

Dimension Vista® System

Dimension Vista Magnesium (MG) Flex® Reagent Cartridge

Imprecision and Abnormal Assay Flags

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

Table 1. Dimension Vista® Affected Product

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date (YYYY-MM-DD)	1st Distribution Date (YYYY-MM-DD)
Dimension Vista Magnesium (MG) Flex® Reagent Cartridge	K3057	10445158	21253BB	2022-09-10	2021-10-07
			21263BA	2022-09-20	2021-11-15
			21335AA	2022-12-01	2021-12-17

Reason for Correction

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 confirmed that the Dimension Vista Magnesium (MG) Flex reagent cartridge lots listed in Table 1 may show higher imprecision across the analytical measurement range for quality control and patient samples. Customers have reported a maximum negative difference of -2.2 mg/dL (-0.9 mmol/L) between two replicates and maximum positive difference between two replicates to be 1.5 mg/dL (0.6 mmol/L).

In addition, “Abnormal Assay” flags may be observed with these lots. As instructed in the Dimension Vista Operator’s Guide, results with an “Abnormal Assay” flag should not be reported.

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. Siemens Healthineers is not recommending a review of previously generated results 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 Vista Magnesium lots listed in Table 1.
- At the present time, Siemens has no replacement lots to offer customers. Siemens suggests using an alternate methodology for magnesium until a replacement lot is available.
- 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.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- Please review this letter with your Medical Director.
- Replacement kits will be provided when a new lot is available.

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 Remote Services Center or your local Siemens Healthineers Technical Support Representative.

Dimension Vista® is a trademark of Siemens Healthcare Diagnostics Inc.