



To the Laboratory Manager
To the attention of the Chairman Medical Board and relevant Head of Departments

09 Oct 2018

Our reference: FSCA 4081

**IMPORTANT:
URGENT PRODUCT SAFETY CORRECTION NOTICE
Ref. 280134 – lot Z019EA1LB - NUCLISENS® Lysis Buffer –
Colored eluates**

Dear bioMérieux Customer,

Our records indicate that your laboratory is using our NUCLISENS® Lysis Buffer ref. 280134 lot Z019EA1LB exp. 28-MAY-2019.

Description of the issue

Following a customer complaint about colored eluates, bioMérieux investigation has confirmed an issue with this specific lot Z019EA1LB of NUCLISENS® Lysis Buffer ref. 280134.

The investigation confirmed that some eluates become colored because of remaining hemoglobin in the eluate ; however only samples naturally containing (or potentially contaminated with) hemoglobin could generate this issue (i.e. Whole Blood samples, Dry Blood Spots and Stools).

The root cause of the coloration is linked to the pH that, for lot Z019EA1LB, has been observed to be 6.96 at 21,0°C instead of [7,0 – 7,2] as per product specification and also linked to possibly poor sample quality (non homogeneous or partially lysed samples). The issue is randomly observed and with a low occurrence.

Impact to customer:

The presence of hemoglobin could cause 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 colored 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. 280134 lot Z019EA1LB exp. 28-MAY-2019 and destroy any stock of this lot Z019EA1LB 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.

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- Contact your local customer service if you have observed the issue and if you have a doubt regarding your results.
- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative 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 faithfully,
Customer Service

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Attachment A: Acknowledgement Form.

**URGENT PRODUCT SAFETY CORRECTION NOTICE
FSCA 4081 - NUCLISENS® Lysis Buffer Colored eluates**

**TO BE RETURNED TO YOUR BIOMÉRIEUX CUSTOMER SERVICE AT THE FOLLOWING
FAX NUMBER : XXXXXXXX**

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “NUCLISENS® Lysis Buffer - Ref 280134 – lot Z019EA1LB - Colored eluates”
- I will implement the required actions as indicated in the Urgent Product Safety 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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