Urgent Field Safety Notice

ASW19-06.A.OUS

September, 2019

Atellica® Solution

Atellica® CH 930 Analyzer – Calibration Issue in Software versions 1.20.0 and below

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

Table 1. Atellica® Solution Affected Product:

Product	Siemens Material Number (SMN)
Atellica CH 930 Analyzer	11067000

Reason for Urgent Field Safety Notice

The purpose of this communication is to inform you of an issue with the Atellica CH 930 Analyzer listed in Table 1 above, installed with Atellica Solution software (SW) versions V1.20.0 or lower and provide instructions on actions your laboratory must take.

Siemens Healthcare Diagnostics, Inc. has confirmed that on the Atellica CH 930 Analyzer, when a Reagent Lot Calibration and a Pack Calibration (C0 adjust) on the same assay are manually ordered at the same time, the Reagent Lot Calibration recovery of the analyte is 5 times higher because the 5x pre-dilution factor is improperly factored into the QC and patient sample result calculation. The following assays are affected: Acetaminophen (Acet), Cholesterol (Chol_2), Glucose Oxidase (GluO), Triglycerides (Trig), Uric Acid (UA), Urea Nitrogen (UN_c) and Inorganic Phosphorus (IP).

- If QC is ordered with calibration and C0 adjust, QC results will be out of range high (red status on the Atellica Solution - Calibration Results Details screen) and the calibration will display a status of “Awaiting Acceptance”.
- If QC is not ordered with calibration and C0 adjust, then the calibration status will be shown as “Valid”. Patient results and QC results will be 5 times higher.

This issue will be corrected in SW V1.20.1, which will be available soon.

Risk to Health

This issue causes QC failures after the calibration run with QC and patient results being 5-fold elevated.

This issue is apparent to the operator as the failed QC will generate alert flags. Therefore, the risk to health is negligible. Siemens is not recommending a lookback of previously generated results due to this issue.

511 Benedict Avenue
Tarrytown, NY 10591

Actions to be Taken by the Customer

1. Do not order Reagent Pack Calibration (C0 Adjust) while the Reagent Lot calibration is in progress.
2. Always run QC after calibration before running patient samples. If QC is ordered with calibration and it recovers out of range high, the calibration status will be 'Awaiting Acceptance'. Reject and re-order the calibration.

- When available, software v1.20.1 will be delivered as follows:
    - For systems running software v1.19.0 or higher, the software will be delivered electronically through the Siemens Smart Remote Service (SRS) and a yellow alert: "A new software update is available and is ready to install." will prompt the user to install the software.
    - For all other system configurations, you will be contacted by your local Siemens Customer Service representative to schedule the software installation.
- Please review this letter with your Medical Director.
- 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 product listed in Table1, 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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FIELD CORRECTION EFFECTIVENESS CHECK

Atellica® CH 930 Analyzer

Calibration Issue in Software versions 1.20.0 and below

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) ASW19-06.A.OUS, dated September 2019 regarding “Calibration Issue in Software versions 1.20.0 and below”.

Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the UFSN instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number(s): _____

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.

If you have any questions, contact your local Siemens technical support representative.

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