SIEMENS

Urgent Field Safety Notice

VC-16-05.A.OUS

August 2016

Dimension Vista® System

Calcium Flex® reagent cartridge, lot 16060BB, discrepant low results on a well set

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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	First Shipment Date	Expiration Date
Calcium	K1023	10445160	16060BB	2016-03-01	2017-02-28

Reason for Recall

Siemens Healthcare Diagnostics has confirmed that Dimension Vista® Calcium (CA) Flex® reagent cartridge lot 16060BB may produce erroneously low results from specific well sets. This issue occurs infrequently, affecting less than 1 per 350 wells (< 0.3%). If calibration is performed using an unaffected well set and samples are subsequently run using an affected well set, CA results may be falsely depressed up to -2.9 mg/dL [-0.72 mmol/L]. If QC is run using an affected well set, QC may detect the issue. The bias observed from customer data for this scenario is shown in Table 2. Bias for serum, plasma and urine specimens are similar.

Table 2. Observed CA bias with lot 16060BB:

Bias with Patient Samples mg/dL [mmol/L]	Bias with Serum Quality Control mg/dL [mmol/L]	Bias with Urine Quality Control mg/dL [mmol/L]
-0.5 to -1.9 [-0.13 to -0.48]	-0.6 to -2.9 [-0.15 to -0.72]	-0.7 to -2.3 [-0.18 to -0.58]

If calibration is performed using an affected well set, CA results for patient and QC samples from subsequent unaffected well sets may be falsely elevated to a magnitude similar to that observed in Table 2.

Risk to Health

When this issue occurs, the potential exists for misinterpretation of calcium levels, which may affect consideration of intervention. Clinical impact would be mitigated by correlation to clinical symptomology and additional investigations to confirm the initial result and/or to determine the

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etiology of an abnormal calcium value. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Discontinue use of and discard the kit lot listed in Table 1.
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens for reporting to the authorities.
- If you have received any complaints of illness or adverse events associated with the product listed in Table 1, immediately contact your local Siemens Customer Care 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 Customer Care Center or your local Siemens technical support representative.

Dimension Vista is a trademark of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

Discrepant Low Results on a Well Set with CA lot 16060BB on the Dimension Vista® System

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice, VC-16-05.A.OUS, dated August 2016 regarding Discrepant Low Results on a Well Set with CA lot 16060BB. 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 provided 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.

Dimension Vista® CA K1023, SMN 10445160	Quantity of Affected Product in inventory that has been discarded	Replacement Quantity Required
Lot 16060BB		

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Customer Sold To #: _____ Customer Ship To #: _____

To fax this completed form please send it to your local Siemens technical support representative

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