

Customer Notification

ACHC24-06.A.OUS

Atellica CH Analyzer

Atellica CI Analyzer

Title	Atellica CH Lactate_3 (Lac_3) Pack Calibration Instability
Date Issued	AUG-2024
Issue Description	<p>Siemens Healthineers has confirmed the potential for a positive drift in quality control (QC) and patient results when using Atellica CH Lactate_3 (Lac_3) on the Atellica® CH and Atellica® CI analyzers. An internal investigation confirmed that, when using the Atellica CH Lac_3 assay, the pack calibration claim of 61 days per the Instructions for Use may not be met. The lot calibration interval of 180 days is not impacted.</p> <p>This issue is applicable to all in-date and future Atellica CH Lac_3 lots until further notice. Siemens Healthineers is currently investigating the root cause of this issue.</p>

Products	Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number
	Atellica CH Lactate_3 (Lac_3)	Lac_3	11537218/00630414610979	All in-date and future lots

Impact to Results A positive drift may impact both QC and patient results. A gradual change in results over time will be noticed by an apparent QC failure, which may delay patient result reporting. Table 1 of the Appendix provides representative data of the drift that may be observed with QC and patient results.

- 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.
 - As a temporary mitigation, perform the instructions provided below to edit the pack calibration interval to 14 days:
 1. Unload and discard any open Lac_3 reagent packs onboard the analyzer.
 2. Navigate to the Lac_3 CH Test Definition and change the pack calibration interval from 61 days to 14 days and save. Refer to Online Help section *Calibration in CH Test Definition > Modifying the Calibration Interval for CH Reagent Packs* for assistance.
 3. Load a fresh Lac_3 reagent pack onto the analyzer.
 4. Recalibrate and ensure QC is in range.
 5. Monitor QC and recalibrate when indicated by QC results.
 - Please retain this letter with your laboratory records and forward this letter to those who may have received this product.
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Resolution A follow-up communication will be provided when "Customer Actions" are no longer required.

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.

Single Registration Number (SRN)

US-MF-000016560

Appendix

Table 1: Atellica CH Lac_3 Reagent Drift for QC and Patient Results

Day	Results mg/dL (mmol/L)			
	QC1	QC2	QC3	Patient (Plasma)
0	14.0 (1.55)	30.4 (3.37)	47.9 (5.32)	32.4 (3.60)
15	15.3 (1.70)	31.5 (3.50)	49.1 (5.45)	33.6 (3.73)
30	17.7 (1.96)	33.6 (3.73)	51.8 (5.75)	35.8 (3.97)
61	22.1 (2.45)	37.9 (4.21)	55.7 (6.18)	40.5 (4.49)

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