SIEMENS

Urgent Field Safety Notice

April 2010

Stratus® CS
STAT Fluorometric Analyzer

Elevated results with Acute Care™ Troponin I TestPak

Our records indicate your facility uses the Stratus® CS STAT Fluorometric Analyzer. In an ongoing effort to keep our customers informed, we would like to inform you that **Siemens Healthcare Diagnostics has received customer reports of observations of falsely elevated CTNI results. The incidence of falsely elevated CTNI results is very low at less than 0.1%.**

These elevations may cause a sample that is below the 99th percentile of the reference population, 0.07 ng/mL [µg/L], to read above this value. In the event this occurs, the CTNI result would be expected to be discordant with the clinical picture, including the classic rise and fall in concentration upon serial sampling. There have been no reports of falsely depressed results.

False elevations could also be caused by various factors such as sample integrity or Heterophilic antibodies. Further information can be found in the CTNI IFU under "**limitations of procedure**". The patient's medical history, clinical presentation and other findings must also be considered.

Siemens is conducting an investigation of these reports to determine a root cause and corrective actions. In the meantime, Siemens is conducting a voluntary corrective action for all CCTNI TestPak lots. **Please repeat positive results above 0.07 ng/mL by an alternate method.** You will be contacted when you can resume normal testing for CTNI on the Stratus® CS analyzer.

We recommend discussing the content of this letter with your laboratory director regarding the need to review previous test results, conduct patient follow up, and/or repeat testing for tests conducted on or after November 1, 2009.

Please complete and submit the attached Completion Notification Form below to indicate that you have received this information.

If you have technical questions or concerns, please contact the Siemens Technical Solutions Center at 800-405-6473 for further assistance. Please forward this notification to anyone to whom you may have distributed this product.

We apologize for the inconvenience that this situation has caused. Thank you for your patience and continued support.

Siemens Healthcare Diagnostics Inc.

10-xx
P.O. Box 6101
Newark, DE 19714-6101
[800-405-6473]
www.siemens.com/diagnostics

SIEMENS

Completion Notification Form

Stratus® CS STAT Fluorometric Analyzer

Acute Care™ Troponin I cTnI TestPak

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated April 2010 regarding Stratus® CS Acute Care™ Troponin I cTnI TestPak. 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.

1. Do you have any of the noted products on hand? (Please check inventories before answering.) Yes ☐ No ☐
2. If the answer to Question 1 is "Yes", do you intend to take the recommended action as requested? Yes ☐ No ☐
3. Did we effectively communicate all necessary information? Yes ☐ No ☐

Name of person completing questionnaire: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____ Phone: _____

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT 800-405-6473

Siemens Healthcare Diagnostics Inc.

10-xx

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

[800-405-6473]
www.siemens.com/diagnostics