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 Date March 27, 2024
 Document Ref# ACHC24-03.A.OUS

Urgent Field Safety Notice:

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

To whom it may concern,

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.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

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Product Manager CEE

Appendix A - Additional Data Describing the Product Issue

Appendix B - Customers with Multiple Atellica Analyzers

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.

1. 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.

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.