SIEMENS Healthineers

Siemens Healthcare Diagnostics Inc.

Urgent Field Safety Notice

VC-18-04.A.OUS

March 2018

Dimension Vista® System

Diluents with Defective Septums

Potentially Discrepant High Results When Using Diluent with Autodilution Feature

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

Table 1. Dimension Vista Affected Diluents:

Diluent	Catalog Number	Siemens Material Number	Lot Number	First Shipment Date	Expiration Date
CTNI Sample Diluent (CTNI SDIL)	KD692	10445205	7BDA34	2017-03-28	2018-06-01
Multi 1 Sample Diluent (MULTI 1 SDIL)	KD693	10469971	7BDA81	2017-04-10	2018-03-01
Multi 2 Sample Diluent (MULTI 2 SDIL)	KD694	10483586	7CDA79 7DDA70	2017-04-11 2017-05-29	2018-09-01 2018-11-01

Reason for Field Action

Siemens Healthcare Diagnostics has confirmed Dimension Vista® Diluent lots listed in Table 1 may have an incomplete slit on the septum in the cap of the vial. A diluent cap with a defective septum has the potential to cause erroneously elevated results if a sample is autodiluted onboard the Dimension Vista System, due to a reduced volume of diluent being pipetted from the vial. Only a portion of each lot has defective septums and only a portion of visually defective septums are functionally defective. Assays used with the affected diluents are listed in Table 2.

Table 2. Assays Used with the Affected Diluents:

Diluent	Assays Used with the Affected Diluents
CTNI Sample Diluent (CTNI SDIL)	Cardiac Troponin I (CTNI)
Multi 1 Sample Diluent (MULTI 1 SDIL)	Estradiol (E2)
Multi 2 Sample Diluent (MULTI 2 SDIL)	B-Type Natriuretic Peptide (BNP), Progesterone (PROG), Total Testosterone (TTST) and Thyroid Stimulating Hormone (TSH)

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Risk to Health

This issue is limited to results that are above the analytical measuring range and undergoing autodilution on the instrument for the assays which utilize the affected diluents. When this issue occurs, falsely elevated results for B-Type Natriuretic Peptide, Cardiac Troponin I, Progesterone, Total Testosterone, and Thyroid Stimulating Hormone could be observed. These substantially elevated values above the Analytical Measurement Range (AMR) would continue to be interpreted as extremely abnormally high. The differences between results would not be expected to cause a clinically significant difference in patient management. For estradiol, a falsely elevated result above the AMR (>1500 pg/mL) has the potential to lead to additional close monitoring for possible ovarian hyperstimulation. The diagnosis of ovarian hyperstimulation syndrome is a clinical diagnosis based on signs and symptoms as well as ultrasound results. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Inspect stock, discontinue use of and discard the Dimension Vista Diluent lots listed in Table 1.
- 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 Diluents with Defective Septums
Potentially Discrepant High Results When Using Diluent with Autodilution Feature

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice, VC-18-04.A.OUS, dated March 2018 regarding Dimension Vista Diluents with Defective Septums, Potentially Discrepant High Results When Using Diluent with Autodilution Feature. 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 affected Dimension Vista Diluent lots 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® Diluent	Quantity of Affected Product in inventory that has been discarded	Replacement Quantity Required

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

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