

# Urgent Field Safety Notice

VC25-01.A.OUS

## Dimension Vista System

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<b>Title</b>	Dimension Vista Magnesium lots 24057BB and 24064BC Depressed QC and Patient Results
<b>Date Issued</b>	Nov-2024
<b>Issue Description</b>	<p>Siemens Healthineers has confirmed through internal investigation of customer complaints the potential for intermittent depressed Magnesium (MG) quality control (QC) and patient results when using flex lots 24057BB and 24064BC on the Dimension Vista® system. Patient data indicates that there is an absolute bias of 0.1 to 1.0 mg/dL (0.04 to 0.41 mmol/L) across the concentration range of 0.7 to 8.7 mg/dL with Dimension Vista MG lots 24064BC and 24057BB. Since the issue is intermittent QC failures may alert customers to the issue before patient samples are processed.</p> <p>This issue is isolated to the two Dimension Vista MG lots mentioned above. Dimension Magnesium is not impacted.</p>

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Products	Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number	Manufacturing Date	Expiration Date
	Magnesium	MG	10445158/ 0084276801569424057BB2025 0225	24057BB	26-Feb-2024	25-Feb-2025
Magnesium	MG	10445158/ 0084276801569424064BC2025 0304	24064BC	04-Mar-2024	04-Mar-2025	

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<b>Impact to Results</b>	Erroneously depressed magnesium QC and patient results across the entire analytical measuring range may occur. The data from internal studies demonstrates variable bias at a given magnesium concentration as shown in the table 1 in the Appendix below. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.
<b>Customer Actions</b>	<ul style="list-style-type: none"><li>• Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.</li><li>• Discontinue use of and discard the lots listed above.</li><li>• 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.</li><li>• Please retain this letter with your laboratory records and forward this letter to those who may have received the product.</li></ul>
<b>Resolution</b>	Siemens Healthineers has introduced additional manufacturing process controls that have resolved this issue.

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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.

Table 1

**Appendix**

**Sample Distribution Based on Customer Complaint Data  
(Below, Within and Above Expected Range)**

<b>Result Range (mg/dL)</b>	<b>Result Range (mmol/L)</b>	<b>Absolute Bias Range (mg/dL)</b>	<b>Absolute Bias Range (mmol/L)</b>	<b>Average Absolute Bias (mg/dL)</b>	<b>Average Absolute Bias (mmol/L)</b>
< 1.6	< 0.66	0.1 to 0.6	0.04 to 0.26	0.3	0.14
1.6 to 2.6	0.66 to 1.07	0.2 to 1.0	0.09 to 0.41	0.5	0.21
> 2.6	> 1.07	0.4 to 0.9	0.15 to 0.37	0.7	0.27

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