



Siemens Healthcare Diagnostics Inc.

**Urgent Field Safety Notice
Follow-Up Information**

POC 19-014.B.OUS

July 2019

Stratus® CS & CS 200 Acute Care™ Diagnostics System

**Follow-Up Communication for:
False Positive cTnI Results for Acute Care™ cTnI TestPak**

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

Product	Siemens Material Number (SMN)
Stratus® CS Acute Care™ cTnI TestPak	10445071

This is a follow up communication to POC 19-014.A.OUS. The purpose of this communication is to inform you that Siemens Healthcare Diagnostics has reduced the expiration dating for all cTnI TestPaks from 180 to 120 days. Therefore, it is no longer required to manually reduce the shelf life for lots starting with 239189002 as they will have the adjusted 120 day expiration date.

Actions to be Taken by the Customer

1. For a list of cTnI TestPak lots manufactured prior to lot 239189002 and recommended actions specific to these lots refer to Table 1 and Table 2 below.
2. Review this Urgent Field Safety Notification Follow-Up Information with your Medical Director or laboratory supervisor.
3. Continue to repeat samples with cTnI results above 0.07 ng/mL or your institution’s established 99th percentile value.

Explanation of TestPak Lot Number

Using TestPak lot #239189002 as an example, below lists explanations of how a lot number is generated just for your information:

- “23” – indicates cTnI product;
- “9” - indicates the year when the product was made. The product was made in 2019 in this example;
- “189” - indicates the day when the product was made. The product was made on the 189th day of the year in this example;
- “002” -indicates manufacturing information.

Siemens is working to resolve this issue and will continue to provide updates when additional information is available. Siemens will reimburse users for repeat tests and discarded cTnI TestPaks (within 2 months of the 180-day 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 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.

Table 1

DO NOT USE THESE TESTPAKS BELOW. THESE TESTPAKS ARE ALREADY BEYOND 120 DAY EXPIRATION DATE	
TestPak Lot	180-day Expiration Date
239035002	8/3/2019
239056002	8/24/2019
239063002	8/31/2019
239070002	9/7/2019
239077002	9/14/2019

Table 2

DO NOT USE THESE TESTPAKS BELOW BEYOND 120 DAY EXPIRATION DATE		
TestPak Lot	180-Day Expiration Date	120-Day Expiration Date (Do Not Use beyond this date)
239105002	10/12/2019	8/13/2019
239112002	10/19/2019	8/20/2019
239119002	10/26/2019	8/27/2019
239126002	11/2/2019	9/3/2019
239154002	11/30/2019	10/1/2019
239161002	12/7/2019	10/8/2019
239168002	12/14/2019	10/15/2019

Additional Information

Stratus® CS & CS 200 are trademarks of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK AND PRODUCT DISCARD FORM

False Positive cTnI Results for Acute Care™ cTnI TestPak

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice Follow-Up Information POC 19-014.B.OUS dated July 2019 regarding False Positive cTnI Results for Acute Care™ cTnI TestPak. Please read each question below and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice Follow-Up Information instructions provided in this letter. Yes No

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

If the answer to 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 Discarded/ Replacement Quantity Required
Stratus® CS Acute Care™ cTnI TestPak, SMN #10445071, [Insert Lot #]	

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Customer Sold To #: _____ Customer Ship To #: _____

Please send a scanned copy of the completed form via email to XXXX@XXXX or to fax this completed form to the Customer Care Center at XXXXXX.

If you have any questions, contact your local Siemens technical support representative.