Follow-up Urgent Field Safety Notice

ACHC24-07.D.OUS

Atellica CH Analyzer
Atellica CI Analyzer

Title

Update to ACHC24-07.C.OUS "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

If you received Urgent Field Safety Notice (UFSN) ACH24-07.C.OUS, this letter supersedes the prior version.

Siemens Healthineers issued an Urgent Field Safety Notice ACHC24-07.C.OUS in March 2025 to inform customers 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 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.

For the Atellica CH Analyzer, there was no change in the instructions from the previous letter UFSN ACHC24-07.C.OUS. Therefore, continue to refer to Appendices B and C for instructions.

For the Atellica CI Analyzer, UFSN ACHC24-07.C.OUS provided inaccurate instructions. This letter updates the customer actions to be taken on the Atellica CI Analyzer. Refer to Appendix D for instructions.

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 Atellica CH Analyzer:
  - 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.
  - Perform the instructions in Appendices B and C
    - Appendix B to temporarily reduce the RCRP measuring interval.
    - Appendix C to install Atellica Solution Software version 1.29.0 or higher.

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- For Atellica CI Analyzer:
    - Perform the instructions in Appendix D.
- For both Atellica CH and Atellica CI analyzers, track additional reagent consumption as a result of these actions to report to Siemens Healthineers for future reimbursement/credit.
- 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.

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 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.	**Atellica CH: Appendix B** - Reduce the measuring interval. **Atellica CI: Appendix D** - Perform confirmation testing using a x5 auto-dilution.
> 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.	**Atellica CH: Appendix B** - Reduce the measuring interval. **Atellica CI: Appendix D** - Perform confirmation testing using a x5 auto-dilution.

Appendix B: Atellica CH Customer Actions to Reduce the Measuring Interval.

Step	Instructions
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. • For **Assay** RCRP (mg/dL) revise to 10 . • For **Assay** RCRP (mg/L) revise to 100.
5	Click **Save**. The software will respond with **Saved successfully**.
6	Click **OK**.
7	Proceed to steps captured in Appendix C.

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

Step	Instructions
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. 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: • Select the **RCRP** assay and confirm that the Test Version on the Definition screen is 1.2. • If not at Test Version 1.2, capture any lab customization settings. • Click **Restore Defaults**. • Re-enter lab customizations, if needed.
4	Confirm in the RCRP CH Test Definition: • **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. • For **Assay** RCRP (mg/dL) revise to 10. • 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.

Appendix D: Atellica CI Customer Actions for Confirmation Testing Using a x5 Auto-dilution

Step	Instructions
1	Navigate to the **CH Test Definition** screen
2	Select **Assay** to open the **Select Assay** list of methods and select **RCRP**.
3	Click **Edit** to open the workflow.
4	The **Definition** screen for RCRP (mg/dL or mg/L) is displayed.
5	Click on step **4 (Ranges).**
6	Select the **Check** tab.
7	Select **Add Range** button.
8	In the **Range Name** box, enter a name (ex. Dose Check).
9	Under the **Within Check > Details** section: • For reporting mg/dL, enter 10 and 25 into the Low and High **Limits** boxes respectively. • For reporting mg/L, enter 100 and 250 into the Low and High **Limits** boxes respectively.
10	Under **Demographics Information**, ensure **Specimen** type of **All** is shown to apply the limit to Serum and Plasma.
11	Uncheck all **Flag result** boxes for **Below Range** and **Above Range.**
12	Click **Save,** an Information box displays **Saved Successfully.**

13	Click **Ok** to close the Information box **Note:** The software automatically rechecks the Flag Results box in the Below Range section however no additional action is needed.
14	All samples within 10 and 25 mg/dL (100 and 250 mg/L) will have a **Within Check** flag on the Atellica CI Worklist.
15	Follow the guidance below for reporting Within Check flagged results. **Initial sample results with a single flag of Within Check cannot be reported** and must be repeated with a "x5" auto-dilution. Note: Auto-repeated test results may display a Within Check flag but do not need to be repeated. • For customers with Siemens middleware, contact your local Siemens support representative for assistance with configuring middleware. • To manually order a "x5" auto-dilution, refer to Atellica CI User Guide. The result from the x5 dilution displays a numeric Conc/Index value with the Diluted worklist icon (🩸) and can be reported. See Table 1 *Atellica CI Analyzer Result Reporting Guidance* for more information.

Table 1: Atellica CI Analyzer Result Reporting Guidance

Onscreen RCRP Conc/Index	Worklist Flags	Recommended Action
< 0.05 mg/dL (< 0.5 mg/L)	< Measuring Interval	Reportable as < 0.05 mg/dL (< 0.5 mg/L) Released directly.
0.05 mg/dL – 10.00 mg/dL (0.5 mg/L – 100.0 mg/L)		Reportable. Released directly.
10.01 mg/dL – 25.00 mg/dL (100.1 mg/L – 250.0 mg/L)	Within Check	Hold. Confirm by RCRP **Repeat Option** with **Dilution** of **x5**
10.01 mg/dL – 25.00 mg/dL (100.1 mg/L – 250.0 mg/L)	🩸 Within Check, Autorepeat 🩸 Within Check, Repeat	Reportable. Released directly.
> 25.00 mg/dL (> 250.0 mg/L)	> Measuring Interval	Reportable. Released directly.
25.00 mg/dL – 125.00 mg/dL (250.0 mg/L – 1250.0 mg/L)	🩸 Autorepeat 🩸 Repeat	Reportable. Released directly.
> 125.00 mg/dL (> 1250.0 mg/L)	🩸 > Measuring Interval, Autorepeat 🩸 > Measuring Interval, Repeat	Reportable. Released directly.

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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.D.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 fscareportingunit.my@siemens-healthineers.com

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