Urgent Field Safety Notice

ACHC26-08.A.OUS

Atellica CH Analyzer
Atellica CI Analyzer

Title

Potential Reagent Carryover Associated with Atellica CH HDL Cholesterol (HDLC) and Atellica CH Total Protein_2 (TP_2)

Date Issued

Sep-2026

Products

Assay / Test Code	Siemens Material Number / Unique Device Identification	Lot Number
Atellica CH HDL Cholesterol (HDLC)	11537213 / 00630414610832	All lots
Atellica CH Total Protein_2 (TP_2)	11537228 / 00630414611082	All lots
	11645755 / 00630414654010	All lots

If your laboratory does not run these assays, no action is required.

Issue Description

Siemens Healthineers has confirmed, through the investigation of customer complaints, the potential for reagent carryover on the Atellica CH and Atellica CI Analyzers. If carryover occurs, it may affect patient samples, quality control (QC), and/or calibrator results.

For the Atellica CH Analyzer:

- Carryover from Atellica CH HDL Cholesterol (HDLC) may cause falsely elevated Atellica CH Enzymatic Hemoglobin A1c (A1c_E, A1c_H) results.

For the Atellica CI Analyzer:

- Carryover from Atellica CH HDL Cholesterol (HDLC) may cause falsely elevated Atellica CH Enzymatic Hemoglobin A1c (A1c_E) results.
- Carryover from Atellica CH Total Protein (TP_2) may cause falsely depressed Atellica CH Direct Bilirubin 2 (DBil_2) results. This interaction does not occur on the Atellica CH Analyzer.

Impact to Results

If carryover occurs, A1c_E/A1c_H results may be falsely elevated, or DBil_2 results may be falsely depressed. Representative biases are shown in Appendix A Table 2 and Table 3, respectively. Assay results should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Customer Actions

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- The Clean 2 probe wash is incorporated in the following Test Definitions Update Packages, which will be available soon:
    - Atellica Solution CH Test Definition Update Package Version 1.2.1
    - Atellica CI Analyzer CH Test Definition Update Package Version 1.2.1

  Note: Customers whose systems are connected to Siemens Remote Services (SRS) may self-install the applicable version.

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- To receive the updated Test Definitions, confirm that your systems are running the following commercially available system software versions:
    - Atellica CH Analyzer Software Version 1.31.1
    - Atellica CI Analyzer Software Version 1.31.51

  Note: The updated Test Definitions can be installed only after the system has been updated to the applicable system software version listed above.
- Once the applicable system software version has been installed and Test Definition Update Package Version 1.2.1 becomes available on your system, follow the installation instructions in the accompanying Release Notes.
- Until the applicable system software versions and Test Definitions have been installed, follow the interim instructions in Appendix B or Appendix C, depending on your current software version.
- If both the applicable system software version and updated Test Definitions are already installed, no further system action is required. For instructions to verify if the Test Definition Update Package Version 1.2.1 has been installed, see Appendix D.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

Resolution The addition of a Clean 2 probe wash addresses these potential interactions.

Single Registration Number (SRN) US-MF-000016560

We 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 Siemens Healthineers technical support representative.

Appendix A Additional Data Describing the Product Issue

Table 2. Impact of HDLC on A1c patient sample results on the Atellica CH and Atellica CI

NGSP Unit (%)			IFCC Unit (mmol/mol)		
A1c	**A1c after HDLC**	**% Bias**	**A1c**	**A1c after HDLC**	**% Bias**
4.58	5.56	21%	26.54	37.25	40%
4.87	6.02	24%	29.71	42.28	42%
5.36	6.45	20%	35.07	46.98	34%
5.70	7.14	25%	38.78	54.53	41%
6.77	7.74	14%	50.48	61.08	21%

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6.87	8.24	20%	51.57	66.55	29%
6.96	8.43	21%	52.56	68.63	31%
7.22	8.81	22%	55.40	72.78	31%
7.76	10.01	29%	61.30	85.90	40%
8.01	9.66	21%	64.04	82.07	28%
8.47	9.57	13%	69.06	81.09	17%
8.71	9.49	9%	71.69	80.21	12%

Table 3. Impact of TP_2 on DBil_2 results on the Atellica CI

Sample Type	**DBil_2 mg/dL (µmol/L)**	**DBil_2 after TP_2 mg/dL (µmol/L)**	**% Bias**
QC	0.2 (3)	0.2 (3)	0%
QC	1.2 (21)	0.9 (15)	-25%
QC	2.4 (41)	1.9 (32)	-21%
Serum	7.7 (132)	7.0 (120)	-9%

Note: This interaction does not occur on the Atellica CH Analyzer

Appendix B Interim instructions for Atellica CH Analyzers with Atellica Solution Software 1.29 and above

A Clean 2 probe wash, programmable by the user in the User Interface, is needed for mitigation of HDLC carryover into Atellica CH A1c_E and A1c_H assays.

1. Follow the Online Help Section "*Preparing to Configure or Edit Assay Test Definitions*," to prepare the system to save changes to the assay Test Definition for the **A1c_E/A1c_H** assays.
2. Navigate to **CH Test Definition**, and under the **Assay** dropdown, select the A1c_E or A1c_H assay.
3. Select **Mitigation** and then **Add Mitigation.**
4. In Donor Assay, select **HDLC.** In Target, select **Reagent.**
5. In Mitigation Reagent, select **Clean 2** and select **Save.**
6. Read the warning statement and then select **Yes.**

For additional guidance on these steps, refer to the Atellica Solution Online Help.

Appendix C Interim instructions for Atellica CH Analyzers with Atellica Solution Software below 1.29 and Atellica CI Analyzers (all software versions)

The ability for users to program a probe wash for Chemistry tests is not available.

If the laboratory has multiple analyzers, customers can separate the assays by performing testing of HDLC on an analyzer separate from A1c_E/A1c_H, and TP_2 on an analyzer separate from DBil_2.

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If the laboratory chooses not to separate the assays as indicated above, batch testing may be performed.

Note: When batch testing, a Clean 2 probe wash must be initiated after completion of HDLC and prior to A1c_E/A1c_H, and after completion of TP_2 and prior to DBil_2. Any of the following will initiate the Clean 2 probe wash:

- After the analyzer has been in Standby status for 12 minutes.
- After completion of any open channel assay.
- After restarting the PCC workstation and all modules. Refer to the Atellica Solution Online Help/ Atellica CI Analyzer Online Help for instructions on system restart.

Appendix D Instructions to verify if the CH Test Definition Update Package Version 1.2.1 has been installed

1. From the System Navigator, under General, select Software Updates and review the list for the following:
    - For Atellica Solution: Atellica CH Test Definition 1.2.1.6
    - For Atellica CI: Atellica CH Test Definition 1.2.1.4
2. If the above Atellica CH Test Definition is visible in the list, no further action needs to be taken.

If the above Atellica CH Test Definition is not visible in the list, follow the instructions in Appendix B or Appendix C (depending on your current software version) until such time when the Atellica CH Test Definition Update Package 1.2.1 becomes available on your system.

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