

Urgent Field Safety Notice

December 2010

Dimension® Clinical Chemistry System

Potential for falsely elevated results with Creatinine (CREA) Flex® reagent cartridge (DF33A) lots FB1251, CA1260 and BB1286

Our records indicate that your laboratory uses Creatinine (CREA) Flex® reagent cartridges (DF33A) on the Dimension® clinical chemistry system. Siemens has confirmed the potential for falsely elevated creatinine results with CREA Flex® reagent cartridge lots FB1251, CA1260 and BB1286 when processing tests from a well that has been punctured. This issue may affect creatinine results for quality control (QC) and patient samples.

The table below shows average elevations in the observed creatinine concentration at two levels of QC processed over a 24-hour period in a controlled study.

Time (hours)	Average Elevation in Creatinine Concentration (mg/dL/[µmol/L])	
	QC Level 1	QC Level 2
8	0.78 mg/dL [69 µmol/L] 0.08 [7 µmol/L]	6.53 mg/dL [577 µmol/L] 0.06 [5 µmol/L]
16	0.14 [12 µmol/L]	0.12 [11 µmol/L]
24	0.19 [17 µmol/L]	0.18 [16 µmol/L]

The magnitude of the elevation may vary depending on how long a well has been open and the number of tests processed out of the well. Therefore, routine QC may or may not detect the issue. In internal testing, a maximum elevation of 0.34 mg/dL [30 µmol/L] was observed after 24 hours. We recommend that you discuss the content of this letter with your laboratory director to determine the need to review previously reported CREA results.

Please discontinue use and discard any remaining inventory of Dimension® CREA Flex® reagent cartridge lots FB1251, CA1260 and BB1286. To expedite processing of product replacement, please use the enclosed fax form to report your no-charge replacement needs to the Customer Service Center. If you must continue to use lots FB1251, CA1260 and BB1286 until replacement product arrives, a new well set should be opened every 8 hours to minimize any impact to CREA test results.

We apologize for the inconvenience that this situation has caused. If you have any technical questions regarding this information, please contact the Siemens Technical Solutions Center at 800-441-9250. Please forward this notification to anyone to whom you may have distributed CREA (DF33A) Flex® reagent cartridges.

Siemens Healthcare Diagnostics Inc.

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P.O. Box 6101
Newark, DE 19714-6101

[800-441-9250]
www.siemens.com/diagnostics

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Falsely elevated results with Creatinine (CREA) Flex[®] reagent cartridges (DF33A)

FIELD CORRECTION EFFECTIVENESS CHECK

Dimension[®] CREA Flex[®] reagent cartridges (DF33A)

Dear Customer:

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated December 2010 regarding Dimension[®] CREA Flex[®] reagent cartridge (DF33A) lots FB1251, CA1260 and BB1286. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page.

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|---|------------------------------|-----------------------------|
| 1. Do you have any of the noted product on hand? (Please check inventories before answering.) | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2. If the answer to Question 1 is Yes, did you take the recommended action as requested? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number:

Street:

City:

State:

Phone:

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT 302-631-8467.