



Urgent Field Safety Notice

August 2011

Dimension® EXL™ Integrated Chemistry System

Low Recovery of QC and Patient Samples with Dimension® EXL Cardiac Troponin I (TNI) Flex® reagent cartridge (RF621) Lots ED2098, EA2111, FB2134 and ED2147

Our records indicate that your laboratory may have received Dimension® EXL Cardiac Troponin I (TNI) Flex® reagent cartridge (RF621) Lot ED2098, EA2111, FB2134, and/or ED2147.

Internal testing has confirmed low recovery of QC and patient samples. Use of one of these lots may show a downward shift in QC and patient results. This decrease may cause a sample that is slightly above the 99th percentile (0.056 ng/mL) of a reference population to read below this value. At higher values of TNI, samples will remain positive and the bias is not clinically significant.

Please immediately discontinue use and discard any remaining inventory of Dimension® EXL TNI Reagent (RF621) Lots ED2098, EA2111, FB2134 or ED2147. Your replacement order for the affected lot(s) is in process, and will be sent to you free of charge. Please complete the attached form and fax it to **(302)631-8467** to indicate that you have received this information. We also ask that you please forward this notification to anyone to whom you may have distributed this product.

Siemens recommends discussing the content of this letter with your laboratory director regarding the need to review test results reported from using Dimension® EXL TNI Reagent Lots ED2098, EA2111, FB2134 or ED2147.

Siemens apologizes 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 Dimension® EXL TNI Reagent (RF621) Lots ED2098, EA2111, FB2134 or ED2147

Siemens Healthcare Diagnostics

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

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

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Low Recovery of QC and Patient Samples with Dimension® EXL Cardiac Troponin I (TNI) Flex® reagent cartridge (RF621) Lots ED2098, EA2111, FB2134 and ED2147

FIELD CORRECTION EFFECTIVENESS CHECK

Dimension® EXL LOCI TNI Reagent (RF621) Lots ED2098, EA2111, FB2134 and ED2147

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated August 2011 regarding *Dimension® EXL TNI Reagent (RF621) Lots ED2098, EA2111, FB2134 or ED2147*. 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.

Please complete and fax by September 16, 2011

1. Did we effectively communicate all necessary information? Yes No

If you selected No, please explain below.

2. Do you now have any of the noted product on hand? (Please check inventories before answering.) Yes No

3. If the answer to the question above is Yes, do you intend to take the recommended action as requested? Yes No

Name of person completing questionnaire:

Instrument Serial Number:

Title:

Institution:

Street:

City:

State:

Phone:

**PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT
(302) 631-8467**

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