



[to be date of distribution]

Product Removal Notice

Dear Valued bioMérieux Customer,

Our records indicate that you have received one or more of the following products:

Description: BacT/ALERT® MP Culture Bottle

Catalog Number: 259797

Lot Number: 1032439, 1032441, 1032443, 1032445 & 1032447

Expiry: 06 August 2013

Description of Issue:

bioMérieux, Inc. has observed an elevated complaint rate of false positive results associated with BacT/ALERT® MP Culture Bottle, lot 1032439, 1032441, 1032443, 1032445, and 1032447. An increased rate of false positive BacT/ALERT® MP results leads to an increased workload for the clinical laboratories using BacT/ALERT.

BacT/ALERT® MP Culture Bottles are used with the BacT/ALERT® 3D Mycobacteria Detection System for recovery and detection of mycobacteria from sterile body specimens other than blood and from digested-decontaminated clinical specimens.

Impact to customer:

An increased rate of false positive BacT/ALERT MP results leads to an increased workload for the clinical laboratories using BacT/ALERT. Each positive alarm requires the laboratory to access the bottle, perform smears (Gram stain and acid fast stain) and subculture to a variety of media. Although this is an inconvenience for the laboratory, it should not have an impact on patient outcome.

According to the instructions for use (IFU), all bottles designated positive should be smeared and sub-cultured. If the smear is negative, indicating a possible false positive, the bottle should be reloaded into the instrument until growth of subculture or re-designation as positive. Bottles re-designated as positive should again be smeared, sub-cultured and reloaded if no organisms are seen on the smear.

Required actions:

We request you take the following action at this time:

1. Ensure this letter and guidance has been distributed and reviewed by all appropriate personnel within your organization.
2. Discontinue use of the referenced part and lot numbers (REF 259797; lot number 1032439, 1032441, 1032443, 1032445, 1032447) and discard remaining inventory according to your facility's procedure for culture media. Contact your local bioMérieux representative for product replacement.

NOTE: Bottles that are already inoculated and/or incubating on the instrument should be allowed to complete their testing/incubation.

[Enter Local Contact Address and telephone]

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3. Continue following the BacT/ALERT® MP Culture Bottle Instructions for Use (IFU) regarding bottles that are flagged positive by the instrument, "Smear and subculture all positive bottles. If the smear is negative, indicating a possible false positive, the bottle should be reloaded into the instrument until growth of the subculture or re-designation as positive. Bottles re-designated as positive should again be smeared, sub-cultured and reloaded if no organisms are seen on the smear
4. Fill out and return the Acknowledgement Form by fax to confirm receipt of this notice and for product replacement.

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact your local bioMérieux Customer Service representative.

Thank you for your continued use of bioMérieux products,

bioMérieux, Inc.

[\[Enter Local Contact\]](#)

[\[Enter Local Contact Address and telephone\]](#)
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Attachment A: Acknowledgement Form.

PRODUCT REMOVAL NOTICE

FCA - 1748 – BacT/ALERT MP Culture bottle false positive issue

Customer Information:

Customer Account Number: _____ Organization Name: _____

Street Address: _____

City, State and Postal Code: _____

Contact Name: _____

Contact Title: _____

Phone Number: _____

Product Information:

Catalog Number	Description	Replacement Qty.

Questions:

	Yes	No
1. Did you read the enclosed Product Removal Notice regarding the BacT/ALERT MP Culture bottles?		
2. Have you followed the instructions and implemented the actions as indicated in this Product Removal Notice?		

Comments:

Signature: _____

Date: _____

It is important that you complete this Acknowledgement Form and return it to bioMérieux.

Please fax this form to: [\[Enter Local Contact\]](#) To the attention of: [\[Enter Local Contact\]](#)