[SIEMENS

Urgent Field Safety Notice

15-42

July 2015

Dimension Vista® System
Creatinine (K1033 SMN 10445161)
Interference from Hemoglobin

Our records indicate that your facility received the following product:

Table 1. Dimension Vista® CREA

Assay	Catalog Number	Siemens Material Number (SMN)
CREA	K1033	10445161

All in-date and future lots are affected.

Reason for Field Action

Siemens Healthcare Diagnostics has determined that Dimension Vista® Creatinine (CREA) may produce depressed results up to 22% (or approximately 0.3 mg/dL [27 µmol/L]) for a creatinine result at 1.5 mg/dL [133 µmol/L] when hemolysis exceeds 200 mg/dL [0.12 mmol/L] of hemoglobin. It is important to note that percent hemoglobin interference with Dimension Vista® CREA is dependent on the creatinine concentration; at a creatinine concentration of 5.0 mg/dL [442 µmol/L], hemoglobin interference at concentrations up to a 1000 mg/dL [0.62 mmol/L] is < 10%. Alternately, with an approximate bias of 0.3 mg/dL ([27 µmol/L]), the percent hemoglobin interference may be higher at low creatinine concentrations (< 0.8 mg/dL [< 71 µmol/L]).

Table 2 shows the Hemoglobin Interference that is listed in the current Dimension Vista® CREA Instructions For Use.

Table 2. Current Hemoglobin (hemolysate) Interference

Test concentration mg/dL [mmol/L]	CREA concentration mg/dL [µmol/L]	Bias %	H Index
500 [0.31]	1.3 [115]	< 10	7

Table 3 shows the Hemoglobin Interference for Dimension Vista® CREA from recent internal testing.

Table 3. Revised Hemoglobin (hemolysate) Interference

Test concentration mg/dL [mmol/L]	CREA concentration mg/dL [µmol/L]	Bias %	H Index
200 [0.12]	1.5 [133]	< 10	4

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

Risk to Health

Depressed creatinine results due to hemolysis as described above may lead to increased estimated Glomerular Filtration Rate (eGFR) values and/or potential misinterpretation of acute kidney injury (AKI). The potential for injury is remote due to continued monitoring, additional diagnostic testing and correlation to patient history and presentation. Siemens is not recommending a review of previously generated results.

Actions to be taken by Customer

- Review this letter with your Medical Director.
- Customers should review their currently established procedure for reporting CREA results for hemolyzed samples and update as necessary for the revised interference information described in this letter.
- If an H index is used on the Dimension Vista® System for CREA, an H index of 4 is consistent with our findings on hemoglobin interference at a creatinine concentration of 1.5 mg/dL [133 µmol/L]. Laboratories can customize the H index for CREA to reflect their own individual operating requirements for reporting interference.
- Per the Dimension Vista® Operator's Guide, when H interference [E111] is encountered, "follow laboratory specific procedures for reporting results when the sample is hemolyzed."

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 local Siemens technical support representative.

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FIELD CORRECTION EFFECTIVENESS CHECK
Dimension Vista® System
Creatinine (CREA) (K1033 SMN 10445161)
Interference from Hemoglobin

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice Letter Number 15-42 dated July 2015 regarding CREA, Interference from Hemoglobin. 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.

Ref: DC 15-06 [C/3222]

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter.	Yes ☐	No ☐
Signed:	Date:	

Name of person completing questionnaire: Block Capitals:	
Title:	
Institution:	Instrument Serial Number:
Street:	
City:	Post Code:
Phone:	Email:
Customer Sold To #:	Customer Ship To #:

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.

Fax: 0845 605 6800

Email: [redacted]@siemens.com

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Urgent Field Safety Notice

15-41

July 2015

Dimension® clinical chemistry system
Creatinine (DF33A SMN 10444968)
Interference from Hemoglobin

Our records indicate that your facility received the following product:

Table 1. Dimension® CREA

Assay	Catalog Number	Siemens Material Number (SMN)
CREA	DF33A	10444968

All in-date and future lots are affected.

Reason for Field Action

Siemens Healthcare Diagnostics has determined that Dimension® Creatinine (CREA) may produce depressed results up to 12.7% (or approximately 0.2 mg/dL [18 µmol/L]) for a creatinine result at 1.5 mg/dL [133 µmol/L] when hemolysis exceeds 300 mg/dL [0.19 mmol/L] of hemoglobin. It is important to note that percent hemoglobin interference with Dimension® CREA is dependent on the creatinine concentration; at a creatinine concentration of 5.0 mg/dL [442 µmol/L], hemoglobin interference at concentrations up to a 1000 mg/dL [0.62 mmol/L] is < 10%. Alternately, with an approximate bias of 0.2 mg/dL([18 µmol/L]), the percent hemoglobin interference may be higher at low creatinine concentrations (< 0.8 mg/dL [< 71 µmol/L]).

Table 2 shows the Hemoglobin Interference that is listed in the current Dimension® CREA Instructions For Use.

Table 2. Current Hemoglobin (hemolysate) Interference

Test concentration mg/dL [mmol/L]	CREA concentration mg/dL [µmol/L]	Bias %	H Index
1000 [0.62]	1.7 [150]	< 10	0

Table 3 shows the Hemoglobin Interference for Dimension® CREA from recent internal testing.

Table 3. Revised Hemoglobin (hemolysate) Interference

Test concentration mg/dL [mmol/L	CREA concentration mg/dL [µmol/L]	Bias %	H Index
300 [0.19]	1.5 [133]	< 10	4

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Risk to Health

Depressed creatinine results due to hemolysis as described above would not be expected to significantly impact medical decisions when using this assay. Siemens is not recommending a review of previously generated results.

Actions to be taken by Customer

- Review this letter with your Medical Director.
- Customers should review their currently established procedure for reporting CREA results for hemolyzed samples and update as necessary for the revised interference information described in this letter.
- If an H index is used on the Dimension® clinical chemistry system for CREA, an H index of 4 is consistent with our findings on hemoglobin interference at a creatinine concentration of 1.5 mg/dL [133 µmol/L]. Laboratories can customize the H index for CREA to reflect their own individual operating requirements for reporting interference.
- Per the Dimension® Operator's Guide, when one or more of the HIL indexes for the method is equal to or greater than the HIL Alert Index, "follow your laboratory's procedures for reporting results when the sample is hemolyzed."

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 local Siemens technical support representative.

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FIELD CORRECTION EFFECTIVENESS CHECK
Dimension® clinical chemistry system
Creatinine (CREA) (DF33A SMN 10444968)
Interference from Hemoglobin

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice Letter Number 15-41 dated July 2015 regarding CREA, Interference from Hemoglobin. 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.

Ref: DC 15-06 [C/3221]

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter.	Yes ☐	No ☐
Signed:	Date:	

Name of person completing questionnaire: Block Capitals:	
Title:	
Institution:	Instrument Serial Number:
Street:	
City:	Post Code:
Phone:	Email:
Customer Sold To #:	Customer Ship To #:

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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