Urgent Field Safety Notice

POC 25-006.A.OUS

Stratus® CS & CS 200 Acute Care™ Diagnostic Systems

Title

False Positive cTnI Results for Acute Care cTnI TestPak

Date Issued

March 2025

Issue Description

The purpose of this communication is to inform you of a potential issue with the products indicated in the table below and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics has identified, through customer complaints, an increased occurrence of random non-repeatable false positive cardiac Troponin I (cTnI) results at any point during the TestPak's shelf life when using the Stratus CS cTnI Acute Care Testpak. This means some cTnI values for samples that are expected to fall within the 99th percentile of the reference population (per the Instructions for Use: 0.00 - 0.07 ng/mL [µg/L]) may exceed this range. The maximum positive bias is 0.42 ng/mL with an average bias of 0.14 ng/mL.

There have been no reports of any false negative results, injuries or deaths.

Product

Product	Siemens Material Number	Unique Device Identification	Lot#
Stratus® CS Acute Care™ cTnI TestPak	10445071	0405686902174VK	From Lot# 234337002 and forward

Impact to Results

The Stratus CS and Stratus CS200 were confirmed to display false positive cTnI results without alerting the user. The data revealed the maximum positive bias is 0.42 ng/mL with an average bias of 0.14 ng/mL when repeated on Stratus CS/SCS platform. An example of the worst-case scenario would be an erroneously elevated cTnI resulting in the incorrect diagnosis of acute myocardial infarction and a clinician opting to acutely anticoagulate a patient with heparin, perform a diagnostic catheterization, or perform percutaneous coronary intervention with angioplasty and/or a stent placement. Mitigations include discordance from other test results, discordance from clinical presentation of the patient, discordance from serial cTnI testing consistent with the standard of care, and the unlikely scenario in which a patient is significantly harmed due to a falsely elevated cTnI.

Customer Actions

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Repeat samples with cTnI results above 0.07 ng/mL or your institution's established 99th percentile value
  - As mentioned above, there is a potential for false positive results when using cTnI TestPaks any time during shelf life; therefore, as an additional measure, customers are advised to perform repeat testing of samples when the cTnI result is above 0.07 ng/mL or your institution's established 99th percentile value.
  - As recommended in the Acute Care™ cTnI TestPak Instructions for Use (IFU), a test result that is inconsistent with the clinical picture and patient history should be interpreted with caution. Furthermore, results should be interpreted as part of serial sampling at admission.

SIEMENS Healthineers

	• Siemens will reimburse users for repeat tests and discarded cTnI TestPaks associated with this field corrective action. Please contact your Siemens Customer Care Center for details regarding the reimbursement process. • If you are a distributor, please ensure your customers receive this UFSN letter. • Complete and return the Field Correction Effectiveness Check Form attached to this letter within 10 days. • Please retain this letter with your laboratory records and forward this letter to those who may have received this product at your site.
Resolution	Siemens is working to resolve this issue and will contact you when additional information is available.
Single Registration Number (SRN)	US-MF-000016336

Siemens Healthcare Sdn. Bhd.
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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice POC 25-006.A.OUS dated March 2025. Please read each question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Page 1 immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Return this completed form as per the instructions provided at the bottom of this page.

1.	I have read and understood the instructions provided in this letter.	Yes ☐	No ☐
2.	We have the affected product(s) on hand? Please check inventories before answering.	Yes ☐	No ☐
3.	All affected Site Personnel have been notified.	Yes ☐	No ☐
4.	A copy of the letter has been retained and posted with our current product labeling.	Yes ☐	No ☐

If the answer to the question #2 above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description **Product Catalog #/SMN #/Lot #**		**Quantity of Affected Product in inventory** **Discarded/Replacement Quantity Required**	
Stratus® CS Acute Care™ cTnI TestPak SMN# 10445071			
Name of person completing questionnaire:			
Title:			
Institution:			
Street:			
City:		**State:**	
Phone:		**Country:**	

Please send a scanned copy of the completed form via email to fscareportingunit.my@siemens-healthineers.com.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.