

Urgent Field Safety Notice

CC 16-07.A.OUS

February, 2016

ADVIA Centaur®
 ADVIA Centaur® XP
 ADVIA Centaur® XPT

ADVIA Centaur Systems Calibrator E Lot to Lot Bias with the Testosterone Assay

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

Table 1. ADVIA Centaur Affected Product(s)

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date
Calibrator E	04634452 (2 pack)	10309079	87226A42	May 9, 2016
			55811A42	May 9, 2016
			53650A42	May 9, 2016
			53624A42	May 9, 2016
			15612A43	November 27, 2016
			17909A43	November 27, 2016
			22868A43	November 27, 2016
			45084A43	November 27, 2016
	04634762 (6 pack)	10321075	86344A42	May 9, 2016
55437A42			May 9, 2016	
54801A42			May 9, 2016	
53651A42			May 9, 2016	
53625A42			May 9, 2016	
15610A43			November 27, 2016	
18375A43			November 27, 2016	
24990A43			November 27, 2016	
04636889 (6 pack Reference)	10335532	91005A42	May 9, 2016	
		53698A42	May 9, 2016	

Reason for Correction

Siemens Healthcare Diagnostics has confirmed a lot to lot bias with Calibrator E for the ADVIA Centaur Testosterone assay.

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Internal investigation demonstrates:

- An average positive bias of 17% across the assay range with Calibrator E kit lots ending in 42 as compared to values generated with the master curve.
- An average negative bias of 7% across the assay range with Calibrator E kit lots ending in 43 as compared to values generated with the master curve.
- The positive bias of Calibrator E kit lots ending in 42 to the master curve compared to the negative bias of Calibrator E kit lots ending in 43 to the master curve is the main driver for the negative bias between values generated with Calibrator E kit lots ending in 42 and Calibrator E kit lots ending in 43.

The bias of the calibrators to the master curve has been corrected with Calibrator E kit lots ending in 44. See Figures 1 and 2 and Table 2 for additional data.

The performance of the Testosterone assay on the ADVIA Centaur CP is not affected.

Calibrator E is also used for calibration of the ADVIA Centaur® Systems Cortisol and Progesterone assays; however, the performance of these assays is not affected.

Risk to Health

The risk to health as a result of this issue is negligible. The biases observed across the assay range would not impact clinical management of patients being evaluated for androgen disorders or chemical castration. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Customers may continue to use Calibrator E kit lots ending in 42 and 43 to calibrate Testosterone on the ADVIA Centaur CP system and the Cortisol and Progesterone assays on any ADVIA Centaur system.
- ADVIA Centaur/ADVIA Centaur XP/ADVIA Centaur XPT Testosterone customers should use Calibrator E kit lots ending in 44 and above.
- Review the information provided in the Additional Information section of this communication.
- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.

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.

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.

Additional Information

- Figure 1 and Figure 2 provide linear regression data comparing Calibrator E kit lots ending in 42, 43 and 44 to the master curve. The data was generated with ADVIA Centaur Testosterone reagent kit lots ending 176, 179 and 180. (Figure 1 shows the data in mass units and Figure 2 shows the data in SI units.)

Figure 1: Method Comparisons Between Calibrator Lots and the Master Curve (Testosterone results in ng/dL)

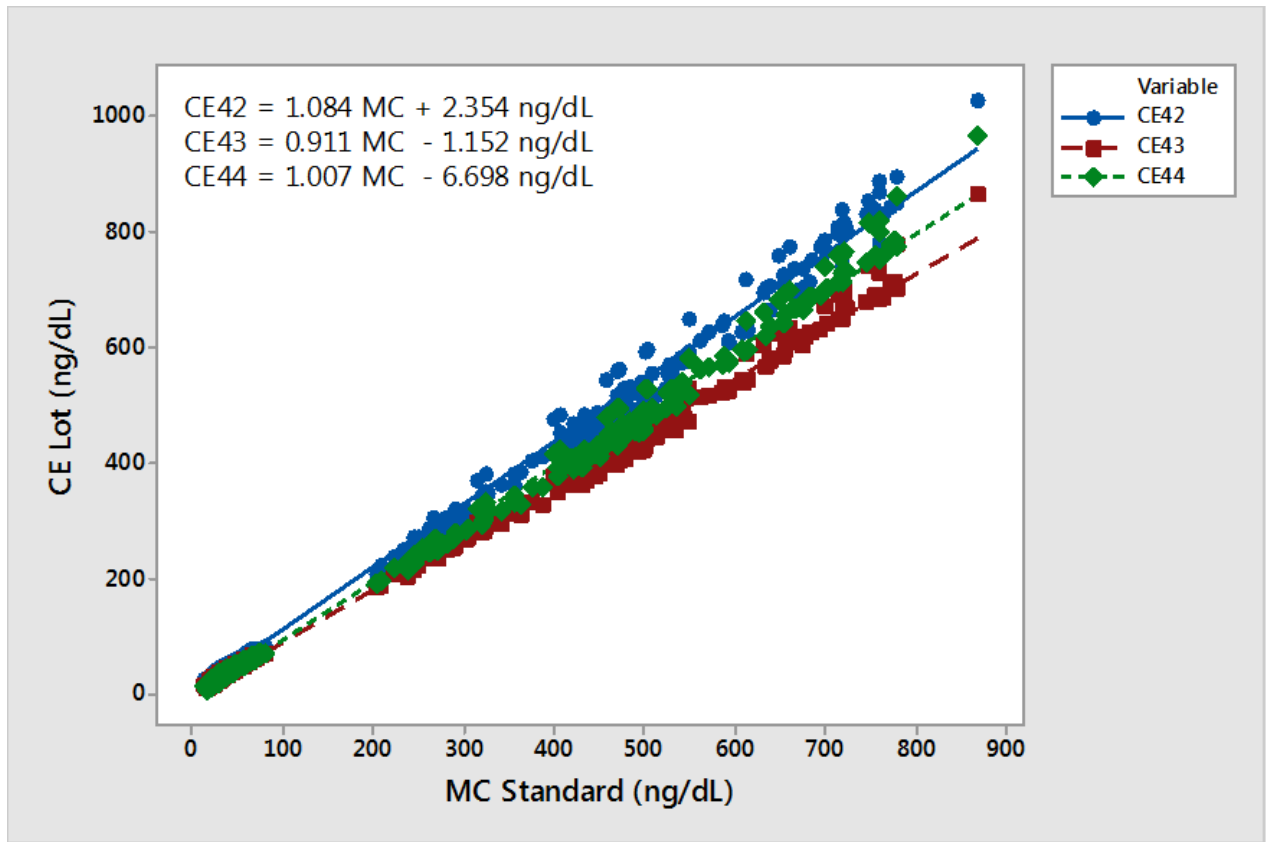


Figure 2: Method Comparisons Between Calibrator Lots and the Master Curve (Testosterone results in nmol/L)

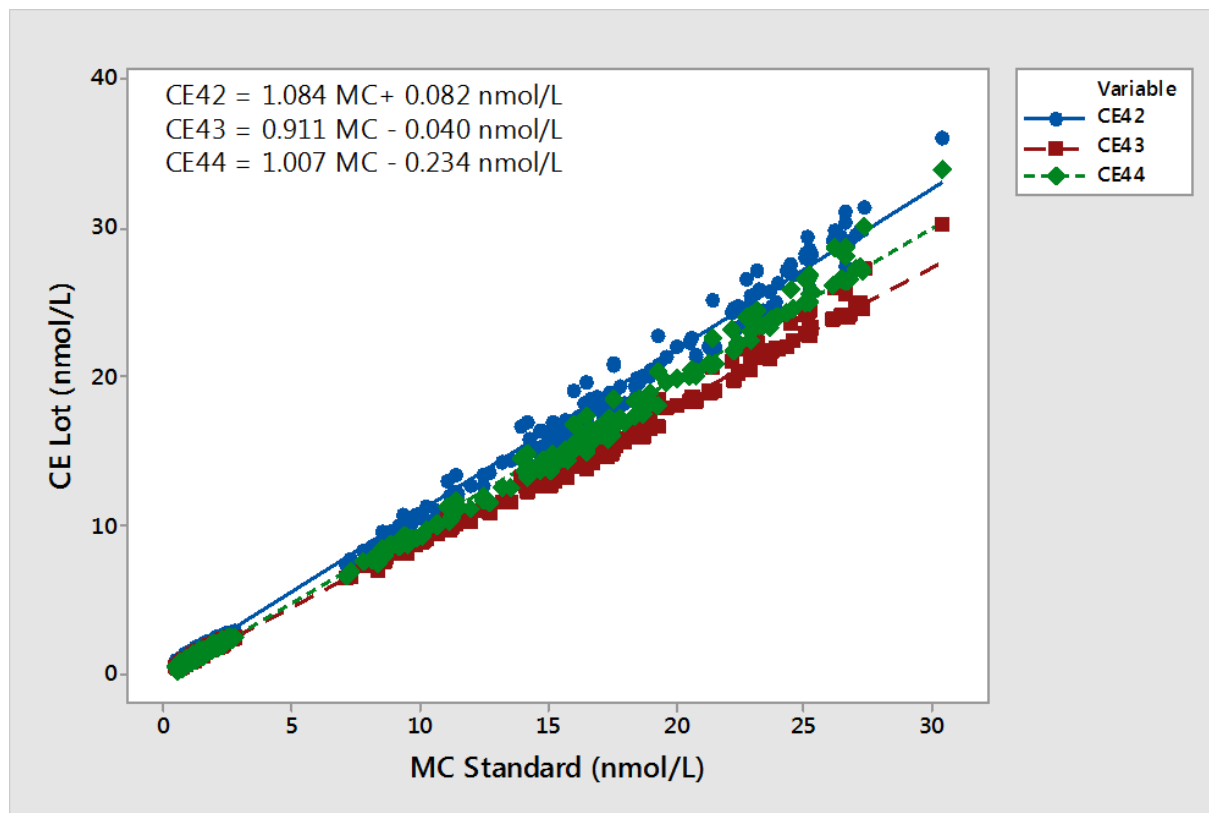


Table 2 provides the average biases between calibrator lots and the master curves across the range of the patient samples tested.

Table 2. Average Biases Between Calibrator Lots and Master Curves

	All Values	30 – 80 ng/dL (1.04 – 2.78 nmol/L)	Above 100 ng/dL (3.47 nmol/L)
CE44 Vs CE42	-17%	-22%	-9%
CE44 vs CE43	3%	-1%	9%
CE43 vs CE42	-20%	-21%	-17%
CE44 vs Master Curve	-4%	-6%	-2%
CE43 vs Master Curve	-7%	-5%	-10%
CE42 vs Master Curve	17%	20%	8%

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- Quality Control values have been evaluated and revised. Revised control values are located on the Bio-Rad website at QCnet.com.
- Testosterone Master Curve Material Lot 07767 should be used with Calibrator E kit lots ending in 43 and higher.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA Centaur Systems Calibrator E Lot to Lot Bias with the Testosterone Assay

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CC 16-07.A.OUS dated February, 2016 regarding ADVIA Centaur Systems Calibrator E Lot to Lot Bias with the Testosterone Assay. Please read each 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.

1. I have read and understood the Urgent Medical Device Correction instructions provided in this letter. Yes No
2. Do you now have any of the noted product on hand? Please check inventories before answering. Yes No

If the answer to the question 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 that has been discarded	Replacement Quantity Required
04634452 (2 pack) Lots 87226A42;55811A42; 53650A42; 53624A42; 15612A43; 17909A43; 22868A43; 45084A43.		
04634762 (6 pack) Lots 86344A42; 55437A42; 54801A42; 53651A42; 53625A42; 15610A43; 18375A43; 24990A43; 38988A43		
04636889 (6 pack Reference) Lots 91005A42; 53698A42		

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.