12 January 2017

<<Title_>>
<<andor_The_Laboratory_Manager_>>
<<Company_Name>>
<<Address_Line_1>>
<<Address_Line_2>>
<<Address_Line_3>>
<<City>>
<<County>>
<<Postal_Code>>

Our reference: FSCA 3285

Dear «First_Name»

IMPORTANT: URGENT PRODUCT SAFETY CORRECTION NOTICE

NucliSENS® easyMAG® and eMAG® : silica drift of performance

Our records indicate that your laboratory is using our NucliSENS® easyMAG® Magnetic Silica (ref 280133) on NucliSENS® easyMAG® and/or eMAG® nucleic acid extraction system.

Thanks to additional quality controls, we have detected a drift of the extraction performances of our magnetic silica with a R-gene bioMérieux downstream application BK-Virus (ref 69-013B) with the following batches of Magnetic Silica:

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

bioMérieux UK Ltd

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Registered Office: Grafton Way, Basingstoke, Hampshire, RG22 6HY – Registered in England No. 1061914

Ref	Product Name	Silica Lots	Expiration Date
		Z017DC1MS	28/04/2017
		Z017DD1MS	28/04/2017
		Z017EA1MS	28/05/2017
		Z017EB1MS	28/05/2017
		Z017FA1MS	28/06/2017
		Z017FB1MS	28/06/2017

Description of the issue

Following the previous FSCA (3037) bioMérieux put in place several additional quality controls (QC) outside the current QC procedure at the release of batches. The released batches performances have been monitored in real-time for stability.

Firstly, bioMérieux detected a drift of performances after few months of self-life for some MagSIL batches released after the first FSCA (3037) for the non-bioMérieux downstream applications. A second FSCA (3203) targeting nine (9) batches of Silica (8 of the ref . 280133 and one of the ref. 200293) was sent on 23-NOV-2016.

In a second time, a drift of the performances results of 20 MagSIL batches already targeted by FSCA 3037 (listed above) was observed after few months of release with the bioMérieux BK-Virus R-gene test used following the IFU conditions.. The last point giving conform results has been done on 02-NOV-2016. Since one bioMérieux assay is impacted, we cannot ensure the usability of these 20 MagSIL batches (listed above) with all bioMérieux applications.
Nevertheless the five (5) remaining MagSIL lot numbers of the FSCA 3037: Z017KC1MS, Z017KF1MS, Z017KG1MS, Z017KH1MS and Z017LA1MS from list of first FSCA (3037) are conform regarding the performance monitoring trend, and can still be used following the corrective actions requested in the FSCA 3037 for all bioMérieux assays and non-bioMérieux downstream applications.

In addition, all the 9 MagSIL batches from FSCA 3203 (Z017KA1MS, Z017KB1MS, Z017LE1MS , Z017MA1MS, Z017NA1MS , Z017NB1MS , Z017NC1MS, Z017ND1MS, 16072701) are still conform regarding the performance monitoring trend and can still be used following the corrective actions requested in the FSCA 3037 for all bioMérieux assays and non-bioMérieux downstream applications

Investigations are still ongoing to refine the root cause and we are working with our MagSIL raw material supplier to solve the problem.

No complaints concerning this decrease of performances in bioMérieux downstream application was recorded.

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.
In this context, for BK virus application, the use of the internal control (from the kit) will not guarantee to detect the performance drift. BK virus application is considered as the worst case application.

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.
- Discard the remaining kit from the 20 silica batches listed above.
- Additional quality controls were applied since the first FSCA, and allowed us to monitor the performances and stability of the MagSil. The last conform monitoring point has been done on 02-NOV-2016 for bioMérieux application following the IFU conditions. Then, a drift of performances has been observed in time and could potentially lead to non-conformity of the batches and impact the bioMérieux applications (after November 2016). Discuss any concern you may have regarding previously reported results since November 2016, with your Laboratory Medical Director to determine the appropriate course of action.
- Continue to apply corrective actions request under:
    - The FSCA 3037 for the last five (5) batches Z017KC1MS, Z017KF1MS, Z017KG1MS, Z017KH1MS and Z017LA1MS.
    - The FSCA 3203 for the nine (9) MagSIL batches : Z017KA1MS, Z017KB1MS, Z017LE1MS, Z017MA1MS, Z017NA1MS, Z017NB1MS, Z017NC1MS, Z017ND1MS, 16072701.
- Contact your local customer service for the replacement of the discarded MagSil kits.
- 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 Department

Attachment A: Acknowledgement Form.

URGENT PRODUCT CORRECTION NOTICE - FSCA 3285 – NucliSENS® easyMAG® and eMAG® : silica drift of performance

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PLEASE RETURN FOR THE ATTENTION OF SHEILA MARSH TO FAX NO. 0044 (0) 1256 816863 OR SCAN AND EMAIL TO SHEILA.MARSH@BIOMERIEUX.COM

Name of the laboratory:

<<Title_>>
<<andor_The_Laboratory_Manager_>>
<<Company_Name>>
<<Address_Line_1>>
<<Address_Line_2>>
<<Address_Line_3>>
<<City>>
<<County>>
<<Postal_Code>>

Customer number:

- ❑ I acknowledge receipt of the bioMérieux letter regarding the "NucliSENS® easyMAG® and eMAG® : silica drift of performance"
- ❑ 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® and eMAG®: silica drift of performances?

NAME: ……

SIGNATURE: ……

DATE: ……