



19th July 2024

URGENT: FIELD SAFETY NOTICE – IDS-24-5091

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 June 2023 and June 2024.

Description of the problem

Through internal BD complaint trending and subsequent internal raw material testing it was identified that the **BD BACTEC™ MGIT™ 960 PZA Kits**, listed in Appendix 1, may intermittently produce falsely resistant results for pyrazinamide (PZA) during susceptibility testing of Mycobacterium tuberculosis isolates.

Clinical risk

PZA is a widely used component in the treatment of tuberculosis, 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 one (1) adverse event 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.

BD Actions:

- BD will issue credit to the customers.



- BD has identified the root cause and is taking action to prevent recurrence of this product issue.

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 August 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, 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 August 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.

	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”	emeafieldaction@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 e-mail 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

BD BACTEC™ MGIT™ 960 PZA Kit

REF: 245128 Lot Numbers: see Appendix 1

Return to emeafieldaction@bd.com as soon as possible or **no later than the 30th August 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 **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 (<i>if applicable</i>):		
Address:		
Postcode:	City:	Country:
Contact Name:		
Job Title:		
Contact Telephone Number:		Contact E-mail Address:
Name of your supplier for this product (<i>if not direct from BD</i>)		
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	3104416	(01) 0038290245128	22-Aug-24
		3122995	(01) 0038290245128	04-Sept-24
		3128412	(01) 0038290245128	21-Sept-24
		3142051	(01) 0038290245128	14-Sept-24
		3156654	(01) 0038290245128	31-Oct-24
		3191569	(01) 0038290245128	06-June-24
		3233971	(01) 0038290245128	22-Nov-24
		3241654	(01) 0038290245128	08-Jan-25
		3248314	(01) 0038290245128	30-Jan-25
		3269157	(01) 0038290245128	13-Feb-25
		3298311	(01) 0038290245128	07-Feb-25
		3298317	(01) 0038290245128	14-Feb-25
		3304389	(01) 0038290245128	26-Mar-25
		3324422	(01) 0038290245128	23-Apr-25
		3338965	(01) 0038290245128	06-Mar-25
		4002353	(01) 0038290245128	21-May-25
		4009894	(01) 0038290245128	28-May-25
		4036330	(01) 0038290245128	19-Jun-25
4051247	(01) 0038290245128	16-Jul-25		