SIEMENS

Urgent Field Safety Notice

CC 16-17.A.OUS

July, 2016

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

Clarification of the Utility of the PSA Assay

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

Table 1. ADVIA Centaur Systems Affected Product(s)

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)
PSA (100 Tests)	PSA	06574155	10310292
PSA (500 Tests)	PSA	02676506	10310293

Reason for Urgent Field Safety Notice

Siemens Healthcare Diagnostics is providing this communication to emphasize that the prostate-specific antigen (PSA) values should be interpreted in accordance with current clinical guidelines for defining biochemical recurrence following radical prostatectomy (e.g., the 2013 American Urological Association (AUA) Guidelines or the 2015 European Association of Urology (EAU)). These guidelines define biochemical recurrence of prostate cancer as a detectable or rising PSA value post-radical prostatectomy that is ≥0.2 ng/mL (ug/L) with a second confirmatory level of ≥0.2 ng/mL (ug/L).

In a recent study, the Limit of Quantitation (LoQ) level for the ADVIA Centaur/XP/XPT PSA assay was evaluated and determined to be 0.04 ng/mL at the level of 20% within laboratory precision. Siemens is generating LoQ for PSA on the ADVIA Centaur CP and will provide the information when it is available.

This applies to all lots of ADVIA Centaur PSA.

The assay meets the intended use as stated in the Instructions for Use.

511 Benedict Avenue
Tarrytown, NY 10591

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Risk to Health

In scenarios where clinicians use the PSA assay in accordance with clinical guidelines for biochemical recurrence (e.g., the 2013 AUA guidelines and/or the 2015 EAU guidelines), there is negligible risk to health.

The risk to health here is limited to scenarios where the threshold for biochemical recurrence is defined independent of the AUA and/or the EAU guidelines which define recurrence of prostate cancer as a detectable or rising PSA value post-radical prostatectomy that is ≥0.2 ng/mL (ug/L) with a second confirmatory level of ≥0.2 ng/mL (ug/L). Where clinicians decide to use a PSA value <0.2 ng/mL (ug/L) as a threshold for identifying patients who may be experiencing biochemical recurrence, the potential exists for unnecessary follow-up and/or treatment for progression of residual disease. Any clinician choosing to use PSA in this manner should be aware of current clinical guidance described above, as well as the Limit of Quantitation of the ADVIA Centaur PSA assay.

Siemens is not recommending a laboratory review of previously generated results.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Please be aware of the utility of the ADVIA Centaur systems PSA assay and the appropriate clinical application in the use of monitoring disease recurrence.
- Please refer to the Additional Information section for suggested wording to communicate the utility of the assay to healthcare providers.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- 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.

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

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.

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Additional Information

Question: How can I communicate this issue to healthcare providers?

Answer:

Siemens suggests the following wording:

The ADVIA Centaur/XP/XPT PSA assay is intended to be used as an aid in the detection of prostate cancer and as an aid in the management (monitoring) of patients with prostate cancer in accordance with current clinical practice guidelines (e.g., the 2013 American Urological Association (AUA) guidelines and/or the 2015 guidelines by the European Association of Urology (EAU)). These guidelines define biochemical recurrence of prostate cancer as a detectable or rising PSA value post-radical prostatectomy that is ≥0.2 ng/mL with a second confirmatory level of ≥0.2 ng/mL. If you have decided to use a threshold for biochemical recurrence <0.2 ng/mL for serial measurements, please be aware of the current clinical guidance described above, as well as the Limit of Quantitation of the ADVIA Centaur PSA assay. Siemens Healthcare Diagnostics has determined the Limit of Quantitation of the ADVIA Centaur/XP/XPT PSA assay is 0.04 ng/mL (ug/L) at the level of 20% within laboratory precision.

Question: Limit of Quantitation (LoQ) data is not provided in the Instructions for Use, how was the value of 0.04 ng/mL (ug/L) generated?

Answer: The LoQ level for the ADVIA Centaur/XP/XPT PSA assay was evaluated in a recent study and determined to be 0.04 ng/mL at the level of 20% within laboratory precision. The LoQ calculations were conducted using within the laboratory precision profile approach per Clinical and Laboratory Standards Institute (CLSI) EP17-A2.

Question: **Is the Limit of Quantitation (LoQ) data for PSA on the ADVIA Centaur CP the same as on the ADVIA Centaur/XP/XPT?**

Answer: Siemens is generating LoQ for PSA on the ADVIA Centaur CP and will provide the information when it is available.

Question: Does this communication mean the ADVIA Centaur PSA assay cannot be used to monitor patients for biochemical recurrence of prostate cancer post-radical prostatectomy?

Answer: PSA values used to monitor for biochemical recurrence of prostate cancer should be interpreted in accordance with current clinical guidelines, which currently define biochemical recurrence as a detectable or rising PSA value post-radical prostatectomy that is ≥0.2 ng/mL (ug/L) with a second confirmatory level of ≥0.2 ng/mL (ug/L) (e.g., the 2013 American Urological Association (AUA) guidelines and the 2015 European Association of Urology (EAU) guidelines).

FIELD CORRECTION EFFECTIVENESS CHECK

Clarification of the Utility of the PSA Assay

Ref: CC 16-17 [C/3602]

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CC 16-17.A.OUS dated July, 2016 regarding Clarification of the Utility of the PSA 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 Field Safety Notice instructions provided in this letter.	Yes ☐	No ☐

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

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

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