



Field Actions UK
bioMérieux UK Ltd

For the attention of the Laboratory Manager

07 JUL 2022

IMPORTANT: URGENT FIELD SAFETY NOTICE
NUCLISENS® Magnetic Silica Ref. 280133
Bacterial nucleic acid contamination leading to no result

Our ref.: 5690 FSCA

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
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,

bioMérieux UK Ltd



While the investigation is still ongoing, the following has been identified:

- ⇒ The issue impacts only applications for bacterial nucleic acids detection, especially *Legionella* species, 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 with the referenced issue is no result, leading to a delayed result. There is no risk of false results 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 were 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 linked to one of our suppliers, and will be investigated further at the supplier's level

Impact to the customer:

Based on the investigation results, there is a potential of no result, leading to possible delayed results, 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 are valid, can be safely performed.**
- If you are encountering invalid negative controls, please stop using and discard the impacted lot, and contact your local bioMérieux representative to order lots unaffected by the issue. A few lots not concerned by the issue are already available.
- Based on benefit / risk analysis and to avoid product 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 as above.
- Please complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux subsidiary at fieldactions.uk@biomerieux.com 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 having been performed 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 apologise 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 team at uktechnical@biomerieux.com.

Yours faithfully,

Field Actions UK

Fieldactions.UK@biomerieux.com

On behalf of bioMérieux Global Customer Services



Attachment A: Acknowledgement Form.

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

PLEASE RETURN TO:
EMAIL: FIELD.ACTIONS.UK@biomerieux.com
BY POST: FIELD ACTIONS, BIOMERIEUX UK LTD, GRAFTON WAY, BASINGSTOKE, HAMPSHIRE, RG22 6HY

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 have implemented the required actions, stopped using and destroyed the affected lots listed in Table 1.

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 an impact on patients’ results, or reports of illness or injury related to the identified issue?
 Yes No

DATE: SIGNATURE: