SIEMENS

Urgent Field Safety Notice

CC 17-04.A.OUS

January 2017

ADVIA Centaur®
ADVIA Centaur® XP
ADVIA Centaur® XPT

FT4 Assay Negative Bias observed with Calibrator A Kit Lots Ending in 90

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

Table 1. ADVIA Centaur Systems Affected Product(s)

Product	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date	Manufacturing Date
Calibrator A (2 pack)	04800646	10285903	07995A90 08451A90 16035A90 32420A90 43871A90 59675A90 62739A90	2017/07/24	2016/03/24
Calibrator A (6 pack)	04800735	10285904	07996A90 21172A90 27221A90 44366A90 63785A90	2017/07/24	2016/03/24

Reason for Recall

Siemens Healthcare Diagnostics has confirmed a negative bias for ADVIA Centaur FT4 when used with Calibrator A kit lots ending in 90 on the ADVIA Centaur, ADVIA Centaur XP and ADVIA Centaur XPT Systems. In addition, Siemens Healthcare Diagnostics confirmed the potential for calibration failures due to above limit calibrator RLU %CVs when using Calibrator A kit lots ending in 90 with the FT4 assay.

The performance of the FT4 assay when used with Calibrator A kit lots ending in 90 on the ADVIA Centaur CP System is not affected.

Customers may continue to use Calibrator A kit lots ending in 90 for the ADVIA Centaur Systems FT3, T3, T4 and TUp assays.

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Internal investigations were performed using available FT4 lots. The investigation confirmed an overall negative bias when comparing Calibrator A kit lots ending in 90 to previously released Calibrator A kit lots ending in 89.

Table 2. FT4 Patient Sample %Bias (CA90 vs. CA89)

FT4 Dose	Average Bias	Range of Bias
<0.89 ng/dL (<11.5 pmol/L)	–11%	-28% to 7%
0.89 ng/dL to 1.76 ng/dL (11.5 pmol/L to 22.7 pmol/L)	–5%	-14% to 0%
>1.76 ng/dL (>22.7 pmol/L)	–7%	-16% to 3%

In some instances the negative bias may cause euthyroid patient samples to result low and outside the reference interval listed in the Instructions for Use (IFU).

Quality Control material and Master Curve Material may result low and outside acceptable ranges.

The root cause of this issue is currently under investigation.

Risk to Health

When this issue occurs, the potential exists for misinterpretation of FT4 values as below the reference interval listed in the IFU when truly normal. Mitigating factors would include the apparent discordance of erroneously low FT4 values when used in conjunction with other thyroid hormone testing during thyroid disorder investigation. Siemens is not recommending a laboratory look back as a result of this issue.

Actions to be Taken by the Customer

ADVIA Centaur FT4 Assay Customers using the ADVIA Centaur, ADVIA Centaur XP & ADVIA Centaur XPT Systems

- Discontinue the use of the Calibrator A kit lots listed in Table 1 for the FT4 assay
- Use Calibrator A kit lots ending in 91 and above to calibrate the FT4 assay.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens for reporting to the authorities.
- Complete the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- Please review this letter with your Medical Director.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Siemens technical support representative.

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

ADVIA Centaur FT4 Assay Customers using the ADVIA Centaur CP Systems

- All available Calibrator A kit lots are acceptable for use on the ADVIA Centaur CP Systems.
- Even if you are solely using the ADVIA Centaur CP system, please complete the Field Correction Effectiveness Check Form attached to this letter within 30 days.

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

When switching to Calibrator A kit lots ending in 91, please be aware that internal investigation determined Calibrator A kit lots ending in 91 demonstrated similar performance to Calibrator A kit lots ending in 89.

Table 3. FT4 Patient Sample %Bias (CA91 vs. CA89)

FT4 Dose	Average Bias	Range of Bias
0.89 ng/dL to 1.76 ng/dL (11.5 pmol/L to 22.7 pmol/L)	1%	-1% to 4%

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.

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FIELD CORRECTION EFFECTIVENESS CHECK

FT4 Assay Negative Bias observed with Calibrator A Kit Lots Ending in 90

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CC 17-04.A.OUS dated January 2017 regarding FT4 Assay Negative Bias observed with Calibrator A Kit Lots Ending in 90. 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 Field Safety Notice instructions provided in this letter. Yes • No •

2. Do you use the FT4 assay on the ADVIA Centaur/XP/XPT Systems? If yes, complete question 3 below. If no, question 3 is not applicable. Yes • No •

3. 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.

Calibrator A Catalog #/SMN #/Lot #	**Quantity of Affected Product in inventory that has been discarded (if applicable)**	**Replacement Quantity Required**
2 pack - Catalog 04800646/SMN 10285903: Lots 07995A90, 08451A90, 16035A90, 32420A90, 43871A90, 59675A90, 62739A90		
6 pack - Catalog 04800735/SMN 10285904: Lots 07996A90, 21172A90, 27221A90, 4366A90, 63785A90		

1. 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:	Email:
Phone:	Post Code:

Unrestricted

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Please complete and return to:
robert.davies@siemens.com or fax to 0845 605 6800

It is important that your organisation takes the actions detailed in the UFSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to this UFSN. Your organisations reply is evidence which, Siemens Healthcare needs to monitor the progress of the UFSN. Without your reply Siemens Healthcare cannot verify the completeness of the UFSN with the MHRA.

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