

Urgent Field Safety Notice

10819674, Rev. A

September 2014

ADVIA Centaur®
 ADVIA Centaur® XP
 ADVIA Centaur® CP

Information Regarding the ADVIA Centaur Systems Calibrator E

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

Table 1. ADVIA Centaur Affected Products

Product	Catalog Number	Siemens Material Number (SMN)	Kit Lot Numbers	Expiration Date
Calibrator E	04634452 (2 pack)	10309079	26284A38 26900A38 27991A38 28192A38 29571A38 31162A38 32488A38 35243AB39 35295AB39 36091AB39 39464AB39 40245AB39 41317AB39	November 29, 2014 November 29, 2014 November 29, 2014 November 29, 2014 November 29, 2014 November 29, 2014 November 29, 2014 November 29, 2014 November 29, 2014 May 15, 2015 May 15, 2015 May 15, 2015 May 15, 2015
	04634762 (6 pack)	10321075	26285A38 27348A38 29169A38 30710A38 31261A38 32687A38 35259AB39 35359AB39 36289AB39 39031AB39 41124AB39	November 29, 2014 November 29, 2014 November 29, 2014 November 29, 2014 November 29, 2014 November 29, 2014 May 15, 2015 May 15, 2015 May 15, 2015 May 15, 2015 May 15, 2015
	04636889 (6 pack ref)	10335532	27236A38 35051A38 35839AB39 40141AB39 41702AB39	November 29, 2014 November 29, 2014 May 15, 2015 May 15, 2015 May 15, 2015

Reason for Correction

Calibrator E is used for calibration of the ADVIA Centaur® Systems Cortisol, Progesterone and Testosterone assays.

Siemens Healthcare Diagnostics has identified a positive bias for Calibrator E kit lots ending in 38 and 39 with the ADVIA Centaur Systems Cortisol and Progesterone assays compared to the respective master curves.

Patient serum samples evaluated with the ADVIA Centaur Cortisol assay and calibrated with Calibrator E kit lots listed in Table 1 demonstrate an average positive bias of 16% across the assay range with a maximum bias of 28%.

Patient serum samples evaluated with the ADVIA Centaur Systems Progesterone assay and calibrated with Calibrator E kit lots ending in 38 and 39 demonstrate a positive bias with samples above 30 ng/mL. The average positive bias on the ADVIA Centaur/ADVIA Centaur XP is 20% with a maximum bias of 39%. The average positive bias on the ADVIA Centaur CP is 17% with a maximum bias of 35%.

The ADVIA Centaur Systems Testosterone assay is not affected by this correction.

Expected Performance of Calibrator E Kit Lots Ending in 40 and Above

For the ADVIA Centaur Systems Cortisol assay, the performance of the assay has been restored with Calibrator E kit lots ending in 40 and above. Siemens is providing data to demonstrate the expected difference when moving to Calibrator E kit lots ending in 40. Refer to Figures 1 – 4 in the Additional Information section. Revised control values for the ADVIA Centaur Systems Calibrator E, kit lots ending in 40 and above, are located on the Bio-Rad website at QCnet.com. Revised values for the Master Curve Material (MCM) are included in the Additional Information section of this letter.

For the ADVIA Centaur and ADVIA Centaur XP Progesterone assay, the performance has been corrected with Calibrator E kit lots ending in 40. Control and MCM values have been evaluated and do not require reassignment. Controls do not require reassignment since values are below 30 ng/mL. MCMs do not require reassignment as the ranges are sufficient to capture the shift. The performance of the assay for results >30 ng/mL with the ADVIA Centaur CP Progesterone assay is currently under investigation and has not been restored with kit lots of Calibrator E ending in 40. Siemens is providing data to demonstrate the expected difference when moving to Calibrator E kit lots ending in 40. Refer to Figures 5 – 8 in the Additional Information section.

A notecard referring to this communication will be included with Calibrator E kit lots ending in 40 and above.

Calibrator E kit lots ending in 40 will be in stock after October 1, 2014.

Risk to Health

The observed positive bias with ADVIA Centaur Systems Cortisol and Progesterone assays with Calibrator E kit lots ending in 38 and 39 does not impact clinical utility. The biases affect regions of the curve that are not clinically relevant in the investigation or monitoring of endocrine disorders or other uses. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Customers may continue to use Calibrator E kit lots ending in 38 and 39 or they may choose to order Calibrator E kit lots ending in 40.
- Please review this letter with your Medical Director.
- Review the information provided in Additional Information section of this communication.
- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.
- Please continue to follow Urgent Field Safety Notice 10811344, Rev. A, dated March 2012 (*ADVIA Centaur Systems Cortisol Assay Onboard Stability and Calibration Interval Change*) and Customer Notification 10817328, Rev. A, dated December 2013 (*ADVIA Centaur Systems Cortisol Calibration Slope Failures*).

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

Refer to Table 2 for a list of Bio-Rad Lyphocheck® Quantitative Urine, Liquichek™ Urine Chemistry, Lyphocheck Immunoassay Plus and Liquichek Immunoassay Plus Serum control lots that have been reassigned for the ADVIA Centaur Cortisol assay. Bio-Rad will list assigned values as “For Use with Calibrator E lot 40 and above” in the insert sheet and Unity reports.

Table 2. Reassigned Lyphocheck and Liquichek Lots for ADVIA Centaur Systems Cortisol

Product	Control Lots
Lyphocheck Quantitative Urine	63320, 63330, 63340, 63350
Liquichek Urine Chemistry	64330, 64340, 64350, 64370, 64380, 64390
Lyphocheck Immunoassay Plus Control	40270, 40280, 40290, 40300
Liquichek Immunoassay Plus Control	40820, 40830, 40840, 40850

Refer to Figures 1 – 2 for the regression graphs for the ADVIA Centaur Cortisol assay and Figures 3 – 4 for the ADVIA Centaur CP Cortisol assay. Calibrator E kit lots ending in 38, 39 and 40 will be referred to as CE38, CE39 and CE40 in the figures.

Figure 1. Comparison of Serum Samples Tested with ADVIA Centaur Cortisol Using Calibrator E Kit Lots Ending in 38 and 40

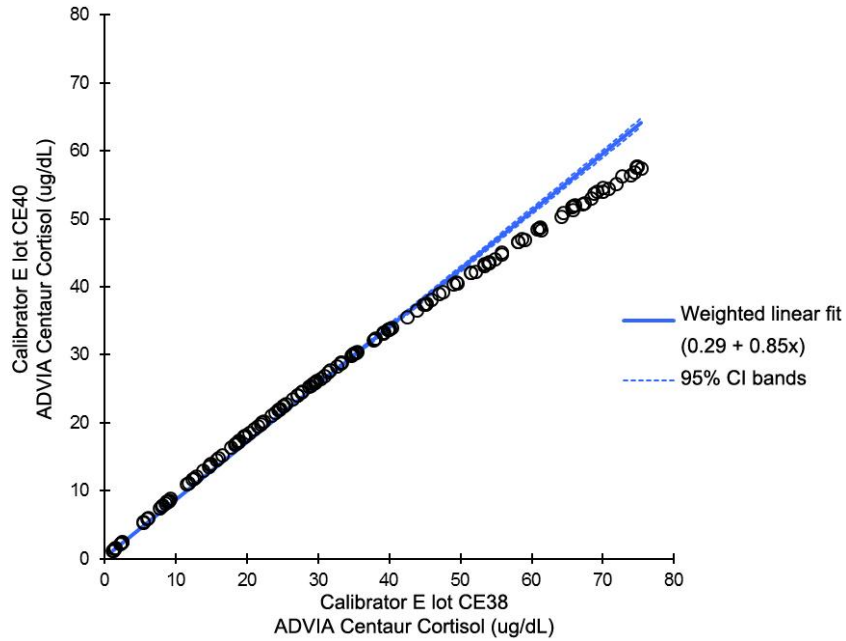


Figure 2. Comparison of Serum Samples Tested with ADVIA Centaur Cortisol Using Calibrator E Kit Lots Ending in 39 and 40

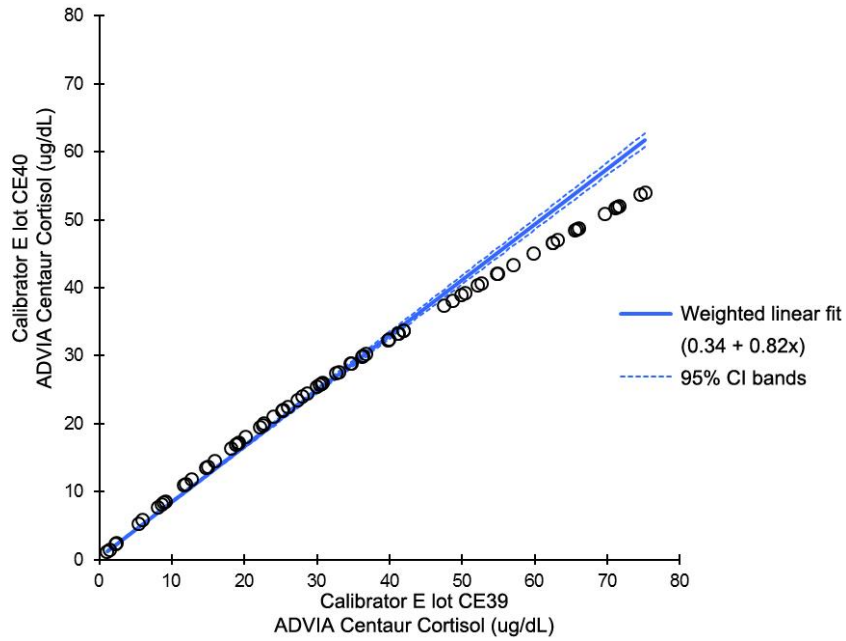


Figure 3. Comparison of Serum Samples Tested with ADVIA Centaur CP Cortisol Using Calibrator E Kit Lots Ending in 38 and 40

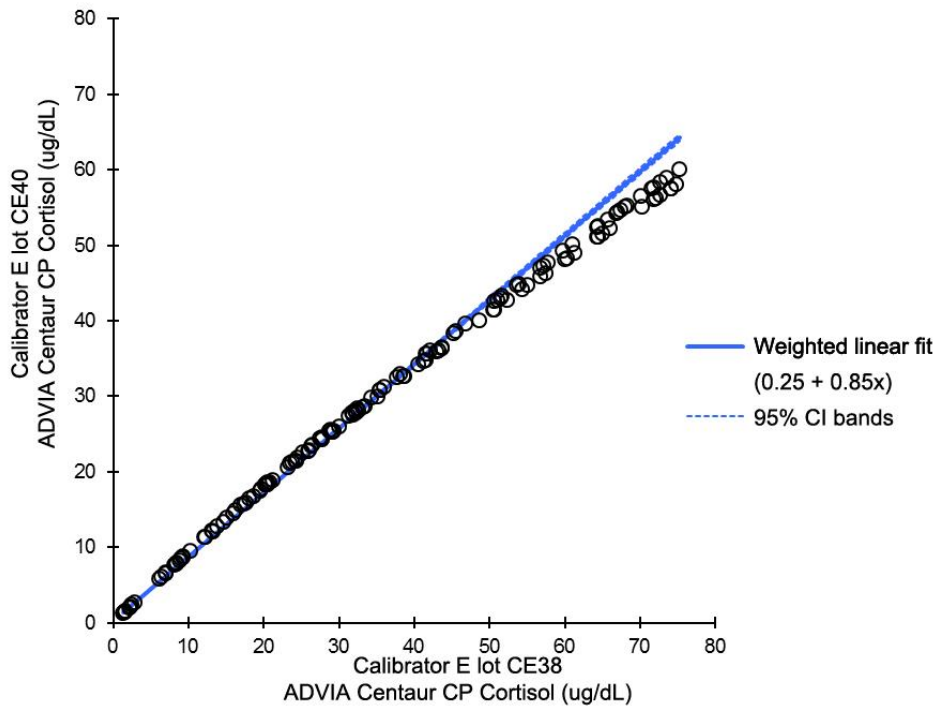
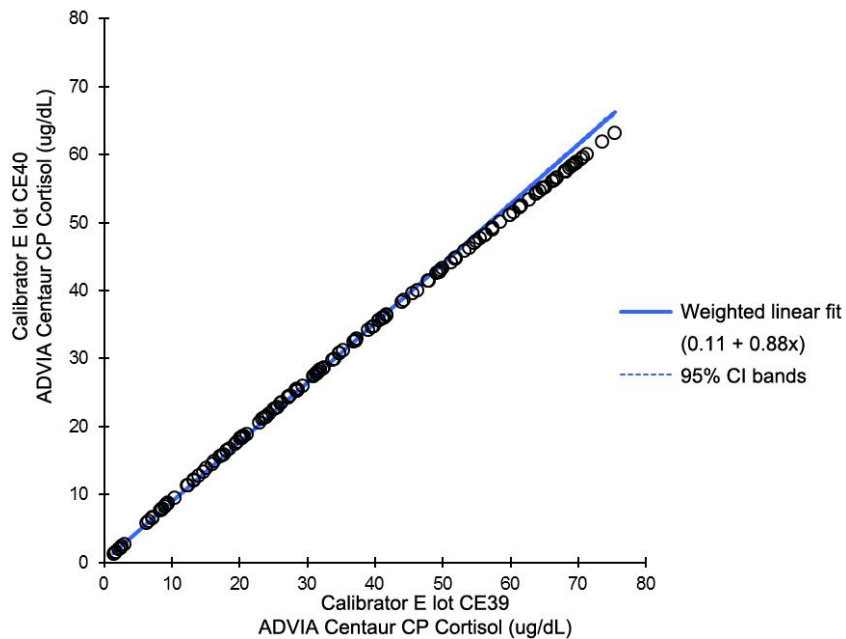


Figure 4. Comparison of Serum Samples Tested with ADVIA Centaur CP Cortisol Using Calibrator E Kit Lots Ending in 39 and 40



Due to the value assignment of Calibrator E kit lots ending in 40 (CE40LA and CE40HA), the values and ranges for MCM and QC material have been reassigned. Refer to Table 3 for the ADVIA Centaur Systems Cortisol assay reassigned MCM values and ranges.

Table 3. ADVIA Centaur and ADVIA Centaur CP Cortisol Reassigned MCM Values and Ranges

Level	Current Target µg/dL (nmol/L)	Current Range µg/dL (nmol/L)	Calibrator E Kit Lots Ending in 40 and Above Target µg/dL (nmol/L)	Calibrator E Kit Lots Ending in 40 and Above Range µg/dL (nmol/L)
M0140935	0.00 (0.00)	< 0.600 (< 16.6)	0.00 (0.00)	< 0.600 (< 16.6)
M0240935	1.00 (27.6)	0.450 – 1.55 (12.4 – 42.8)	0.992 (27.4)	0.446 – 1.54 (12.3 – 42.5)
M0340935	2.36 (65.1)	1.65 – 3.07 (45.5 – 84.7)	2.09 (57.7)	1.65 – 3.07 (40.3 – 75.0)
M0440935	7.01 (193.4)	4.91 – 9.11 (135.5 – 251.3)	6.41 (176.9)	4.49 – 8.33 (123.9 – 229.8)
M0540935	15.0 (413.9)	10.5 – 19.5 (289.7 – 538.0)	13.8 (380.7)	9.66 – 17.9 (266.5 – 493.9)
M0640935	32.9 (907.7)	23 – 42.8 (634.6 – 1181)	31.4 (866.3)	22.0 – 40.8 (607.0 – 1126)
M0740935	87.3 (2409)	> 69.8 (>1926)	85.2 (2351)	> 69.7 (>1882)

Refer to Figures 5 – 6 for the regression graphs for the ADVIA Centaur Progesterone assay and Figures 7 – 8 for the ADVIA Centaur CP Progesterone assay. Calibrator E kit lots ending in 38, 39 and 40 will be referred to as CE38, CE39 and CE40 in the figures.

Figure 5. Comparison of Serum Samples Tested with ADVIA Centaur Progesterone Using Calibrator E Kit Lots Ending in 38 and 40

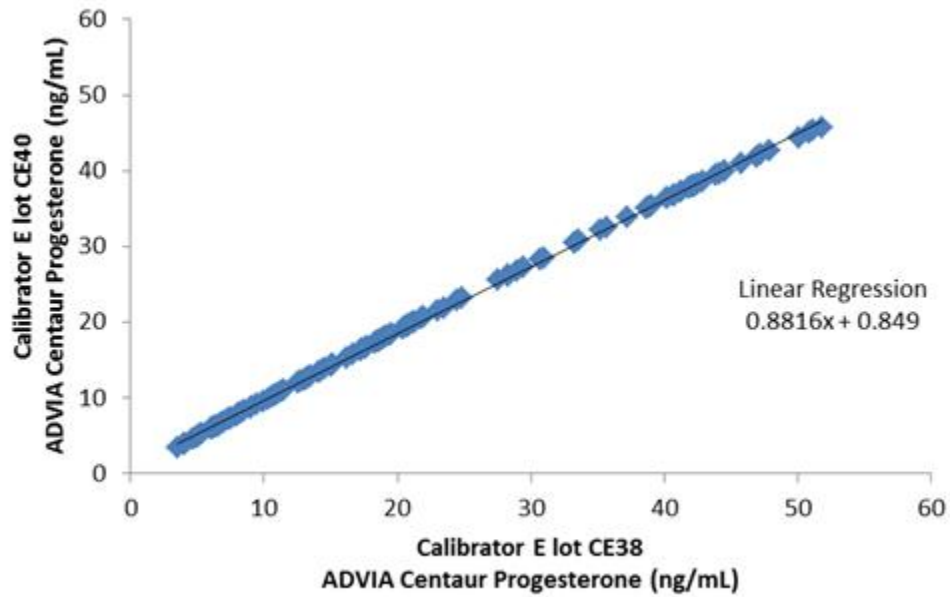


Figure 6. Comparison of Serum Samples Tested with ADVIA Centaur Progesterone Using Calibrator E Kit Lots Ending in 39 and 40

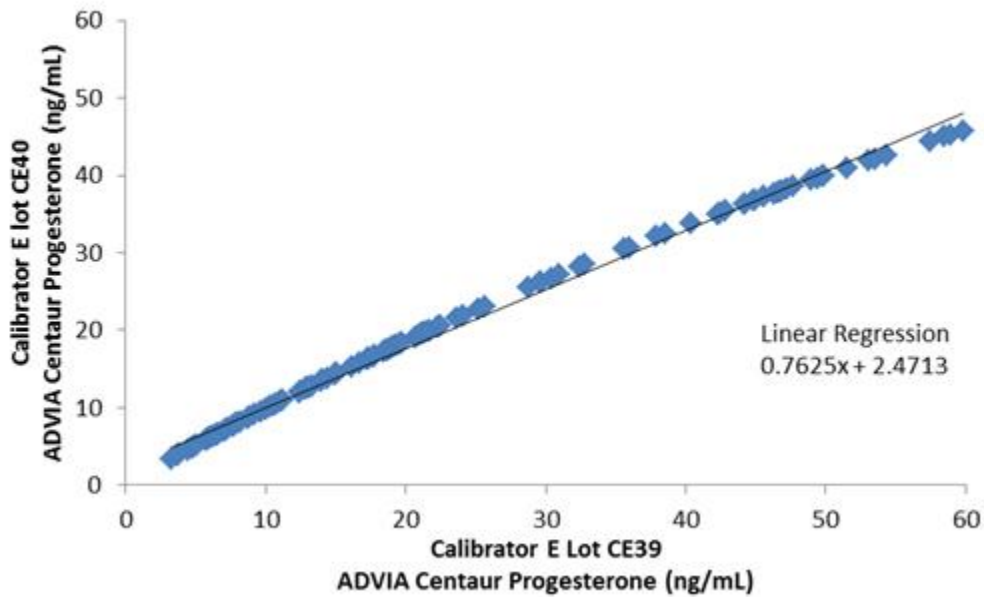


Figure 7. Comparison of Serum Samples Tested with ADVIA Centaur CP Progesterone Using Calibrator E Kit Lots Ending in 38 and 40

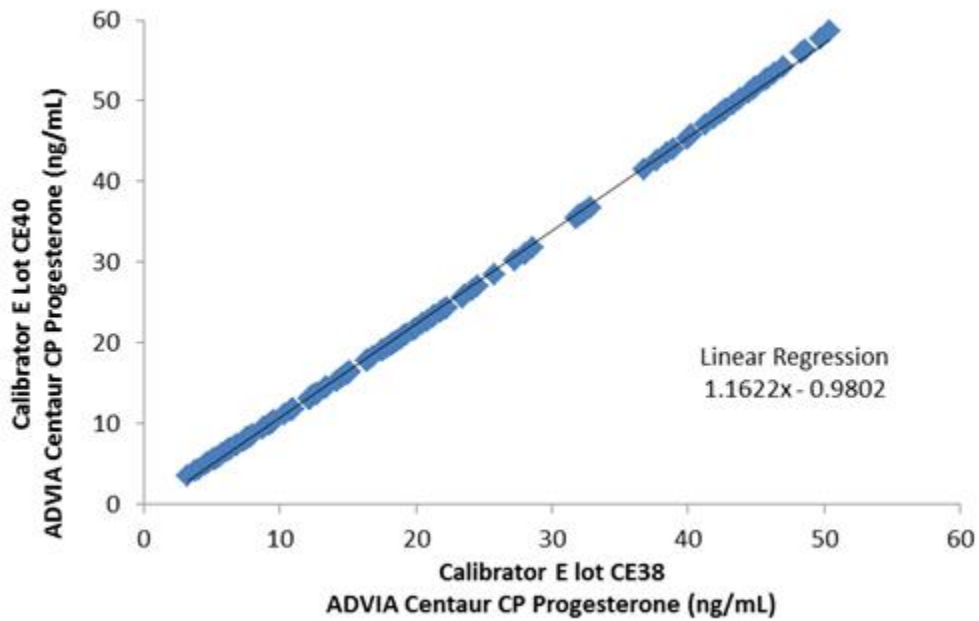
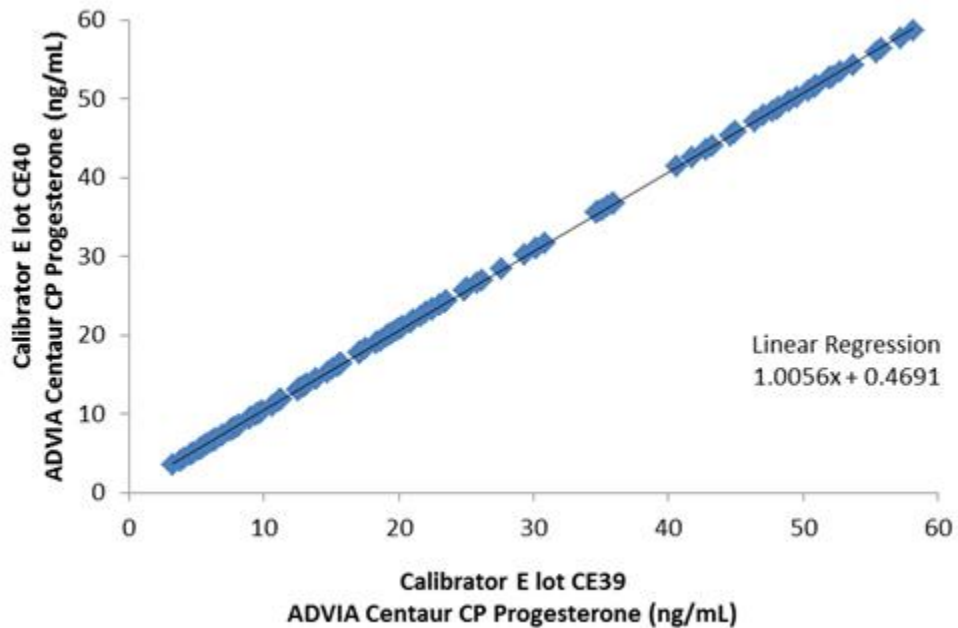


Figure 8. Comparison of Serum Samples Tested with ADVIA Centaur CP Progesterone Using Calibrator E Kit Lots Ending in 39 and 40



ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.
Liquichek and Lyphocek are trademarks of Bio-Rad Laboratories.

FIELD CORRECTION EFFECTIVENESS CHECK

Information Regarding the ADVIA Centaur Systems Calibrator E

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 10819674, Rev. A dated September 2014 regarding Information Regarding the ADVIA Centaur Systems Calibrator E. 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 (###) ###-####. If you have any questions, contact your local Siemens technical support representative.