

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	2023-05-31	2021-05-04
			74536672	2024-03-31	2022-03-22
			74732386	2024-11-30	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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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 Multiquel Control

Quality Control	With Current Calibrator Value				With Reassigned Calibrator Value			
	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

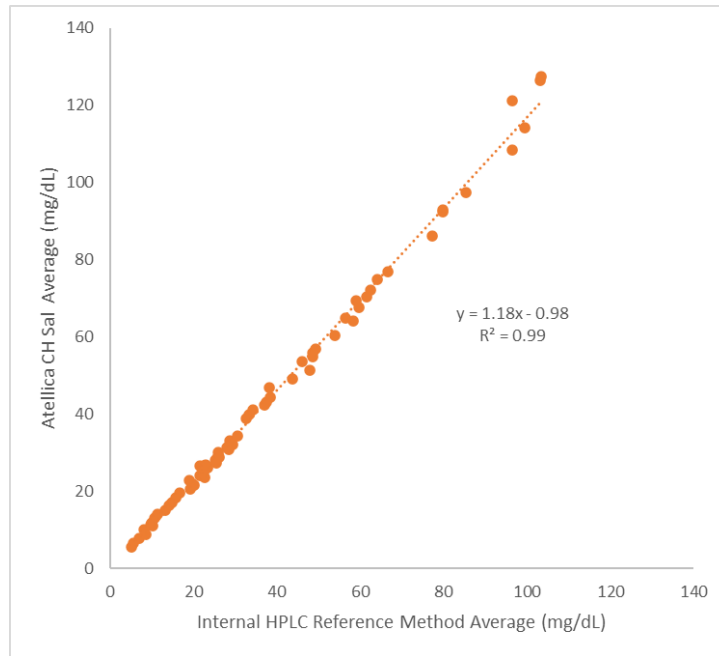
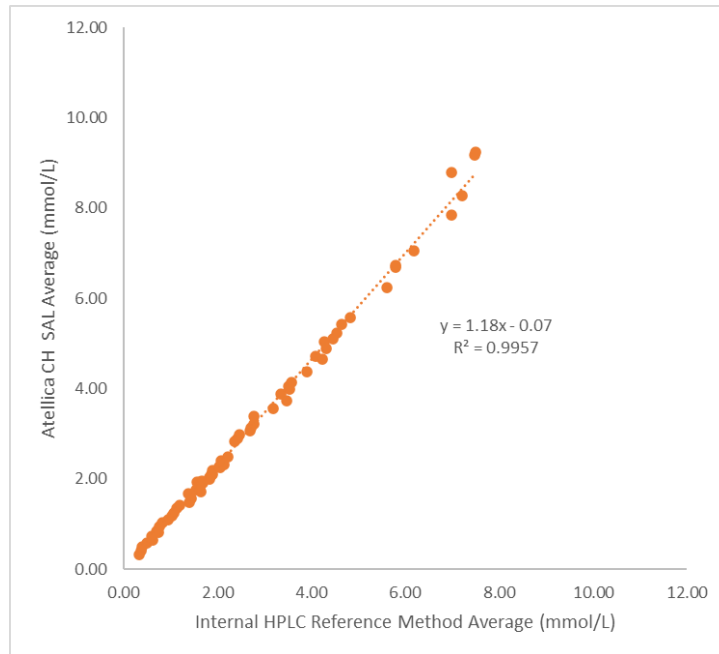


Figure 2. Internal HPLC (Reference Method) vs Atellica CH Sal Method Comparison (mmol/L) Before Calibrator Reassignment



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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.