

27 May 2005

702330-1

URGENT PRODUCT RECALL NOTICE

BacT/ALERT® Classic 120 System
BacT/ALERT® Classic 240 System
BacT/VIEW® Data Management System
BacT/ALERT® Text Data Management System
BPA and BPN Activation Bar Code Instructions

All Models
All Models
All Models
All Models
Part Numbers: 514253-1

ATTENTION: BacT/ALERT® BPA and BacT/ALERT® BPN Users

Dear bioMérieux Customer:

bioMérieux, Inc., Durham, North Carolina, U.S.A., has identified a software issue that affects all **BacT/ALERT® Classic systems**. An internal investigation of a customer complaint has determined that the current BacT/ALERT BPA and BPN algorithms are not correctly applied when using the **BacT/ALERT Generic Bar Code Labels**. This condition will not allow the detection of positive samples which could lead to the transfusion of undetected microbiological contaminated blood products.

BacT/ALERT® Generic Bar Code Labels are used to replace damaged or unreadable bar codes that are printed on the BacT/ALERT BPA and BacT/ALERT BPN culture bottles. We have determined that the root cause of this issue is an error within the BPA and BPN Activation Barcode Instructions that were used to update the software for the BacT/ALERT Classic system when BacT/ALERT BPA and BacT/ALERT BPN culture bottles were launched.

Please Note: This issue only affects the BacT/ALERT Classic system, and does not affect the BacT/ALERT 3D System. Also, this issue does not affect BacT/ALERT BPA and BacT/ALERT BPN culture bottles loaded into BacT/ALERT Classic system using the bar codes present on the labels of the culture bottles. Please refer to Attachment B for pictures and descriptions of BacT/ALERT Classic systems, BacT/ALERT 3D systems, and the BacT/ALERT Generic Bar Code Labels.

Effective immediately customers **must discontinue use** of BacT/ALERT Generic Bar Code Labels to load BacT/ALERT BPA and BPN culture bottles into the BacT/ALERT Classic system. BioMérieux expects to send you a software update for your BacT/ALERT Classic system in approximately eight weeks.

Instructions are included in Attachment C to determine if there were BacT/ALERT BPA and BacT/ALERT BPN culture bottles loaded using BacT/ALERT Generic Bar Code Labels. Please contact your local bioMérieux Customer Service Representative (For US Customers call 1-800-682-2666 prompt 3) for further assistance if it is determined that BacT/ALERT BPA and BacT/ALERT BPN culture bottles were loaded into the system using BacT/ALERT Generic Bar Code Labels.

- Please ensure that this letter is distributed to all appropriate laboratory personnel within your organization.
- Please complete and return the acknowledgement form in Attachment A via fax to confirm receipt of the recall notice.
- Please take any other necessary actions in accordance with your facility's policies and procedures to address the issues raised in this notification.

bioMérieux, Inc. is committed to providing our customers with the highest quality product possible, and we sincerely apologize for any inconvenience that this may cause your laboratory. If you require additional

assistance, please contact your local bioMérieux Customer Service Representative (For US Customers call 1-800-682-2666 prompt 3). Thank you for your continued use of bioMérieux, Inc. products.

Sincerely,

Troy C. Quander.
Associate Staff Regulatory Affairs Specialist

Attachments

Attachment A

CUSTOMER ACKNOWLEDGEMENT FORM

**URGENT
PRODUCT RECALL NOTICE**

| | |
|---|-------------------------------|
| BacT/ALERT® Classic 120 System | All Models |
| BacT/ALERT® Classic 240 System | All Models |
| BacT/VIEW® Data Management System | All Models |
| BacT/ALERT® Text Data Management System | All Models |
| BPA and BPN Activation Bar Code Instructions | Part Numbers: 514253-1 |

Contact's Name: _____ Institution: _____

Street Address: _____

City, State, Postal Code: _____

Contact's Telephone Number: _____

Please complete the following:

- We received the notice of product recall on _____
mo/day/yr
- We are using a BacT/ALERT Classic system yes _____ no _____
- We are using a BacT/ALERT 3D system yes _____ no _____
- We understand that effective immediately BacT/ALERT Generic Bar Codes Labels **must not** be used to load BacT/ALERT BPA and BacT/ALERT BPN culture bottles into the BacT/ALERT Classic system
- We have followed instructions in Attachment C to review the BacT/ALERT Classic system data management system to determine which BacT/ALERT BPA and BacT/ALERT BPN culture bottles were loaded into the system using BacT/ALERT Generic Bar Codes Labels
 - BacT/ALERT Generic Bar Codes Labels Used:

 Yes _____ No _____
- We understand that a software upgrade will be introduced to correct the BacT/ALERT Classic system in approximately eight weeks

Signature: _____ Date: _____

Please return this completed form to bioMérieux Regulatory Affairs:

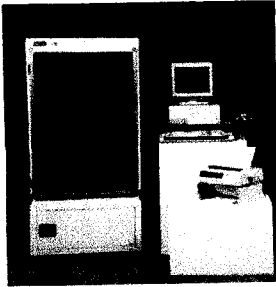
Fax:
(enter local Regulatory fax number here)

Mail: bioMérieux, Inc.
(enter local address here)

Attachment B

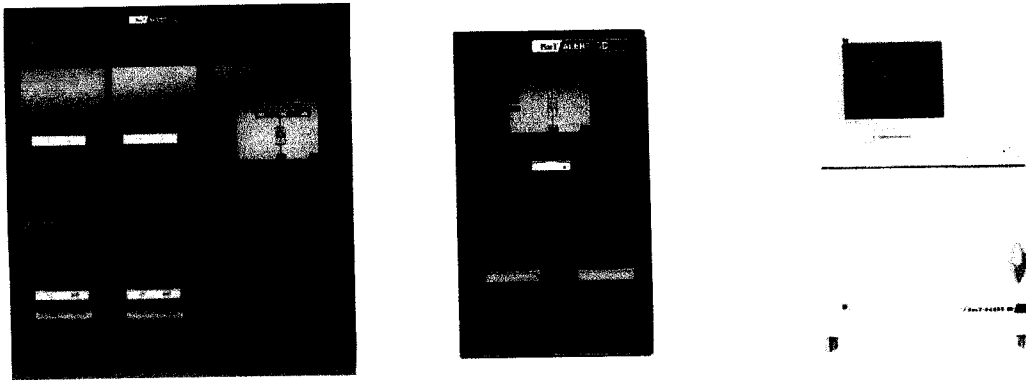
The BacT/ALERT Classic System is the first generation of BacT/ALERT Microbial Detection systems. Most notably the System has a door that opens to reveal either 120 or 240 cells. If your system has drawers with 60 cells in each, it is not a BacT/ALERT Classic system and is not affected by this problem.

Picture 1 – BacT/ALERT Classic systems



The BacT/ALERT 3D systems are the latest generation of the BacT/ALERT Microbial Detection Systems. Most notably, each BacT/ALERT 3D system has drawers with 60 cells in each, or in the case of the BacT/ALERT 3D 60 only 60 cells.

Picture 2 – BacT/ALERT 3D systems



BacT/ALERT® Generic Bar Code Labels are replacement barcodes that can be placed over the original bottle barcode. Most often they are used when the original barcode is damaged or unreadable. These replacement barcode labels do not designate a bottle type. The user chooses the bottle type from the list provided by the BacT/ALERT software.

Picture 3 – BacT/ALERT Generic Bar Code label



Attachment C

How to determine if generic bar codes have been used with BPA or BPN bottles on the BacT/ALERT Classic system:

In BacT/VIEW C.30 systems:

1. Log on.
2. Go to the "Bottle data" screen of "Data manager".
3. Click the "Query" button or choose "Browse"->"Begin query" from the menu.
4. Enter
G]
(G followed by a right square bracket) in the "Bottle ID" field.
5. Enter
BPA;BPN
in the "Type" field.
6. Press F9 to perform the query.
7. If a bottle is found, press the "Print screen" key to print the other data about this bottle.
8. Press <Alt-F> to advance to the next such bottle, and repeat from step 7, until all bottles have been printed.

In BacT/ALERT Text E.20 systems:

1. Log on.
2. Choose "More BacT/Alert functions...".
3. Choose "Editing functions...".
4. Choose "Edit bottle data".
5. Press <Shift-F1> to begin a query.
6. Enter
G]
(G followed by a right square bracket) in the "Bottle ID" field.
7. Enter
BPA;BPN
in the "Type" field.
8. Press F9 to perform the query.
9. If a bottle is found, press the "Print screen" key to print the other data about this bottle.
10. Press Form Feed (FF) on the printer to advance the paper.
11. Press <Alt-F> to advance to the next such bottle, and repeat from step 9, until all bottles have been printed.