Follow-up Urgent Field Safety Notice

ACHC25-07.B.OUS

Atellica CH Analyzer
Atellica CI Analyzer

Title Potential for Falsely Depressed Results with the Atellica CH UCFP Assay

Date Issued Aug-2025

Products

Assay	Test Code	Siemens Material Number / Unique Device Identification	Lot Number
Atellica CH Urinary/Cerebrospinal Fluid Protein	UCFP	11097543 / 00630414279206	All lots

Issue Description

Siemens Healthineers previously issued an Urgent Field Safety Notice (ACHC25-07.A.OUS) communicating the potential for falsely depressed patient, quality control (QC), and/or calibration results with the Atellica CH UCFP assay. The initial Urgent Field Safety Notice included instructions to change the well status setting to "Empty" in certain scenarios. This follow-up communication provides a set of simplified instructions in the Customer Actions section below.

All future lots are impacted until further notice. Siemens is working to determine root cause and restore the assay performance.

See "Appendix" for Detailed Customer Instructions.

Impact to Results

When this issue occurs, there is a potential for falsely depressed result(s). If QC or calibration is affected, an apparent delay in testing may occur. The maximum negative bias observed during the investigation was -19.0 mg/dL (-190 mg/L), which may occur across the measuring interval. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Customer Actions

- Moving forward, keep only one (1) Atellica CH UCFP reagent pack onboard the system at a time.
- Unload any Atellica CH UCFP packs that are currently onboard the system.
- Siemens is instructing customers to perform QC on each well. Follow the instructions provided below:
  - Enable QC on Pack Change By Assay Type for CH to allow for QC to be processed when switching between wells. (See "Appendix" for detailed instruction)

    Note: This setting enables QC on Pack Change for all CH assays. All QC Levels for CH assays for which this is not required should be deselected in the QC Master List.

- **If your lab is using the Atellica to monitor QC:**
  - Enable Patient QC Flagging to allow for impacted patient results to be identified after a QC failure. (See "Appendix" for detailed instruction)

    Note: All impacted patient results will have a "QC Fail" flag. Ensure that a result with a flag of "QC Fail" is held for review so that it can be rerun after passing QC.

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- Upon QC failure, manually reorder QC.
- Verify that QC results are passing. Once acceptable QC has been obtained, repeat all UCFP testing for all patient results flagged with "QC Fail."
  - If QC results are still unacceptable after 2 attempts, unload the reagent pack and replace with a fresh pack.
  - If you experience repeated QC issues on consecutive wells, follow your laboratory protocol for additional QC troubleshooting to evaluate potential alternative causes for QC failures.

- **If your lab uses the Atellica Data Manager or other middleware to monitor QC:**
  - After a failed QC, ensure any UCFP samples processed after the failed QC are held for review.
  - Repeat QC.
  - Verify QC results are passing and repeat any held UCFP testing for patient results obtained since the failed QC.
    - If QC results are still unacceptable after 2 attempts, unload the reagent pack and replace with a fresh pack.
    - If you experience repeated QC issues on consecutive wells, follow your laboratory protocol for additional QC troubleshooting to evaluate potential alternative causes for QC failures.

- As a result of these actions, track additional reagent consumption (number of tests) to report to Siemens Healthineers for future reimbursement/credit.
- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 10 days.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

Single Registration Number (SRN)

US-MF-000016560

Resolution

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

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.

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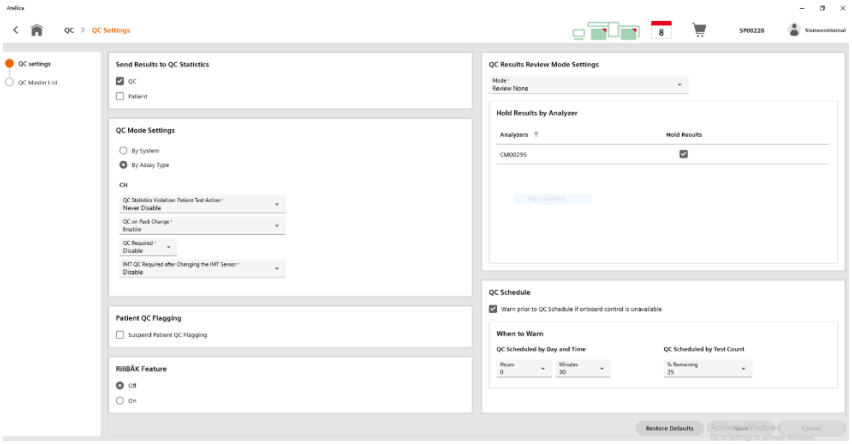
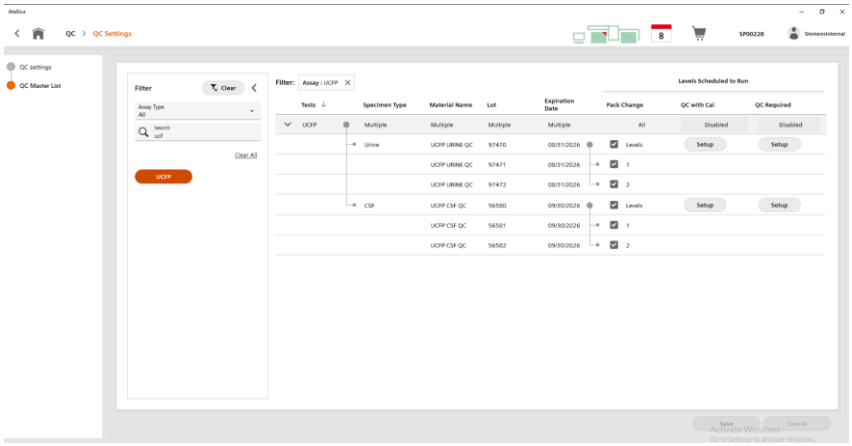
Appendix Customer Actions – Enable QC on Pack Change By Assay Type

Refer to Atellica Solutions and Atellica CI Analyzer Online Help Guide 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** and choose **Enable**.
4. Select **Save**.
5. Under QC settings, click on **QC Master List** and search for UCFP.
6. If pack change is not set to All, click **Setup** and select all QC levels for both sample types.
7. For all CH assays for which QC on Pack Change is *not* required, expand the QC list and deselect all levels of QC.

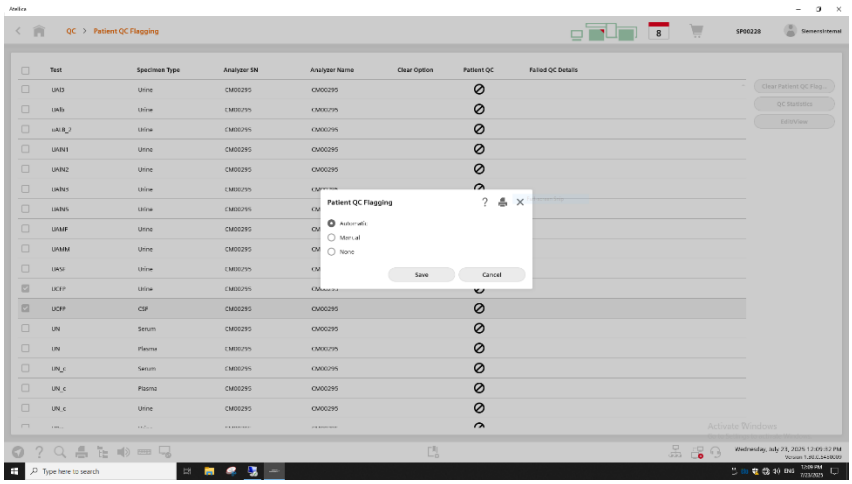


8. Select **Save**.

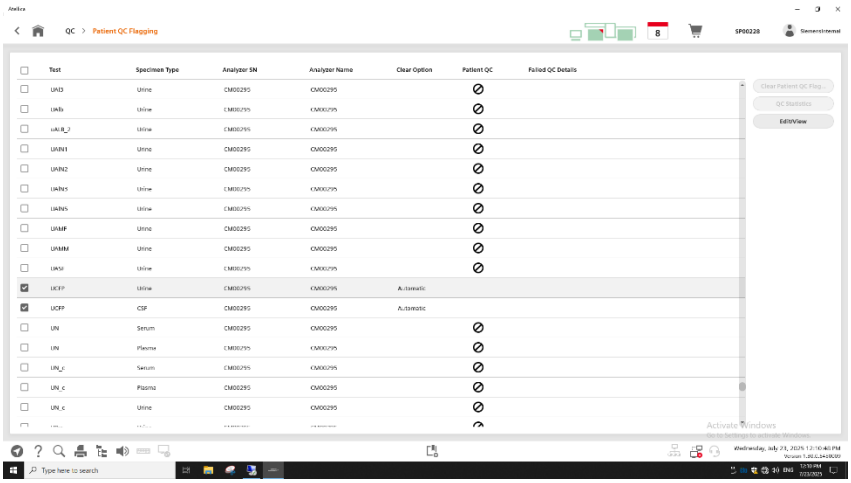
Customer Actions – Enable Patient QC Flagging, for labs using the Atellica to monitor QC

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

1. From the System Navigator icon under QC, select **Patient QC Flagging.**
2. Select **UCFP** Urine and CSF specimen types, **Edit/View**, select **Automatic** and click **Save**.



3. Ensure Patient QC Flagging is set to **Automatic** for Urine and CSF sample types.



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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Medical Device Correction ACHC25-07.B.OUS dated Aug-2025. Please read each question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Page 1 immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Return this completed form as per the instructions provided at the bottom of this page.

1. Have you read and understood the instructions provided in this letter? Yes ☐ No ☐
2. Were affected Site Personnel notified? Yes ☐ No ☐
3. Was a copy of the letter retained and posted with the current product labeling? Yes ☐ No ☐

Name of person completing questionnaire:			
Title:			
Institution:			
Street:			
City:		**State:**	**Zip Code:**
Phone:		**Country:**	

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

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.