Urgent Field Safety Notice

AIMC 23-03.A-2.OUS

January, 2023

ADVIA Centaur® XP
ADVIA Centaur® XPT

ADVIA Centaur Folate –Negative Bias when Customers use Whole Blood (FolateBA/FolBA) Calibration for Serum Samples

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

Table 1. ADVIA Centaur Affected Product(s)

Assay	Siemens Material Number (SMN)	Kit Lot #	Mfg. Date (YYYY-MM-DD)	Exp. Date (YYYY-MM-DD)	Unique Device Identification (UDI)
ADVIA Centaur Folate 100 test kit	10310308	16275336	2022-06-20	2023-03-20	(01)00630414204192(10)16275336(17)20230320
		21333336	2022-06-20	2023-03-20	(01)00630414204192(10)21333336(17)20230320
		22318336	2022-06-20	2023-03-20	(01)00630414204192(10)22318336(17)20230320
		23066336	2022-06-20	2023-03-20	(01)00630414204192(10)23066336(17)20230320
		27947338	2022-08-29	2023-05-29	(01)00630414204192(10)27947338(17)20230529
		62967344 and higher	2022-10-26	2023-07-26	(01)00630414204192(10) 62967344(17)20230726
ADVIA Centaur Folate 500 test kit	10325366	16276336	2022-06-20	2023-03-20	(01)00630414450940(10)16276336 (17)20230320
		21334336	2022-06-20	2023-03-20	(01)00630414450940(10)21334336(17)20230320
		22079336	2022-06-20	2023-03-20	(01)00630414450940(10)22079336(17)20230320
		27946338	2022-08-29	2023-05-29	(01)00630414450940(10)27946338(17)20230529
		41225342	2022-09-30	2023-06-30	(01)00630414450940(10)41225342(17)20230630
		62966344 and higher	2022-10-26	2023-07-26	(01)00630414450940(10)62966344 (17)20230726

This issue affects all current and future lots of the ADVIA Centaur Folate assay until the Instructions for Use are updated.

Reason for Correction

Siemens Healthcare Diagnostics Inc. received customer complaints regarding a negative bias with serum samples for the ADVIA Centaur Folate assay. The Siemens investigation found the negative bias occurred when a whole blood calibration (FolateBA/FolBA) was used to test serum samples with the lots listed in Table 1. The purpose of this communication is to provide information regarding this bias and instructions on actions your laboratory must take.

Siemens previously announced the availability of improvements to the ADVIA Centaur Folate assay through the implementation of distinct calibrations for serum and whole blood samples. The

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improvements were communicated through Customer Bulletin 11641602 *(ADVIA Centaur XP and XPT Systems Folate Assay Improvement – Distinct Calibration of Serum and Whole Blood*,) available on Siemens Document Library in September 2022. The bulletin provided specific instructions which must be followed to implement the improvements for the appropriate sample type(s) used in your laboratory. Tables 2, 3 and 4 below summarize the Test Definition (TDef) and Master Curve (MC) and software requirements for each sample type. Upon receipt of kit lots ending in 336 and above, customers who utilized the FolateBA/FolBA test for serum samples as described in the Instructions for Use rather than the above mentioned bulletin may have obtained erroneously low results. Quality Control (QC) results, especially QC samples at the higher end of the assay range, may be out of range. Refer to Figure 1 in Additional Information for expected differences in results if the whole blood calibration is used for serum samples.

Customers who followed the instructions for serum samples in Customer Bulletin 11641602 are not affected.

Whole blood samples are not impacted by this issue as the ADVIA Centaur Folate (SMN 10629859) Instructions for Use provide information regarding the treatment of whole blood samples and utilization of ratio tests to generate results.

Table 2. ADVIA Centaur® XPT Software and Test Definition Requirements

SW version	Test Definition and Version	LIS Code*	Test Definition Sample Type Update
1.7 and above	FolateBA 2.3	FolateBA	Update specimen type to whole blood, remove serum
1.7 SP1	FolSerum 1.0	FolSerum	Specimen type is serum

Table 3. ADVIA Centaur® XP, XPT Sample Type, TDef and Master Curve (MC)Card Information

Sample Type	TDef Assay ID	Name on MC
Whole Blood (RBC Hemolysate)	FolateBA	FolBA
Serum	FolSerum	FolSR

***Note: For the ADVIA Centaur® XPT system the LIS Code field in the test definition is customer definable.**

Table 4. ADVIA Centaur® XP Software and Test Definition Requirements

SW version	Test Definition and Version*	LIS Code*	Test Definition Sample Type Update
7.6 SP1	1.0.EW (HBsAg customers)	FolateBA	Adds test parameters for FolSerum assay

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SW version	Test Definition and Version*	LIS Code*	Test Definition Sample Type Update
7.6 SP1	1.0.EX (HBsII customers)	FolSerum	Adds test parameters for FolSerum assay

Note: For the ADVIA Centaur® XP system you must have test definition version 1.0.CV or higher installed to update to test definition version 1.0.EW or 1.0.EX. ADVIA Centaur XP systems require software version 5.2 and higher or 7.2 and higher. For the ADVIA Centaur® XP system the LIS Code field in the test definition is customer definable.

In order to implement the enhancement to the ADVIA Centaur Folate assay and obtain correct results for serum samples, the appropriate TDef and Master Curve Card and Calibrator Value assignment and software must be used to calibrate the assay for the sample type used in your laboratory. The ADVIA Centaur Folate Instructions for Use will be updated accordingly. This issue impacts the lots listed in Table 1 and higher. However, once you have completed these instructions for one lot, no additional changes are required for subsequent lots.

Risk to Health

If this issue occurs, there is a potential for QC failures or erroneous patient results. There is negligible risk to health as the folate biases observed near the deficient/indeterminate/normal cutoffs would not lead to a clinically significant difference in patient management. Folate test results would be correlated with patient's clinical history, signs and symptoms, as well as evaluation of Vitamin B12 and other hematologic and neurologic parameters. Siemens Healthineers is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Follow the instructions in this Urgent Field Safety Notice until the ADVIA Centaur Folate Instructions for Use are updated.
- ADVIA Centaur XPT Customers:
    - Before updating to the new reagent lot, ensure you have processed all serum samples necessary for lot-to-lot comparisons using your existing inventory.
    - Once you have updated to the new reagent lot you will not be able to process serum samples with the previous reagent lot.
    - If your laboratory runs both serum and whole blood sample types, then both assays must be calibrated with the new reagent lot.
    - If your laboratory runs one sample type, calibrate only the sample type you use by disabling the TDef that is not used.
    - Update Steps for ADVIA Centaur XPT Customers

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- Note: All Folate customers should scan the FolBA MC Card first and then FolSR MC Card; this must be completed regardless of the sample type you chose to run.

    1. Ensure there are no FolateBA tests pending.

    2. Scan the FolBA MC Card for kit lots ending in 336 or higher.

    3. Confirm serum specimen type is removed. Once you have completed these instructions, no additional changes are required for subsequent lots.

- ADVIA Centaur XP Customers
    - If your laboratory runs both serum and whole blood sample types, then both assays must be calibrated with the new reagent lot.
    - If your laboratory runs one sample type, calibrate only the sample type you use.
- Once you have completed these instructions for one lot, no additional changes are required for subsequent lots.
- 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 Healthineers Customer Care Center or your local Siemens Healthineers 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 may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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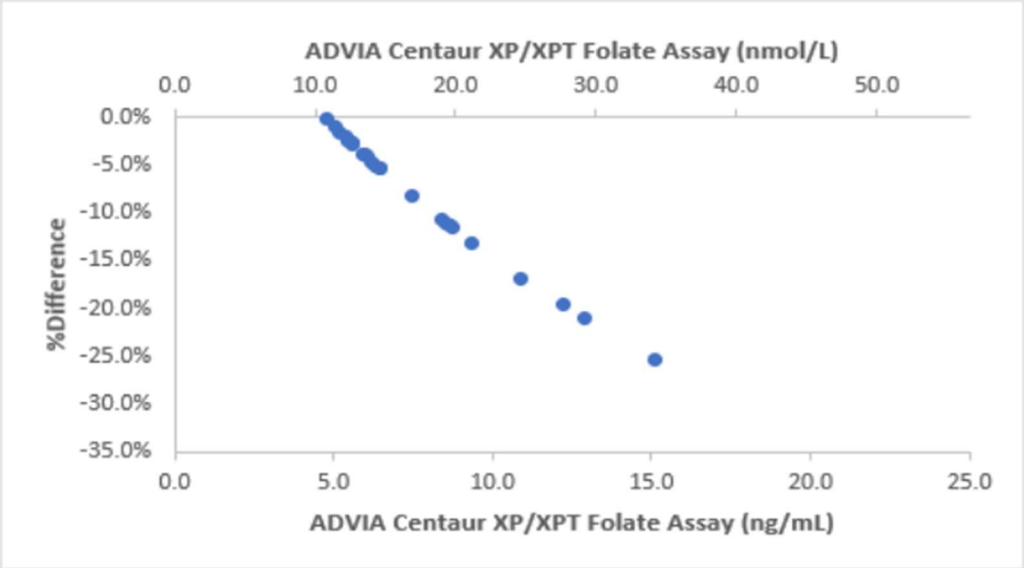
Additional Information

Figure 1 shows the percent difference observed when serum sample results are unintentionally generated using a whole blood calibration (FolateBA/FolBA) compared to results generated using the appropriate Master Curve and Calibrator Assignments for serum samples. The graph below shows biases above 10% reside in the serum folate normal range.

Figure 1: ADVIA Centaur Folate - Serum Samples



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FIELD CORRECTION EFFECTIVENESS CHECK

ADVIA Centaur Folate –Negative Bias when Customers use Whole Blood (Fol) Calibration for Serum Samples

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety notice (UFSN) AIMC 23-03.A-2.OUS dated January 2023 regarding ADVIA Centaur Folate –Negative Bias when Customers use Whole Blood (Fol) Calibration for Serum Samples Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the UFSN instructions provided in this letter. Yes ☐ No ☐

Name of Person Completing Questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Customer Sold To #: Customer Ship To #:

Please send a scanned copy of the completed form via email to XXXXXX

Or to fax this completed form to the Customer Care Center at XXXXX.

If you have any questions, contact your local Siemens Healthineers technical support representative.

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