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Urgent Field Safety Notice:

Stratus® CS & CS 200 Acute Care ™ Diagnostic System
False Positive cTnI Results for Acute Care ™ cTnI TestPak

Dear Sirs,

Our records indicate that your facility may have received the following product:

Table 1. Stratus® CS & CS 200 Affected Product

Product	Siemens Material Number (SMN)	Lot Number
Stratus® CS Acute Care™ cTnI TestPak	10445071	From Lot # 238330002 forward

The purpose of this communication is to inform you of an issue with the product indicated in Table 1 above and provide instructions on actions for your laboratory to take.

Reason for this Urgent Field Safety Notice

Siemens Healthcare Diagnostics has identified the following issues with cTnI results when using the Stratus CS cTnI Acute Care TestPak:

- Increased rate of false positive cTnI results beginning 2 months prior to the end of the product's shelf life due to a positive bias and increased imprecision. The maximum observed patient bias near the 99th percentile of the reference population (per Instructions for Use: 0.07 ng/mL [ug/L]) was a cTnI negative patient sample of 0.05 ng/mL that read as 0.10 ng/mL.
- Increased rate of random non-repeatable false positive cTnI results at any time in the product's shelf life. This means some cTnI results for a sample which is expected to be within the 99th percentile of the reference population, 0.00 - 0.07 ng/mL [ug/L], may read above this value. Typical false positive values have been reported in the range of 0.08 to 0.50 ng/mL.

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

Risk to Health

In rare circumstances, a falsely increased troponin result may lead to inappropriate intervention for myocardial infarction. A troponin result would be used as part of a standard triage together with the acute clinical condition (symptoms and vital signs), ECG and serial troponin testing. Since troponin test results are used for immediate diagnostic support, Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

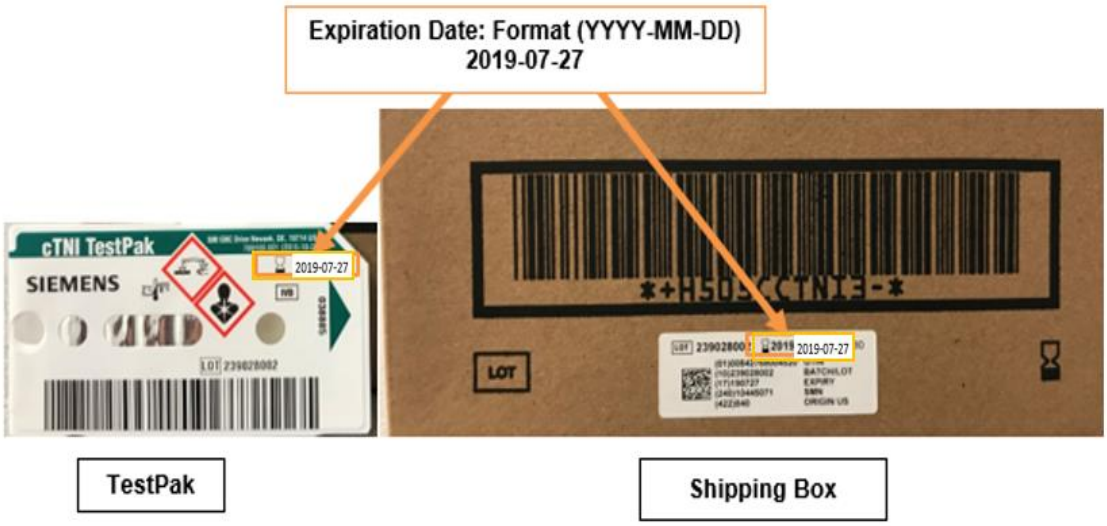
Siemens is recommending the following two actions:

1. Do Not Use cTnI TestPaks within 2 months of Expiration

Through internal testing, we have determined that the upward trend in cTnI bias could impact results beginning 2 months prior to the end of shelf life. Therefore, do not use cTnI TestPaks within 2 months of Expiration. Please discard any cTnI TestPak that is within 2 months of Expiration.

The expiration date is printed on the shipping box containing the cTnI TestPaks and on each cTnI TestPak, as shown below (see expiration date shown in Image 1).

Image 1: Example of an expiration date on cTnI TestPaks and shipping box containing cTnI TestPaks



For example, to determine if you can use the cTnI TestPak in the illustration above, subtract 2 months from the expiration date 2019-07-27. In this case, the cTnI TestPak should not be used after 2019-05-27. Please note, since the instrument is unable to determine the new expiration date based on the barcode, the expiration date must be calculated manually before use.

2. 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 non-repeatable 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 is working to resolve this issue and will contact you when additional information is available. Siemens will reimburse users for repeat tests and discarded cTnI TestPaks (within 2 months of the printed expiration date) associated with this field corrective action. Please contact your Siemens Customer Care Center for details regarding the reimbursement process.

Please complete and submit the attached Field Correction Effectiveness Check form to indicate that you have received this information. Please acknowledge receipt of this letter and return the response form even if you do not have product on hand. Retain this letter with your laboratory records, and we also ask that you please forward this notification to anyone to whom you may have distributed this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

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