BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 Fax:
+41 21 556 30 99
www.BD.com

16th May 2022

URGENT: FIELD SAFETY NOTICE – BDB-22-4384c

BD OneFlow™ LST REF: 658619
BD OneFlow™ PCST REF: 659912
Lot Numbers: see Table 1

Type of Action: Product Removal

Attention: Laboratory Manager, Clinical Personnel, Risk Manager

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

Dear Customer,

BD is conducting a Field Safety Corrective Action to remove specific lots of the products mentioned in Table 1 below. According to our distribution records your organisation may have received one or more of the affected products.

Product name	Product Code (REF)	Lot Number	Expiry Date
BD OneFlow™ LST	658619	1071401	28/02/2023
		1160783	31/03/2023
		1180261	31/03/2023
		1258383	31/07/2023
BD OneFlow™ PCST	659912	1266231	31/07/2023
		1316879	31/07/2023

Table 1: Affected products

Description of the problem

BD determined through internal investigation that a common material lot used to manufacture the affected products has an uncharacteristic profile exhibited by an extra peak in a flow histogram that has been confirmed to be caused by CD8 contamination.

The product defect resembles a compensation issue when lot-to-lot verification is performed between different lots of the BD OneFlow™ products. It is possible that this issue could appear as a compensation artifact, or as an unexpected population of events in the kappa gate.

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 Fax:
+41 21 556 30 99
www.BD.com

This Field Safety Corrective Action is related ONLY to the product codes and lot numbers listed in Table 1. No other lot numbers are affected.

Clinical risk

The risk of erroneous results is low should the product defect have the appearance of a compensation artifact. Although it is possible that an unexpected population of events may be seen in the kappa gate in the analysis of the BD OneFlow™ LST or PCST tubes, detection of such a population of events would be well below the sensitivity for these assays when used as intended. Therefore, the risk of false positive results in this scenario is also low given that it is below the level of sensitivity of the OneFlow™ assays. Depending on the clinical scenario, this could result in the laboratory performing follow-up tests or in the administration of unnecessary therapeutic treatment, which could result in mild to severe health consequences depending on the treatment administered. Therefore, if this product was used to generate patient results, it may be necessary to review analyses.

BD has not received any reports of serious injury related to this issue.

Actions taken by BD

BD is taking corrective actions to prevent recurrence of this type of issue.

Actions to be taken by the END USER / HEALTHCARE ORGANISATION:

For existing users of the abovementioned products, BD requires that the actions below are taken.

1. Inspect your inventory, locate and quarantine any unused units of the affected lot numbers as per Table 1. Destroy all affected products.

2. If you have further distributed the product within your organisation, please identify those facilities 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 analyses associated with these affected lots.

4. Complete the Customer Response Form on page 4 indicating:
   - the quantities destroyed **OR**
   - that your organisation does not have any impacted units left in inventory

5. Return the completed Customer Response Form to **YOUR DISTRIBUTOR/ PRODUCT SUPPLIER** for replacement product **as soon as possible or no later than 17th June 2022.**

6. If you experience any issues with the products listed in Table 1, please report as a complaint as per your normal process.

For units destroyed, replacement devices will be sent. If you no longer use the product, it is still important that you return the Customer Response Form for our reconciliation purposes**.**

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 Fax:
+41 21 556 30 99
www.BD.com

Actions to be taken by the DISTRIBUTOR:

For existing distributors of the abovementioned products, BD requires that the actions below are taken.

1. Inspect your inventory, locate and quarantine any unused units of the affected lot numbers as per Table 1. Destroy all affected products.

2. If you have further distributed the product, please identify those facilities and notify them at once of this product removal.

3. Complete the Customer Response Form on page 4 indicating:
   - the quantities destroyed **OR**
   - that your organisation does not have any affected units left in inventory

4. Return the completed Customer Response Form to <<insert contact details here>> for replacement product **as soon as possible or no later than 17th June 2022.**

5. If you experience any issues with the products listed in Table 1, please report as a complaint as per your normal process.

For units destroyed, replacement devices will be sent. If you no longer use the product, it is still important that you return the Customer Response Form for our reconciliation purposes**.**

Contact reference person

If you have any questions about this, please contact your local BD representative or the local BD office on <<insert telephone details here>> or e-mail <<insert contact email address here>>.

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,

Lorna Darrock
Sr. Manager, Post Market Quality
EMEA Quality

BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 Fax:
+41 21 556 30 99
www.BD.com

Customer Response Form - BDB-22-4384c

BD OneFlow™ LST **REF:** 658619
BD OneFlow™ PCST **REF:** 659912
Lot Numbers: see Table 1

Please read in conjunction with Field Safety Notice BDB-22-4384c and return completed and signed form as soon as possible or **no later than the 17th June 2022** to <*<insert fax/email address here>>*.

- **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 *(Please complete the table below with the lot number and the number of units destroyed).*

REF:	Lot Number/s:	Units destroyed *(insert quantity below)*

Account/Organisation Name:	
Department *(if applicable)*:	
Address:	
Postcode:	**City:**
Contact Name:	
Job Title:	
Contact Telephone Number:	**Contact E-mail Address:**
Name of your supplier for this product *(if not direct from BD)*	
Signature:	**Date:**

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

**If you were forwarded this Field Safety Notice via a distributor/3rd party, please return your completed form to that organisation for reconciliation purposes.*