



Circular No. 23 / 2025

29 -07-1446 H  
29 -01-2025

بالتقدم بثقة  
Moving Forward  
With Confidence



Field Safety Corrective Action of Atellica CH Analyzer from Siemens Healthcare Diagnostics Inc.

Source	SFDA- Saudi Food & Drug Authority. <a href="https://ade.sfda.gov.sa/Fsca/PublishDetails/252">https://ade.sfda.gov.sa/Fsca/PublishDetails/252</a>
Product	Atellica CH Analyzer.
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 Lot Number: All lots
Reason	It has been confirmed the occurrence of "No Calculation" flags when using the Atellica CH RCRP assay on the Atellica® CH Analyzer. This flag is only triggered for some samples when the CRP concentration is less than the low end of the measuring interval of 0.05 mg/dL (0.5 mg/L)..
Action	1. For the affected product listed above, please perform the steps in "Customer Actions" of the attachment. 2. The resolution for the "No Calculation" flag on samples with CRP concentrations <0.05 mg/dL (<0.5 mg/L) is implemented in the upcoming Atellica Solution Software (SW) v1.29.4. 3. 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: <a href="mailto:vigilance-md@moh.gov.om">vigilance-md@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie  
Director General





نتقدم بثقة  
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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 23/2025 dated 29/11/2025 Regarding SFDA Field Safety Corrective Action of Atellica CH Analyzer 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

# Customer Notification

ACHC24-07.A.OUS

## Atellica CH Analyzer

<b>Title</b>	Atellica CH Revised C-Reactive Protein (RCRP) "No Calculation" Flag										
<b>Date Issued</b>	SEP-2024										
<b>Issue Description</b>	<p>Siemens Healthineers has confirmed the occurrence of "No Calculation" flags when using the Atellica CH RCRP assay on the Atellica® CH Analyzer. This flag is only triggered for some samples when the CRP concentration is less than the low end of the measuring interval of 0.05 mg/dL (0.5 mg/L). When this flag is triggered, the concentration/index is reported as "Error." Results within or above the measuring interval of 0.05 – 25.00 mg/dL (0.5 – 250.0 mg/L) are not impacted. For the RCRP assay, no other conditions will trigger this flag.</p> <p>This issue does not affect Atellica CH RCRP results on the Atellica® CI Analyzer.</p>										
<b>Products</b>	<table border="1"><thead><tr><th>Assay</th><th>Test Code</th><th>Siemens Material Number/Unique Device Identification</th><th>Lot Number</th></tr></thead><tbody><tr><td>Atellica CH Revised C-Reactive Protein (RCRP)</td><td>RCRP</td><td>11537223/00630414610887</td><td>All lots</td></tr></tbody></table>	Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number	Atellica CH Revised C-Reactive Protein (RCRP)	RCRP	11537223/00630414610887	All lots		
Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number								
Atellica CH Revised C-Reactive Protein (RCRP)	RCRP	11537223/00630414610887	All lots								
<b>Impact to Results</b>	For some results below the measuring interval, "Error" is posted instead of the numerical result and should be reported as <0.05 mg/dL (<0.5 mg/L).										
<b>Customer Actions</b>	<ul style="list-style-type: none"><li>For the product listed in the table above, please perform the following steps:<ol style="list-style-type: none"><li>For customers using ADM (Atellica Data Manager), contact your local Siemens support representative to create a rule for the RCRP assay to convert a "No Calculation" flag to a &lt;0.05 mg/dL (&lt;0.5 mg/L) result.</li><li>For customers not using ADM, RCRP test results that produce a "No Calculation" flag can be reported as &lt;0.05 mg/dL (&lt;0.5 mg/L).</li></ol></li><li>Please retain this letter with your laboratory records and forward this letter to those who may have received this product.</li></ul>										
<b>Resolution</b>	The resolution for the "No Calculation" flag on samples with CRP concentrations <0.05 mg/dL (<0.5 mg/L) is implemented in the upcoming Atellica Solution Software (SW) v1.29.										
<b>Single Registration Number (SRN)</b>	US-MF-000016560										

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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**Siemens Healthineers**  
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