

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
Manufacturer	Siemens Healthcare Diagnostics Inc.
Country of Origin	USA
Reference	<u>Attached</u>
Reason of Alert	NHRA initiates this FSN due to the occurrence of 'No Calculation' flags in the Atellica CH RCRP assay on the Atellica® CH Analyzer for CRP concentrations below 0.05 mg/dL (<0.5 mg/L), resulting in an 'Error' instead of a numerical result.
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.W.L.L at sharon@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

Customer Notification

ACHC24-07.A.OUS

Atellica CH Analyzer

Title	Atellica CH Revised C-Reactive Protein (RCRP) “No Calculation” Flag										
Date Issued	SEP-2024										
Issue Description	<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>										
Products	<table><tr><th>Assay</th><th>Test Code</th><th>Siemens Material Number/Unique Device Identification</th><th>Lot Number</th></tr><tr><td>Atellica CH Revised C-Reactive Protein (RCRP)</td><td>RCRP</td><td>11537223/00630414610887</td><td>All lots</td></tr></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								
Impact to Results	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).										
Customer Actions	<ul style="list-style-type: none">For the product listed in the table above, please perform the following steps:<ol style="list-style-type: none">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 <0.05 mg/dL (<0.5 mg/L) result.For customers not using ADM, RCRP test results that produce a “No Calculation” flag can be reported as <0.05 mg/dL (<0.5 mg/L).Please retain this letter with your laboratory records and forward this letter to those who may have received this product.										
Resolution	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.										
Single Registration Number (SRN)	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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