# Urgent Field Safety Notice

**ASW20-03.A.OUS**

**February, 2020**

## Atellica® Solution

## Atellica® CH 930 Analyzer – Issue with Auto-reruns and Test Definition Updates

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 Correction

The purpose of this communication is to inform you of the issues listed in Table 2 below, that can occur on the Atellica CH 930 Analyzer, installed with Atellica Solution software (SW) versions v1.21.0 SP1 or lower and provide instructions on actions your laboratory must take.

These issues will be corrected in SW v1.22.0 and v1.21.11, which will be available soon.

**Table 2. Description of Observed Behaviors**

| Issue Number | Observed Behavior | Description of Observed Behavior |
|---|---|---|
| | | |
| 1 | Editing an assay Test Definition and switching to another assay's Test Definition screen without saving the changes using the 'save' button on the screen, may corrupt the settings of the assay's test definition. | On the Atellica CH 930 Analyzer, after editing Test Definition (TDef) parameters for an assay, if the changes are not 'saved' using the steps documented in the online help, and the user abruptly selects another assay to edit, there is a potential to overwrite some parameters of the original assay that was being edited with the settings of the newly selected assay if the 'save' button on the dialog box displayed after selecting the new assay is clicked.<br><br>If an overwrite of settings occurs, it can impact some or all TDef parameters on the screen and potentially affect the results for the affected assay. Incorrect calculation and reporting of patient and QC results could be generated for the following parameters:<br>• Range values (Assay Hi/Lo, Panic Ranges)<br>• Auto-Rerun Trigger |





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| | | • Measuring Interval Ranges<br>• Unit<br>• Correlation Coefficients<br>• LIS Code<br><br>Based on the affected fields, the following issues are possible:<br>1. Result reported with incorrect unit<br>2. Result can be interpreted differently (because of incorrect edits to measuring interval).<br>3. No Auto-repeat<br>4. Incorrect result calculated by applied correlation coefficients<br>5. No Hi/Lo flag on results<br>6. Result associated to wrong test due to incorrect LIS Code<br><br>All chemistry assays are impacted.<br><br>The probability of this issue occurring is extremely low and requires a specific timing window. |
| 2 | Auto-Rerun or Auto-Dilution results may generate a result of Zero (0) for quantitative assays or Negative for qualitative assays if a well of the reagent pack is not calibrated. | If the Atellica CH 930 Analyzer runs out of reagent in one well of a reagent pack while processing an auto-rerun or auto-dilution, the system attempts to use the next well of a reagent pack, however if the next well of the pack does not have a valid calibration, the auto-rerun or auto-dilution will be reported as Zero (0) for quantitative assays or Negative for qualitative assays instead of 'ERROR'. |

**Table 3. Risk to Health**

| Issue Number | Risk to Health |
|---|---|
| 1 | This issue is caused by the modification of the Test Definition (TDef) settings. Depending on the field impacted, there is a potential to affect the accuracy of patient or QC results. Worst-case, this may include but is not limited to erroneous results due to a change in units, measurement ranges or other settings or cause a delay in reporting.<br><br>As the likelihood of a user overwrite of the TDef setting and the subsequent significant clinical effect is unlikely, Siemens Healthineers is not recommending the review of previously generated patient results. |





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|---|---|
| 2 | The auto-rerun or auto-dilution function may be used to verify a particular result or to obtain results above the analytical measuring range (AMR). Any discrepancy between the initially obtained neat result and the second result after auto-rerun or auto-dilution of Negative or Zero (0) will be apparent to the operator and questioned.<br>Siemens is not recommending a review of previously generated patient results. |

## Actions to be Taken by the Customer

The following actions must be taken until your system has been updated to software version V1.22.0 (or V1.21.11 for Atellica Solution with decapper modules) or higher which resolves the issues listed above.

1. When making modifications to an assay's Test Definition settings on the Setup>Test Definition>CH Test Definition screen, always follow the instructions outlined in the Atellica Solution online help 1.20 instructions "*Editing Assay Identification Parameters in CH Test Definition."* Each Test Definition must be saved using the 'Save' button on the CH Test Definition screen before starting modifications on another assay's Test Definition. After changing any setting on the Definition, Calculation, or Calibration tabs of the CH Test Definition screen, select Save and then OK. Verify that QC results are not affected, and that results, units, and flags are reported correctly for any Test Definition that has been updated before running patient samples.
2. Ensure all reagent packs have a valid calibration (all wells) before running samples. This information is available on the screen Calibration > Calibration Overview. Refer to the Atellica Solution online help 1.20 instructions, "*Viewing Assay Reagent Calibration Order Status".*

- When available, software v1.22.0 and/or v1.21.11 will be delivered as follows:
    - For systems running software v1.19.0 or higher, that are connected to the Smart Remote Service (SRS), the software will be delivered electronically through 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 Healthineers technical support 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.





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- If you have received any complaints of illness or adverse events associated with the product 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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## FIELD CORRECTION EFFECTIVENESS CHECK

Atellica® CH 930 Analyzer – Issue with Auto-reruns and Test Definitions Updates

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics UFSN ASW20-03.A.OUS dated February, 2020 regarding Atellica® CH 930 Analyzer – Issue with Auto-reruns and Test Definitions Updates. 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:

Street:

City: State:

Phone: Country:

Customer Sold To #: Customer Ship To #:

Please send a scanned copy of the completed form via email to: xxxx@yyyy.com, Or to fax this completed form to the Customer Care Center at: xxx-xxx-xxxx.

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





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