SIEMENS

Urgent Field Safety Notice

10818132, Rev. A

April 2014

ADVIA Centaur®
ADVIA Centaur® XP
ADVIA Centaur® CP

Fluorescein Interference with ADVIA Centaur Systems TSH3 Ultra, Vitamin D and ADVIA Centaur BRAHMS Procalcitonin Assays

Our records indicate that your facility has received the following product:

Table 1. ADVIA Centaur Affected Products

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Kit Lots Ending In	Expiration Date
ADVIA Centaur Systems TSH3 Ultra 100T, 500T	TSH3 Ultra (TSH3-UL)	06491072 06491080	10282378 10282379	266 267 269 270 271 272 273	17 April 2014 17 June 2014 01 August 2014 30 September 2014 18 November 2014 21 January 2015 18 November 2014
ADVIA Centaur Systems VitD 100T, 500T	Vitamin D (VitD)	10491994 10699201 10631021 10699533	10491994 10699201 10631021 10699533	023 024 025 026 027 050 051 052 053 054	07 July 2014 08 September 2014 08 December 2014 09 February 2015 10 April 2015 08 August 2014 20 September 2014 11 December 2014 10 December 2014 07 March 2015
ADVIA Centaur BRAHMS PCT 100T	Procalcitonin (PCT)	10378883	10378883	020 021 022 023 024	11 July 2014 15 December 2014 24 February 2015 25 February 2015 03 July 2015

Reason for Correction

Siemens Healthcare Diagnostics has confirmed that samples containing fluorescein may show interference with the ADVIA Centaur® Systems TSH3 Ultra, Vitamin D and the ADVIA Centaur BRAHMS Procalcitonin assays.

Evidence suggests that patients undergoing fluorescein dye angiography can retain small amounts of fluorescein in the body for up to 48 to 72 hours post-treatment. In the cases of patients with renal insufficiency, retention could be much longer.

Samples containing fluorescein can produce falsely depressed values when tested with the ADVIA Centaur TSH3 Ultra assay. With fluorescein interference, observed TSH3 Ultra values can be as low as <0.01 mIU/L. These falsely low values are important when monitoring for thyroid cancer as the physician may determine that adequate suppression of TSH has been obtained. Samples should be resubmitted post fluorescein clearance to ensure there is no interference with TSH3 Ultra test results.

Samples containing fluorescein can produce falsely depressed values when tested with the ADVIA Centaur BRAHMS Procalcitonin assay. With fluorescein interference, observed Procalcitonin values can be as low as <0.02 ng/mL. Samples should be resubmitted post fluorescein clearance to ensure there is no interference with Procalcitonin test results.

Samples containing fluorescein can produce falsely elevated values when tested with the ADVIA Centaur Vitamin D assay. With fluorescein interference, observed Vitamin D values can be as high as >150 ng/mL (>375 nmol/L). Samples should be resubmitted post fluorescein clearance to ensure there is no interference with Vitamin D test results.

The ADVIA Centaur Systems TSH3 Ultra, Vitamin D and ADVIA Centaur BRAHMS Procalcitonin assays Instructions For Use (IFUs) will be revised to include a statement regarding the potential for fluorescein interference.

Risk to Health

Fluorescein has been shown to impact the results of TSH, Vitamin D and Procalcitonin. The compound is used systemically to assist in angiographic imaging. Fluorescein dye angiography is a low frequency procedure and is unlikely to occur coincidentally with testing for thyroid function, Vitamin D or clinical Procalcitonin levels. There is no risk to health.

Actions to be Taken by the Customer

- Testing blood drawn from a patient that has undergone the procedure described, without allowing clearance of fluorescein, is not recommended.
- Customers may continue to use all lots referenced in this communication for testing any sample that does not contain fluorescein.
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.

- If you have received any complaints of illness or adverse events associated with the ADVIA Centaur Systems TSH3 Ultra, Vitamin D or Procalcitonin assays, immediately contact your local Siemens Customer Care Center or your local Siemens technical support representative.

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 has caused. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

Siemens Healthcare Diagnostics
511 Benedict Ave.
Tarrytown, NY 10591
www.siemens.com/diagnostics

FIELD CORRECTION EFFECTIVENESS CHECK

Fluorescein Interference with ADVIA Centaur Systems TSH3 Ultra, Vitamin D and ADVIA Centaur BRAHMS Procalcitonin Assays

Ref: CC 14-12 [C/2733]

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 10818132, Rev. A dated April 2014 regarding Fluorescein Interference with ADVIA Centaur Systems TSH3 Ultra, Vitamin D and ADVIA Centaur BRAHMS Procalcitonin Assays. Please read the statement below and indicate the appropriate answer. Fax/email this completed form to Siemens Healthcare Diagnostics at the fax/email provided at the bottom of this page.

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

Name of person completing questionnaire:	
Title:	
Institution:	Instrument Serial Number:
Street:	
City:	Post Code:
Phone:	Email:

PLEASE FAX or EMAIL THIS COMPLETED FORM within 30 days of receipt to
FAX 0845 605 6800
EMAIL robert.davies@siemens.com

It is important that your organisation takes the actions detailed in the in the FSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to the FSN.

Your organisations reply is evidence which Siemens Healthcare, and subsequently the MHRA, needs to monitor the progress of the FSN. Without your reply Siemens Healthcare Diagnostics cannot properly verify the completeness of the FSN and the MHRA may need to issue a Medical Device Alert.