PLEASE DELIVER UPON RECEIPT to LAB DIRECTOR or LAB MANAGER

19.10.2017.
Urgent Product Correction Notice

Dear Valued bioMérieux customer,

Our records indicate that your laboratory uses the VITEK® 2 Gram-Positive (GP) Identification (ID) test kit for bacterial identification.

Description of Issue:
Customers have reported, and an internal investigation has confirmed, occurrences of atypical negative O129R reactions for *Enterococcus casseliflavus* ATCC® 700327™ in association with three (3) VITEK® 2 GP ID Lots listed in *Table 1* below, causing failure of the Quality Control (QC) testing for the VITEK® 2 GP ID card. In accordance with the VITEK® 2 GP ID Instructions For Use, the expected O129R reaction for ATCC® 700327™ strain is positive. As a precaution, bioMérieux is also including in the scope of this notice all GP ID card lots manufactured with the same raw materials as the lots listed in *Table 1* (See Appendix B for a complete list of lot numbers).
(Please note that you may have recently received a letter regarding this issue for lots 2420240403 and 2420303403.)

TABLE 1: VITEK® 2 GP ID QC Failure Confirmation

Reference	Description	Batch / Lot	Expiration
21342	VITEK® 2 Gram-Positive (GP) Identification (ID) Test Kit	2420240403	24-JUL-2018
		2420303403	24-SEP-2018
		2420348103	09-NOV-2018

The internal investigation determined that a positive dSOR reaction that occurs early in the incubation of the card is causing an earlier end to the analysis of the card leading to an atypical negative reaction for O129R. The VITEK® 2 stops analysis early in these situations since it has sufficient data to identify *Enterococcus casseliflavus* ATCC® 700327™ strain.

Analysis of Potential Impact to Results:
In order to assess the potential impact on the identification of clinical isolates a simulation was performed where all Gram positive organisms identified by the GP ID card were defaulted to dSOR-positive early in the incubation of the card. The resultant data was analysed and identification performance was assessed. The initial analysis showed the potential for misidentification of the 28 organisms listed in *Appendix A*.

As the list in Appendix A represents the worst case scenario (dSOR indiscriminately forced positive without consideration of actual growth patterns in dSOR for specific organisms), and is not a representation of frequently occurring clinical isolates, an in-depth growth pattern analysis was performed to determine which organisms are truly at risk of being misidentified.

- For 23 of the organisms listed, the growth pattern for the dSOR well remains flat from the initial reading to the end of analysis. These growth patterns are correctly interpreted by the VITEK® 2 as negative. Due to the lack of change (organism growth), the dSOR reaction is unlikely to give a false positive result. Therefore, 23 of the listed organisms are not impacted.

- For five (5) of the organisms, the growth pattern for the dSOR well exhibits measureable change during the first few hours of processing. Due to this early growth, the dSOR reaction is at risk of becoming false positive. If this occurs, the potential for an organism misidentification exists. The five (5) impacted organisms are listed in *Table 2*.

TABLE 2: Potential Organism Misidentifications

Species	Potential Incorrect Identification if dSOR is False Positive
Enterococcus gallinarum	*Enterococcus faecium, Enterococcus casseliflavus*
Staphylococcus caprae	*Staphylococcus carnosus ssp carnosus, Staphylococcus capitis*
Staphylococcus kloosii	*Staphylococcus gallinarum*
Streptococcus downei	*Streptococcus sobrinus*
Streptococcus gallolyticus ssp gallolyticus	*Streptococcus mutans*

Note that the organism misidentification occurs at the species level; the genus level identification is correct.

Impact to customer:
Evaluation of the identified issue for the three (3) lots listed in *Table 1* indicates the potential for misidentification of clinical isolates in addition to QC failure for the O129R well. QC failure would prevent the use of the GP ID card lot. However, even if QC results for *Enterococcus casseliflavus* ATCC® 700327™ are acceptable, the potential for misidentification of the five species listed in *Table 2* remains.

As stated previously, and as a precaution, bioMérieux is expanding the scope of this notice to include all GP ID lots manufactured with the same dSOR well raw materials as the lots listed in Table 1. (See Appendix B for a complete list of lot numbers.) Internal measures have been taken in Manufacturing and Quality Control to prevent recurrence of this issue.

Actions:
Please note that a similar notice was issued in August 2017 with regards to two VITEK® 2 GP ID card lots (2420240403 and 2420303403). At that time, customers were instructed to discontinue use of the two lots because the initial investigation showed potential misidentification of the 28 species listed in Appendix A.

Although this notice refers to the same issue as the August 2017 notice, the in-depth growth-pattern analysis has determined that the referenced VITEK® 2 GP ID card lots are acceptable for use providing the following actions are taken:

- Please confirm this letter has been distributed and reviewed by all appropriate personnel within your organization.

- Please create a VITEK® 2 Software bioART Rule (See Appendix C) to provide for warning in the event one of the seven organism identifications listed as **Potential Incorrect Identification if dSOR is False Positive** in *Table 2* is provided by the VITEK® 2. If you do encounter one of these seven organisms while using the impacted lots, the following actions are recommended:

    - If the dSOR is negative, the results can be reported as tested.
    - If the dSOR is positive, the isolate should be tested by another method.

- Please store this letter with your bioMérieux system documentation.

- Complete the attached Acknowledgement Form and return it to your local bioMérieux representative.

bioMérieux is committed to providing our customers with the highest quality products, and we apologize for any inconvenience this has caused your business. If you have any questions or concerns, please contact your local bioMérieux representative.

Thank you for your continued use of bioMérieux products,

bioMérieux

A&B d.o.o.

Attachment A: Acknowledgement Form.

URGENT PRODUCT CORRECTION NOTICE

FSCA - 3666 – VITEK® 2 GP ID – QC Performance for *E. casseliflavus* ATCC® 700327™

Customer Information:

Customer Account Number: _____ Organization Name: _____

Street Address: _____

City, State and Postal Code: _____

Contact Name: _____

Contact Title: _____

Phone Number: _____

Product Information:

Catalog Number	Description	Lot Number
21342	VITEK® 2 GP ID Test Kit	See Appendix B

Questions:

		Yes	No
1.	Have you read the enclosed Urgent Product Correction Notice regarding VITEK® 2 GP ID *Enterococcus casseliflavus* ATCC® 700327™ QC Issue?		
2.	Have you followed the instructions and implemented the actions as indicated in this Urgent Product Correction Notice? If no, please indicate the reason in the Comments section below.		
3.	Have you received reports of illness or injury related to the described VITEK® 2 GP ID issue?		
Comments:			

Signature: _____ Date: _____

It is important that you complete this Acknowledgement Form and return it to bioMérieux.

Please fax this form to: **01/2396 899**

APPENDIX A

Species	Potential Incorrect Identification if dSOR is False Positive
Abiotrophia defectiva	*Globicatella sanguinus, Kocuria kristinae, Gemella morbillorum*
Enterococcus durans	*Enterococcus faecium*
Enterococcus gallinarum	*Enterococcus faecium, Enterococcus casseliflavus*
Gemella haemolysans	*Gemella sanguinus*
Granulicatella adiacens	*Kocuria kristinae, Gemella morbillorum*
Kocuria rhizophila	*Kocuria kristinae, Kocuria rosea*
Leuconostoc citreum	*Enterococcus columbae*
Leuconostoc lactis	*Aerococcus viridans, Enterococcus columbae, Leuconostoc mesenteroides ssp cremoris, Leuconostoc pseudomesenteroides*
Leuconostoc mesenteroides ssp cremoris	*Enterococcus columbae*
Leuconostoc mesenteroides ssp mesenteroides	*Enterococcus columbae, Leuconostoc pseudomesenteroides*
Leuconostoc pseudomesenteroides	*Enterococcus columbae, Streptococcus parasanguinus*
Staphylococcus caprae	*Staphylococcus carnosus ssp carnosus, Staphylococcus capitis*
Staphylocccus cohnii ssp cohnii	*Staphylococcus vitulinus, Staphylococcus sciuri, Staphylococcus auricularis*
Staphylocccus equorum	*Staphylococcus gallinarum, Staphylococcus xylosus, Aerococcus viridans*
Staphylocccus hominis ssp novobiosepticus	*Staphylococcus hominis ssp hominis*
Staphylococcus kloosii	*Staphylococcus gallinarum*
Streptococcus anginosus	*Streptococcus gordonii, Streptococcus sanguinus, Streptococcus porcinus, Streptococcus thoraltensis*
Streptococcus canis	*Streptococcus equi ssp zooepidemicus*
Streptococcus constellatus ssp constellatus	*Streptococcus pseudoporcinus, Streptococcus gordonii*
Streptococcus cristatus	*Streptococcus sangunius*
Streptococcus downei	*Streptococcus sobrinus*
Streptococcus dysgalactiae ssp equisimilis	*Streptococcus dysgalactiae ssp dysgalactiae, Streptococcus porcinus, Streptococcus pseudoporcinus*
Streptococcus equi ssp equi	*Streptococcus equi ssp zooepidemicus, Streptococcus sanguinus*
Streptococcus gallolyticus ssp gallolyticus	*Streptococcus mutans*
Streptococcus gallolyticus ssp pasteurianus	*Streptococcus uberis, Streptococcus mutans*
Streptococcus infantarius ssp coli	*Streptococcus mutans, Streptococcus alactolyticus*
Streptococcus intermedius	*Streptococcus parasanguinus*
Streptococcus mitis	*Streptococcus thoraltensis, Streptococcus parasanguinus, Streptococcus sanguinus*

APPENDIX B

REF #	Product Name	Lot #	Expiry Date
21342	VITEK® 2 GP ID	2420192403	6-Jun-18
		2420198203	12-Jun-18
		2420200103	14-Jun-18
		2420204103	18-Jun-18
		2420205103	19-Jun-18
		2420209203	23-Jun-18
		2420214403	28-Jun-18
		2420217203	1-Jul-18
		2420220203	4-Jul-18
		2420226403	10-Jul-18
		2420229203	13-Jul-18
		2420239203	23-Jul-18
		2420240403	24-Jul-18
		2420243203	27-Jul-18
		2420247403	31-Jul-18
		2420248203	1-Aug-18
		2420253203	6-Aug-18
		2420261403	14-Aug-18
		2420267103	20-Aug-18
		2420282403	4-Sep-18
		2420289403	11-Sep-18
		2420290103	12-Sep-18
		2420296403	18-Sep-18
		2420300203	22-Sep-18
		2420302103	24-Sep-18
		2420303103	25-Sep-18
		2420303403	24-Sep-18
		2420307103	29-Sep-18
		2420309403	1-Oct-18
		2420314203	6-Oct-18
		2420317203	9-Oct-18
		2420317403	9-Oct-18
		2420320103	12-Oct-18
		2420321103	13-Oct-18
		2420322103	14-Oct-18
		2420330113	22-Oct-18
		2420331403	23-Oct-18
		2420348103	9-Nov-18
		2420352403	13-Nov-18
		2420353403	14-Nov-18