2 International Business Park Road
The Strategy #08-08
Singapore 609930
Registration No. 201114149N
bd.com

PRODUCT NOTIFICATION
IDS-25-5412
BD BACTEC™ MGIT™ 960 PZA Kit

11 November 2025

Dear Customer,

CC: Chairman Medical Board and relevant head of department

Type of Field Action:
Product Advisory (No disposition of Product)

Affected Product:

Product Name (Brand Name as per labelling)	Catalog No.
BD BACTEC™ MGIT™ 960 PZA Kit	245128

Description of the 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.

Clinical Risk Statement:
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.

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Complaint & Adverse Event Statement:
No new adverse events have occurred since BD's last field action communication related to this matter.
Actions for Clinical

Actions for Clinical Users:
Clinical users should refer to the updated Instructions for Use (IFU) available at https://www.bd.qarad.eifu.online/hcp. Additional languages will be added as translations are completed.

Actions to be taken by BD:

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.

Please Take the Following Actions:

1. Please follow the recommended actions indicated in this Letter.

2. Complete and return the attached Customer Response Form to the BD contact noted on the form confirming acknowledgement of the notification, whether or not you have any affected product, so that BD may confirm your receipt of this notification and clearly indicating the applicable contact person at your facility to support the software upgrade, when available.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Yours Sincerely,

Signed by:
Gaurav Verma
Signer Name: Gaurav Verma
Signing Reason: I approve this document
Signing Time: 10-Nov-2025 | 9:55:33 PM PST
AAFA2E5F88004BF59A2BF6F108409CF6

_____
Gaurav Verma
Regional RA and SEA Quality Director

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CUSTOMER RESPONSE FORM

IDS-25-5412

BD BACTEC™ MGIT™ 960 PZA Kit

Please fill in the information below so that we may acknowledge your receipt of this notification. Simply complete and return the completed form to **SEA_Quality** SEA_Quality@bd.com **/ local BD representative** by **05 December 2025.**

Please tick as appropriate.

☐ I have read and understood the attached notice & will share this Advisory Notice with all users within my facility.

Completed by:

Name:	
Signature:	
Date:	
Facility / Address / Telephone Number:	