Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

نتقدم بثقة
Moving Forward with Confidence

رؤية عمان 2040

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 67 **dated** 23/3/2025 **Regarding SFDA Field Safety Notice of Atellica CH and Atellica CI Analyzers from (mfr: Siemens Healthcare Diagnostics Inc).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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Circular No. 67 / 2025

23 -09-1446 H
23 -03-2025

Field Safety Notice of Atellica CH and Atellica CI Analyzers from Siemens Healthcare Diagnostics Inc.

Source	SFDA- Saudi Food & Drug Authority https://ade.sfda.gov.sa/Fsca/PublishDetails/323
Product	Atellica CH and Atellica CI Analyzers.
Manufacturer	Siemens Healthcare Diagnostics Inc.
Local agent	Diamond Stone investment.
The affected products	Assay: Atellica CH Revised C-Reactive Protein (RCRP) Test Code: RCRP Siemens Material Number/Unique Device Identification: 11537223/00630414610887 All lots.
Reason	Incorrect software flagging may occur for the Atellica CH RCRP assay that may potentially lead to an erroneous result.
Action	1. Please review the attachment with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable. 2. 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. 3. 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. 4. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Ph. Ibrahim Nasser Al Rashdi
Director General

سلطنة عمان - وزارة الصحة - مركز سلامة الدواء
SULTANATE OF OMAN - MINISTRY OF HEALTH
DRUG SAFETY CENTER

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Drug Safety Center

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P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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.
511 Benedict Avenue
Tarrytown, NY 10591
siemens-healthineers.com

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. • 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	Atellica CH Analyzer customers, proceed to steps captured in Appendix C.

Siemens Healthineers
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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. 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.

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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.

Siemens Healthineers
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