Follow-up Urgent Field Safety Notice

ACHC24-07.F.OUS

Atellica CI Analyzer

Title

Resolution of the Incorrect Software Flagging for the Atellica CH Revised C-Reactive Protein (RCRP) Assay on the Atellica CI Analyzer

Date Issued

DEC-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 resolved the incorrect software flagging issue previously communicated in Urgent Field Safety Notice ACHC24-07.D.OUS (March 2025). This correction applies to Atellica CI Analyzers running software version 1.30.51 and higher. See Table 1 in the Appendix for scenarios with incorrect software flagging that have been resolved.

Note: This resolution is only for the Atellica CI Analyzer. Customers using the Atellica CH Analyzer should follow the instructions in resolution letter ACHC24-07.E.OUS.

Customer Actions

- Once Atellica CI Analyzer software version 1.30.51 or higher is installed:
  - RCRP sample results between 10-25 mg/dL (100-250mg/L) no longer need to be repeated at a x5 auto-dilution as indicated in ACHC24-07.D.OUS.
  - If the “Within Check" flag was implemented, it can be removed. Perform the following steps to remove the “Within Check" Flag.
    1. Go to the **CH Test Definition** screen.
    2. Click the **Assay** field to open the “Add or Edit an Assay” window.
    3. Select **RCRP** and click **Edit**
    4. The **Definition** screen for RCRP (mg/dL or mg/L) is displayed, verify the Test Version is 1.4 or greater.
    5. Click on ❺ **Ranges** and select the **Check** tab
    6. Confirm the appropriate Defined Range (e.g. Dose Check) is selected from the Defined Ranges list.
    7. To ensure the correct Defined Ranges are removed, verify the following:
       - For Reporting in mg/dL, 10 and 25 in the Low and High Limit boxes respectively.
       - For Reporting in mg/L, 100 and 250 in the Low and High Limit boxes respectively.
    8. Click the **Delete Range** button.
    9. Select **Yes** to remove the selected range.

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- Once the above actions are complete, record the additional reagent consumption due to the confirmation testing using x5 auto-dilution on the Field Correction Effectiveness Check form so reimbursement/credit can be provided.
- Please review this letter with your Medical Director.
- 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 to those who may have received this product.

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 **Table 1. Observed Scenarios with Incorrect Software Flagging**

Scenario Description	Error description
Missing > Measuring Interval flag (Falsely depressed result without a flag)	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.
> Measuring Interval flag	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.

Siemens Healthineers
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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Follow-up Urgent Field Safety Notice ACHC24-07.F.OUS dated DEC-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.	Do you require reimbursement/credit for the additional reagent consumption due to confirmation testing using x5 auto-dilution?	Yes ☐	No ☐
3.	Were affected Site Personnel notified?	Yes ☐	No ☐
4.	Was a copy of the letter retained and posted with the current product labeling?	Yes ☐	No ☐

If the answer to question #2 above is yes, please complete the table below for reimbursement/credit.

Product Description **Product Catalog #/SMN #**		**Additional Reagent Consumption**	
Atellica CH Revised C-Reactive Protein/11537223		**Number of Tests:**	
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.**

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