Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152
bd.com

URGENT: Medical Device Correction
IDS-25-5412-FA
Type of Action: Product Advisory
BD BACTEC™ MGIT™ 960 PZA Kit

Date: 03Nov2025

Affected Product

This follow-up letter does not introduce new lots. For previously communicated affected lots, please refer to previous Field Safety Notifications Ref# IDS-24-5091 and IDS-24-5091-EXP.

Product Name	Catalog No.
BD BACTEC™ MGIT™ 960 PZA Kit	245128

For the Attention of: Lab Manager/Risk Manager

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.

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

Clinical Impact:

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.

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Please Take the Following Actions:

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.

Action TO 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.

Action to be taken by customer

1. Ensure the contents of this notification are read and understood.

2. Share and post this customer letter within your facility network and forward to any customers to whom you may have distributed the product to ensure awareness.

3. Complete the attached Customer Response Form and return to the BD contact noted on the form whether or not you have any of the impacted material so that BD may acknowledge your receipt of this notification per FDA requirements.

4. Report any adverse health consequences experienced with the use of this product to BD. Events may also be reported to the FDA's MedWatch Adverse Event Reporting program via:
   Web: MedWatch website at www.fda.gov/medwatch
   Phone: 1-800-FDA-1088 (1-800-332-1088)

Product Distribution Time Frame
04May2023 thru 17Apr2025

Contact Information:

If you require further assistance, please contact:

BD Contact	US Contact Information	Areas of Support
North American Regional Complaint Center	**Phone:** 1-844-8BD-LIFE (1-844-823-5433) Say "Complaints" when prompted Mon–Fri 8:00am and 5:00pm CT **or** **Email:** productcomplaints@bd.com	Product Complaints, Technical Questions
Recall related questions	BDRC12@bd.com	Recall questions

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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.

Sincerely,

Jeffrey Andrews, M.D.
VP, Medical Affairs

Carol Nieto
VP, Quality Management

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CUSTOMER RESPONSE FORM

(IDS-25-5412)

BD BACTEC™ MGIT™ 960 PZA Kit

Please assist BD by acknowledging this action using one of the following methods:
Website: https://bdx.my.site.com/CC360/s/impactedproducts?rn=IDS-25-5412
Email: BDRC12@bd.com
Fax: 312-949-0034

Facility: _____

Please print full, current facility name. Do not use initials.

Street Address: _____

City:_____ **State**: _____ **Zip**: _____

Response Form Completed By:	
Name:	
Title:	
Telephone No.	
Fax No.	
Email Address	

Please check all that apply:

☐ I have read and understood the attached notice and taken appropriate actions.

Please assist BD with assuring these communications are delivered to the appropriate person/function within your facility if that is not you.

Name:	
Title:	
Telephone No.	
Fax No.	

SUBMIT