shelf Pack



Case Carton

ACKNOWLEDGEMENT FORM

Please read in conjunction with Field Safety Notice PAS-014-408 FA & return form to BDUK_customerservice@bd.com or by fax to: (01865) 781528 / 717313 **no later than 28th July 2014**.

Option 1 ☐ **YES**, I have affected product and will return in exchange for replacement product
(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-014-408 FA, BD, DC3, Laagstraat 57, B- 9140 Temse, Belgium)

Option 2 ☐ **YES**, I have affected product and I confirm that this has been destroyed on site in exchange for replacement product.
(Fill out and return this form to BD at fax/e-mail above)

Option 3 ☐ I have **NO** affected product left in inventory
(Fill out and return this form to BD at fax/e-mail above).

Option 4 ☐ **YES**, I have affected product which we use in research studies but we have conducted an evaluation and determined that the reduced recovery of mononuclear cells **does not** impact the results of our studies. Consequently, we choose not to return the recalled lots. *(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 *(Option 1 or Option 2)*	
Signature :	Date :

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