Field Actions UK
bioMérieux UK Ltd

For attention of the Laboratory Manager

28 SEP 2021

IMPORTANT: URGENT FIELD SAFETY NOTICE
MYLA® V4.7 (V4.7.1) - Ref. 423270 ; V4.8 (V4.8.1 or V4.8.2) - Ref. 423434
Bottle unloaded before the end of incubation – potential false negative result WITH VIRTUO®

Our reference: 5308-2 FSCA

Dear bioMérieux Customer,

Our records indicate that your laboratory has received one or more of the products listed below:

Reference	Product Name	Version
423434	MYLA® SOFTWARE	V4.8 ; V4.8.1 ; V4.8.2
423270	MYLA® SOFTWARE	V4.7.1
423270	MYLA® SOFTWARE	V4.7

Following one customer complaint, a MYLA® software anomaly has been confirmed which can result in a bottle maximum test time (MTT) being reset to the default MTT. The bottle may then be unloaded before the desired incubation time.
This can occur specifically when an identification of a paired bottle is made outside of MYLA® and the result is sent back to MYLA® from the Laboratory Information System (LIS).

Note: This issue could appear if MTT is driven by LIS requests. It will not occur if customer is using MTT feature directly through VIRTUO® instrument interface.

Below is an example of the workflow that can generate this anomaly:

- Two LIS requests, one for aerobic bottle, one for anaerobic bottle, are sent to MYLA® for one specimen. Both LIS requests are sent with an extension of the standard incubation time (MTT) to 14 days. By default, the incubation time is 5 days as per specified in the bottle Instructions for Use.
- One of the two bottles turns positive and is automatically unloaded from the VIRTUO® instrument (to do a subculture).
- The identification is made outside of MYLA® and the result is sent back to MYLA® from the LIS as a request containing an offline identification result.

As a result of this anomaly, the MTT of the second bottle is updated back to the default MTT of 5 days after receiving the offline identification result. This second bottle will be then be unloaded when the incubation time reaches 5 Days (which could be immediately, depending on the duration already incubated). Thus presenting the risk of a false negative result.

For the anomaly to occur, the conditions below must be met:

Conditions	Yes	No
You are using MYLA® (V4.7, V4.7.1, V4.8, V4.8.1 or V4.8.2) in conjunction with BCI Connect	❑	❑
AND		
You are managing Blood Culture analyses on BACT/ALERT® VIRTUO® connected to MYLA®	❑	❑
AND		
Your Blood Culture workflow is based on 2 or more bottles with the same specimen (same specimen/laboratory ID)	❑	❑
AND		
You are using the LIS capability to send Blood Culture requests containing the incubation expected duration (MTT)	❑	❑
AND		
You are sending requests other than Blood Culture (Offline SU, ID,) on the same specimen than the one used for BC *note: this condition is applicable only if it occurs after the previous ones, chronologically speaking*	❑	❑

If one or more answers is NO, your laboratory is not at risk for this anomaly.

Impact to customer:

The risk for the customers/patients is to obtain a false negative result due to the bottle being unloaded before the end of scheduled incubation time.

Required actions:

We request you to take the following actions at this time:

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product.

- **Please check if you meet the requested conditions for a potential issue mentioned in Table 2 above:**

  → If you answer “No” to one of these questions, you are not impacted by this anomaly. Please indicate this on the customer acknowledgement form.

  → If you answer “Yes” to all those questions, please contact bioMérieux to assist you in resolving the problem. Please indicate this on the customer acknowledgement form.

  An Annex (**Annex 1**) is attached to assist you on identification of the issue’s conditions. In case of any doubt, do not hesitate to contact your bioMérieux representative should you need assistance with these conditions verification.

- For tests previously performed using MYLA® and VIRTUO® (as detailed in Table 2), we recommend you to identify any possible false negative result that may have occurred, to analyse the related risks and to determine appropriate actions, if relevant.
- Contact your bioMérieux Field Service Engineer to apply the mandatory correction as needed.
  - Next MYLA® version (V4.9) fixes the issue.
  - Awaiting this version to be released, specific workaround can be applied aligned with customer workflow.
- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative at fieldactions.uk@biomerieux.com to confirm receipt of this notice.

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologise 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 at uktechnical@biomerieux.com.

Thank you for your continued use of bioMérieux products,

Sincerely,

Field Actions UK
Fieldactions.UK@biomerieux.com

On behalf of bioMérieux Global Customer Services

Attachment A: Acknowledgement Form.

URGENT FIELD SAFETY NOTICE

FSCA 5308-2 - MYLA® V4.7, V4.7.1, V4.8, V4.8.1 or V4.8.2
Ref. 423270 ; 423434
Bottle unloaded before the end of incubation – potential false negative result WITH VIRTUO®

PLEASE RETURN TO:

EMAIL: FIELDACTIONS.UK@biomerieux.com

BY POST: FIELD ACTIONS, BIOMERIEUX UK LTD, GRAFTON WAY, BASINGSTOKE, HAMPSHIRE, RG22 6HY

Name of the laboratory:

City:

Customer number:

❑ I acknowledge receipt of the bioMérieux letter regarding "MYLA® V4.8/V4.8.1/V4.8.2 ref. 423434 and MYLA® V4.7/V4.7.1 ref. 423270 – bottle unloaded before the end of incubation - potential false negative result with VIRTUO®"

❑ I will implement the required actions indicated in the Urgent Field Safety Notice.

Based on table 2 (Issue required conditions):

❑ I met conditions of a potential issue (ticked box "Yes" for all questions) and I have called bioMérieux for Workaround application

OR

❑ I did not meet all conditions of a potential issue (ticked box "No" for at least one question), so I am not impacted by this issue

❑ Have you encountered impact on patients' results, or reports of illness or injury related to the identified issue ?

❑ Yes ❑ No

DATE ..... **SIGNATURE :** .....