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 111 **dated** 29/5/23 **Regarding NCMDR Field Safety Notice of Atellica CH 930 Analyzer from (mfr: Siemens Healthcare Diagnostics GmbH).**

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

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

Sultanate of Oman
Ministry of Health
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سلطنة عُمان
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مسقط

Circular No. 111 **/ 2023**

09 -11-1444 H
29 -05-2023

Field Safety Notice of Atellica CH 930 Analyzer from Siemens Healthcare Diagnostics GmbH.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19518
Product	Atellica CH 930 Analyzer.
Description	IVD.
Manufacturer	Siemens Healthcare Diagnostics GmbH.
Local agent	Diamond Stone Investment.
The affected products	Product: Atellica CH Toxicology Calibrator (TOX CAL) Siemens Material Number (SMN): 11099440 Unique Device Identification (UDI): 00630414597614 Lot Numbers: 74285306, 74536672, 74732386 Expiration Date: 2023-05-31, 2024-03-31, 2024-11-30 Manufacturing Date: 2021-05-04, 2022-03-22, 2022-11-21
Reason	Positive bias for the Atellica CH Salicylate (Sal) assay on proficiency surveys
Action	1. Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable. 2. Until the updated lot-specific value sheets are available on Document Library, keep a copy of the attached FSN as a reference for the updated salicylate calibrator values. 3. Perform the instructions provided in Additional Information section in the attached FSN. 4. 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
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

SIEMENS Healthineers

Urgent Field Safety Notice

ACHC23-03.A.OUS

April 2023

Atellica CH® 930 Analyzer

Reassignment of the Atellica CH Toxicology Calibrators (TOX CAL) for the Atellica CH Salicylate (Sal) Assay

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

Table 1. Atellica CH 930 Affected Product(s)

Product	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Numbers	Expiration Date	Manufacturing Date
Atellica CH Toxicology Calibrator (TOX CAL)	11099440	00630414597614	74285306 74536672 74732386	2023-05-31 2024-03-31 2024-11-30	2021-05-04 2022-03-22 2022-11-21

Reason for Correction

The purpose of this communication is to inform you of an issue with the product indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. received customer complaints regarding a positive bias for the Atellica CH Salicylate (Sal) assay on proficiency surveys. During our investigation of these complaints, comparison studies were performed with the Atellica CH Sal assay and the internal HPLC reference method using quality control material, calibrators, and spiked serum samples. Assay comparisons produced an average linear regression slope of 1.18, confirming the positive bias reported. This bias is observed across the measuring interval (refer to Figures 1 and 2 in the Additional Information section).

To correct for the positive bias and to better align with the internal reference method, the values for Atellica CH Toxicology Calibrator (TOX CAL) lots 74285306, 74536672, and 74732386 have been adjusted. After adjustment, the representative data produced a linear regression slope of 0.97 to the internal HPLC method.

Refer to Table 2 in the Additional Information section for the reassigned Sal calibrator values. Revision 2 of the calibrator lot-specific value sheets are in preparation and will be available on Document Library soon. There are no changes to the assigned values of the other analytes contained in the Atellica CH TOX CAL.

Patient and QC results are expected to shift approximately -18% when using the reassigned calibrator values. Based on the negative shift, it may be necessary to adjust your laboratory's QC ranges. Refer to Table 3 in the Additional Information section for representative QC data.

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Tarrytown, NY 10591

Siemens Healthcare Diagnostics is actively investigating the root cause and is implementing changes to manufacturing processes to prevent this issue from recurring.

Risk to Health

This issue leads to erroneously elevated salicylate results which may lead to increased patient monitoring and repeat testing with a negligible potential for injury. Results would be used with clinical signs and symptoms, other laboratory tests and serial salicylate testing of patient samples.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Until the updated lot-specific value sheets are available on Document Library, keep a copy of this letter as a reference for the updated salicylate calibrator values.
- Perform the instructions provided in Additional Information section below.
- 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.

Additional Information

Perform a lot calibration for the salicylate assay:

- Remove and discard any opened salicylate reagent packs onboard.
- Enter the reassigned value from Table 2 for the calibrator lot in use in your laboratory.
- Load a fresh reagent pack and perform a lot calibration (not a pack calibration).
- Review QC targets and ranges and adjust accordingly.

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Table 2. Current and Reassigned Sal Values for Atellica CH TOX CALs

Calibrator Lot	Current Value (mg/dL)	Reassigned Value (mg/dL)	Current Value (mmol/L)	Reassigned Value (mmol/L)
74285306	25.9	21.2	1.88	1.54
74536672	26.2	21.5	1.90	1.56
74732386	26.6	21.8	1.93	1.58

Table 3. Representative Quality Control Data for Bio-Rad Liquid Assayed Multiqual Control

	With Current Calibrator Value				With Reassigned Calibrator Value			
Quality Control	Mean (mg/dL)	Range (mg/dL)	Mean (mmol/L)	Range (mmol/L)	Mean (mg/dL)	Range (mg/dL)	Mean (mmol/L)	Range (mmol/L)
Level 1 45911	6.38	4.62 - 8.14	0.462	0.335 - 0.590	5.23	3.79 - 6.67	0.379	0.275 - 0.484
Level 2 45912	13.8	11.7 - 15.8	0.996	0.844 - 1.15	11.3	9.59 - 13.0	0.817	0.692 - 0.943
Level 3 45913	18.8	16.5 - 21.2	1.36	1.19 - 1.53	15.4	13.5 - 17.4	1.12	0.976 - 1.25

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Figure 1. Internal HPLC (Reference Method) vs Atellica CH Sal Method Comparison (mg/dL) Before Calibrator Reassignment

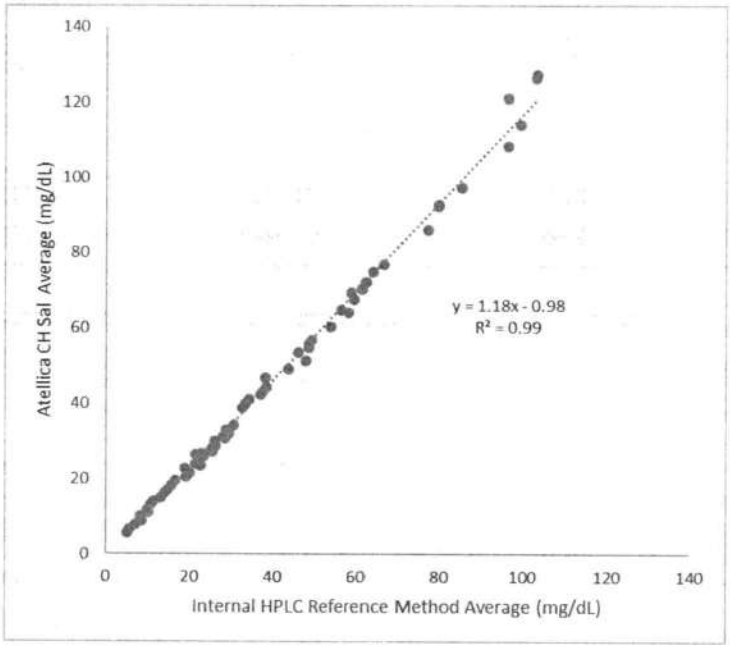
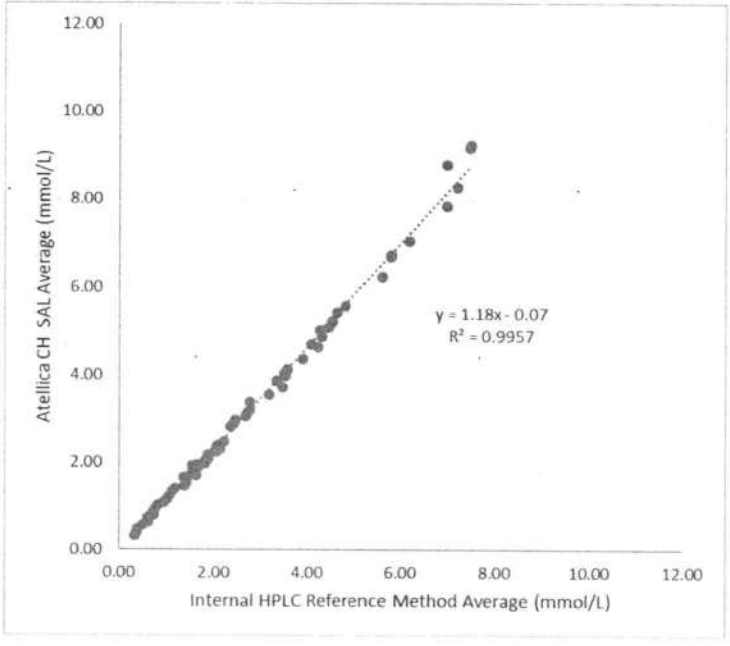


Figure 2. Internal HPLC (Refence Method) vs Atellica CH Sal Method Comparison (mmol/L) Before Calibrator Reassignment



Atellica is a trademark of Siemens Healthcare Diagnostics Inc.

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FIELD CORRECTION EFFECTIVENESS CHECK

Reassignment of the Atellica CH Toxicology Calibrators (TOX CAL) for the Atellica CH Salicylate (Sal) Assay

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) ACHC23-03.A.OUS dated April 2023 regarding Reassignment of the Atellica CH Toxicology Calibrators (TOX CAL) for the Atellica CH Salicylate (Sal) Assay. 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 ☐
2. In the table below, please indicate in the number of open salicylate reagent packs discarded during the recalibration process.

Product Description and SMN #	Replacement Quantity Required
Atellica CH Salicylate (Sal) Reagent 11097523	

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 XXXX@XXXX.

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

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

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