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Urgent Field Safety Notice (ASW 21-02):

Atellica® IM 1300 Analyzer / Atellica® IM 1600 Analyzer / Atellica® CH 930 Analyzer

Multiple issues in Software v1.23.2 and lower

Dear Sirs,

Our records indicate that your facility may have received one or more of the following products:

Table 1. Atellica® Solution Affected Product(s):

Product	Siemens Material Number (SMN)
Atellica CH 930 Analyzer	11067000
Atellica IM 1300 Analyzer	11066001
Atellica IM 1600 Analyzer	11066000

Reason for Urgent Field Safety Notice

Siemens Healthcare Diagnostics has identified the following issues with the Atellica Solution products listed in Table 1, which are installed with Atellica Solution software (SW) versions V1.23.2 (SMN 11469032) or lower and provide instructions on actions your laboratory must take.

These issues will be corrected in software version 1.24 or higher, which will be available soon.

Description of Observed Behaviors

Issue	Observed Behavior	Description of Observed Behavior
1	<p>Atellica CH 930 or IM 1300 and IM 1600 analyzers</p> <p>Patient orders may be run on an Analyzer where the assay has been disabled.</p>	<p>A patient order may sporadically be processed at an analyzer where the assay has been disabled by the user for any reason (e.g. if QC is out of range). A potentially discrepant result may be reported from the analyzer where the assay was disabled depending on the reason for it being disabled. This issue only occurs if the following conditions are met:</p> <ul style="list-style-type: none"> - A Cal/QC workorder is not able to be run on an analyzer because the targeted analyzer was down. - The Analyzer is then put back into service but patient processing for the assay was disabled by the user and at the same time patient samples were loaded from the sample handler drawer. <p>Note: If the Atellica Solution has multiple analyzers connected, then it is possible that the patient order may be processed at an analyzer where the assay has not been disabled. In this case the issue will not occur.</p> <p>Any assay on the CH or IM analyzers may be affected if it was disabled on one of the analyzers.</p>
2	<p>Atellica IM 1300 and Atellica IM 1600</p> <p>Analyzers may operate and report results in a service 'bypass' mode.</p>	<p>On the Atellica IM 1300 and Atellica IM 1600 Analyzers, a 'bypass' mode is available for service personnel to operate the system during servicing. This mode requires use of a service interlock override tool to bypass the top covers. The tool is required to be removed from the system before it can be used for routine sample processing. An unlikely but possible software logic error can cause the system to start operating in 'bypass' mode (without use of the service tool) when the analyzer covers are opened and closed in a sequence.</p> <p>When running in this mode, the analyzer will not stop processing results when vacuum, pressure or thermal issues arise on the system and may result in potentially discrepant results being reported without appropriate flags.</p> <p>Any assay on the IM analyzers may be affected after both the front and back covers have been opened and closed.</p>
3	<p>Atellica CH 930 Analyzer</p> <p>Manual entry of Atellica A1c_E - Calibrator bottle values.</p>	<p>On the Atellica CH 930 Analyzer, when manually entering calibrator bottle values for the Atellica A1c_E assay from the keyboard, the system may use default bottle values instead of the entered values until a system reboot occurs. The use of default calibrator bottle values can result in up to a -7% relative bias in the A1c_E result.</p> <p>The system uses the correct calibrator bottle values if the assay barcode is scanned. No other assays are affected.</p>
4	<p>Atellica CH 930 Analyzer</p> <p>Incorrect Lot Calibration Interval for Ammonia assay in Test Definition Parameters</p>	<p>The test definition for the Ammonia assay incorrectly allows for a 60-day lot calibration interval. The correct calibration interval for the Ammonia assay is 30 days as indicated in the Instructions for Use (IFU). Based on Siemens Healthineers' investigation, there is no statistically significant drift observed at clinically relevant concentrations of ammonia, including values approximating the reference interval (19-54 ug/dL or 11-32 μmol/L) when results are generated using a calibration that is >30 days. A worst-case bias of negative 17% was observed at an ammonia</p>

		concentration of approximately 700 ug/dL (410 µmol/L) at 62 days post lot calibration. No other assays are affected.
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Risk to Health

Issue Number	Risk to Health
1	Worst case, the potential exists for a sample to be tested using an assay that has been disabled, which may lead to the reporting of discrepant patient results. Mitigations include correlation to clinical information such as clinical presentation, other laboratory and diagnostic results and patient history, operator investigation or analyzer having no reagents or running out of reagents due to continuous testing. Due to the remote probability of this event, Siemens is not recommending a review of previously generated results.
2	Worst case, the unlikely but possible potential exists that this issue may lead to the reporting of discrepant patient results in the presence of instrument errors. Mitigations include correlation to clinical information such as clinical presentation, other laboratory and diagnostic results and patient history, manual QC result review, operator investigation and event log review that indicates that the system is in 'bypass' mode setting. Due to the remote probability of this event, Siemens is not recommending a review of previously generated results.
3	The management of patients with hyperglycemia is dependent upon the monitoring of diet, lifestyle, glucose concentrations, HbA1c, and the adjustment of therapy to glycemic control. A negative bias of up to 7.0% (relative percent) may be considered clinically significant at clinically relevant HbA1c values and may result in the modification of the therapy for hyperglycemia. The modification of hyperglycemic therapy can increase the risk of occurrence of hyperglycemia, which may be observed through personal glucose monitoring and/or patient symptoms. Siemens is not recommending a review of previously generated results.
4	When ammonia results are generated using a calibration that exceeds 30 days the observed differences are negligible and would not lead to a clinically significant difference in patient management. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

The following actions must be taken until your system has been updated to software version 1.24 or higher which resolves the issues listed below. Siemens Healthineers will notify you when an updated software version is available.

Issue Number 1: Patient orders may be run on an Analyzer where the assay has been disabled.

- When reporting results, ensure that the result for the assay that is disabled on one analyzer, came from an analyzer where the assay had not been disabled and all QC results are within the laboratory acceptable range.
- To check if an assay is enabled or disabled, navigate to Setup > Test Definition > Assay List > CH or IM tab. An assay is enabled if the box is checked in the column for an analyzer.

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3. The Audit Trail screen (System->Logs->Audit Trail.Log) can be checked to see if an assay had been disabled in the past.

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Issue Number 2: Analyzers may operate and report results in a service ‘bypass’ mode.

1. Always ensure that the system covers are properly physically closed and latched. The lock glyph on the System > Status screen for an analyzer indicates whether the cover is locked or unlocked. Ensure that there are no ‘yellow’ unlocked glyphs displayed.
2. Before starting sample processing, check the Operator Event log and ensure that the following error code is not present:

“03 600 00 44: A cover is open with the Service Bypass Tools in place. Ensure all operators are clear of moving subassemblies to avoid personal injury or system damage. Corrective Action: Contact the local technical support provider for assistance.”

- Refer to the online help Alerts section 03 IM Event Troubleshooting if the error code is present.

Issue Number 3: Manual entry of Atellica A1c_E - Calibrator bottle values.

1. It is recommended to always scan the calibrator bottle values via the barcode on the A1c_E CAL Table of Assigned Values (TAV) sheet received with the calibrator bottles. If the bottle values are scanned, the issue does not occur.
2. If the calibrator bottle values are entered manually, restart the CH Analyzer by following the directions in the online help: “Starting Analyzers within the System”.

Issue Number 4: Ammonia Lot Calibration

1. Navigate to **Calibration > Calibration Results** and select the Ammonia Assay.
 2. Record the date and time of the Ammonia Lot calibration. A lot calibration will need to be performed 30 days from the recorded date.
 3. Ensure the Ammonia assay has a lot calibration performed every 30 days.
- 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 products listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local 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 technical support provider.

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to



Sincerely yours,

Siemens Healthcare Diagnostics GmbH

A handwritten signature in black ink, appearing to read "Franz Schwarz".

i.V. Dipl. Ing. Franz Schwarz
Quality Management CEE

A handwritten signature in black ink, appearing to read "Dr. Brigitte Gassner".

i.A. Dr.ⁱⁿ Brigitte Gassner
Product Manager Austria & SEE