SIEMENS Healthineers
Siemens Healthcare Diagnostics Inc.

Urgent Field Safety Notice

ASW21-01.A.OUS

October, 2020

Atellica® IM 1300 Analyzer
Atellica® IM 1600 Analyzer

Test Definition scanning may reset custom settings to defaults.

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 IM 1300 Analyzer	11066001
Atellica IM 1600 Analyzer	11066000

Reason for Urgent Field Safety Notice

Siemens Healthcare Diagnostics has identified an issue with the Atellica Solution products listed in Table 1 through investigation of customer complaints for software (SW) versions V1.23.1 (SMN 11485021) or lower.

This behavior will be corrected in a future software version.

Description of Observed Behaviors

When a 2D Master Curve and TDef barcode for a new kit lot of reagent is scanned and the TDef version is a newer version than the version that is currently on the system, some of the customer defined settings for that assay may reset to default values. The TDef settings shown in Table 2 are affected.

This issue does not apply to Atellica CH Analyzer assays.

Table 2. Test Definition (TDef) Default Values:

Issue Number	TDef Setting	Description of Observed Behaviour
1	HIL Alert Indices	HIL Alerts will be disabled. Tests will not be flagged with HIL flags.

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	• Hemolysis Threshold • Icteric Threshold • Lipemic Threshold	Default Values: Disabled Disabled Disabled
2	QC Statistics Violation - Patient Tests	Patient orders will continue to be run even if there are QC Statistics violations of 'Error' or 'Warning'. Appropriate QC result flagging and evaluation is not impacted by this issue. Default Value: Never Disable (i.e. don't disable running patient orders if there are QC Statistics Violations).
3	Auto Cal Expiration Triggers Automatically Order Calibration Auto Cal (Lot) Expiration Time Auto Cal (Pack) Expiration Time Auto Cal New Lot Trigger Auto Cal IFU Change Trigger	Calibration orders will be created automatically by the system. Default Values: Enabled Enabled, 1 day Enabled, 24 hours Enabled Disabled
4	Pack Calibration Interval Pack Calibration Interval (Days) Pack Calibration Interval (Hours)	Pack calibrations will expire using the Siemens defined value instead of the customized value. Default Values: Varies based on the Assay Varies based on the Assay
5	Calibrator Onboard Stability Cal OBS Refrigerated Cal OBS Unrefrigerated	After being loaded on the Sample Handler, calibrator samples will expire using the Siemens defined value instead of customized value. Default Values: Varies based on the Assay Varies based on the Assay

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Risk to Health

Issue Number	Risk to Health
1	This issue only affects user customized TDef settings. The HIL flagging is disabled due to this issue. Worst-case, the potential exists that a sample with a truly elevated HIL may not be flagged and a potentially erroneous patient result is reported without alert. Mitigations include the result correlation to the clinical information such as clinical presentation, other laboratory and diagnostic results and patient history. Siemens is not recommending a review of previously generated results due to the remote probability of a clinically significant impact on patient results.
2	This issue only affects user customized TDef settings. Customizations to the QC Statistics Violation settings of the definition tab as displayed in table 2 can be reverted to the Siemens default settings with no impact to health. Mitigations include manual QC result review and investigation. Siemens is not recommending a lookback of previously generated results due to this issue.
3-5	This issue only affects user customized TDef settings. Customizations to the calibrator settings of the definition tab as displayed in table 2 can be reverted to the Siemens default settings with no impact to health. Siemens is not recommending a lookback of previously generated results due to this issue.

Actions to be Taken by the Customer

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

1. After scanning a new version of the 2D Master Curve and Test Definition barcodes included in the reagent package, verify the settings of the customized fields, if applicable, on the Setup/Test Definition/IM Test Definition screen listed below. Verify that QC results are not affected, and that results related parameters (e.g. units) and all associated customized parameters listed below are setup correctly. If necessary, re-enter any customized settings.

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Result Calculation Tab
HIL Alert Indices
• Hemolysis Threshold
• Icteric Threshold
• Lipemic Threshold
Calibration Tab
Pack Calibration Interval (Days)
Pack Calibration Interval (Hours)
QC Statistics Violation
Auto Cal Expiration Triggers
• Auto Cal (Lot) Expiration Time
• Auto Cal (Pack) Expiration Time
• Auto Cal New Lot Trigger
• Auto Cal IFU Change Trigger
Cal OBS Refrigerated
Cal OBS Unrefrigerated

2. Additionally, after scanning an updated TDef, the Audit Trail Log can be reviewed to determine which fields have been impacted. Changes to the listed fields are reported in the Audit Trail screen (System->Logs->Audit Trail.Log).

- 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.

Atellica is a trademark of Siemens Healthcare Diagnostics Inc.

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FIELD CORRECTION EFFECTIVENESS CHECK

Test Definition Scanning may reset custom settings to defaults

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) ASW21-01.A.OUS, dated October, 2020 titled “Test Definition Scanning may reset custom settings to defaults”. 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:

Please send a scanned copy of the completed form via email to the following e-mail address: XXXX@XXXX,

Or 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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