

**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):**

| <b>Product</b>            | <b>Siemens Material Number (SMN)</b> |
|---------------------------|--------------------------------------|
| 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:**

| <b><u>Issue Number</u></b> | <b><u>TDef Setting</u></b> | <b><u>Description of Observed Behaviour</u></b>                        |
|----------------------------|----------------------------|--|
| 1                          | HIL Alert Indices          | HIL Alerts will be disabled. Tests will not be flagged with HIL flags. |

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|   |  |  |
|---|--|--|
|   | <ul style="list-style-type: none"> <li>• Hemolysis Threshold</li> <li>• Icteric Threshold</li> <li>• Lipemic Threshold</li> </ul>  | <p><u>Default Values:</u><br/>Disabled<br/>Disabled<br/>Disabled</p>   |
| 2 | QC Statistics Violation - Patient Tests  | <p>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.</p> <p><u>Default Value:</u><br/>Never Disable<br/>(i.e. don't disable running patient orders if there are QC Statistics Violations).</p> |
| 3 | <p>Auto Cal Expiration Triggers</p> <p>Automatically Order Calibration<br/>Auto Cal (Lot) Expiration Time<br/>Auto Cal (Pack) Expiration Time<br/>Auto Cal New Lot Trigger<br/>Auto Cal IFU Change Trigger</p> | <p>Calibration orders will be created automatically by the system.</p> <p><u>Default Values:</u><br/>Enabled<br/>Enabled, 1 day<br/>Enabled, 24 hours<br/>Enabled<br/>Disabled</p>   |
| 4 | <p>Pack Calibration Interval</p> <p>Pack Calibration Interval (Days)<br/>Pack Calibration Interval (Hours)</p>   | <p>Pack calibrations will expire using the Siemens defined value instead of the customized value.</p> <p><u>Default Values:</u><br/>Varies based on the Assay<br/>Varies based on the Assay</p>  |
| 5 | <p>Calibrator Onboard Stability</p> <p>Cal OBS Refrigerated<br/>Cal OBS Unrefrigerated</p>   | <p>After being loaded on the Sample Handler, calibrator samples will expire using the Siemens defined value instead of customized value.</p> <p><u>Default Values:</u><br/>Varies based on the Assay<br/>Varies based on the Assay</p>   |

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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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| <b>Result Calculation Tab</b>   |
|---|
| HIL Alert Indices   |
| <ul style="list-style-type: none"> <li>• Hemolysis Threshold</li> </ul>             |
| <ul style="list-style-type: none"> <li>• Icteric Threshold</li> </ul>               |
| <ul style="list-style-type: none"> <li>• Lipemic Threshold</li> </ul>               |
|   |
|   |
| <b>Calibration Tab</b>  |
| Pack Calibration Interval (Days)  |
| Pack Calibration Interval (Hours)   |
| QC Statistics Violation   |
| Auto Cal Expiration Triggers  |
| <ul style="list-style-type: none"> <li>• Auto Cal (Lot) Expiration Time</li> </ul>  |
| <ul style="list-style-type: none"> <li>• Auto Cal (Pack) Expiration Time</li> </ul> |
| <ul style="list-style-type: none"> <li>• Auto Cal New Lot Trigger</li> </ul>        |
| <ul style="list-style-type: none"> <li>• Auto Cal IFU Change Trigger</li> </ul>     |
| 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.
- 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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