



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

13 July 2016

Our reference: FSCA 3037

IMPORTANT:

**URGENT PRODUCT SAFETY
CORRECTION NOTICE**

**NucliSENS® easyMAG® performance
issue**

Dear customer,

Our records indicate that your laboratory is using our NucliSENS® easyMAG® nucleic acid extraction system. We have observed a decrease of extraction performances for some specific downstream applications due to the Magnetic Silica (MagSIL) (ref: 280133) for the following batches:

Ref	Product Name	Lots	Expiration Date
280133	Magnetic Silica MagSIL	Z017BB1MS	28/02/2017
		Z017BF1MS	28/02/2017
		Z017CA1MS	28/03/2017
		Z017BE1MS	28/02/2017
		Z017CC1MS	28/03/2017
		Z017CD1MS	28/03/2017
		Z017CH1MS	28/03/2017
		Z017BD1MS	28/02/2017
		Z017DB1MS	28/04/2017
		Z017BA1MS	28/02/2017
		Z017CF1MS	28/03/2017
		Z017CE1MS	28/03/2017
		Z017CG1MS	28/03/2017
		Z017DA1MS	28/04/2017
		Z017DC1MS	28/04/2017
		Z017DD1MS	28/04/2017
Z017EA1MS	28/05/2017		
Z017EB1MS	28/05/2017		

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	Z017FB1MS	28/06/2017
	Z017FA1MS	28/06/2017
	Z017KC1MS	28/09/2017
	Z017KF1MS	28/09/2017
	Z017KG1MS	28/09/2017
	Z017KH1MS	28/09/2017
	Z017LA1MS	28/10/2017

Description of the issue

Following customer complaints about amplification performance issues with home brew PCR and RT-PCR assays, bioMérieux investigation has confirmed an issue with specific batches of Magnetic Silica (ref: 280133) (refer to list above).

The investigation demonstrated no or not significant impact on performances when using NucliSENS® easyMAG® extraction reagents with the bioMérieux IVD downstream applications (PCR/RT-PCR ARGENE) and NucliSENS easyQ HIV 1 v2.0 (NASBA technology).

The investigation concluded that downstream applications were only impacted when the extraction volume was higher than 400µL and for double stranded nucleic acids target.

Double stranded nucleic acid applications with small (< 40Kbp) and medium genome sizes (< to 1200 Kbp) i.e DNA Viruses are more impacted than higher human genomic DNA and bacterial applications (> to 1200Kbp).

Single stranded RNA virus applications are not impacted unless the RNA is extracted without a matrix (i.e in water).

Impact to customer:

The decrease of downstream application performances can lead to a risk of false negative, invalid or under-quantification results.

However, this risk can be managed by following Good Laboratory Practice with the use of appropriate controls (IC with same nature/structure than the target and/or external controls) that should detect the issue, especially false negative or under-quantification results.

We would like to emphasize that downstream ARGENE and NucliSENS easyQ HIV 1 v2.0 applications performed according to their IFU are not impacted.

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.
- Reduce the sample input volume to 200µl until the silica problem is solved.
- Use an extraction internal control which mimic the target (with same nature/structure), and/or external controls as recommended in the IFU and in Good Laboratory Practice to detect any extraction performance issue.
- 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.
- Complete and return the Acknowledgement Form in Attachment A by Fax to confirm receipt of this notice.

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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

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Attachment A: Acknowledgement Form.

URGENT PRODUCT CORRECTION NOTICE

FSCA 3037 – NucliSENS® easyMAG® performance issue

TO BE RETURNED TO YOUR BIOMERIEUX CUSTOMER SERVICE AT THE FOLLOWING

FAX NUMBER :

Name of the laboratory:

City:

Customer number:

- I acknowledge receipt of the bioMérieux letter regarding the “NucliSENS® easyMAG® performance issue”
- 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® easyMAG® performance issue?

DATE

SIGNATURE :

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