SIEMENS

Urgent Field Safety Notice

Customer Information Update

February 2012

Dimension® Clinical Chemistry System

Update: Potential for falsely elevated results with multiple Creatinine (CREA) Flex® reagent cartridge (DF33A) lots

This letter is to inform you of an update to the Urgent Field Safety Notice dated November 2011, titled "Potential for falsely elevated results with multiple Creatinine (CREA) Flex® reagent cartridge (DF33A) lots."

Siemens Healthcare Diagnostics would like to provide an update of the work we have been conducting to address this issue. We have identified possible solutions and are in the process of validating them. Siemens is working diligently to complete the validation process, and we are confident that once it is completed, we will have taken steps to correct this issue as it stands today and to prevent it from reoccurring in the future.

As a reminder, we ask that you please continue to follow the instructions below provided in the earlier Urgent Field Safety Notice (November 2011).

For Lots GA2196, GA2203, DC2221, DB2221, GA2229 and FA2237:
Siemens recommends discontinuing use and discarding any remaining inventory of these Dimension® CREA Flex® reagent cartridge lots.

For Other Dimension® CREA Flex® lots manufactured after lot FA2237:
Until further notice, as a precautionary measure Siemens recommends that QC should be analyzed more frequently, at least every 8 hours.

How to identify lots manufactured after lot FA2237:

The Dimension® Lot Number contains 6 characters - 2 letters and 4 numbers. The first two characters are internal indicators. The 3rd – 6th characters (numbers) represent the year and Julian date of expiration. Therefore, all flex lots with numbers (characters 3 – 6) that are equal to or greater than 2238 are newer than flex lot FA2237.

We appreciate your continued support, and we apologize for the inconvenience that this situation has caused. As stated in the Urgent Field Safety Notice, Siemens will notify customers when normal testing may resume.

If you currently use the Dimension® CREA method and have not already done so, please complete the FIELD CORRECTION EFFECTIVENESS CHECK form attached to the original Urgent Field Safety Notice (November 2011) and fax it to (302) 631-8467.

For 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.

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