Urgent Field Safety Notice

ACHC22-07.A.OUS

September 2022

Atellica® CH 930 Analyzer

Falsely Elevated Lithium Results

Our records indicate that your facility may have received the following products:

Table 1. Atellica CH Affected Products

Assay	Test Code	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Number
Lithium_2	LITH_2	11532401	00630414287935	All lots
Lithium	Li	11097535	00630414006789	All lots

Reason for Correction

The purpose of this communication is to inform you of an issue with the products indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed customer complaints indicating the potential for falsely elevated LITH_2 and Li results on the Atellica CH 930 Analyzer. Preliminary investigation has indicated that this issue may be due to foam formation in the reagent packs resulting in inconsistent reagent delivery. The observation of falsely elevated results is random in nature and only impacts the LITH_2 and Li reagents. See Tables 2 and 3 below for the observed worst case results.

This issue may impact calibrators, quality control and patient samples. Siemens understands the urgency of this issue and is working towards a resolution. See the “Additional Information” section for further instructions.

Table 2. Observed Worst Case Elevated Li Results Based on Customer Data

Sample	Expected Value mmol/L	Worst Case Result mmol/L
Sample 1	0.51	2.16
Sample 2	0.90	2.50
Sample 3	< 0.10	1.12

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Table 3. Observed Worst Case Elevated LITH_2 Results Based on Siemens Testing

Sample	Expected Value mmol/L	Worst Case Result mmol/L
QC L1	0.59	> 3.00
QC L2	0.99	> 3.00
QC L3	2.03	> 3.00
Serum Patient Sample	< 0.10	1.46

Risk to Health

Worst case, there is a potential for erroneously elevated lithium patient results, which may lead to inappropriate dosage adjustment potentially affecting treatment efficacy. Mitigations include close patient monitoring including signs and symptoms, and serial lithium testing. A review of previously generated results is not recommended as patient results would not be used in isolation, rather results would be used in conjunction with overall clinical presentation and serial testing.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Discontinue use of and discard the kit lots listed in Table 1.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

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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Additional Information

Siemens is temporarily discontinuing production and distribution of the Atellica CH lithium reagents until the issue is resolved. In the interim, Siemens is recommending that customers transition to an alternate lithium assay. Siemens offers alternate lithium assays on the following systems: Dimension Vista® systems, Dimension® clinical chemistry systems, and ADVIA® Chemistry systems. The lithium assays on these platforms are not impacted by this issue.

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