



Please distribute the attached customer letter.

To the Laboratory Manager

To the attention of the Healthcare center Chairman

To the attention of the Reactovigilance correspondent

Address
City, Date

Our reference: FSCA 2494

IMPORTANT:

URGENT PRODUCT CORRECTION NOTICE

MYLA V3 – Ref. 415603 and 411402

Dear bioMérieux Customer,

Our records indicate that your laboratory operates one or more MYLA V3 server(s). Please read this information regarding an issue that could impact your system.

Description of the issue

It has been observed that MYLA server, in high volume customers, could slow down because of the volume (“weight”) of the data to manage.

The MYLA server could stop due to a security mechanism which prevents MYLA functionality if any execution needs more than 5 minutes. This security mechanism is in place to avoid higher database degradation.

This issue will be resolved in a future MYLA version. As a corrective measure, a software patch has been created to modify the start-up phase for MYLA and will be installed via VILINK or by a bioMérieux representative. This correction will be able to maintain the server performances and prevent the reported issue from recurring.

Impact to customer:

Based on the results of the investigation, the potential risk associated with the MYLA server not rebooting is a delayed ID result on VITEK MS, but not on other systems such as VITEK 2 or BacT/ALERT that can work independently from MYLA and where the results are available on the systems.

The delay caused by the above described issue has been evaluated as not overpassing the 24hour timeframe.

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Required actions:

- Ensure this letter has been distributed and reviewed by all appropriate personnel within your organization.
- Contact your local bioMérieux representative to install the software patch on your MYLA server.
- Complete and return the Acknowledgement Form in Attachment A by Fax to confirm receipt of this notice.

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.

Yours sincerely,
Customer Service

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Attachment A: Acknowledgement Form.

PLEASE RETURN TO YOUR CUSTOMER SERVICE

Fax :

Name of the laboratory:

City:

Customer number:

I acknowledge the receipt of bioMérieux Urgent Product Correction Notice informing this laboratory on the MYLA reboot issue and on the server patch installation via VILINK connection.

I have followed the instructions and implemented the actions as indicated in this Urgent Product Correction Notice.

Have you received reports of illness or injury related to the identified issue?

Yes or No

DATE

SIGNATURE :

DATE

SIGNATURE :

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