BioMerieux SA Alerts Customers about Potential Inaccurate Test Results When using NucliSENS® easyMAG® Magnetic Silica for Nucleic Acid Extraction

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death

Recalled Product:

- NucliSENS® easyMAG® Magnetic Silica (Reference Number: 280133)
- Lot Numbers: Z017BB1MS, Z017BF1MS, Z017CA1MS, Z017BE1MS, Z017CC1MS, Z017CD1MS, Z017CH1MS, Z017BD1MS, Z017DB1MS,

Z017BA1MS, Z017CF1MS, Z017CE1MS, Z017CG1MS, Z017DA1MS, Z017DC1MS, Z017DD1MS, Z017EA1MS, Z017EB1MS, Z017FB1MS, Z017FA1MS, Z017KG1MS, Z017KH1MS

- Distribution Dates: See List Below:
- Devices Recalled in the U.S.: 1892 nationwide

Device Use

The NucliSENS® easyMAG® Magnetic Silica (MagSIL) is used to extract nucleic acids (RNA or DNA) from biological samples, such as blood, tissue, etc., which could then be used in various applications for molecular infectious disease assays, molecular oncology assays, and molecular genetics assays.

Reason for Recall

BioMerieux is recalling the NucliSENS® easyMAG® Magnetic Silica (MagSil) because of effects on nucleic acids extraction performance. MagSil is used to extract and purify genetic material from patient samples. Kits with the affected lots of the Magnetic silica have exhibited a decrease of extraction performance with certain downstream applications. The detection problem could lead to a risk of false negative or invalid results for clinical laboratory tests. The use of the affected product may cause serious adverse health consequences, including death.

Who May be Affected

- Laboratories who utilize the NucliSENS® easyMAG® nucleic acid extraction system as part of diagnostic applications.
- Health care providers who utilize laboratories who use the NucliSENS® easyMAG® nucleic acid extraction system as part of diagnostic applications.
- All patient groups receiving a diagnosis using laboratories that utilize the NucliSENS® easyMAG nucleic acid extraction system as part of diagnostic applications.

What to Do

On July 18, 2016 and on August 10, 2016, bioMerieux sent Urgent Product Safety Correction Notices to affected customers. Please follow the company's second correction notice dated August 10, 2016 for detailed instructions. The notice asked customers to:

- Reduce the sample input volume to 200µl
    - Note: If using bioMerieux downstream applications (PCR/RT-PCR ARGENE) and NucliSENS easyQ HIV 1 v2.0 (NASBA technology), the sample input should be in accordance with the intended for use (IFU) claims for the assay and should be no greater than 400µl.

    - The laboratory must verify that the expected performance is not affected by the extraction reagents.
- Use an internal extraction control which mimics the target sample (with same nature/structure/volume/matrix) or is designed to detect decreased assay performance (including the extraction process), and/or external controls as recommended in the instructions for use and as required by US regulation to detect any extraction performance issue.
- Do not use for single-stranded RNA virus applications if the RNA is extracted without a matrix (i.e. in water).
- Please review all results that were generated with the affected lots of extraction reagent to determine the appropriate course of action.
- If you observe any issues with extraction or assay performance, contact your local customer service representative.
- 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 this product.

Contact Information:

Customers with questions may contact bioMerieux Clinical Customer Service at (800) 682-2666 or bioMerieux Industry Customer Service at (800) 634-7656.

Date Recall Initiated:

July 18, 2016

How do I report a Problem?

Consumers may report adverse reactions or quality problems they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm) either online, by regular mail or by FAX to 1-800-FDA-0178.

Full List of Distribution Dates:

Lot Number	Distribution Start Date	Distribution End Date
Z017BB1MS	01/14/2016	01/28/2016
Z017BF1MS	01/04/2016	05/09/2016
Z017CA1MS	02/17/2016	05/09/2016
Z017BE1MS	12/21/2015	12/21/2015
Z017CC1MS	02/08/2016	04/21/2016
Z017CD1MS	03/08/2016	04/28/2016

Lot Number	Distribution Start Date	Distribution End Date
Z017CH1MS	04/05/2016	04/18/2016
Z017BD1MS	12/21/2015	01/08/2016
Z017DB1MS	02/23/2016	04/05/2016
Z017BA1MS	10/27/2015	01/04/2016
Z017CF1MS	03/23/2016	04/12/2016
Z017CE1MS	03/16/2016	04/01/2016
Z017CG1MS	02/23/2016	04/01/2016
Z017DA1MS	04/14/2016	05/02/2016
Z017DC1MS	04/26/2016	05/24/2016
Z017DD1MS	05/11/2016	ongoing
Z017EA1MS	04/26/2016	ongoing
Z017EB1MS	06/17/2016	ongoing
Z017FB1MS	04/12/2016	04/18/2016
Z017KF1MS	05/09/2016	06/08/2016
Z017KG1MS	05/09/2016	ongoing
Z017KH1MS	06/03/2016	ongoing

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2016 Medical Device Recalls
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2015 Medical Device Recalls
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2014 Medical Device Recalls
(/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)

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