# Urgent Field Safety Notice

**ACHC24-07.C.OUS**

## Atellica CH Analyzer
## Atellica CI Analyzer

**Title** Incorrect Software Flagging for the Atellica CH Revised C-Reactive Protein (RCRP) Assay

**Date Issued** MAR-2025

**Products**

| Assay | Test Code | Siemens Material Number/Unique Device Identification | Lot Number |
|---|---|---|---|
| Atellica CH Revised C-Reactive Protein (RCRP) | RCRP | 11537223/00630414610887 | All lots |

**Issue Description**

Siemens Healthineers has confirmed that incorrect software flagging may occur for the Atellica CH RCRP assay that may potentially lead to an erroneous result. The probability of occurrence for an erroneous result in the absence of a flag is less than 0.1%. The probability of occurrence for an erroneous result with an error flag is 1% or less. This incorrect flagging is mitigated through the customer actions listed in this letter. This issue can present with serum or plasma and with all Atellica CH RCRP reagent lots.

See Appendix A for additional information regarding the observed scenarios.

**Impact to Results**

Depending on the scenario, erroneous results may be reported or an apparent delay in obtaining a final result may occur due to this issue. Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings. See Appendix A for additional details.

**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.
- For both Atellica CH and Atellica CI analyzers, perform the instructions in Appendix B to temporarily reduce the measuring interval.
    - Until the measuring interval is restored, track additional reagent consumption as a result of these actions to report to Siemens Healthineers for future reimbursement/credit.
- Additionally, for Atellica CH Analyzers, perform the instructions in Appendix C to remove rules for flagging of "No Calculation" results and to install Atellica Solution Software version 1.29.0 or higher.
- Complete and return the Field Correction Effectiveness Check form attached to this letter within 30 days.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

**Resolution**

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

**Siemens Healthineers**
Siemens Healthcare Diagnostics Inc.
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SIEMENS Healthineers

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.

**Appendix A: Observed Scenarios**

| Scenario Description | Analyzers Impacted | Error Description | Mitigation |
|---|---|---|---|
| No Calculation flag | Atellica CH | No Calculation flags can be inappropriately posted for samples with true C-reactive protein (CRP) concentrations that are less than or above the measuring interval of 0.05 – 25.00 mg/dL (0.5 - 250.0 mg/L). | Appendix C – Remove any rules for the No Calculation flag. Install Atellica Solution Software version 1.29.0 or higher. |
| > Measuring Interval flag | Atellica CH | A sample with true CRP concentration of approximately 35.00 to 200.00 mg/dL (350.0 to 2,000.0 mg/L) can sometimes display falsely depressed initial results 0.30 to 24.00 mg/dL (3.0 to 240.0 mg/L), accompanied by a > Measuring Interval flag on the analyzer. | Appendix B - Reduce the measuring interval. |
| Missing > Measuring Interval flag (Falsely depressed result without a flag) | Atellica CH Atellica CI | In rare situations, samples with true CRP concentrations above the measuring interval can report as within the measuring interval (with results displaying between 12.00 to 18.00 mg/dL (120.0 to 180.0 mg/L) on the analyzer) and without the > Measuring Interval flag. | Appendix B - Reduce the measuring interval. |
| > Measuring Interval flag | Atellica CH Atellica CI | In rare instances, samples with true CRP concentrations of approximately 10.00 to 14.00 mg/dL (100.0 to 140.0 mg/L) can initially display as > Measuring Interval with no numerical RCRP value. The subsequently auto-diluted result is not displayed. Instead, Error is displayed and is accompanied by Conc Error and Repeat flags. | Appendix B - Reduce the measuring interval. |

**Appendix B: Customer Actions for Atellica CH and CI Analyzers to Reduce the Measuring Interval.**

| Step | Instructions for Atellica CH and CI Analyzers |
|---|---|
| 1 | Navigate to the **CH Test Definition** screen. |
| 2 | Select the **RCRP Assay**. |
| 3 | Confirm that **Repeat when Outside Measuring Interval** is checked for both Serum and Plasma. |
| 4 | Under **Measuring Intervals**, revise the **High** field for both Serum and Plasma.<br>• For **Assay** "RCRP (mg/dL)" revise to 10 .<br>• For **Assay** "RCRP (mg/L)" revise to 100. |
| 5 | Click **Save**. The software will respond with "Saved successfully." |
| 6 | Click **OK**. |
| 7 | Atellica CH Analyzer customers, proceed to steps captured in Appendix C. |

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**Appendix C: Customer Actions for Atellica CH Analyzer to Remove Rules for the No Calculation Flag and Install Atellica Solution Software Version 1.29.0 or Higher.**

| Step | Instructions for Atellica CH Analyzer |
|---|---|
| 1 | Ensure that any rules for the No Calculation flag previously added to the Laboratory Information System (LIS) or any middleware are removed. For customers with Siemens middleware, contact your local Siemens support representative to request the rules be removed. |
| 2 | If currently on Atellica Solution Software version 1.29.0 or higher, proceed to Step 3.<br>If not currently on Atellica Solution Software version 1.29.0 or higher, install this version as soon as possible. |
| 3 | Once Atellica Solution Software version 1.29.0 or higher is installed, navigate to the **CH Test Definition** screen:<br>• Select the **RCRP** assay and confirm that the Test Version on the Definition screen is 1.2.<br>• If not at Test Version 1.2, capture any lab customization settings.<br>• Click **Restore Defaults**.<br>• Re-enter lab customizations, if needed. |
| 4 | Confirm in the RCRP CH Test Definition:<br>• **Repeat when Outside Measuring Interval** is checked for both Serum and Plasma. |
| 5 | Under **Measuring Intervals**, revise the **High** field for both Serum and Plasma.<br>• For **Assay** "RCRP (mg/dL)" revise to 10.<br>• For **Assay** "RCRP (mg/L)" revise to 100. |
| 6 | Navigate to **Calibration Results**. |
| 7 | Select **Assay** button. |
| 8 | Select **RCRP assay**. |
| 9 | Delete any entry in the **Date From** field. |
| 10 | Select **Apply**. |
| 11 | Invalidate all Lot and Pack calibrations for RCRP assay. |
| 12 | Calibrate the RCRP assay prior to running samples. |

Note: After the above instructions have been followed, in rare instances, there may still be samples with CRP concentrations above the measuring interval that may generate a No Calculation flag. Please follow your routine sample troubleshooting steps in these cases.



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**FIELD CORRECTION EFFECTIVENESS CHECK**

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice ACHC24-07.C.OUS dated MAR-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 **XXXX@XXXX.**

Or to fax this completed form to the Customer Care Center at **XXXXXX.**

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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