

## Urgent Field Safety Notice

VC-15-12.A.OUS

September 2015

**Dimension Vista® Systems  
Magnesium Flex® reagent cartridge (K3057 SMN 10445158)  
Lot 15063BA, erroneous low results on a well set**

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Our records indicate that your facility received the following product lot:

**Table 1. Dimension Vista® MG**

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number
MG	K3057	10445158	15063BA

### Reason for Field Action

Siemens Healthcare Diagnostics has received customer complaints for the Dimension Vista® Magnesium (MG) (K3057, 10445158) when using lot 15063BA. The complaints were related to erroneous low results on a small number of reagent wells.

Data collected from the customer complaints shows that there is the potential for under-recovery on certain wells for quality control (QC) and patient sample results. When this issue occurred, the under-recovery ranged from -0.3 mg/dL [0.12 mmol/L] to -1.6 mg/dL [0.66 mmol/L]. The average under-recovery was -1.0 mg/dL [0.41 mmol/L]. This issue is demonstrating a low frequency of occurrence, with an estimated one (1) in every 10,000 tests that may be affected. Siemens internal investigations were unable to reproduce this issue, likely due to the low probability of occurrence. A root cause investigation is ongoing.

Repeating the sample on a new well of reagent or a new flex cartridge resolves the issue. This issue is likely to be detected by quality control (QC) or calibrators if they are run on the affected wells of reagent.

### Risk to Health

The potential for clinical impact due to this issue is remote and limited to administration of unnecessary magnesium replacement therapy. Magnesium replacement therapy is generally well tolerated and administration is based on the severity of clinical manifestations and the degree of hypomagnesemia. Replacement therapy would instigate close continued monitoring especially in patients with impaired renal function at risk for hypermagnesemia. Siemens is not recommending a laboratory look back as a result of this issue.

### Actions to be taken by Customer

Please do the following:

- Discontinue use and discard your remaining inventory of the reagent lot listed in Table 1.
- Indicate your replacement product needs on the attached Field Correction Effectiveness Check Form and fax the form to your local Siemens technical support representative within 30 days. Siemens will replace any unused inventory of the affected lot at no charge.
- Please review this letter with your Medical Director.

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 local Siemens technical support representative.

**FIELD CORRECTION EFFECTIVENESS CHECK**  
**Dimension Vista® Systems**  
**Magnesium (MG) (K3057 SMN 10445158)**  
**Lot 15063BA, erroneously low results on a well set**

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice Number VC-15-12.A.OUS dated September 2015 regarding MG, erroneous low results on a well set. Please read each question and indicate the appropriate answer. Fax this completed form to your local Siemens technical support representative.

1. I have read and understood the Urgent Field Safety Notice instructions provide in this letter. Yes  No

2. Do you now have any of the noted product on hand? Please check inventories before answering. Yes  No

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

<b>Dimension Vista® MG (K3057, SMN 10445158)</b>	<b>Quantity of Affected Product in inventory that has been discarded</b>	<b>Replacement Quantity Required</b>
Lot # 15063BA		

Name of person completing questionnaire: \_\_\_\_\_

Title: \_\_\_\_\_

Institution: \_\_\_\_\_

Instrument Serial Number: \_\_\_\_\_

Street: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_

Phone: \_\_\_\_\_

Country: \_\_\_\_\_

Customer Sold To #: \_\_\_\_\_

Customer Ship To #: \_\_\_\_\_

Please fax this completed form to your local Siemens technical support representative.