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13th September 2023

URGENT: FIELD SAFETY NOTICE – IDS-23-4859

BD BACTEC™ Plus Aerobic/F Culture Vials

REF: 442023 Lot Numbers: See Table 1

Type of Action: Advisory

Attention: Laboratory Managers, Laboratory Directors, Purchasing Managers

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

Dear customer,

BD is issuing an advisory Field Safety Notice for specific lots of **BD BACTEC™ Plus Aerobic/F Culture Vials**. According to our distribution records your organisation may have received the impacted product in table 1. Affected product was distributed by BD from April 2023.

Product Code (REF)	UDI-DI	Manufacturer's SRN	Lot Number	Expiry Date
442023	038290HXRPGWNNMN	US-MF-000018910	3062843	07 Dec 2023
			3062846	08 Dec 2023
			3062849	08 Dec 2023
			3062847	08 Dec 2023
			3067489	11 Dec 2023
			3067488	11 Dec 2023

Table 1: Impacted product

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

Description of the problem

BD has confirmed through two customer complaints that certain vials of the **BD BACTEC™ Plus Aerobic/F Culture Vials**, noted above, have a labeling issue where duplicate barcode sequence numbers have been identified on more than one vial.
An internal collision analysis revealed that it is unlikely that a customer site will receive vials with duplicate sequence numbers. This is based on the distribution of sequence number label batches for the affected lots and the regional distribution patterns. Although unlikely, this issue could cause a customer to receive more than one **BD BACTEC™ Plus Aerobic/F Culture Vials** with duplicate sequence numbers.

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Clinical risk

Duplicated sequence numbers have been identified with the impacted lots of BD BACTEC™ vials, and in the rare occurrence that a site receives multiple affected lots, this issue may result in culture vials with these duplicate sequence numbers being scanned into the BD BACTEC™ fluorescent series instruments. This event will cause a mis-association of patient blood culture results under certain, very limited conditions. In the majority of scenarios, the instrument's pop-up alerts will notify users of any vials that have duplicate sequence numbers which are already in or recently removed from the instrument. Built-in safeguards will also prevent users from re-entry of vials in some cases, minimising the risk of mis-association of patient results. However, if a vial is scanned into the BD BACTEC™ fluorescent series instruments with a duplicate sequence number to a vial removed within 0-5 hours prior, there is a risk of mis-association of patient data.

Mis-association can lead to incorrect results being reported to the clinician, which could then lead to a delay or absence of appropriate diagnosis and treatment. Clinical implications of these adverse diagnostic outcomes range from mild to severe, depending on the clinical status of the patients involved and the specific manifestation of the error. However, severe patient harm is unlikely due to the instrument's safety features, such as real-time user alerts and the narrow period of time within which mis-association can occur. Good clinical practice, which includes the administration of empiric therapy and therapy review and the availability of supplemental diagnostic information for differential diagnosis, also reduces the possibility of patient harm.

To date, there have been two adverse events reported for the related issue, with no injuries reported.

There is no requirement for customers to return any BD BACTEC™ Plus Aerobic/F Culture Vials to BD. These products can continue to be used in accordance with the guidance in this safety notice.

BD Actions:

BD is investigating and will implement appropriate measures to prevent recurrence of this product issue.

Customer Actions:

- Review the information in **Table 1** to determine if **BD BACTEC™ Plus Aerobic/F Culture Vials** in your possession are impacted.
- Users should verify that the accession number on the BD BACTEC™ Instrument loading screen matches the vial's accession number while scanning and loading onto the instrument. If an error message or other system action occurs when loading vials into the BD BACTEC™ Instrument that indicates a potential issue with duplicate sequence numbers, it is recommended to follow the instructions within the message and to view the table of "System Alerts" located in "7 – Troubleshooting" of the BD BACTEC™ FX Instrument User's Manual before taking any further action in vial processing. The link to the BD BACTEC™ FX Instrument User's Manual is as follows: https://eifu.bd.com/en/search/search-results?term=441385&cats=9444_,9441_9443,9441_9442,1185_,1185

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- There are no additional follow-up activities recommended for processed patient samples.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 9th October 2023**.
- Circulate this notice to all those who need to be aware within your organisation or to any organisation where the potentially affected product has been transferred.
- If you experience any issues, please report as a complaint as per your normal process.

Distributor Actions:

- Review the information in **Table 1** to determine if the **BD BACTEC™ Plus Aerobic/F Culture Vials** in your possession are impacted.
- 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 **9th October 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 and ensure that all recommended actions have been implemented as required	Complete the form in its entirety and retain a copy of this notification for your records	<<insert contact email address here>>
Purchased from a **distributor/3rd party**	Complete the form in its entirety and ensure that all recommended actions have been implemented as required	Complete the form in its entirety and retain a copy of this notification for your records	Return the form to your distributor/3rd party

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

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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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Customer Response Form – IDS-23-4859

BD BACTEC™ Plus Aerobic/F Culture Vials

REF: 442023 Lot Numbers: See Table 1

Return to **<< insert email address>>** as soon as possible or **no later than the 9th October 2023**.

By signing below, you confirm this Field Safety Notice has been read, understood and that all recommended actions have been implemented as required.

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.*