BD Switzerland Sàrl
Terre Bonne Park – A4
Route de Crassier 17
1262 Eysins – Switzerland
Tél: +41 21 556 30 00
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www.BD.com

<<Customer notification Date>>

URGENT: FIELD SAFETY NOTICE – BDB-23-4854

BD™ CD11b APC, CE

REF: 333143 **Lot Numbers:** 3114710

Type of Action: Product Removal

Attention: Clinical Laboratory Staff, Clinical Personnel, Risk Managers, Biomedical Personnel, Purchasing Managers

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

Dear customer,

BD is conducting a product removal Field Safety Corrective Action for a specific lot of **BD™CD11b APC, CE**. According to our distribution records your organisation may have received the impacted product in Table 1. Product was distributed by BD between May 2023 and June 2023.

Product Code (REF)	Lot Number	Expiry Date	UDI-DI	Manufacturer's SRN
333143	3114710	28 Feb 2025	(01)00382903331437	US-MF-000017797

Table 1: Impacted product

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

Description of the problem

BD has confirmed through eight (8) customer complaint investigations that the above affected lot of **BD™CD11b APC, CE** has low or dim fluorescence signal reported.

Clinical risk

This issue concerns the quality of the cell staining in patient samples that have been diagnosed, or are suspected to have a hematological malignancy, which can lead to potential false negative results and misdiagnosis and may delay treatment. The patient may be asked to return to collect additional samples, which may involve bone marrow aspiration.

To date there has been no adverse events reported for the related issue.

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BD Actions:

BD has implemented the appropriate corrective actions to prevent recurrence.

Clinical/End User Actions:

- Clinical laboratory staff should cease use of the affected lot of **BD™ CD11b APC, CE**.
- Identify if the affected lot is available at the laboratory, ensure the new reagent lot validation internal procedure is followed and check the results.
- Quarantine, and replace all units of the affected lot with an unaffected lot accordingly.
- If the affected lot was used in testing of patient samples, review the results of the lot validation testing to identify if the intensity of staining was appropriate, and review the patient results for accuracy and consider other diagnostic tests, if necessary.

Customer Actions:

- Inspect your inventory, identify, and quarantine any units of the affected lot of **BD™ CD11b APC, CE**.
- Destroy all units of the affected lot.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 30th November 2023**.
- Circulate this notice to all those who need to be aware within your organisation or to any organisation where the affected product has been transferred.
- If you experience any issues, please report as a complaint as per your normal process.

Distributor Actions:

- Cease distribution of the affected lot of **BD™CD11b APC, CE**.
- Identify, quarantine, and destroy all units of the affected lot of **BD™CD11b APC, CE**.
- Identify the facilities where you have distributed affected product and notify them immediately of this notice.
    - Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes by **30th November 2023**.
- Complete and return the Customer Response Form following completion of your reconciliation activities.
- If you experience any issues, please report as a complaint as per your normal process.

	End User with Inventory	End User with ZERO inventory	Where to send completed form
Purchased **directly** from BD	Complete the form in its entirety Upon receipt, BD will process the response, and provide replacement product.	Complete form and check the box indicating “no inventory”	<<insert BD email address>>
Purchased from a **distributor/3rd party**	Complete all fields on the form and contact your distributor to arrange replacement product.	Complete form and check the box indicating “no inventory”	Return the form to your distributor

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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
Associate Director, Post Market Quality
EMEA Quality

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Return to <*<insert fax/email address here>>* as soon as possible or **no later than 30th November 2023**

- **I confirm this Field Safety 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 facility. Affected product has been used.

All product that is not available for destruction will be considered as dispositioned at your location and therefore physically unavailable unless otherwise specified.

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. Replacments will only be sent on completion and return of this form).*

REF:	Lot Number:	Units destroyed *(Insert unit quantity below)*
333143	3114710	

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.*