SIEMENS

Field Safety Notice

Siemens Healthcare Diagnostics Limited
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Our Reference	FSN VC 14-03
Date	03/04/2017
Internet	www.siemens.com/diagnostics

FIELD SAFETY NOTICE

Please find attached a Field Safety Notice (FSN). This is an important communication about medical safety issued by Siemens Healthcare Diagnostics.

It is important that your organisation takes the actions detailed in the FSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to the FSN.

Your organisations reply is evidence which Siemens Healthcare, and subsequently the MHRA, needs to monitor the progress of the FSN. Without your reply Siemens Healthcare Diagnostics cannot properly verify the completeness of the FSN and the MHRA may need to issue a Medical Device Alert

Attachment:

FSN VC 17-04

If you have any questions or enquiries regarding this bulletin, please do not hesitate to contact the Siemens Healthcare Diagnostics Helpdesk on 0845 600 1955.

Alternatively, you may email us at addresses at the head of this document.

Yours faithfully
Eric Donnachie
Regulatory Affairs Manager

Siemens Healthcare Diagnostics Limited

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SIEMENS

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:

Unrestricted

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

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.

FIELD CORRECTION EFFECTIVENESS CHECK

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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.email this completed form to Siemens Healthcare Diagnostics at the email address provided at the bottom of this page.

Ref: VC17-04

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:	
Street:	
City:	Post Code:
Phone:	Email:
Signed:	Dated:

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

It is important that your organisation takes the actions detailed in the FSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to this FSN. Your organisations reply is evidence which, Siemens Healthcare, and subsequently the MHRA, needs to monitor the progress of the FSN. Without your reply Siemens Healthcare cannot verify the completeness of the FSN and the MHRA may need to issue a Medical Device Alert.

Please return to :eric.donnachie@siemens-healthineers.com

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