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Urgent Field Safety Notice:

Atellica CH Analyzer
Atellica CI Analyzer
Potential for Depressed Results with Atellica CH Enzymatic Hemoglobin A1c when Processing Atellica CH Revised C-Reactive Protein on the Same Analyzer

To whom it may concern,

Our records indicate that you have received:

Assay	Test Code	Siemens Material Number / Unique Device Identification	Lot Number
Atellica CH Enzymatic Hemoglobin A1c (A1c_E)	A1c_E, A1c_H	11097536 / 00630414220505	All lots

Siemens Healthineers has confirmed, through investigation of customer complaints, a potential for depressed results with the Atellica CH Enzymatic Hemoglobin A1c (A1c_E) assay when processing the Atellica CH Revised C-Reactive Protein (RCRP) assay on the same analyzer.

Based on the review of global customer data:

- Customers processing A1c_E and RCRP on separate analyzers are not impacted.
- When both assays are run on the same analyzer, depressed A1c_E results may occur. The frequency and magnitude of the negative bias and imprecision increase over time and are not consistent with the assay Instructions For Use (IFU).
- A higher proportion of RCRP tests to total photometric tests increases the likelihood of observing the issue.
- When this issue is present, Quality Control (QC) results demonstrate a negative trend and increased imprecision.
- QC result behavior is consistent with observed impact to patient sample results.
- This issue is not reagent lot specific.
- There is no indication that other assays are affected.

Siemens Healthineers is actively investigating the root cause and the resolution for this issue.

Impact to Results

There is a potential for falsely depressed A1c_E results if this issue occurs. If QC results fall outside established ranges, an apparent delay to testing may occur. Based on available data from a small subset of customer sites, maximum observed bias and imprecision estimates are provided in Tables 1 and 2 of the Appendix.

The magnitude of negative bias and imprecision increase over time and with RCRP testing volume. Representative longitudinal QC data from a customer site are included in Figures 1 and 2 in the Appendix. As with all laboratory testing, results of this test should always be interpreted in conjunction with the patient's medical history and other findings.

Customer Actions

- **If your laboratory is not processing RCRP and A1c_E on the same analyzer, no action is required.**
- If your laboratory is processing RCRP and A1c_E on the same analyzer, monitor A1c_E QC for evidence of negative bias and increased imprecision.
- If QC concerns are not resolved through routine troubleshooting:

  For customers with multiple Atellica CH or Atellica CI analyzers:

  - Separate A1c_E and RCRP onto different analyzers.
  - After separation, replace all reaction cuvettes on the analyzer designated for A1c_E testing.

  For customers with a single Atellica CH or Atellica CI analyzer:

  - Contact your Siemens Healthineers Customer Care Center or your local technical support representative for further instruction.
- Please review this letter with your Medical Director to determine the appropriate course of action, including evaluation of any previously generated results, if applicable.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- Retain this letter with your laboratory records and forward it to others who may have received this product.

Resolution

A follow-up communication will be provided when "Customer Actions" are no longer required.

We appreciate your continued partnership and apologize for any inconvenience this situation may cause. If you have any questions or require assistance, please contact your Siemens Healthineers Customer Care Center or your local technical support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Electronically signed by: Gudrun Kapl
Reason: I have reviewed this document
Date: Mar 3, 2026 14:05:00 GMT+1

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Legal Form: Gesellschaft mit beschraenkter Haftung; Company Seat: Vienna; Commercial Court Registration: FN 135042 t; Commercial Court: Vienna; DVR: 0816540

Appendix

Figure 1. Representative set of impacted QC Level 1 (Blue; left) and 2 (Orange; right) results in National Glycohemoglobin Standardization Program (NGSP) units (%A1c)

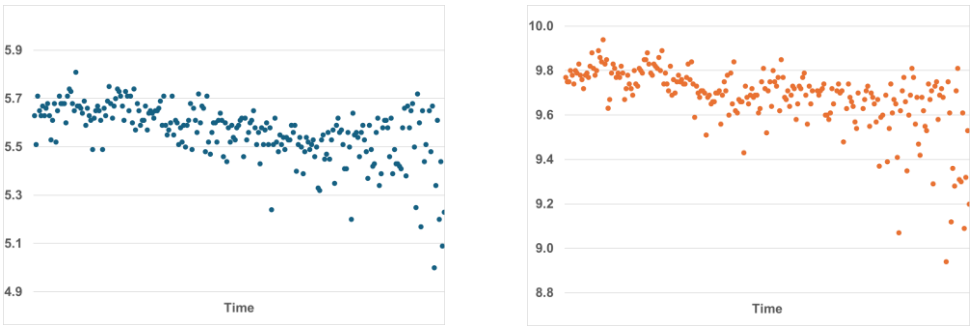

Figure 2. Representative set of impacted QC Level 1 (Blue; left) and 2 (Orange; right) results in International Federation of Clinical Chemistry (IFCC) units (mmol/mol)

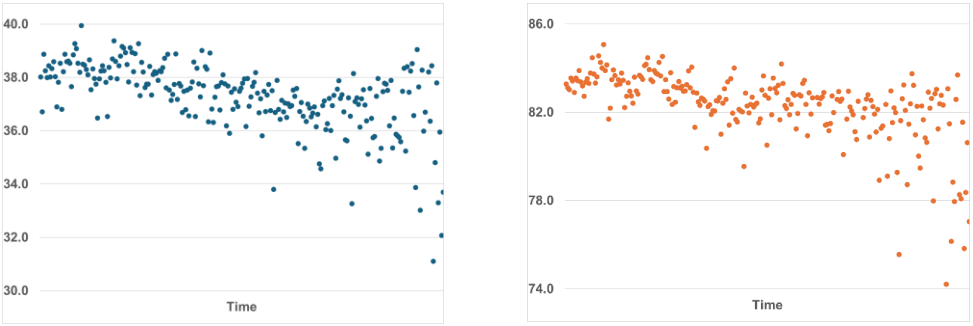

Table 1. Maximum bias observed

NGSP units (%A1c)			IFCC units (mmol/mol)		
	QC1	QC2		QC1	QC2
Expected Result	5.60	9.70	Expected Result	37.71	82.51
Observed	4.44	8.94	Observed	24.59	74.21
% Bias (relative)	-21%	-8%	% Bias (relative)	-35%	-10%

Table 2. Maximum imprecision observed

NGSP units (%A1c)			IFCC units (mmol/mol)		
	QC1	QC2		QC1	QC2
Concentration	5.43	9.55	Concentration	32.98	80.89
Within-Lab %CV	8.7%	2.1%	Within-Lab %CV	11.0%	2.8%