SIEMENS

Urgent Field Safety Notice

CC 16-02.A.OUS

October 2016

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

CA 19-9 Bias Between the ADVIA Centaur CP and the ADVIA Centaur/XP/XPT

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)	Kit Lots Ending In	Expiration Date	Manufacturing Date
CA 19-9 (50 test kit)	CA 19-9	10491379	10491379	380 382 384 386 388 390	2016-10-21 2017-01-09 2017-02-06 2017-03-24 2017-05-14 2017-06-12	2015-12-21 2016-03-09 2016-04-06 2016-05-24 2016-07-14 2016-08-12
CA 19-9 (250 test kit)	CA 19-9	10491244	10491244	380 382 384 386 388 390	2016-10-21 2017-01-09 2017-02-06 2017-03-24 2017-05-14 2017-06-12	2015-12-21 2016-03-09 2016-04-06 2016-05-24 2016-07-14 2016-08-12

Reason for Correction

Siemens Healthcare Diagnostics has observed that the CA 19-9 assay on the ADVIA Centaur® CP does not meet the correlation to the CA 19-9 assay on the ADVIA Centaur/XP/XPT systems as stated in the Instructions for Use (IFU). The ADVIA Centaur CP generates lower results for patient samples. See Table 2 for biases and differences between the systems.

With Quality Control material and external quality assessment material, customers may observe a bias where the ADVIA Centaur CP CA 19-9 results are higher than the ADVIA Centaur/XP/XPT CA 19-9 results.

Siemens is actively pursuing the cause of this issue.

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This issue applies to all current, in-date and future kit lots until the issue is resolved and a follow-up communication is issued.

This observation impacts customers who use the CA 19-9 assay interchangeably between the ADVIA Centaur CP and ADVIA Centaur/XP/XPT systems when interpreting serial monitoring of patients. This communication does not impact customers who use CA 19-9 results solely from either the ADVIA Centaur/XP/XPT system or the ADVIA Centaur CP system.

Siemens has confirmed that the CA 19-9 assay maintains its clinical utility and may continue to be used on either the ADVIA Centaur/XP/XPT systems or the ADVIA Centaur CP, when the systems are not used interchangeably.

Table 2 provides a summary of biases and differences for CA 19-9 observed during internal testing between the ADVIA Centaur CP and ADVIA Centaur/XP/XPT using patient samples. Figures 1 and 2 show the absolute biases for the lower level dose segments. Figures 3 through 5 show the percent biases for the higher level dose segments. The data is presented in this manner to clearly depict performance across the analytical measuring range of the assay.

Table 2. Biases and Differences observed between CA 19-9 patient values generated on the ADVIA Centaur CP and the ADVIA Centaur/XP/XPT Systems

Dose Segments (U/mL)	N	Average Absolute Bias (U/mL)	Absolute Bias Range (U/mL)		Average %Bias	%Bias Range	
1.2 - 10	172	-1.6	-6.8	3.3	-26%	-81%	78%
> 10 - 25	178	-2.3	-16.4	7.7	-16%	-83%	44%
> 25 - 35	46	-2.5	-7.7	5.0	-9%	-31%	17%
> 35 - 60	75	-2.7	-13.6	13.8	-6%	-30%	24%
> 60 - 700	412	-20.7	-171	83.0	-7%	-51%	65%

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Figure 1. Absolute Bias observed between CA 19-9 patient values generated on the ADVIA Centaur CP and the ADVIA Centaur/ XP/ XPT Systems for Dose Segment 1.2 – 10 U/mL

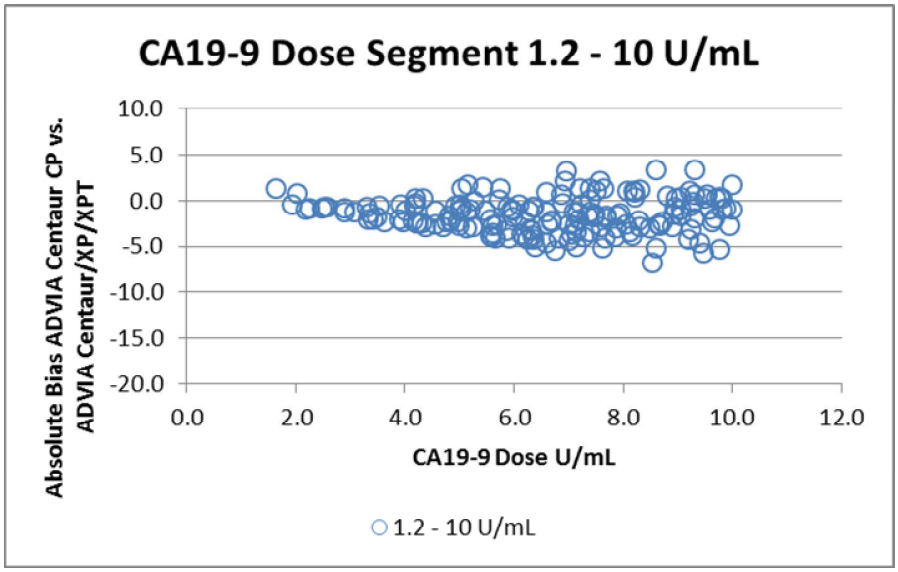

Figure 2. Absolute Bias observed between CA 19-9 patient values generated on the ADVIA Centaur CP and the ADVIA Centaur/XP/XPT Systems for Dose Segment >10 – 25 U/mL

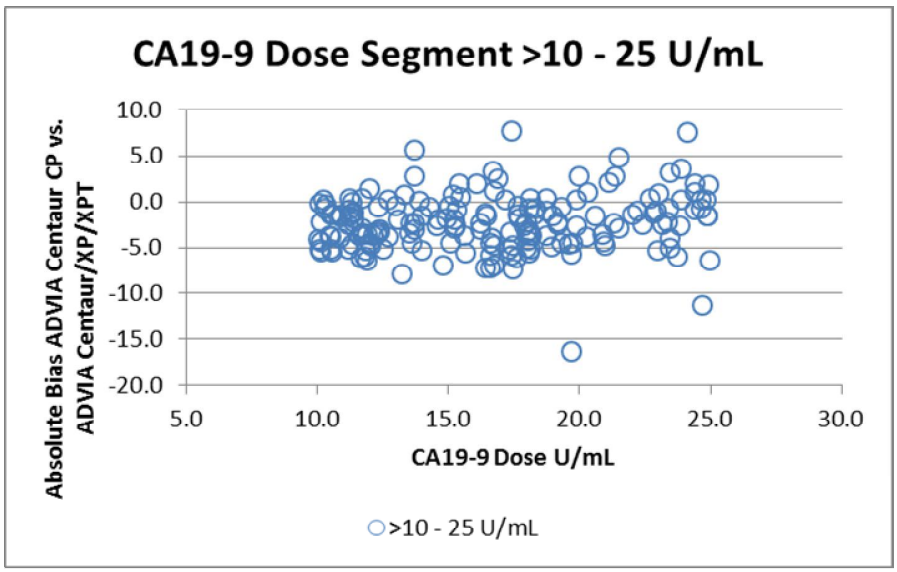

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Figure 3. %Bias observed between CA 19-9 patient values generated on the ADVIA Centaur CP and the ADVIA Centaur/XP/XPT Systems for Dose Segment >25 – 35 U/mL

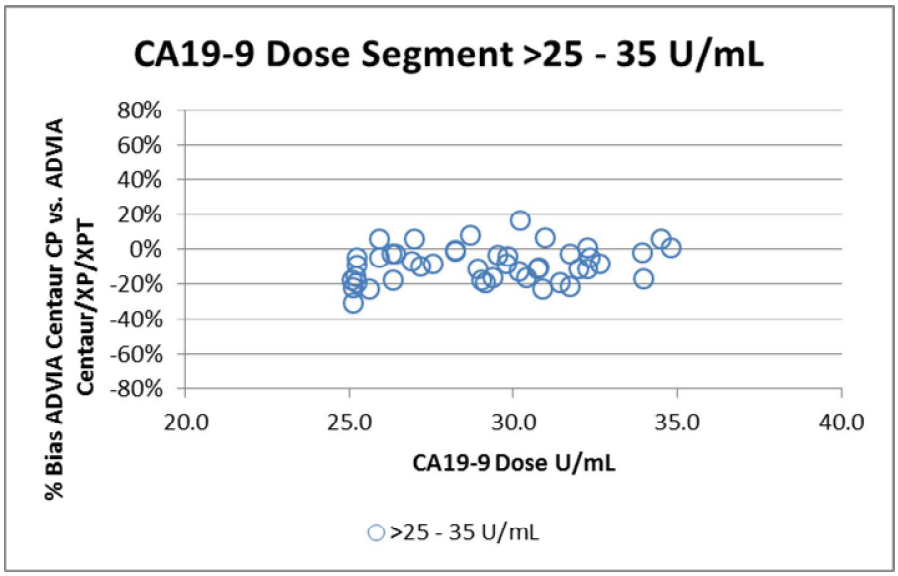


Figure 4. %Bias observed between CA 19-9 patient values generated on the ADVIA Centaur CP and the ADVIA Centaur/ XP/ XPT Systems for Dose Segment >35 – 60 U/mL

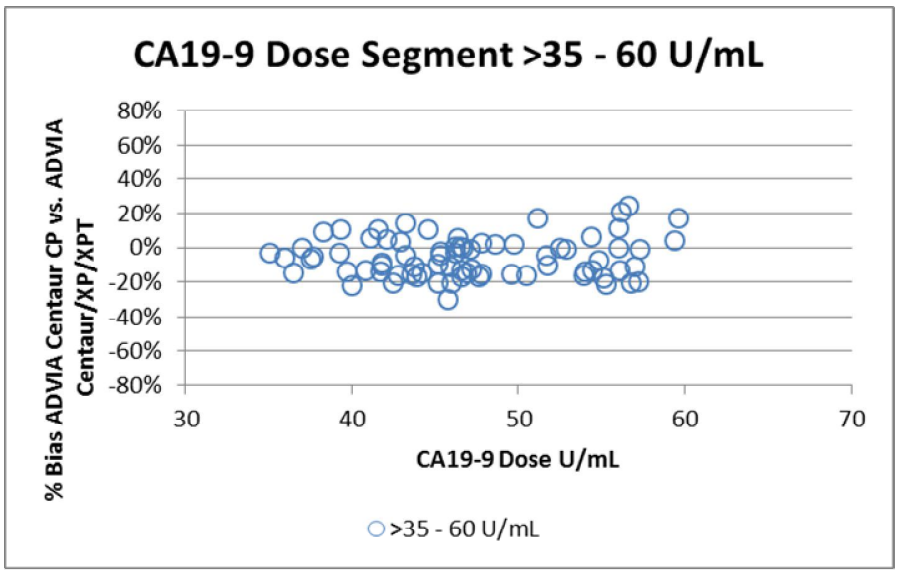
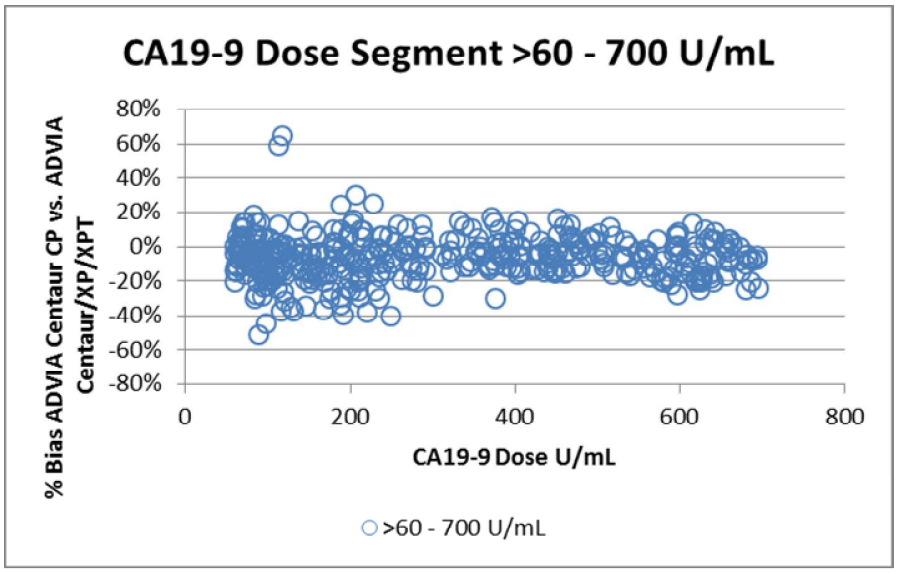


Figure 5. %Bias observed between CA 19-9 patient values generated on the ADVIA Centaur CP and the ADVIA Centaur/XP/XPT Systems for Dose Segment >60 – 700 U/mL



Risk to Health

The potential for injury is remote and limited to laboratories that may be alternating the use of ADVIA Centaur CP and ADVIA Centaur/XP/XPT during serial monitoring of patients for CA 19-9 during treatment. In cases where the systems are used interchangeably, the potential bias observed may lead to misinterpretation of trending in CA 19-9 values or may be uninformative for treatment decisions which may cause a delay in assessing a rise in CA 19-9 levels until other diagnostic modalities or routine monitoring is employed. For customers using the ADVIA Centaur CP and ADVIA Centaur/XP/XPT for CA 19-9 interchangeably, a look back of patient results over the previous three months is recommended.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Customers may continue to use the ADVIA Centaur systems CA 19-9 assay to report results on the ADVIA Centaur/XP/XPT and ADVIA Centaur CP systems.
- Customers should not use the ADVIA Centaur/XP/XPT systems interchangeably with the ADVIA Centaur CP when generating CA 19-9 results for monitoring patients. Serial monitoring of patients may continue when either system is used independently.

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- 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.
- 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.

Additional Information

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

Answer:

Siemens suggests the following wording:

The ADVIA Centaur CA 19-9 assay is indicated for the serial measurement of CA 19-9 to aid in the management and monitoring of cancer patients (Please refer to your IFU for additional information). CA 19-9 values must be interpreted in conjunction with all other clinical and laboratory data before a medical decision is determined.

Please be aware that if you have had CA 19-9 testing performed, you may wish to retest or re-baseline your patient in cases where all of the following events have occurred:

1. You have had CA 19-9 testing performed on your patient(s) within the past three months, and

2. Your CA 19-9 result(s) did not correlate with the clinical status or other laboratory testing on your patient, and

3. You have not had follow up CA 19-9 testing on your patient(s) after date when your laboratory discontinued the use of CA 19-9 on your Centaur systems interchangeably.

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.

ADVIA Centaur is a trademark of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

CA 19-9 Bias Between the ADVIA Centaur CP and the ADVIA Centaur/XP/XPT

This response form is to confirm receipt of the enclosed Siemens Healthcare Urgent Field Safety Notice CC 16-02.A.OUS dated October 2016 regarding CA 19-9 Bias Between the ADVIA Centaur CP and the ADVIA Centaur/XP/XPT.

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.

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 Siemens Technical Representative at (65) 6366-3376. If you have any questions, contact your local Siemens technical support representative.

Signature:

Date:

Company Stamp:

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