1030 Eskdale Road
Winnersh Triangle
Wokingham
RG41 5TS
www.BD.com

2nd April 2024

URGENT: FIELD SAFETY NOTICE – IDS-23-4910-B

BD BACTEC™ MicroMGIT™ Calibration Vial

REF: 441049 **Lot Numbers:** 3268593

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 a specific lot 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 31st October 2023 and 15th November 2023.

Product Code (REF)	Lot Number	Expiry Date	UDI	Manufacturer's SRN
441049	3268593	11-Sept-2025	(17)250911(10)3268593 (01) 0 038290 441049 0	US-MF-000018910

Table 1: Impacted product

This product removal is limited to the lot number listed in Table 1.

Description of the problem

In November 2023, BD initiated a Field Action for the **BD BACTEC™ MicroMGIT™ Calibration Vials** regarding low fluorescence and or low/media fill.

Since the initiation of this Field Action, BD has received a further four (4) complaints in relation to low fluorescence for the lot number listed in Table 1. This lot number was not part of the previous Field Action. Based on these additional four (4) complaints BD is continuing to investigate root cause.

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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. Read and understand the preparation of interpretive negative and positive control tubes and the manual read information located within the product Instructions For Use (IFU). The IFU can be accessed and downloaded from the following link, please search under the product code (REF 8809501): https://www.bd.qarad.eifu.online/

BD Actions

1. BD will issue credit to customers.
2. BD will update the corrective and preventive action plan based on additional investigation results.

Customer Actions

- Identify, quarantine, cease use of and destroy all unused affected **BD BACTEC™ MicroMGIT™ Calibration Vials,** lot number 3268593.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 3rd May 2024**.
- 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, and destroy all unused affected **BD BACTEC™ MicroMGIT™ Calibration Vials**, lot number 3268593.
- 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 **3rd May 2024.**
- 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.

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	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 you will receive **credit** for unused product	Complete form and check the box indicating "no inventory"	BDUKFieldAction@bd.com
Purchased from a **distributor/3rd party**	Complete all fields on the form and contact your distributor to arrange for **credit**	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 the local BD office on **0800 917 8776** or e-mail BDUKFieldAction@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,

Kinga Stolinska
Director, Post Market Quality
EMEA Quality

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Customer Response Form – IDS-23-4910-B

BD BACTEC™ MicroMGIT™ Calibration Vial

REF: 441049 **Lot Numbers:** 3268593

Return to BDUKFieldAction@bd.com as soon as possible or **no later than the 3rd May 2024.**

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

REF:	Lot Number/s:	Units destroyed *(insert quantity below)*
441049	3268593	

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.*