SIEMENS

Urgent Field Safety Notice

VC-18-03.A.OUS

January 2018

Dimension Vista® System
Calcium Flex® reagent cartridge Lot 17171BD
Potentially Discrepant Low Results on a Well Set

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	17171BD	2017-08-01	2018-06-20

Reason for Field Action

Siemens Healthcare Diagnostics has confirmed Dimension Vista® Calcium (CA) Flex® reagent cartridge lot 17171BD may produce erroneously low results from specific well sets.

- Quality Control (QC) may not detect the issue prior to patient testing if the CA calibration and QC are both processed in either an affected or unaffected well set.
- If CA reagent calibration is performed using an unaffected well set and QC and samples are subsequently processed using an affected well set, CA results may be falsely depressed, with observed biases from -0.3 mg/dL [-0.075 mmol/L] to -2.8 mg/dL [-0.7 mmol/L].
- If CA reagent calibration is performed using an affected well set, and QC and patient samples are subsequently processes using an unaffected well set, CA results may be falsely elevated. Positive bias observed was of a similar magnitude as the negative bias stated above.
- The observed bias for serum, plasma, and urine specimens are similar.

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

PO Box 6101
Newark, DE 19714-6101
www.siemens.com/diagnostics

Actions to be Taken by the Customer

- Discontinue use of and discard the Dimension Vista Calcium Flex reagent lot 17171BD.
- Please review this letter with your Medical Director.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens for reporting to the authorities.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- 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

Dimension Vista Calcium Flex reagent cartridge Lot 17171BD
Potentially Discrepant Low Results on a Well Set

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice, VC-18-03.A.OUS, dated January 2018 regarding Calcium Flex reagent cartridge Lot 17171BD, Potentially Discrepant Low Results on a Well Set. Please read each question and indicate the appropriate answer.

Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

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

2. Do you now have any Dimension Vista CA Flex reagent cartridge Lot 17171BD 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 17171BD		

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 your local Siemens Technical Support Representative. If you have any questions, contact your local Siemens Technical Support Representative.

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