



نتقدم بثقة  
Moving Forward  
with Confidence



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 51 dated 24/4/24 Regarding NCMDR Field Safety Notice of Atellica CH Analyzer and Atellica CI Analyzer from (mfr: Siemens Healthcare Diagnostics GmbH).

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





Circular No. 51 / 2024

15 -10-1445 H  
24 -04-2024

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Field Safety Notice of Atellica CH Analyzer and Atellica CI Analyzer from Siemens Healthcare Diagnostics GmbH.

Source	NCMDR - National Center Medical Device Reporting- SFDA. <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=20990">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=20990</a>
Product	Atellica CH Analyzer and Atellica CI Analyzer.
Description	In-vitro diagnostics - immunological products.
Manufacturer	Siemens Healthcare Diagnostics GmbH.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Assay: Atellica CH Iron3 Test Code: Iron3 Siemens Material Number   Unique Device Identification: 11537211   00630414610849 All lots
Reason	The potential for falsely elevated Chol_2, LDLC, and Trig_2 results on the Atellica® CH and Atellica® CI analyzers when the previous result in the cuvette was Iron3.
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. Refer to short-term mitigation steps in "Appendix B" in the attachment while Siemens works towards transitioning customers back to the Iron_2 assay. 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:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie  
Director General



# Urgent Field Safety Notice

ACHC24-03.A.OUS

## Atellica CH Analyzer Atellica CI Analyzer

<b>Title</b>	Atellica CH Iron3 (Iron3) Impacting Atellica CH Cholesterol_2 (Chol_2), Atellica CH LDL Cholesterol (LDLC), and Atellica CH Triglycerides_2 (Trig_2) Results										
<b>Date Issued</b>	13-Mar-2024										
<b>Issue Description</b>	<p>Siemens Healthineers has confirmed the potential for falsely elevated Chol_2, LDLC, and Trig_2 results on the Atellica® CH and Atellica® CI analyzers when the previous result in the cuvette was Iron3. This issue can impact calibrator, quality control (QC), and patient results.</p> <p>See "Appendix A" for Additional Data in Tables 1 – 3.</p> <p>All future lots are impacted until further notice.</p> <p>The Atellica CH HDL Cholesterol (HDLC) and Atellica CH Iron_2 (Iron_2) assays are not impacted by this issue.</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 Iron3</td><td>Iron3</td><td>11537211 / 00630414610849</td><td>All lots</td></tr></tbody></table>	Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number	Atellica CH Iron3	Iron3	11537211 / 00630414610849	All lots		
Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number								
Atellica CH Iron3	Iron3	11537211 / 00630414610849	All lots								
<b>Impact to Results</b>	<ul style="list-style-type: none"><li>Falsely elevated Chol_2, LDLC, and Trig_2 results may occur. Internal studies have demonstrated a positive bias ranging from 2-16%, see Appendix A. The results would be used in conjunction with the patient's medical history, clinical presentation, and other findings such as their cardiovascular risk profile.</li></ul>										
<b>Customer Actions</b>	<ul style="list-style-type: none"><li>Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.</li><li>Refer to short-term mitigation steps in "Appendix B" while Siemens works towards transitioning customers back to the Iron_2 assay.</li><li>Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.</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>	Siemens is actively working to ramp up the supply volume to support customer conversion to the Iron_2 assay. We anticipate being able to support an end to the mitigation within a six month timeframe. A follow up communication will be provided when "Customer Actions" are no longer required. These mitigations will remain in effect until the solution is provided.										



## Appendix A Additional Data Describing the Product Issue

Table 1. Impact of Iron3 Carryover on Chol\_2 Results

Chol_2 mg/dL	Chol_2 After Iron3 mg/dL	Chol_2 mmol/L	Chol_2 After Iron3 mmol/L	% Bias
108	125	2.80	3.24	16%
164	188	4.25	4.87	15%
194	224	5.02	5.80	15%
300	345	7.77	8.94	15%

Table 2. Impact of Iron3 Carryover on LDLC Results

LDLC mg/dL	LDLC After Iron3 mg/dL	LDLC mmol/L	LDLC After Iron3 mmol/L	% Bias
67	76	1.74	1.97	13%
106	119	2.75	3.08	12%
163	176	4.22	4.56	8%

Table 3. Impact of Iron3 Carryover on Trig\_2 Results

Trig_2 mg/dL	Trig_2 After Iron3 mg/dL	Trig_2 mmol/L	Trig_2 After Iron3 mmol/L	% Bias
93	101	1.05	1.14	9%
140	150	1.58	1.70	7%
217	239	2.45	2.70	10%
535	545	6.05	6.16	2%
806	820	9.11	9.27	2%

## Appendix B Customers with Multiple Atellica Analyzers

Segregate Iron3 to a single analyzer and perform Chol\_2, Trig\_2, and LDLC testing on a different analyzer(s). For customers utilizing automation systems, please consult the appropriate instructions to perform the steps below.

- On the system(s) that will run Iron3 assay:
  - Allow the system to complete testing and go into standby.
  - Once in standby, disable the Chol\_2, LDLC, and Trig\_2 assays by following instructions in the Atellica Online Help "About Enabling and Disabling Assays on the System."
  - Resume processing all assays except Chol\_2, LDLC, and Trig\_2.

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Tarrytown, NY 10591  
siemens-healthineers.com

2. On the system(s) that will run Chol\_2, LDLC, and Trig\_2 assay:
  - Allow the system to complete testing and go into standby.
  - Once in standby, disable the Iron3 assay by following instructions in the Atellica Online Help "About Enabling and Disabling Assays on the System."
  - For Atellica CH:
    - Perform 221 Chol\_2 tests to eliminate the Iron3 reagent impact prior to testing with Chol\_2, LDLC, or Trig\_2.
  - For Atellica CI:
    - Perform 130 Chol\_2 tests to eliminate the Iron3 reagent impact prior to testing with Chol\_2, LDLC, or Trig\_2.
  - Resume processing all assays except Iron3.
3. You may request 1 replacement kit of Chol\_2 reagent to be used in the steps above, via the attached FIELD CORRECTION EFFECTIVENESS CHECK response form.

### Customers with a Single Atellica Analyzer

Stop use of Iron3 and identify alternative methods for Iron testing. Prior to continuing routine processing on the Atellica system for assays besides Iron3, follow the steps below:

1. When the system is in standby, disable the Iron3 assay by following instructions in the Atellica Online Help "About Enabling and Disabling Assays on the System."
2. Remove Iron3 reagent prior to testing with Chol\_2, LDLC, or Trig\_2.
  - For Atellica CH:
    - Perform 221 Chol\_2 tests to eliminate the Iron3 reagent impact prior to testing with Chol\_2, LDLC, or Trig\_2.
  - For Atellica CI:
    - Perform 130 Chol\_2 tests to eliminate the Iron3 reagent impact prior to testing with Chol\_2, LDLC, or Trig\_2.
3. Resume all testing except for Iron3.
4. You may request 1 replacement kit of Chol\_2 reagent to be used in the steps above, via the attached FIELD CORRECTION EFFECTIVENESS CHECK response form.

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511 Benedict Avenue  
Tarrytown, NY 10591  
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**FIELD CORRECTION EFFECTIVENESS CHECK**

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice **ACHC24-03.A.OUS** dated 13-Mar-2024. 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. I have read and understood the instructions provided in this letter. Yes  No
- 2. We have the affected product(s) on hand? Please check inventories before answering. Yes  No
- 3. All affected Site Personnel have been notified. Yes  No
- 4. A copy of the letter has been retained and posted with our current product labeling. Yes  No

If the answer to the question #2 above is yes, please complete the table below to request your 1 replacement kit of Atellica CH Chol\_2.

Product Description Product Catalog #/SMN #/Lot #		Replacement Quantity	
Atellica CH Chol_2 / SMN 11097609		1	
Name of person completing questionnaire:			
Title:			
Institution:			
Street:			
City:		State:	
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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 Tarrytown, NY 10591  
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