



[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:

REF	Description	Lot	Expiry
259788	BacT/ALERT® iLYM	1043262	16FEB2016
259790	BacT/ALERT® SN	1042739	09JAN2016
259791	BacT/ALERT® FA	1042923	25JAN2016
259791	BacT/ALERT® FA	1042979	28JAN2016

**Description of Issue:**

The above-referenced products may have been exposed to non-normal shipping conditions during transit. Bottles that have been exposed to non-normal shipping conditions may experience media degradation and impact growth performance.

BacT/ALERT® Culture Bottles are used with the BacT/ALERT® Microbial Detection System in qualitative procedures for enhanced recovery and detection of aerobic and facultative anaerobic microorganisms (bacteria and yeast).

**Impact to customer:**

The potential risk to product exposed to non-normal shipping conditions is a potential to cause accelerated product aging and thus can lead to media degradation. Media degradation in turn impacts growth performance including delayed growth or no growth (clinical false negative result).

**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 number 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]  
[www.biomerieux.com](http://www.biomerieux.com)



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.**

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

[\[Enter Local Contact Address and telephone\]](#)  
[www.biomerieux.com](http://www.biomerieux.com)



**Attachment A: Acknowledgement Form.**

**PRODUCT REMOVAL NOTICE**

FSCA - 2768 – BacT/ALERT IDC Distribution

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**Customer Information:**

Customer Account Number: \_\_\_\_\_ Organization Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City, State and Postal Code: \_\_\_\_\_

Contact Name: \_\_\_\_\_

Contact Title: \_\_\_\_\_

Phone Number: \_\_\_\_\_

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**Product Information:**

Catalog Number	Description	Replacement Qty.

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**Questions:**

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

**Comments:**  
\_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

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