Urgent Field Safety Notice

ACHC26-06.A.OUS

Atellica CH Analyzer
Atellica CI Analyzer

Title Potential for Well-to-Well Bias Affecting Atellica Enzymatic Hemoglobin A1c Assay Results

Date Issued JUN-2026

Products

Assay	Test Codes	Siemens Material Number/ Unique Device Identification	Lot Numbers
Atellica CH Enzymatic Hemoglobin A1c (A1c_E)	A1c_E A1c_H	11097536 / 00630414220505	All in-date lots

Issue Description

Siemens Healthineers has confirmed, through internal investigation of customer complaints, the potential for intermittent well-to-well bias affecting the A1c_E/A1c_H assay when used on the Atellica CH and Atellica CI systems.

This observed bias does not affect every A1c_E reagent lot or reagent pack. However, affected wells cannot currently be identified prospectively, therefore all in-date lots are considered potentially impacted until further notice. Under certain circumstances, this issue may result in:

- Falsely depressed patient results when lot calibration is performed using an affected well and patient testing is subsequently performed using an unaffected well.
- Falsely elevated patient results when lot calibration is performed using an unaffected well and patient testing is subsequently performed using an affected well.

To support continued use of the assay while ensuring result quality, Siemens Healthineers is implementing the customer actions described below.

Detailed instructions are provided in Appendices A and B. Representative performance data is provided in Appendix C.

Impact to Results

Erroneously elevated or depressed A1c results may occur due to the issue described. Representative data is shown in Appendix C, Table 1. These maximum differences may occur across the measuring interval. Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Customer Actions

- Siemens Healthineers is instructing customers to perform QC on each reagent well used for all A1c_E/A1c_H testing.
- Enable "QC on Pack Change By Assay Type" to ensure QC is performed whenever testing transitions between wells.

  Please note that enabling this setting will apply "QC on Pack Change" for all CH assays**.** For CH assays where this functionality is not required, QC levels should be deselected within the QC Master List. Refer to Appendix A for detailed instructions.

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If your lab is using the Atellica CH to monitor QC:

- Enable Patient QC Flagging to allow identification of potentially impacted patient results following a QC failure. Refer to Appendix B for detailed instructions.

  Note: All potentially impacted patient results will display a "QC Fail" flag. Results displaying this flag must be held from reporting and rerun after passing QC is obtained.
- Upon QC failure:
  - Unload the reagent pack and load a new pack.
  - Repeat QC testing.
  - After acceptable QC results are obtained, repeat all A1c_E/A1c_H patient testing associated with results flagged with "QC Fail."

If your lab uses the Atellica Data Manager or other middleware to monitor QC:

- Following a QC failure, hold all A1c_E/A1c_H samples processed after the failed QC event for review.
- Unload the reagent pack and load a new pack.
- Repeat QC testing.
- After acceptable QC results have been obtained, repeat any held A1c_E/A1c_H samples since the failed QC event.

- If repeated QC failures occur across consecutive wells, follow your laboratory's standard troubleshooting procedures to evaluate potential alternative causes for QC failure.
- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.
- As a result of these actions, track reagent inventory, associated with implementation of these actions, to report to Siemens Healthineers once a resolution is provided.

Resolution

A follow-up communication will be provided once the "Customer Actions" described above are no longer required. The follow-up communication will include an option for reporting A1c_E reagent inventory, including additional and/or discarded A1c_E/A1c_H tests or wells, to Siemens Healthineers for credit.

Single Registration Number (SRN)

US-MF-000016560

We apologize for the inconvenience this situation may cause and appreciate your partnership as we work toward resolution. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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Appendix A (All Atellica Analyzers)

Enabling QC on Pack Change By Assay Type

Refer to Atellica Solutions Online Help/Atellica CI Analyzer Online Help for more detailed information on these settings.

1. From the System Navigator icon under QC, select **QC Settings**.
2. Under QC Mode Settings, select **By Assay Type**.
3. For CH, click the drop-down menu for **QC on Pack Change,** choose **Enable,** and select **Save**.
4. Under QC settings, click on **QC Master List** and search for A1c_E or A1c_H.
5. If pack change is not set to "All," click **Setup** and select all QC levels.
6. For CH assays where QC on Pack Change is *not* required, expand the QC list, deselect all QC levels, and select **Save**.

Appendix B (Labs using the Atellica Analyzer to monitor QC)

Enabling Patient QC Flagging

Refer to Atellica Solutions Online Help/Atellica CI Analyzer Online Help for more detailed information on these settings.

1. From the System Navigator icon under QC, select **Patient QC Flagging.**
2. Select **A1c_E** or **A1c_H**, then **Edit/View**, select **Automatic** and click **Save**.
3. Ensure Patient QC Flagging is set to **Automatic**.

Appendix C

Table 1. Representative Atellica CH A1c_E/A1c_H Performance Data

Maximum Observed Well-to-Well Bias

	NGSP Unit (%HbA1c)		**IFCC Unit (mmol/mol)**	
	Expected Result	**Absolute Bias**	**Expected Result**	**Absolute Bias**
Falsely Depressed	5.77	-0.70	39.57	-7.60
Falsely Elevated	5.71	4.45	38.95	48.59

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