[SIEMENS

Urgent Field Safety Notice

VC-16-04.A.OUS.DM

June, 2016

Dimension® clinical chemistry system
Dimension® Creatinine (CRE2) Flex® reagent cartridge
Bias at low end of the urine Analytical Measurement Range

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

Table 1. Dimension Affected Products

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number
Dimension CRE2	DF33B	10872079	All lots (including all future lots until a solution is implemented)

Reason for Customer Notification

Siemens Healthcare Diagnostics has confirmed that Dimension® Creatinine (CRE2) Assay exhibits a negative bias at the low end of the urine Analytical Measurement Range (AMR) (see Table 2.). The Limit of Quantitation (LoQ) claim (5 mg/dL [442 µmol/L]) for urine samples is not met. Siemens is actively investigating the root cause of the issue and is working to implement a solution. This issue also affects all future lots of CRE2 until a solution is implemented. The serum/plasma CRE2 AMR is not affected by this issue.

Table 2. Dimension CRE2 Bias at low urine concentrations

Assay	Maximum Observed Bias mg/dL [µmol/L] at 9.83 mg/dL [869 µmol/L]	Maximum Observed Bias mg/dL [µmol/L] at 13 mg/dL [1149 µmol/L]	Maximum Observed Bias mg/dL [µmol/L] at 16.6 mg/dL [1467 µmol/L]
Dimension CRE2	-2.65 [-234 µmol/L]	-2.29 [-202 µmol/L]	-1.14 [-101 µmol/L]

Risk to Health

The bias observed for urine creatinine samples < 13 mg/dL [1149 µmol/L] would not impact clinical interpretation of adult eGFR calculations or clinical interpretation of laboratory tests utilizing creatinine as a correction factor, such as Urine Albumin/Creatinine ratio and/or Urine Protein/Creatinine ratio. Siemens is not recommending a review of previously generated results due to this issue.

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

Actions to be Taken by the Customer

- Review this letter with your Medical Director.
- Customers should review the information on bias contained in Table 2.
- Siemens recommends that customers report urine CRE2 values that are less than 13 mg/dL [1149 µmol/L] as "< 13 mg/dL [1149 µmol/L]" rather than actual numeric results.
- Instructions for changing the CRE2 lower end of the AMR to 13 mg/dL [1149 µmol/L] are as follows:

    1. From the Operating Menu, select **F6: SYSTEM CONFIG > F1: METHOD PARAM**.
    2. At the prompt, type your password and select **Enter**.
    3. Select the CRE2 assay by selecting the assigned key(s).
    4. Key in the following highlighted parameters for changing the lower limit of the AMR to 13 mg/dL [1149 µmol/L]:
       Parameter Urine
       Assay 0.65– 20.00 [57 - 1768]*
       *Système International d'Unités [SI Units]
       Note: Urine samples are automatically diluted 1:20. Parameter Assay values are undiluted values.
    5. Select F5: **STORE & PRINT**
    6. Select Exit to return to the Operating Menu.

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 is a trademark of Siemens Healthcare Diagnostics.

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

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FIELD CORRECTION EFFECTIVENESS CHECK

CRE2 Bias at the low end of the urine Analytical Measurement Range

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice Number VC-16-04.A.OUS.DM dated June 2016 regarding CRE2 Bias at the low end of the urine Analytical Measurement Range. Please read the question and indicate the appropriate answer. Please return this completed form within 14 working days

Ref: VC16-04 [C/3530]

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:	Email:
Signed:	Date:

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Fax: 0845 605 6800

Email: robert.davies@siemens.com

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