



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

Address  
City, Date

Our reference: FSCA 4613

**IMPORTANT:  
URGENT PRODUCT SAFETY NOTICE  
Ref. 200292 – lot 19040201- NUCLISENS® Lysis  
Buffer – Colored eluates**

Dear bioMérieux Customer,

Our records indicate that your laboratory is using our NUCLISENS® Lysis Buffer ref. 200292 - lot 19040201 - exp. 28-FEB-2021.

**Description of the issue**

Following a customer complaint about colored eluates, bioMérieux investigation has confirmed an issue with this specific lot 19040201 of NUCLISENS® Lysis Buffer ref. 200292, occurring on whole blood samples or other specimen containing blood.

Previous investigations for colored eluates highlighted that this issue could be multifactorial (quality of the blood, detergent concentration in Lysis), including pH of lysis buffer out of specification.

Re-measurement of pH of lysis buffer lot 19040201 during current investigation showed an out of specification pH (7,05) according to intermediate manufacturing pH control specifications (from 7,1 to 7,2). Batch record review showed that pH of this lot was conform to these specifications at the time of manufacturing (7,2).

The current investigation showed that the root cause is a pH meter dysfunction leading to an erroneous pH measure during manufacturing step. As a consequence, the quantity of HCl added in the bulk was too high to adjust pH of this lysis buffer.

**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.

**To be noted that colored eluates only occurs on whole blood samples or other specimen containing blood, such as Dry Blood Spots and stools (not on all claimed matrix), because of remaining hemoglobin in the eluate.**

**Samples with no hemoglobin are not impacted with this issue and could be used with the lysis buffer lot 19040201 with expected performance.**



**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.
- Please stop using the impacted Lysis buffer (lot 19040201) for testing of whole blood samples and other specimen containing blood. Samples with no hemoglobin are not impacted with this issue and could be used with the lysis buffer lot 19040201 with expected performance.
- 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 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



**Attachment A: Acknowledgement Form.**

**URGENT PRODUCT SAFETY NOTICE**

**FSCA 4613 - NUCLISENS® Lysis Buffer Colored eluates**

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**TO BE RETURNED TO YOUR bioMERIEUX 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 200292 – lot 19040201 - Colored eluates”
- ☐ I will implement the required actions as indicated in the Urgent Product Safety Notice.
- ☐ Have you received reports of illness or injury related to the NUCLISENS® Lysis Buffer – Colored eluates issue?

**DATE .....**

**SIGNATURE : .....**