Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	Atellica CH Revised C-Reactive Protein (RCRP)
Device Model	11537223
Lot No.	All lots
Manufacturer	Siemens Healthcare Diagnostics Inc.
Country of Origin	USA
Reference	Attached
Reason of Alert	NHRA initiates this FSN due to incorrect software flagging in the Atellica CH Revised C-Reactive Protein (RCRP) assay, which may lead to erroneous results if not corrected.
Action should be taken	Please refer to "Actions to be taken by Customer/ User" in the attached FSN And for more information please contact the authorized representative Wael Pharmacy Co.at S.khattak@waelpharmacy.com.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh

FSCA 2025 0077

18/Aug/2025

Follow-up Urgent Field Safety Notice

ACHC24-07.E.OUS

Atellica CH Analyzer

Title

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

Date Issued

AUG-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

In March 2025, Siemens Healthineers issued an Urgent Field Safety Notice, communicating that incorrect software flagging may occur for the Atellica CH RCRP assay, which may potentially lead to an erroneous result. Atellica CH customers were instructed to remove any previously entered rules for the "No Calculation" flag, install Atellica Solution Software version 1.29.0 or higher, and reduce the upper end of the Atellica CH RCRP measuring interval.

Siemens is pleased to inform you that beginning with Atellica Solutions software version 1.30.0 and higher, this incorrect software flagging has been resolved, and the original measuring interval can be restored on the Atellica CH Analyzer. See Table 1 in the Appendix for scenarios with incorrect software flagging that have been resolved.

Note: If you also have an Atellica CI Analyzer you will receive an additional letter at a future date when the updated software is available.

Customer Actions

- Please review this letter with your Medical Director.
- 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.
- Once Atellica Solution Software version 1.30.0 or higher is installed perform the instructions provided below.
    1. In the **Results > Worklist** screen, select any RCRP samples and complete the "**Move to Historical**" workflow.
    2. Restore the measuring interval:
        - Navigate to the **CH Test Definition** screen.
        - Select the RCRP assay.
        - Document/record any lab customizations.
        - Click **Restore Defaults** and confirm the Test Version on the Definition screen is 1.3.
        - Under **Measuring Intervals**, confirm the High field for both Serum and Plasma is restored to 25 for mg/dL or 250 for mg/L.
        - Re-enter lab customizations, if needed.

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3. Activate the RCRP corrections:
    - Navigate to the **Calibration > Results** screen.
    - **Invalidate** all Active Lot and Pack calibrations for the RCRP Assay.
    - Complete the Lot calibration workflow to restore Active calibrations for available reagents.

- Once the above actions are complete, record the additional reagent consumption due to the reduced measuring interval on the Field Correction Effectiveness Check form so reimbursement/credit can be provided.
- 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.

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
No Calculation flag	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).
> Measuring Interval flag	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.
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
Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591
siemens-healthineers.com

FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Follow-up Urgent Field Safety Notice ACHC24-07.E.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.	Do you require reimbursement/credit for the additional reagent consumption due to the reduced measuring interval?	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 the 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.**

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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