Please distribute the attached customer letter:
To the Laboratory Manager
To the attention of the Healthcare center Chairman

Brussels, 29 September 2017

Our reference: FSCA 3630

URGENT PRODUCT SAFETY CORRECTION NOTICE
Ref 200292 - Lot 17022802 - NucliSENS® Lysis Buffer - Colored eluates

Dear customer,

Our records indicate that your laboratory is using our NucliSENS® Lysis Buffer **ref. 200292 lot 17022802** exp. 28-Jan-2019.

Description of the issue
Following a customer complaint about colored eluates, bioMérieux investigation has confirmed an issue with this specific **batch 17022802** of NucliSENS® Lysis Buffer **ref. 200292**. The investigation confirmed that the eluate becomes coloured because of the presence of the heme group from the hamogoblin presents in whole blood samples including Dry Blood Spot. **The root cause** of the coloration has been **confirmed** to be linked to the pH that, for lot 17022802, has been observed to be 6.9 at 21,0°C instead of [7,0 – 7,2] as per product specification.

Impact to customer:
The investigation confirmed that the presence of haemoglobin causes the inhibition of the PCR resulting, in most of the cases in uninterpretable test results as also the extraction internal control (IC) would be inhibited, invalidating the test. In this case, there is a potential risk related to possible delayed results.

Considering that the NucliSENS® Lysis Buffer is used in various protocols and downstream applications and assuming a conservative approach and the worst case scenario in which the IC would not be inhibited, or not used although it is part of good laboratory practices, the tests run with coloured eluates could potentially result in false negative results.

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

- **Stop using** the NucliSENS® Lysis Buffer **ref. 200292 lot 17022802** exp. 28-Jan-2019 and **destroy** any stock of this lot 17022802 you might have in your laboratory.

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

- Contact your local customer service if you observe the issue.

bioMérieux Benelux bv

Hogeweg 5, Postbus 2104, 5300 CC Zaltbommel, The Netherlands
Phone.: +31 (0)418 68 10 40 - Fax: +31 (0)418 68 10 68 – www.biomerieux.com
Bank: ABN Amro Bank 52.42.15.952 - K.v.K.: 16034483 - BTW n° NL003418741B01

- **Complete and return** the Acknowledgement Form in Attachment A by e-mail: customer.service.benelux@biomerieux.com or Fax: + 32 (0) 2 743 01 87 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.

URGENT PRODUCT SAFETY CORRECTION NOTICE

FSCA 3630 – NucliSENS® Lysis Buffer Colored eluates.

TO BE RETURNED TO YOUR BIOMERIEUX CUSTOMER SERVICE AT THE FOLLOWING

E-MAIL: customer.service.benelux@biomerieux.com **OR FAX NUMBER** : + 32 (0) 2 743 01 87

Name of the laboratory:

City:

Customer number:

❑ I acknowledge receipt of the bioMérieux letter regarding the "NucliSENS® Lysis Buffer – Colored eluates"

❑ I will implement the required actions as indicated in the Urgent Product Correction Notice.

❑ Have you received reports of illness or injury related to the NucliSENS® Lysis Buffer – Colored eluates issue?

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

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