Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 35 **dated** 14/2/2023 **Regarding NCMDR Field Safety Corrective Action of ADVIA Centaur® XP, ADVIA Centaur® XPT from (mfr: Siemens Healthcare Diagnostics Inc).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc · Email: dg-padc@moh.gov.om

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Circular No. 35 / 2023

23-07-1444 H

14-02-2023

FSCA of ADVIA Centaur® XP, ADVIA Centaur® XPT from Siemens Healthcare Diagnostics Inc.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=18424
Product	ADVIA Centaur® XP, ADVIA Centaur® XPT.
Description	Immunoassay system.
Manufacturer	Siemens Healthcare Diagnostics Inc.
Local agent	Bahwan Healthcare Center.
The affected products	ADVIA Centaur Folate 100 test kit (Material Number) 10310308, ADVIA Centaur Folate 500 test kit (Material Number) 10325366, Check attached FSN for affected lots.
Reason	Negative bias with serum samples for the ADVIA Centaur Folate assay.
Action	1. Customers to follow the instructions in this Urgent Field Safety Notice until the ADVIA Centaur Folate Instructions for Use are updated. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

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P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Medical Devices Sector

قطاع الأجهزة الطبية

NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Recall

Reference Number: mdprc 015 01 23 000

Date submitted: 1/24/2023

Back

Manufacturer:	Siemens Healthcare Diagnostics Inc.
Device Type:	ADVIA Centaur® XP, ADVIA Centaur® XPT
Description:	Immunoassay system
Medical Device Identifier:	ADVIA Centaur Folate 100 test kit (Material Number) 10310308, ADVIA Centaur Folate 500 test kit (Material Number) 10325366, Check attached FSN for affected lots.
Reason of Field Safety Corrective Action:	Negative bias with serum samples for the ADVIA Centaur Folate assay.
Remedy Action:	Customers to follow the instructions in this Urgent Field Safety Notice until the ADVIA Centaur Folate Instructions for Use are updated.
Athorized Representative/Importer/Distributor:	ABDULREHMAN AL GOSAIBI GTB
Report Source:	NCMDR
Source Ref. Number:	7D5155F747261
SFDA Comments:	SFDA urges all healthcare providers that have devices subjected to this safety alert to contact the company.
Attachments:	SIEMENS ADVIA.pdf

View History

SIEMENS Healthineers

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

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.

ADVIA Centaur is trademarks of Siemens Healthcare Diagnostics Inc.

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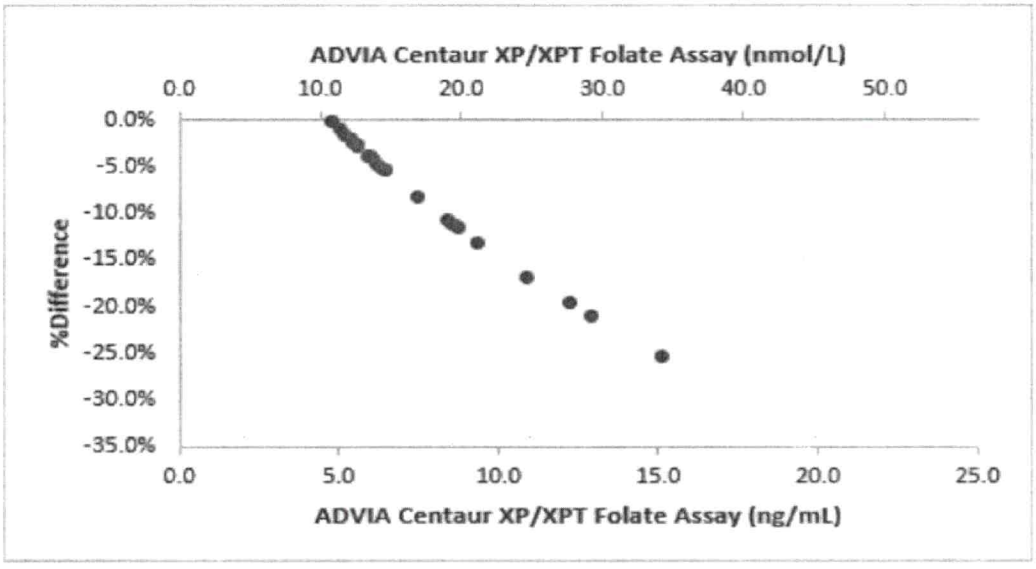
Additional Information

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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