SIEMENS Healthineers

Follow Up
Urgent Field Safety Notice

ACHC22-07.B.OUS

February 2023

Atellica® CH 930 Analyzer

Resolution of Atellica® CH 930 Analyzer Falsely Elevated Lithium Results

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

Table 1. Atellica CH Affected Product

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

Reason for Communication

In September 2022, Siemens Healthcare Diagnostics, Inc. issued an Urgent Field Safety Notice (UFSN), ACHC22-07.A.OUS, to inform customers with in-date reagent lots of the potential for falsely elevated lithium results.

Investigation findings have since identified the reagent chimney within the reagent packs contributed to foam formation.

Siemens has implemented changes to the lithium reagent pack and test definition. Starting with reagent lot 130031 the lithium reagents will be packaged using reagent packs without the chimney. Atellica Solution Software (SW) v1.27 or higher must be installed prior to running LITH_2.

This SW version includes:

- Change in Onboard Stability from 52 days to 30 days
- Change in Pack Calibration Interval from 14 days to 9 days
- All other performance characteristics remain the same

The Instructions for Use for the LITH_2 assay (11417035, Rev. 03) has been updated with the above information.

Siemens is actively working towards replenishing inventory levels for this product. In order to ensure that all customers have an adequate supply, full order quantities may not be immediately available.

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Actions to be Taken by the Customer

- Customers may now order Lithium_2 reagents for use on the Atellica® CH 930 Analyzer. Please be advised that new orders will have to be placed.
- The SMN has not changed.
- Ensure your system has been upgraded to Atellica Solution Software (SW) v1.27 or higher prior to running LITH_2.
- Download the latest revision of the IFU.

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

If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Atellica is a trademark of Siemens Healthcare Diagnostics Inc.

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