Please distribute the attached customer letter.
To the Laboratory Manager
To the attention of the Laboratory Medical Director

Address
City, Date

Our reference: FSCA#5690

IMPORTANT:

URGENT FIELD SAFETY NOTICE

NUCLISENS® Magnetic Silica Ref. 280133

Bacterial nucleic acid contamination leading to no result

Dear bioMérieux Customer,

Our records indicate that your laboratory received products listed in table 1 below:

Table 1: Impacted lot of NUCLISENS® Magnetic Silica® Ref. 280133

REF #	Product name	Lot Number	Expiry date
280133	NUCLISENS® Magnetic Silica	Z012ME1MS	28-DEC-2022
280133	NUCLISENS® Magnetic Silica	Z012MF1MS	28-DEC-2022
280133	NUCLISENS® Magnetic Silica	Z012MH1MS	28-DEC-2022
280133	NUCLISENS® Magnetic Silica	Z012MK1MS	28-DEC-2022
280133	NUCLISENS® Magnetic Silica	Z012ML1MS	28-NOV-2022
280133	NUCLISENS® Magnetic Silica	Z012MG1MS	28-NOV-2022
280133	NUCLISENS® Magnetic Silica	Z012NE1MS	28-NOV-2022
280133	NUCLISENS® Magnetic Silica	Z012ND1MS	28-NOV-2022
280133	NUCLISENS® Magnetic Silica	Z012NC1MS	28-NOV-2022
280133	NUCLISENS® Magnetic Silica	Z012NB1MS	28-NOV-2022
280133	NUCLISENS® Magnetic Silica	Z013AF1MS	28-JAN-2023
280133	NUCLISENS® Magnetic Silica	Z013AG1MS	28-JAN-2023
280133	NUCLISENS® Magnetic Silica	Z013AH1MS	28-JAN-2023

Subsidiary name (if applicable) / **Nom de la filiale** (si approprié)

280133	NUCLISENS® Magnetic Silica	Z013AK1MS	28-JAN-2023
280133	NUCLISENS® Magnetic Silica	Z013AL1MS	28-JAN-2023

Description of the issue

Following complaints from the field for contamination observed on extraction reagents with Legionella spp nucleic acids using easyMAG® and EMAG® extraction systems, bioMérieux initiated an investigation to assess product issue and identify the root-cause,

While the investigation is still ongoing the following have been identified:

- ⇨ The issue impacts only applications for bacterial nucleic acids detection, especially Legionella spp, and other applications like 16S rDNA, 23S rDNA. All applications for which the extraction negative controls are valid (negative status) are not impacted by the issue.
- ⇨ The only hazard associated to the referenced issue is a no result leading to delayed result. There is no risk of false result caused by the issue as a negative extraction control has to be run to assess the level of contamination. Therefore, the issue should always be detected by the customer.
- ⇨ Few cultivable/growing bacteria, mainly from the family of Bacillus (environmental bacteria), were detected in contaminated silica raw material and no cultivable/growing Legionella spp bacteria was detected. In conclusion, the silica lots are mainly contaminated by nucleic acid from bacteria and in particular from Legionella spp. The investigation confirmed that there is no safety risk for users.

  Note: our reagents are not claimed as DNA free, so environmental bacteria traces can be present
- ⇨ The root cause of the referenced issue is linked to raw material silica coming from a Supplier, and has to be determined at supplier level

Impact to customer:

Based on the investigation results, there is a potential of no result leading to possible delayed result when using lots of NUCLISENS® Magnetic Silica listed in Table 1.

Required actions:

We request you to take the following actions:

- 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.

- You can continue to use the impacted lots of the NUCLISENS® Magnetic Silica Ref 280133 listed in Table 1 except for bacterial nucleic acid detection applications especially Legionella spp, and other applications such as 16S rDNA, 23S rDNA. **We confirm that all applications for which the negative controls is valid, can be safely performed.**

- If you are encountering invalid negative control, please, stop using, and discard the impacted lot, and contact your local bioMérieux representative to order lots not concerned by the issue. A few lots not concerned by the issue are already available.
- Based on benefice/risk analysis and to avoid products backorder, you may receive for a short period of time some lots listed in Table 1 with an insert. This insert will contain the same information & actions required just above.
- Please complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative to confirm receipt of this notice.
- Discuss any concerns you may have regarding previously reported patients' results obtained with any of the lots listed in Table 1 (in case of the negative control not performing as required per product Instructions for Use) with your Laboratory Medical Director to determine the appropriate course of action.

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 FIELD SAFETY NOTICE

FSCA 5690 - NUCLISENS® Magnetic Silica Ref. 280133 – Bacterial nucleic acid contamination leading to no result

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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® Magnetic Silica Ref 280133 – Bacterial nucleic acid contamination leading to no result".
- ❑ I am not impacted by the issue since I am not using applications for bacteria nucleic acids detection, especially Legionella spp, and other applications like 16S rDNA, 23S rDNA.
- ❑ I am in the situation of using applications for bacteria nucleic acids detection, especially Legionella spp, and other applications like 16S rDNA, 23S rDNA. I implement the required actions, stop using and destroy the affected lots listed in Table 1 as indicated in the Urgent Field Safety Notice. I complete the table below.

REF #	Product Name	Lot #	Quantity received	Quantity discarded
280133	NUCLISENS® Magnetic Silica	Z012ME1MS		
280133	NUCLISENS® Magnetic Silica	Z012MF1MS		
280133	NUCLISENS® Magnetic Silica	Z012MH1MS		
280133	NUCLISENS® Magnetic Silica	Z012MK1MS		
280133	NUCLISENS® Magnetic Silica	Z012ML1MS		
280133	NUCLISENS® Magnetic Silica	Z012MG1MS		
280133	NUCLISENS® Magnetic Silica	Z012NE1MS		
280133	NUCLISENS® Magnetic Silica	Z012ND1MS		
280133	NUCLISENS® Magnetic Silica	Z012NC1MS		
280133	NUCLISENS® Magnetic Silica	Z012NB1MS		
280133	NUCLISENS® Magnetic Silica	Z013AF1MS		
280133	NUCLISENS® Magnetic Silica	Z013AG1MS		
280133	NUCLISENS® Magnetic Silica	Z013AH1MS		

280133	NUCLISENS® Magnetic Silica	Z013AK1MS		
280133	NUCLISENS® Magnetic Silica	Z013AL1MS		

❑ Have you encountered impact on patients' results, or reports of illness or injury related to the identified issue ?

❑ Yes ❑ No

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