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

Address
City, Date

Our reference: FSCA 3203

IMPORTANT:

URGENT PRODUCT SAFETY CORRECTION NOTICE

NucliSENS® easyMAG®, NucliSENS® miniMAG® and eMAG® performance issue

Dear customer,

Our records indicate that your laboratory is using our NucliSENS® easyMAG®, NucliSENS® miniMAG® and eMAG® nucleic acid extraction systems that are using NucliSENS® easyMAG® magnetic silica. Thanks to additional quality controls with a parameter (1ml specimen/BK virus) which mimic the worst case condition, we have detected a drift of the extraction performances using the following batches of Magnetic Silica:

Ref	System	Product Name	Silica Lots	Expiration Date
280133	NucliSENS easyMAG/eMAG	Magnetic Silica MagSIL	Z017KA1MS	28-sept-17
			Z017KB1MS	28-sept-17
			Z017LE1MS	28-oct-17
			Z017MA1MS	28-nov-17
			Z017NA1MS	28-dec-17
			Z017NB1MS	28-dec-17
			Z017NC1MS	28-dec-17
			Z017ND1MS	28-dec-17
200293	miniMAG	Nucl. Magnetic Extraction Reag	16072701	28-aug-17

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.

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bioMérieux SA au capital de 12 029 370 € - RCS 673 620 399 Lyon – Siège social : 69280 Marcy l'Etoile - France

In addition, the released batches performances have been monitored in real-time for stability at two levels:

1- In worst case situation with the BK test in 1 ml of specimen,
2- With representative tests of bioMérieux applications (RNA & DNA target for ARGENE range and NucliSENS range).

Regarding the real-time stability performance monitoring, a drift of the performances results with the BK test with 1mL of plasma (1ml specimen/BK virus worst case application) was observed after few months of release, for some MagSIL batches (listed below).

The four (4) batches (Z017KA1MS, Z017KB1MS, Z017LE1MS and Z017MA1MS) are outside the specification for BK test.
The five (5) batches of MagSIL (NucliSENS® easyMAG® Magnetic Silica (ref. 280133): Z017NA1MS, Z017NB1MS, Z017NC1MS, Z017ND1MS and NucliSENS® magnetic extraction reagents (ref. 200293, lot16072701) are close to the limit of acceptance and could be in the future outside of specifications. By preventive measure, these batches are included on the scope of this FSCA.

The investigation demonstrated no or no significant impact on performances when using NucliSENS® easyMAG®, NucliSENS® miniMAG® and eMAG® extraction reagents with the bioMérieux IVD downstream applications (PCR/RT-PCR ARGENE®) and NucliSENS easyQ® HIV 1 v2.0 (NASBA technology) if they are used according to the IFU.

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).

The investigation are on-going and has not yet identified the root cause. bioMérieux is working with his MagSIL raw material supplier to solve the problem.

Impact:

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 Practices with the use of appropriate controls (internal control with same nature/structure than the target and/or external controls) that should detect the issue, especially false negative or under-quantification results leading to a risk of delayed result.

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.
- Use systematically an extraction internal control which mimic the extracted target (with same nature/structure), and/or external controls as recommended in the IFU and in Good Laboratory Practices to detect any extraction performance issue.
- In case of detected issue, reduce the sample input volume to 200µl.
- Discuss any concern you may have regarding previously reported results with your Laboratory Medical Director to determine the appropriate course of action.

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- 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.

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

Attachment A: Acknowledgement Form.

URGENT PRODUCT CORRECTION NOTICE

FSCA 3203 – NucliSENS® easyMAG®, NucliSENS® miniMAG® and eMAG® performance issue

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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® easyMAG® and NucliSENS® mini MAG® and eMAG® 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® and NucliSENS® mini MAG® and eMAG® performance issue?

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