



Urgent Field Safety Notice Customer Information Update

August 2010

**Stratus® CS
STAT Fluorometric Analyzer**

Update: Elevated results with Acute Care™ Troponin I TestPak


Over the last 3 months we have been communicating the different stages of testing and the steps that Siemens Healthcare Diagnostics has taken to solve the reports of observations of falsely elevated Acute Care™ Troponin I results on the Stratus CS® Analyzer.

Siemens Healthcare Diagnostics has identified the source of the falsely elevated results and implemented appropriate preventive actions to ensure the quality of future lots. Testing on lots **230200002** and greater has confirmed that you may resume standard testing with the CTNI TestPaks and retesting of positive result on an alternate method is no longer required.

Siemens Healthcare Diagnostics is now announcing that this issue has been fully resolved and that Troponin I testing on the Stratus CS Analyzer can go back to normal and no longer requires an alternate method for positive result verification.

Going forward, all Stratus CS CTNI testing should be conducted using lot numbers 230200002 and above. If you have TestPaks with lower lot numbers in stock, please contact the Siemens customer Service Centre at 1-800-241-0420, option 5 for information on how to replace your current stock with the corrected lots. Siemens has manufactured the corrected lots in large quantities, however, that does not negate the need for possible allocations on the Troponin TestPaks as needed.

We would like to sincerely thank you for your patience and trust in Siemens to find an adequate solution to this issue. **If you have technical questions or concerns, please contact the Siemens Technical Support Center at 1-800-405-6473 for further assistance**


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