SIEMENS Healthineers

Urgent Field Safety Notice

ACHC23-03.A.OUS.CHC

April 2023

ADVIA® 1800 Chemistry System

ADVIA® 2400 Chemistry System

ADVIA® Chemistry XPT

Reassignment of the ADVIA Chemistry ToxAmmonia Calibrators for the ADVIA Chemistry Salicylate (SAL) Assay

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

Table 1. ADVIA Chemistry Affected Product(s)

Product	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Numbers	Expiration Date	Manufacturing Date
ADVIA Chemistry ToxAmmonia Calibrator	10309217	00630414479286	9520531 9520341	2023-05-31 2024-03-31	2021-05-04 2022-03-22

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 ADVIA Chemistry Salicylate (SAL) assay on proficiency surveys. During our investigation of these complaints, comparison studies were performed with the ADVIA Chemistry 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 1.24, 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 ADVIA Chemistry ToxAmmonia Calibrator lots 9520341 and 9520531 have been adjusted. After adjustment, the representative data produced a linear regression slope of 1.02 to the internal HPLC method.

Refer to Table 2 in the Additional Information section for the reassigned SAL calibrator values. Calibrator lot-specific value sheets reflecting values from Table 2 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 ADVIA Chemistry ToxAmmonia Calibrator.

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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.

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 10 working 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 1800-815-508 or your local Siemens Healthineers technical support representative.

Additional Information

To recalibrate the method, follow the instructions below:

- For ADVIA 1800/2400
    - While the analyzer is in Ready state, through the calibration setup window, replace the current factor value (FV) with the adjusted factor value from Table 2.
    - Perform a Restart of the software.

- Calibrate the assay with the adjusted factor value (FV).
- If the calibration fails due to calibration tracking:
    1. Select the Calibration icon.
    2. Open the Calibration/RBL History Window.
    3. Locate the most recent passing salicylate calibration and select the Reset checkbox.
    4. Select save.
    5. Recalibrate the assay with the adjusted factor value (FV) from Table 2 and run quality control material.
- Review QC targets and ranges and adjust accordingly.

- For ADVIA XPT
    - While the analyzer is in Ready state, through the calibrator definition window, edit the active calibrator definition and replace the current factor value (FV) with the adjusted factor value from Table 2.
    - Perform a Restart of the software.
    - Calibrate the assay with the adjusted factor value (FV).
    - If the calibration fails due to calibration tracking:
        1. Select the Calibration icon, then select the Chemistry tab.
        2. Locate the most recent passing salicylate calibration and select the Reset box.
        3. Recalibrate the assay with the adjusted factor value (FV) from Table 2 and run quality control material.
    - Review QC targets and ranges and adjust accordingly.

Table 2. Current and Reassigned SAL Values for ADVIA Chemistry ToxAmmonia Calibrators

Calibrator Lot	Current Value (mg/dL)	Reassigned Value (mg/dL)	Current Value (mmol/L)	Reassigned Value (mmol/L)
9520341	26.5	21.7	1.92	1.57
9520531	26.5	21.7	1.92	1.57

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	6.43	3.37 - 9.50	0.466	0.244 - 0.688	5.27	<3.00 - 7.79	0.382	<0.200 - 0.564
Level 2 45912	14.7	11.5 - 17.9	1.07	0.836 - 1.30	12.1	9.43 - 14.7	0.877	0.686 - 1.07
Level 3 45913	19.3	16.0 - 22.6	1.40	1.16 - 1.63	15.8	13.1 - 18.5	1.15	0.951 - 1.34

Figure 1. Internal HPLC (Refence Method) vs ADVIA Chemistry SAL Method Comparison (mg/dL) Before Calibrator Reassignment

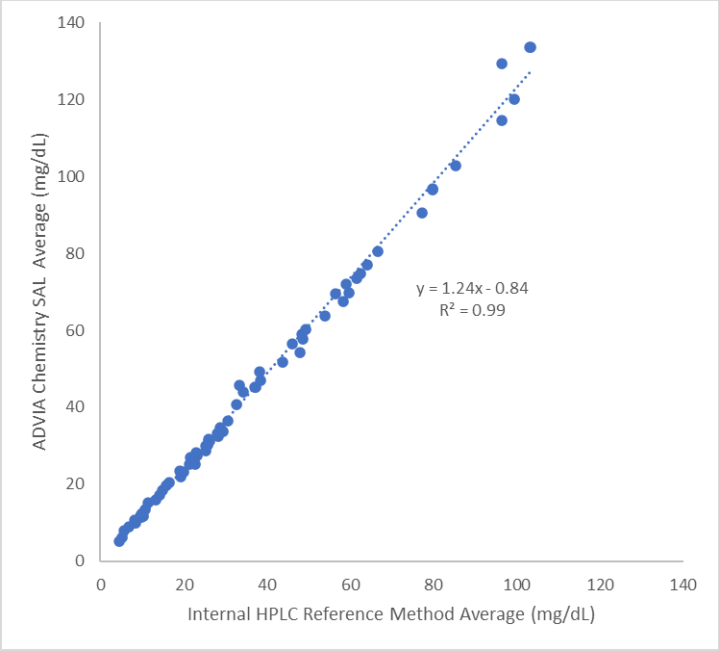
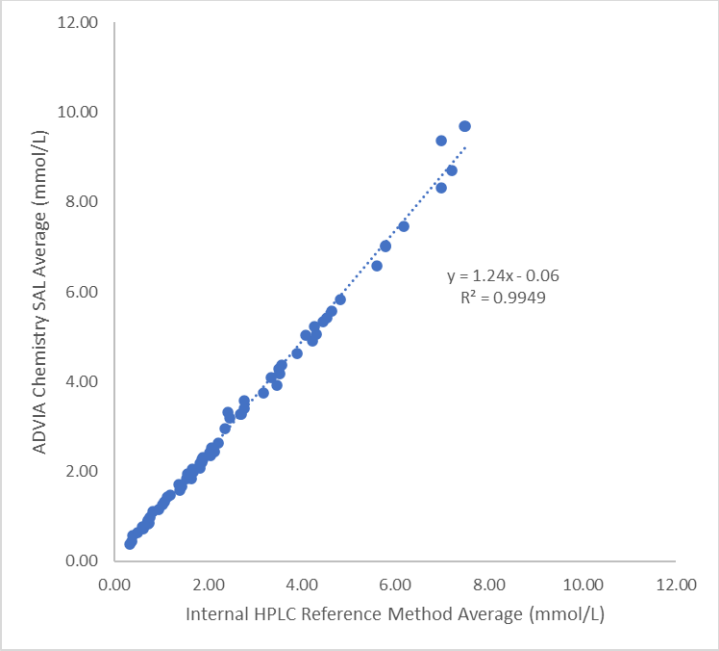


Figure 2. Internal HPLC (Refence Method) vs ADVIA Chemistry SAL Method Comparison (mmol/L) Before Calibrator Reassignment



FIELD CORRECTION EFFECTIVENESS CHECK

Reassignment of the ADVIA Chemistry ToxAmmonia Calibrator for the ADVIA Chemistry 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.CHC dated April 2023 regarding Reassignment of the ADVIA Chemistry ToxAmmonia Calibrator for the ADVIA Chemistry Salicylate (SAL) Assay. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Sdn Bhd 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:

Please send a scanned copy of the completed form via email to fscareportingunit.my@siemens-healthineers.com

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

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