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Urgent Field Safety Notice:

Atellica® CH 930 Analyzer

Falsely Depressed Enzymatic Hemoglobin A1c (A1c_E and A1c_H) Results due to Reagent Carryover from the Urinary/Cerebrospinal Fluid Protein (UCFP) Assay

Dear Sirs,

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

Table 1. Atellica CH Product

Assay	Test Code	Siemens Material Number (SMN)	Lot Number
Atellica CH Urinary/Cerebrospinal Fluid Protein	UCFP	11097543	All lots

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. has confirmed the potential for Atellica CH Urinary/Cerebrospinal Fluid Protein reagent carryover impacting Enzymatic Hemoglobin A1c (A1c_E and A1c_H) results. Falsely depressed Enzymatic Hemoglobin A1c results are observed when the assay is processed after the UCFP test on the Atellica CH 930 Analyzer (See tables 2-3). This issue can impact A1c_E/A1c_H results for quality control (QC), patient samples, and calibrators. No other assays are impacted by UCFP reagent carryover on the Atellica CH 930 Analyzer.

Investigation of this issue indicates that use of Reagent Probe Cleaner 1 (RPC1) wash in place of Reagent Probe Cleaner 2 (RPC2) wash is an effective mitigation in preventing UCFP reagent carryover.

The resolution of this issue will be implemented in SW v1.25.1 which will be available soon. In the interim, please follow the instructions in the “Additional Information” section.

Table 2. Impact of UCFP carryover on Hemoglobin A1c (%) Results

Sample	A1c_E result (%)	A1c_E result after UCFP (%)	% Bias
QC L1	5.06	4.00	-21
Patient Pool 1	7.46	6.73	-10
QC L2	8.56	6.74	-21
Patient sample 1	12.14	9.04	-26

Table 3. Impact of UCFP carryover on Hemoglobin A1c (mmol/mol) Results

Sample	A1c_E result (mmol/mol)	A1c_E result after UCFP (mmol/mol)	% Bias
QC L1	31.8	20.2	-36
Patient Pool 1	58.0	50.0	-14
QC L2	70.0	50.2	-28
Patient sample 1	109.2	75.3	-31

Risk to Health

In scenarios where Hb A1c is run after UCFP, the potential exists for misinterpretation of Hb A1c levels, which may affect consideration of intervention. Clinical impact would be mitigated by correlation to clinical history and symptomology as well as to additional laboratory testing such as blood glucose values and/or serial Hb A1c testing. Siemens is not recommending a review of previously generated results.

Additional Information

- If your laboratory has multiple Atellica CH 930 Analyzers, Siemens recommends testing the Atellica CH UCFP assay on a separate analyzer from the A1c_E/ A1c_H assay.
- If your laboratory has only one Atellica CH 930 Analyzer and UCFP is being processed, the instrument must go into standby status before processing A1c_E/A1c_H tests. Going into standby initiates the RPC1 wash

mitigation. To minimize standby instances and workflow disruption, batch testing the UCFP or A1c_E/A1c_H assays may be considered.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- 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.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

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