4th November 2025

NEW

URGENT: FIELD SAFETY NOTICE – IDS-25-5412

BD BACTEC™ MGIT™ 960 PZA Kit

REF: 245128

Type of Action: Advisory

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

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

Dear Customer,

BD is issuing an advisory Field Safety Notice for **BD BACTEC™ MGIT™ 960 PZA Kit**. This follow-up letter does not introduce new lots. For previously communicated affected lots, please refer to previous Field Safety Notification references IDS-24-5091 and IDS-25-5091-B

According to our distribution records your organisation may have received the product in Table 1.

Product name	Product Code (REF)	Basic UDI-DI	Manufacturer's SRN
BD BACTEC™ MGIT™ 960 PZA Kit	245128	038290OPKQGYUDKE	US-MF-000018910

Table 1: Impacted product

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

Device Type

BD BACTEC™ MGIT™ 960 PZA Kit is supplied in a brown box labelled with the product name and contains two lyophilised vials of pyrazinamide and six vials of BD BACTEC™ MGIT™ 960 PZA Supplement.

Figure 1: BD BACTEC™ MGIT™ 960 PZA Kit

Primary clinical purpose of devices

The BD BACTEC™ MGIT™ 960 PZA Kit is a rapid qualitative procedure for susceptibility testing of *Mycobacterium tuberculosis*, from culture, to pyrazinamide (PZA). The BD BACTEC™ MGIT™ 960 PZA Kit is used with the BD BACTEC MGIT System.

Description of the product problem

BD is pleased to announce that we have resumed production of a modified version of the BD BACTEC™ MGIT™ 960 PZA Kit which includes modified inoculation methods and reduced shelf-life.

BD has conducted a thorough review of the performance from all supported inoculum sources using the synthetic raw material and the following change has been implemented for the BD BACTEC™ MGIT™ 960 PZA Kit.

- **Only inoculum prepared from MGIT tubes 3-5 days post-positivity can be currently supported.**
- Inoculum prepared from MGIT tubes 1-2 days past instrument positivity are currently not supported.
- Inoculum prepared from solid media are currently not supported.

Additionally, the shelf life of the product has been adjusted from 18 months to 13 months to reflect the latest internal supporting data.

Clinical risk

BD's investigation has determined that the product functions as intended when testing with inoculum prepared from MGIT tubes 3-5 days post-positivity. The use of the product under these revised conditions does not introduce any further or incremental risk. These modifications have been implemented to address and reduce the potential for false resistance previously observed in the product.

As the scope, root cause, and related adverse diagnostic outcome (e.g., false resistance) have not changed or expanded beyond the initial field action, there are no additional clinical recommendations for retesting or reviewing previous patient test results.

No new adverse events have occurred since BD's last field action communication related to this matter.

Clinical User Actions

Clinical users should refer to the updated Instructions for Use (IFU) available at [redacted] Additional languages will be added as translations are completed.

BD Actions:

1. BD will continue to work with global regulatory authorities to reintroduce BD BACTEC™ MGIT™ 960 PZA Kit. BD will resume receiving and fulfilling customer orders for this product

in markets where permitted, based upon regulatory requirements while maintaining ongoing quality improvements and performance monitoring.

2. BD continues to investigate long-term solutions and will actively work with global regulatory authorities to reintroduce the BD BACTEC™ MGIT™ 960 PZA Kit with the original claims.

To date, BD does not plan to initiate any further advice or information in a follow-up FSN.

Customer Actions:

- Review the information in this notice.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 1st December 2025.**
- This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation which this action has an impact.
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
- Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Distributor Actions:

- Review the information in this notice.
- This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation which this action has an impact.
- Identify the facilities where you have distributed the **BD BACTEC™ MGIT™ 960 PZA Kit** and notify them immediately of this notice.
    - Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes by **1st December 2025.**
    - There is no requirement to return your customer response forms to BD, you should maintain these on file at your facility. Return only your final consolidated response form.
- Complete and return the Customer Response Form following completion of your reconciliation activities.
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
- Please report all device-related incidents to the manufacturer, or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

		Where to send completed form
Purchased **directly** from BD	Complete the form in its entirety and retain a copy of this notification for your records	[redacted]
Purchased from a **distributor/3rd party**	Complete the form in its entirety and retain a copy of this notification for your records	Return the form to your distributor/3rd party

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Contact reference person

If you have any questions about this, please contact your local BD representative or the local BD office or e-mail [redacted].

The Regulatory Authority of your country has been informed about this communication to customers.

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]
EMEA Quality

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

4th November 2025

Customer Response Form – IDS-25-5412

BD BACTEC™ MGIT™ 960 PZA Kit

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Return to [redacted] as soon as possible or **no later than the 1st December 2025**.

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.*