



[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:

Product Number	Lot Number	Description	Expiration Date
410851	1033291	BacT/ALERT® FA PLUS Culture Bottle	15 OCT 13

**Description of Issue:**

BacT/ALERT® FA PLUS Culture Bottle, lot 1033291 yielded reflectance results above the stability specification at the 11-month timeframe. Bottles that have reflectance results near or greater than the initial value threshold specification when first loaded on the instrument could have an increased probability of false positive results.

BacT/ALERT® FA PLUS Culture Bottle 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) from blood and other normally sterile body fluids.

**Impact to customer:**

The impact associated with a reflectance value above the internal specification is an increased potential for initial value threshold (IVT) instrument false positive results. 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. Cultures which were initially determined false positive and were designated positive, should be smeared and sub-cultured. To date, there have been no complaints from the field of false positive results related to initial value threshold.

**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 (REF 410851; lot number 1033291) 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.

3. Continue following the BacT/ALERT® FA PLUS 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

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subculture or re-designation as positive. Bottles that were initially determined false positive and were re-designated positive, should be smeared and sub-cultured.”

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.**

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

**Attachment A: Acknowledgement Form.**

[\[Enter Local Contact Address and telephone\]](#)  
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**PRODUCT REMOVAL NOTICE**

FCA - **XXXX** – BacT/ALERT FA PLUS Reflectance Stability Specification Failure

**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 FA Plus Reagent 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: [\[Enter Local Contact\]](#)



[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:

Product Number	Lot Number	Description	Expiration Date
410853	1033633	BacT/ALERT® PF PLUS Culture Bottle	20 NOV 13

**Description of Issue:**

BacT/ALERT® PF PLUS Culture Bottle, lot 1033633 yielded reflectance results above the stability specification at the 11-month timeframe. Bottles that have reflectance results near or greater than the initial value threshold specification when first loaded on the instrument could have an increased probability of false positive results.

BacT/ALERT® PF PLUS Culture Bottle are used with the BacT/ALERT® Microbial Detection System in qualitative procedures for enhanced recovery and detection of aerobic and facultative microorganisms (bacteria and yeast) from blood. The BacT/ALERT® PF PLUS Culture Bottle provides for detection of microorganisms when only a small volume of blood is available.

**Impact to customer:**

The impact associated with a reflectance value above the internal specification is an increased potential for initial value threshold (IVT) instrument false positive results. 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. Cultures which were initially determined false positive and were designated positive, should be smeared and sub-cultured. To date, there have been no complaints from the field of false positive results related to initial value threshold.

**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 (REF 410853; lot number 1033633) 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.

3. Continue following the BacT/ALERT® PF PLUS 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

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subculture or re-designation as positive. Bottles that were initially determined false positive and were re-designated positive, should be smeared and sub-cultured.”

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.**

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

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**Attachment A: Acknowledgement Form.**

**PRODUCT REMOVAL NOTICE**

FCA - **XXXX** – BacT/ALERT PF PLUS Reflectance Stability Specification Failure

**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 PF PLUS Reagent 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: [\[Enter Local Contact\]](#)