20th May 2025

URGENT: FIELD SAFETY NOTICE – IDS-24-5091-B

BD BACTEC™ MGIT™ 960 PZA Kit

REF: 245128 **Lot Numbers:** see Appendix 1

Type of Action: Product Removal

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

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™ MGIT™ 960 PZA Kit**. According to our distribution records your organisation may have received the impacted product in Appendix 1. Product was distributed between October 2024 and April 2025.

Description of the problem

In mid-2024, BD initiated a field action for the BD BACTEC™MGIT™ 960 PZA Kits. Later that year, following an internal investigation and based on positive expanded performance test results, BD implemented a modification to the raw material to address the issue. BD resumed production while conducting further stability testing.

However, BD has received additional complaints regarding the affected product of intermittent false resistance results for pyrazinamide (PZA) during susceptibility testing of *Mycobacterium tuberculosis* isolates. Concurrently, BD's additional stability testing suggests that the implemented corrective action may not fully resolve the issue and further investigation is necessary.

Clinical risk

PZA is a widely used component in the treatment of tuberculosis, and its exclusion based on false resistance results can result in a less optimal treatment regimen. This could include an extended length of treatment and increased risk of medication side effects, such as hepatotoxicity, peripheral neuropathy, and hypersensitivity reactions.

To date, there has been four (4) adverse events worldwide related to this issue.

Clinical User Actions

- Customers should discard the affected product immediately.

- There are no recommendations for retesting or reviewing previous patient test results; however, this does not preclude any clinician or institution from performing additional retesting or review if they deem necessary and have resources available to them. Laboratories should be aware that the availability and validation status of PZA Drug Susceptibility Testing (DST) methods vary by country and laboratory setting. We recommend consulting your national TB program, public health authority, or reference laboratory to determine the most appropriate testing strategy based on local testing infrastructure and regulatory guidance.

Action taken by BD

- BD has paused manufacturing of the affected product and will issue credit as applicable. Replacement product is currently unavailable.
- BD will continue to investigate this issue.
- BD will communicate when supply is available or when appropriate next steps are decided.

Customer Actions:

- Cease use of any unused affected lots of **BD BACTEC™ MGIT™ 960 PZA Kit**.
- Identify and quarantine all unused affected lots of **BD BACTEC™ MGIT™ 960 PZA Kit**.
- 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 30th June 2025.**
- 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 lots of **BD BACTEC™ MGIT™ 960 PZA Kit**.
- 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 June 2025**.
- 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 you will receive	Complete form and check the box indicating “no inventory”	RFQNGO@bd.com

	credit for unused product		
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 RFQNGO@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

Customer Response Form - IDS-24-5091-B

BD BACTEC™ MGIT™ 960 PZA Kit

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Return to RFQNGO@bd.com as soon as possible or **no later than the 30th June 2025**

- **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 **Appendix 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 **Appendix 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 (1 unit = 1 box of 8 vials) *(insert quantity below)*

Account/Organisation Name:		
Department *(if applicable)*:		
Address:		
Postcode:	**City:**	**Country:**
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.*

Appendix 1 - Product Code and Lot numbers

This Field Safety Corrective Action is limited to the lot numbers listed in Appendix 1.

Manufacturer's SRN: US-MF-000018910

Product Name	Catalog Number	Lot or Serial Number	UDI-DI	Expiration Date
BD BACTEC™ MGIT™ 960 PZA Kit	245128	4150998	(01) 0038290245128	2025-08-29
		4177908	(01) 0038290245128	2025-09-10
		4178500	(01) 0038290245128	2025-10-08
		4262031	(01) 0038290245128	2025-07-18
		4262037	(01) 0038290245128	2025-08-29
		4262039	(01) 0038290245128	2025-09-10
		4262040	(01) 0038290245128	2025-10-22
		4262044	(01) 0038290245128	2025-11-26
		4284443	(01) 0038290245128	2025-12-24
		4284445	(01) 0038290245128	2025-12-24
		4284449	(01) 0038290245128	2025-12-31
		4304789	(01) 0038290245128	2026-03-11
		4304796	(01) 0038290245128	2026-02-20
		4347228	(01) 0038290245128	2025-12-31
		4347230	(01) 0038290245128	2026-03-18
		4352110	(01) 0038290245128	2026-02-04
		4362418	(01) 0038290245128	2026-03-18
		5020153	(01) 0038290245128	2026-03-25