16 January 2017

<<Title_>>
<<andor_The_Laboratory_Manager_>>
<<Company_Name>>
<<Address_Line_1>>
<<Address_Line_2>>
<<Address_Line_3>>
<<City>>
<<County>>
<<Postal_Code>>

Our reference: FSCA 3134

Dear bioMerieux Customer

IMPORTANT: PRODUCT SAFETY NOTICE - VIDAS® 3 software version 1.1.4 (ref. 412590)

Our records indicate that your laboratory operates one or more VIDAS® 3 software version 1.1.4. Please read this information regarding limitations that could impact your system. Apart from the anomaly #2, all the discussed anomalies have been discovered internally.

Description of the VIDAS® 3 software version 1.1.4 limitations:

1- **The "error code 0550CAPU1" posted in case of tip lost does not suggest the appropriate troubleshooting.**

This anomaly concerns a risk of contamination of the reagents/samples or system and could lead to a possible impact on patient results.
Required actions:
In case of error message "error 0550 risk of contamination" linked to a tip lost during the sample collection:

- Do not follow the instructions given by the instrument.
- Call immediately bioMérieux.
- The system must be decontaminated by a bioMérieux Field Service Engineer before using.

2- **For customer using automatic pipetting mode : non-justified "error code 0400FAPU1".**

This anomaly concerns a risk of contamination of the samples which can be reload on another instrument and could lead to a possible impact on patient results.
If the system fails in detecting liquid level while there is liquid on the tube, the error 400 will occur and will be visible on the loading map.

bioMérieux UK Ltd

Grafton Way, Basingstoke, Hampshire, RG22 6HY
Tel.: +44 (0)1256 461881 - Fax: +44 (0)1256 816863 - www.biomerieux.co.uk
Registered Office: Grafton Way, Basingstoke, Hampshire, RG22 6HY – Registered in England No. 1061914

Required actions:
Check if the volume of sample is higher than the dead volume (indicated on the user manual):

- If there is not enough sample, the error 400 is justified and there is no impact. Follow the instructions given by instrument.
- If there is enough sample, please apply the following actions:
  - Stop using the pipettor, and use only the manual pipetting mode.
  - Discard all loaded tubes processed in the same time than the affected sample.
  - Perform a retrospective analysis in case of delivered results to the LIS with these samples.
  - Call bioMérieux.

3- Stop section during analytical phase can induce drop on the strip or into the instrument.

This anomaly concerns a risk of customer and/or instrument contamination which could lead to a possible impact on next patient results.
Required actions:
When a section is stopped by any means (stop section, door opened, alarms or power supply failure) during analytical phase, please decontaminate the SPR tunnel and strip tray following decontamination procedure in User Manual (*Cleaning the SPR® blocks* and *Cleaning the Section Strip Tray*).
We also recommend you to avoid the stop of a section during analytical phase (stop button or door opening during run).

4- **For customer managing their internal/external Quality control via Quality Control Module of VIDAS®3 only.**

When an Quality Control (QC) has already been used, any QC configuration change (short name, full name and/or level) in VIDAS®3 software, will not be taken into account by the VIDAS®3 Quality Control Module. Indeed, a new QC is created instead of modifying the previous one. The new QC is not associated to the history of results from QC before modification.
This anomaly could lead to a risk to wrongly report/accept patient results due to the no detection of the drift of the QC results values.
Required actions:
We advise you to avoid QC modification for short name, full name and/or level.

5- For countries applying winter time change only.

When the winter time change occurs while samples and/or reagents are loaded, the “on board stability” time is not well managed (1 hour delay to obtain the automatic stability warning message).
This anomaly could lead to a possible impact on patient results due to the use of expired stability reagents or samples.
Required actions:
During this time change, samples and reagents “time on board” has to be monitored by the user instead of using Vidas®3 monitoring.

Required actions:

- 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, including others to whom you may have transferred our product.

- Apply the required actions described above and associated to each reported limitation.

- Discuss any concern you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

- 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 Department

Attachment A: Acknowledgement Form.

FIELD SAFETY NOTIFICATION NOTICE

FSCA 3134 – VIDAS®3 v1.1.4 Limitations correction

PLEASE RETURN FOR THE ATTENTION OF CUSTOMER SERVICE DEPARTMENT TO FAX NO. 0044 (0) 1256 816863

Name of the laboratory:

<<Title_>>
<<andor_The_Laboratory_Manager_>>
<<Company_Name>>
<<Address_Line_1>>
<<Address_Line_2>>
<<Address_Line_3>>
<<City>>
<<County>>
<<Postal_Code>>

Customer number:

❑ I acknowledge the receipt of bioMérieux Urgent Field Notice informing this company on the VIDAS®3 v1.1.4 product limitation.

❑ I have followed the instructions and implemented the actions as indicated in the Urgent Field Notice.

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

❑ Yes or ❑ No

NAME: ……

SIGNATURE: ……

DATE: ……