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Date September 01, 2022

Document Ref# VC-22-01.B.OUS

Urgent Field Safety Notice:

Dimension® clinical chemistry system

Dimension® Magnesium (MG) Flex® reagent cartridge
Imprecision & Abnormal Reaction Flags

To whom it may concern,

Our records indicate that your facility may have received the following product:

Table 1. Dimension® Affected Products

Assay	Siemens Material Number (SMN)/REF (Catalog Number)	Unique Device Identification (UDI)	Lot Number	Expiration Date (YYYY-MM-DD)	Date of First Shipment (YYYY-MM-DD)
MG	10444963/ DF57	00842768014185FA235022121610444963840	FA2350	2022-12-16	2022-01-10
		00842768014185FA235622122210444963840	FA2356	2022-12-21	2022-02-20
		00842768014185GA236322122910444963840	GA2363	2022-12-29	2022-02-17
		00842768014185FA301923011910444963840	FA3019	2023-02-19	2022-01-25

Reason for Urgent Field Safety Notice

The purpose of this communication is to inform you of an issue with the products listed in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthineers has received reports that the Dimension Magnesium (MG) Flex reagent cartridge lots listed in Table 1 may exhibit imprecision for Quality Control (QC) and produce “Abnormal Reaction” flags. The issue is not always detected by QC and erroneous results may be produced in the absence of an “Abnormal Reaction” flag. Based on customer data, imprecision leading to erroneous, unflagged patient results with a bias of -15 to -59% may occur. As instructed in the Dimension Operator’s Guide, any results with an “Abnormal Reaction” flag should not be reported. The issue appears to be intermittent. The 4 lots listed in Table 1 were manufactured with a common raw material.

Risk to Health

When this issue occurs, there is a potential for QC failures or erroneous patient results. This could lead to additional investigation for hypo- or hypermagnesemia which may include repeat and follow-up testing. Mitigations would include correlation of test results with patient's clinical history, signs and symptoms of electrolyte imbalance as well as serial testing. A review of previously generated results is not recommended as magnesium levels are not interpreted in isolation, rather as adjunct to clinical assessment and testing of other analytes.

Actions to be Taken by the Customer:

For the products listed in Table 1, please perform the following steps:

- Discontinue use and discard Dimension MG lots listed in Table 1.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens Healthineers for reporting to the authorities.
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Remote Services Center or your local Siemens Technical Support Representative.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Dimension is a trademark of Siemens Healthineers.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Electronically signed by: Gudrun Kapl
Reason: I am approving this document
Date: Aug 31, 2022 16:06 GMT+2

i.A. Dipl.-Ing. Gudrun Kapl

Electronically signed by: Carina Marie Viehboeck
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Date: Aug 31, 2022 16:03 GMT+2

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