

Urgent Field Safety Notice

VC17-04.A.OUS

March 2017

Dimension® EXL™ integrated chemistry system
Dimension Vista® System
Dimension EXL TNI, Dimension Vista DIGXN, E2, FERR, PRL, TSH
Incorrect Biotin Non-Interference Units in IFUs

Our records indicate that your facility may have received the products listed in Table 1.

Reason for Field Action

Siemens Healthcare Diagnostics has confirmed that the concentrations for Biotin listed in the Non-Interfering Substances section of the current Dimension and Dimension Vista Instructions For Use for Dimension TNI, Dimension Vista DIGXN, E2, FERR, PRL, TSH have incorrect units, and incorrectly state the level at which biotin does not interfere. In the cases of TNI, E2, FERR, PRL, and TSH, there is significant interference at the levels incorrectly stated in the current IFU. DV E2, a competitive assay, exhibits a positive bias while the other methods (sandwich assays) exhibit a negative bias. DIGXN SI units for Biotin are incorrect by a factor of 100 lower than the level at which biotin does not interfere, in the current IFU. Dimension (DM) and Dimension Vista (DV) Affected product:

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number
DM Troponin I (TNI)	RF621	10464525	All lots (including all future lots until Instructions For Use is updated)
DV Digoxin (DIGXN)	K6435	10488927	All lots (including all future lots until Instructions For Use is updated)
DV Estradiol (E2)	K6463	10489099	All lots (including all future lots until Instructions For Use is updated)
DV Ferritin (FERR)	K6440	10445136	All lots (including all future lots until Instructions For Use is updated)
DV Prolactin (PRL)	K6462	10488398	All lots (including all future lots until Instructions For Use is updated)
DV Thyroid Stimulating Hormone (TSH)	K6412	10445104	All lots (including all future lots until Instructions For Use is updated)

Table 1. Biotin Units in Non-Interfering Table:

*Dimension® EXL TNI and Dimension Vista® DIGXN, E2, FERR, PRL, TSH
Incorrect Biotin Non-Interference Units in IFUs*

Assay	Current Conventional Units in IFU	Current SI Units in IFU	Corrected Conventional Units	Corrected SI Units
DM EXL TNI	100 ng/mL	410 µmol/L	Correct as is	409 nmol/L
DV DIGXN	50 ng/mL	2.04 nmol/L	Correct as is	204 nmol/L
DV E2	100 ng/mL	409 µmol/L	Correct as is	409 nmol/L
DV FERR	100 ng/mL	410 µmol/L	Correct as is	409 nmol/L
DV PRL	0.2 mg/dL	8.2 mmol/L	100 ng/mL	409 nmol/L
DV TSH	500 ng/mL	2050 µmol/L	Correct as is	2050 nmol/L

The corrected, Biotin conventional and SI units provided in this letter, in the Non-Interfering Table (Table 2), supersedes the information related to this section in the current IFU's for the assays listed above for Dimension and Dimension Vista products until the IFU's are updated.

Risk to Health

The probability of misinterpretation of results for the assays described above due to this issue is remote, and would be limited to the scenario where a patient taking biotin supplements in excess of the daily recommended allowance has a blood sample drawn before biotin is cleared to a level that does not interfere with laboratory testing. Mitigations include correlation to clinical history and presentation as well as to other diagnostic laboratory testing, serial testing, and/or concomitant imaging studies depending on the analyte. Siemens is not recommending a lookback as a result of this issue.

Actions to be Taken by the Customer

- Review the information contained in Table 2.
- Review this letter with your Medical Director.
- 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 products listed in Tables 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 and Dimension Vista are trademarks of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

*Dimension® EXL TNI and Dimension Vista® DIGXN, E2, FERR, PRL, TSH
Incorrect Biotin Non-Interference Units in IFUs*

**Dimension® EXL™ TNI and Dimension Vista® DIGXN, E2, FERR, PRL, TSH
Incorrect Biotin Non-Interfering Units in IFUs**

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice VC17-04.A.OUS dated March 2017 regarding Incorrect Biotin Non-Interference Units in IFUs. Please read the 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 ☐

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. If you have any questions, contact your local Siemens technical support representative.