

Urgent Field Safety Notice

ACHC24-03.A.OUS

Atellica CH Analyzer

Atellica CI Analyzer

Title Atellica CH Iron3 (Iron3) Impacting Atellica CH Cholesterol_2 (Chol_2), Atellica CH LDL Cholesterol (LDLC), and Atellica CH Triglycerides_2 (Trig_2) Results

Date Issued 13-Mar-2024

Issue Description 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.

See “Appendix A” for Additional Data in Tables 1 – 3.

All future lots are impacted until further notice.

The Atellica CH HDL Cholesterol (HDLC) and Atellica CH Iron_2 (Iron_2) assays are not impacted by this issue.

Products

| Assay | Test Code | Siemens Material Number/Unique Device Identification | Lot Number |
|-------------------|-----------|------------------------------------------------------|------------|
| Atellica CH Iron3 | Iron3 | 11537211 / 00630414610849 | All lots |

Impact to Results

- 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.

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.
- Refer to short-term mitigation steps in “Appendix B” while Siemens works towards transitioning customers back to the Iron_2 assay.
- 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 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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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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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 cruinnfsngroup@cruinn.ie

Or to fax this completed form to the Customer Care Center at 01 **6297401**

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.