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16th November 2023

URGENT: FIELD SAFETY NOTICE – IDS-23-4910

BD BACTEC™ MicroMGIT™ Calibration Vial

REF: 441049 **Lot Numbers:** See Table 1

Type of Action: Product Removal

Attention: Clinical Personnel, Laboratory Manager, Risk Manager, Purchasing 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 **BD BACTEC™ MicroMGIT™ Calibration Vials**. According to our distribution records your organisation may have received the impacted product in Table 1. Product was distributed by BD between March 2023 and September 2023.

Product Code (REF)	Lot Number	Expiry Date	UDI	Manufacturer's SRN
441049	2067938	02-Feb-2024	(17)240202(10)2067938 (01)00382904410490	US-MF-000018910
	2209320	24-Jul-2024	(17)240724(10)2209320 (01)00382904410490	

Table 1: Impacted product

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

Description of the problem

BD has confirmed through 45 (forty-five) customer complaints that the BD BACTEC™ MicroMGIT™ Calibration Vial batches mentioned above had performance failures due to low fluorescence and/or low media fill.

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Clinical risk

Incorrect fluorescence level emitted by affected BD BACTEC™ MicroMGIT™ can lead to false positive detection of Mycobacteria tuberculosis, which may lead to incorrect diagnosis or inappropriate treatment. The practice of confirmatory testing for Mycobacteria tuberculosis following a positive result from a qualitative test method significantly reduces the likelihood of misdiagnosis and subsequent inappropriate treatment and can also reduce the duration of incorrect treatment if administered.

To date, there has been no adverse events worldwide related to this issue.

Actions for Clinical Users

1. No patient follow up activities are required.
2. Refer to the Instructions for Use, which can be accessed and downloaded, https://eifu.bd.com/ using the product code (REF) in table 1, to follow the instructions for the preparation of interpretive negative and positive control tubes in the absence of a calibrator vial and the manual read information.

BD Actions

BD has identified the root cause and is taking corrective actions to prevent recurrence of this issue.

Customer Actions

- Cease use of any unused affected BD BACTEC™ MicroMGIT™ Calibration Vials.
- Identify and quarantine all unused affected BD BACTEC™ MicroMGIT™ Calibration Vials.
- Make a note of the lot numbers and destroy all unused affected units.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 4th December 2023**.
- Circulate this notice to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred.
- If you experience any issues, please report as a complaint as per your normal process.

Distributor Actions

- Cease distribution.
- Identify, quarantine, making a note of the lot numbers then destroy all unused affected BD BACTEC™ MicroMGIT™ Calibration Vials.
- 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 **4th December 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	Complete form and check the box indicating "no inventory"	EMEAFieldAction@bd.com

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	Upon receipt, BD will process the response, and you will receive **replacements** for unused product		
Purchased from a **distributor/3rd party**	Complete all fields on the form and contact your distributor to arrange for **replacements**	Complete form and check the box indicating "no inventory"	Return the form to your distributor

Contact reference person

If you have any questions about this, please contact your local BD representative or or e-mail EMEAFieldAction@bd.com

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,

[redacted]
Associate Director, Post Market Quality
EMEA Quality

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REF: 441049

Return to EMEAFieldAction@bd.com as soon as possible or **no later than the 4th December 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. **Replacement** product will only be sent on completion and return of this form).*

REF:	Lot Number/s:	Units destroyed *(insert quantity below)*
441049	2067938	
	2209320	

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.*