SIEMENS

Urgent Field Safety Notice

CC 15-12.A.OUS

May 2015

ADVIA Centaur®
ADVIA Centaur® XP
ADVIA Centaur® XPT
ADVIA Centaur® CP

ADVIA Centaur CP TnI Ultra Method Comparison Slope Versus ADVIA Centaur/ADVIA Centaur XP/ADVIA Centaur XPT

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

Table 1. ADVIA Centaur Systems Affected Product(s)

Assay	Siemens Material Number (SMN)	Lot Number
ADVIA Centaur TnI-Ultra 100 test kit	10317708	Kit Lots ending in 088, 089, 090, 091, 093 and 094 and all future lots until the issue is resolved and a follow-up communication is issued.
ADVIA Centaur TnI-Ultra 500 test kit	10317709	

Reason for Correction

Siemens Healthcare Diagnostics has observed a system-to-system bias between the TnI-Ultra™ assay on the ADVIA Centaur® CP and ADVIA Centaur/ADVIA Centaur XP/ADVIA Centaur XPT systems with the ADVIA Centaur CP generating lower results than the ADVIA Centaur/ADVIA Centaur XP/ADVIA Centaur XPT system. Siemens is actively pursuing the cause of this issue.

This observation impacts customers who use the TnI-Ultra assay on both the ADVIA Centaur CP and ADVIA Centaur/ADVIA Centaur XP/ADVIA Centaur XPT systems interchangeably when interpreting serial testing in patient samples. This communication does not impact customers who use TnI-Ultra results solely from either the ADVIA Centaur/ADVIA Centaur XP/ADVIA Centaur XPT system or the ADVIA Centaur CP system.

The differences in troponin values observed between the ADVIA Centaur CP and ADVIA Centaur/ADVIA Centaur XP/ADVIA Centaur XPT systems become more pronounced at increasing concentrations. The slopes observed in a multi-reagent lot (kit lots ending in 088, 089, 090, 091, 093 and 094) method comparison when using patient samples ranging from 0.01 ng/mL (µg/L) to 50.0 ng/mL (µg/L), ranged from 0.58 to 0.71 across lots. As shown in Table 2, the affect is most apparent at troponin concentrations well above the 99th percentile. The average absolute differences and median absolute differences across the assay range are shown in Table 2.

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Siemens internal investigation has confirmed the clinical utility of the assay at the 99th percentile for healthy individuals (0.02 - 0.06 ng/mL (µg/L)) is not impacted by this issue.

Table 2. Absolute Differences Between Systems (ADVIA Centaur CP vs. ADVIA Centaur/ADVIA Centaur XP/ADVIA Centaur XPT)

Assay Range (ng/mL; µg/L)	Average Absolute Difference	Median Absolute Difference
0.02 and 0.06	-0.01	-0.01
0.07 and 0.1	-0.02	-0.02
0.11 and 0.19	-0.04	-0.03
0.2 and 1.09	-0.18	-0.17
1.1 and 5.0	-1.18	-1.14
>5.0	-8.66	-9.21

The 99th percentile is maintained on both the ADVIA Centaur/ADVIA Centaur XP/ADVIA Centaur XPT and ADVIA Centaur CP systems.

Risk to Health

The potential for injury is extremely unlikely and limited to laboratories that may be alternating the use of ADVIA Centaur CP and ADVIA Centaur/ADVIA Centaur XP/ADVIA Centaur XPT during serial troponin testing when troponin values are above the 99th percentile, approximating 0.07 – 0.20 ng/mL(µg/L) . The difference in this scenario may be due to potential differences between the ADVIA Centaur CP and ADVIA Centaur/ADVIA Centaur XP/ADVIA Centaur XPT systems and not reflective of a true change in troponin values. In other scenarios, the potential for clinical impact is mitigated by serial testing for a rising or falling pattern of troponin values and/or other indications warranting follow up investigation at higher troponin values. Siemens is not recommending a review of previously generated results due to this issue.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Customers may continue to use the ADVIA Centaur TnI-Ultra assay to report patient results on the ADVIA Centaur/ADVIA Centaur XP/ADVIA Centaur XPT and ADVIA Centaur CP systems. Values within the 99th percentile range of 0.02 to 0.06 ng/mL(µg/L) are interchangeable for serial measurement between the ADVIA Centaur/ADVIA Centaur XP/ADVIA Centaur XPT and ADVIA Centaur CP systems.
- Customers should consider that values significantly greater than the 99th percentile will show differences between the ADVIA Centaur CP and ADVIA Centaur/ADVIA Centaur XP/ADVIA Centaur XPT systems and should consider this difference when interpreting the results.
- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.

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Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

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

Additional Information

Product availability may vary from country to country and is subject to varying regulatory requirements. Due to local regulations, the ADVIA Centaur XPT is not available in all countries.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA Centaur CP Tnl Ultra Method Comparison Slope Versus
ADVIA Centaur/ADVIA Centaur XP/ADVIA Centaur XPT

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice PQC CC 15-12.A.OUS dated May 2015 regarding ADVIA Centaur CP Tnl Ultra Method Comparison Slope Versus ADVIA Centaur/ADVIA Centaur XP/ADVIA Centaur XPT. Please read the question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Please fax this completed form to the Customer Care Center at (XXX) XXX-XXXX. If you have any questions, contact your local Siemens technical support representative.

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