



Urgent Field Safety Notice

VC-18-01.A.OUS

November 2017

Dimension Vista®

LOCI 8 CAL Lot 7CD076

Calibration Failures or QC/ Patient Sample Shifts on the Estradiol Assay

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

Table 1. Dimension Vista® Affected Product

Calibrator	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date	1 st Distribution Date
Dimension Vista® LOCI 8 CAL	KC646	10488192	7CD076	2018-04-01	2017-05-10

Reason for Correction

The purpose of this communication is to inform you of an issue with the product indicated in Table 1 above and provide recommended actions for your laboratory.

Siemens Healthcare Diagnostics has confirmed an increase in the number of failed calibration events or negative bias with Quality Control (QC) and patient samples when using Dimension Vista® LOCI 8 Calibrator lot 7CD076 to calibrate Estradiol (E2) Assay.

As a result of the issue on LOCI 8 calibrator lot 7CD076 the following two scenarios may occur:

1. Estradiol (E2) calibration failures due to slope and percent deviation being out of acceptable range (slope recovering >1.05 and percent deviation recovering $>5\%$).
2. In the event an acceptable calibration is achieved with the LOCI 8 Calibrator lot 7CD076, customers may observe an overall negative bias for Estradiol with Quality Control (QC) and patient samples. Depending on the target ranges used, QC results may fall outside of acceptable ranges.

A summary of bias results is provided in Table 2.



Table 2: Estradiol (E2) Serum Sample % Bias

E2 Concentrations	Average bias	Potential Range of Bias
< 80 pg/mL (293.7 pmol/L)	-32%	-33% at a concentration of 51.3 pg/mL (188.3 pmol/L) -30% at a concentration of 74.9 pg/mL (275.0 pmol/L)
80 pg/mL (293.7 pmol/L) to 200 pg/mL (734.2 pmol/L)	-23%	-26% at a concentration of 105.5 pg/mL (387.3 pmol/L) -19% at a concentration of 185.1 pg/mL (679.5 pmol/L)
201 pg/mL (737.9 pmol/L) to 500 pg/mL (1835.5 pmol/L)	-10%	-15% at a concentration of 242.5 pg/mL (890.2 pmol/L) -6% at a concentration of 465.9 pg/mL (1710.3 pmol/L)
>500 pg/mL (1835.5 pmol/L)	6%	+7% at a concentration of 693.5 pg/mL (2545.8 pmol/L) -1% at a concentration of 1343.3 pg/mL (4931.3 pmol/L)

The LOCI 8 Calibrator is used to calibrate three other Dimension Vista assays; Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH), and Prolactin (PRL). These other assays continue to perform without experiencing this issue.

Risk to Health

The probability of misinterpretation of estradiol results due to the observed negative bias is remote and limited to the low end of the measuring range (e.g. <80 pg/mL [293.7 pmol/L]). Estradiol is not used in isolation but is correlated with clinical history and presentation, as well as additional diagnostic laboratory testing. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Calibrate the E2 assay using an alternate lot of LOCI 8 CAL.
- Discontinue use of and discard LOCI 8 CAL lot 7CD076.
- Review your inventory of this product 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. Please review this letter with your Medical Director.
- If you have received any complaints of illness or adverse events associated with the products 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 registered trademark of Siemens Healthcare Diagnostics



FIELD CORRECTION EFFECTIVENESS CHECK

LOCI 8 CAL Lot 7CD076 Calibration Failures or QC/Patient Sample Shifts on the Estradiol assay

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics UFSN VC-18-01.A.OUS dated November 2017 regarding LOCI 8 CAL lot 7CD076 Calibration failures or QC/Patient Sample Shifts on the Estradiol assay. 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 UFSN instructions provided in this letter. Yes No
- 2. Do you now have any of the noted product(s) on hand? Please check inventories before answering. Yes No
- 3. Did you discard LOCI 8 CAL lot 7CD076? Yes No

If the answer to the question 2 above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory that has been discarded	Replacement Quantity Required
Dimension Vista® LOCI 8 CAL Catalog Number KC646 (SMN 10488192) Lot 7CD076		

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 the Customer Care Center within 30 days. If you have any questions, contact your local Siemens Technical Support Representative.

To fax this completed form sends it to Customer Care Center at (xxx) xxx-xxxx or please send scanned copy of the completed form via email XXXXXXXX within 30 days. If you have any questions, contact your local Siemens Technical Support Representative.