



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

Address  
City, Date

Our reference: FSCA 3337

**IMPORTANT:**

**URGENT PRODUCT SAFETY  
CORRECTION NOTICE**

**Ref 200292 NucliSENS® Lysis Buffer –  
Colored eluates**

Dear customer,

Our records indicate that your laboratory is using our NucliSENS® Lysis Buffer ref. 200292 lot 16092902 exp. 28-AUG-2018.

**Description of the issue**

Following a customer complaint about colored eluates, bioMérieux investigation has confirmed an issue with this specific batch 16092902 of NucliSENS® Lysis Buffer ref. 200292.

The investigation confirmed that the eluate becomes coloured because of the presence of the heme group from the haemoglobin 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 16092902, has been observed to be 6.9 instead of 7.1 +/-0.1 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 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 16092902 exp. 28-AUG-2018 and discard any stock of this lot 16092902 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



- 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

---

**BIOMERIEUX**



**Attachment A: Acknowledgement Form.**

**URGENT PRODUCT CORRECTION NOTICE**

**FSCA 3337 – NucliSENS® Lysis Buffer Colored eluates.**

---

**TO BE RETURNED TO YOUR BIO MÉRIEUX 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 – 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 : .....**

---

**BIO MÉRIEUX**