(Insert Date)

URGENT
PRODUCT NOTIFICATION

BacT/ALERT® 3D System - All Models

ATTENTION: BacT/ALERT® MP & MB Users

Dear bioMérieux Customer:

bioMérieux, Inc., Durham, North Carolina, U.S.A., has identified a software issue that affects the **BacT/ALERT 3D, BacT/ALERT 3D 60** and the **BacT/ALERT 3D Combo** instruments. Our internal investigation determined that the software is functioning incorrectly after a positive BacT/ALERT MP or BacT/ALERT MB bottle is unloaded. This situation applies only to the BacT/ALERT MP/MB bottles when tested on the BacT/ALERT 3D instrument platform.

The BacT/ALERT MP/MB bottles use two distinct algorithms to determine a positive sample. The first algorithm runs for the first four days after a bottle is loaded. This algorithm was designed to detect the faster growing organisms other than Mycobacteria that typically may be considered contaminants in digested-decontaminated clinical specimens. The second algorithm, designed for detecting Mycobacteria, begins testing one and a half days after the bottle is loaded and runs until the bottle is unloaded. The problem occurs when a bottle is detected positive with the first non-Mycobacteria algorithm, but remains negative to date with the Mycobacteria algorithm, is unloaded. Under these circumstances, the bottle will revert back to a status of negative-to-date in the BacT/ALERT 3D instruments. **If a bottle is determined positive by the Mycobacteria algorithm the bottle status remains positive even after it is unloaded.**

When a BacT/ALERT MP/MB bottle is determined positive by either algorithm on a BacT/ALERT 3D Signature system the positive result is sent to the data management system (BacT/VIEW® or OBSERVA®) and remains positive even if the positive bottle status at the BacT/ALERT 3D reverts back to negative-to-date. However, when a BacT/ALERT MP/MB bottle reverts back to negative-to-date on a SelectLink system the negative-to-date status is sent to the LIS and overrides the previous presumptive positive result. The BacT/ALERT 3D Select system bottle result also will be incorrect (negative to date) when obtained from the Control Module after the bottle is unloaded.

The package insert recommends that all bottles designated positive should be smeared and subcultured for acid-fast bacilli. If the acid-fast smear is negative for acid-fast bacilli, the package insert recommends performing a Gram Stain. If both the acid-fast smear and Gram stains are negative, indicating a possible false positive, the bottle should be loaded back into the instrument until growth is detected on the subculture, or the bottle is determined positive or negative by the instrument.

The package insert also instructs the user to report preliminary results only after an acid-fast stain has been performed.

The system properly performs the function of alerting the user to a presumptive positive bottle; and although the BacT/ALERT 3D status may revert to negative-to-date for the BacT/ALERT MP or BacT/ALERT MB bottle, an instrument result should not be reported to a physician until confirmed by smear or subculture.

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bioMérieux expects to send you an update packet for your BacT/ALERT 3D instrument within the second quarter of the year 2006 that will correct this software when the bottles are unloaded.

We recommend implementation of the following action until your system is updated:

> After unloading a BacT/ALERT MP/MB bottle determined to be positive within the first four days of testing immediately proceed to the 'Edit Bottle Detail' screen on the BacT/ALERT 3D. Check the bottle's status. If the status has changed to negative-to-date manually change the status back to positive and press the check button to save the change. The results that have been manually changed to positive via the 'Edit Bottle Detail' screen will be marked on the BacT/ALERT 3D reports with a stick figure. Additional documentation for this manual status change can be logged offline.

The following actions should be taken concerning this product:

- Please complete the attached form (Attachment A) and return to bioMérieux; see Attachment A for fax number and address.
- Please ensure that this notification is distributed to all appropriate laboratory personnel within your organization.

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 bioMérieux's Customer Support at *(Insert local service number.)*

Respectfully,

(Insert Regulatory Information)

Attachments

Attachment A

CUSTOMER ACKNOWLEDGEMENT FORM

URGENT
PRODUCT ADVISORY NOTICE

BacT/ALERT 3D System: All Models

Contact's Name:_____ Institution_____

Street Address:_____

City, State, Postal Code:_____

Contact's Telephone Number:_____

Please complete the following:

- We received the notice on _____
  mo/day/yr
- We currently have BacT/ALERT 3D Instrument:_____
- We currently have BacT/ALERT 3D Combo: _____
- We understand that bioMérieux recommends using the correction described in this Advisory Notice to minimize errors or confusion until the BacT/ALERT 3D system has been updated

Signature: _____ Date: _____

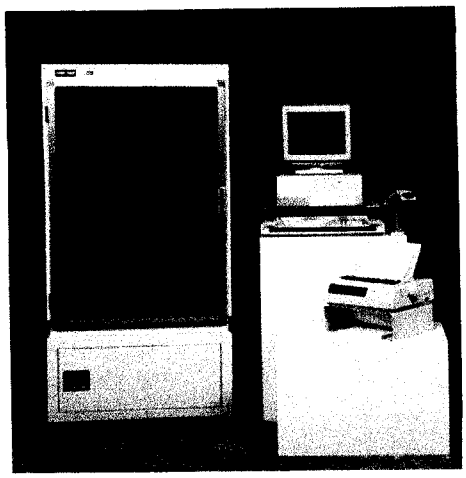
Please return this completed form to bioMérieux Regulatory Affairs:

local address & fax number

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 you have a BacT/ALERT Classic system, it 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