SIEMENS Healthineers
Siemens Healthcare Diagnostics Inc.

Urgent Field Safety Notice

ASW18-03.A.OUS
September, 2018

Cc to Chairman Medical Board and relevant
Head of Departments

Atellica® IM 1300 Analyzer
Atellica® IM 1600 Analyzer
Atellica® CH 930 Analyzer
Atellica® Sample Handler Prime

Multiple Issues Identified in Atellica Solution System Software in V 1.14.2 and lower.

Our records indicate that your facility may have received one or more or a combination 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
Atellica CH 930 Analyzer	11067000
Atellica Sample Handler Prime	11069001

Reason for Urgent Medical Device Correction

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 V1.14.2 (SMN 11316393) or lower.

These behaviors are corrected in SW V1.15, which will be available soon.

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Table 1. Description of Observed Behaviors

Issue Number	Observed Behavior	Description of Observed Behavior
1	The cover interlocks on the Atellica Magline ™ Transport for the Atellica CH 930 Analyzer, IM 1300 Analyzer, and IM 1600 Analyzer may not work as expected.	When an Atellica Magline Transport cover in the front or back of an analyzer is opened, carrier motion may continue and the operator may not be alerted that a cover is open.
2	The Atellica IM 1300 Analyzer and IM 1600 Analyzer may use the T3/T4/VB12 Ancillary Reagent after expiration.	The following scenarios may occur: • T3 and T4 results generated using expired T3/T4/VB12 Ancillary Reagent are reported with a result flag, “OBS extended”. • VB12 dilution results generated with expired T3/T4/VB12 Ancillary Reagent are not reported with a flag.
3	The Atellica IM 1300 Analyzer and Atellica IM 1600 Analyzer may not calibrate T4.	Intermittent failures may occur when calibrating the T4 assay due to observed errors in one or more replicates. The result in the Worklist will be flagged with a “Signal shape error”.
4	The Atellica CH 930 may report incorrect serum indices for Hemolysis, Icterus and Lipemia (H, I, and L) for any test run on the patient sample.	The CH analyzer generates H, I, and L serum indices in two ways. • Method 1: If the Setup->Settings->General Setup->Patient->HIL Ordering option is set to “Always order” or “According to TDef”, for samples with one or more of the following tests, ALT, AST, LDLP, and UN_c, the indices are calculated from one of these tests. • Method 2: For samples without one of the tests listed in “Method 1” above, the indices are generated independently and are correct. The serum indices calculated when ‘Method 1’ is used may not be consistent with the sample or the independently derived H, I, and L indices using “Method 2”.

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Risk to Health

Issue Number	Risk to Health
1	The potential exists, though remote, for the operator to be hit by moving carriers when reaching into the Atellica Magline Transport. This may occur only if the cover has been removed and the Magline Transport has not been put into standby mode. In addition, there is a potential for loss of sample and delay in testing. Siemens is not recommending a laboratory look back of previously generated results as no erroneous results will be generated by the system.
2	For the two scenarios that can occur: • If T3/T4/VB12 Ancillary Reagent is used for T3 and T4 testing beyond its on-board stability, all results will be flagged to alert the user. • In scenarios where T3/T4/VB12 Ancillary Reagent is used beyond its on-board stability as wash reagent for VB12, the risk to health is remote and limited to misinterpretation of erroneously elevated VB12 results which may affect consideration of intervention. Clinical impact would be mitigated by correlation to clinical presentation and clinical history, as well as other diagnostic laboratory testing such as complete blood count, folate and methylmalonic acid testing. Siemens is not recommending a laboratory look back of previously generated results as the possibility for this event is remote.
3	As this issue would be apparent to the user, the risk to health is negligible. Siemens is not recommending a laboratory look back of previously generated results.
4	This issue may cause incorrect flagging of results, depending on the direction and degree of index difference and the analyte HIL index threshold. In the scenario of a higher HIL index than the true index, results may be flagged for a high specimen index when truly below the index threshold for an analyte, which would be apparent to the user. Worst case, in the scenario of a significantly lower HIL index than the true index, results may not be flagged as appropriate. The likelihood of inappropriate flagging leading to an index change and a subsequent clinically significant effect is remote. 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 with software version 1.15 which resolves issues 1-4.

1. The system must be safely stopped prior to opening the Atellica Magline Transport covers. Please follow the procedure “Removing Atellica Magline Transport Covers” by searching the Atellica Solution online help or refer to the Operator’s guide (April 2018). To replace the covers and resume operation, follow the procedure “Installing Atellica Magline Transport Covers” as detailed in the Atellica Solution online help or Operator’s Guide (April 2018).
2. Check the Onboard Stability of T3/T4/VB12 Ancillary Reagent packs daily and replace them before they expire:
    - On the command bar select **Inventory > Reagent Overview**

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- For any T3/T4/VB12 Ancillary Reagent packs, review the **Onboard Stability**
- Replace any pack before the Onboard Stability reaches 0d 0h.

3. If a T4 calibration fails, increase the number of replicates in the Calibration order as follows:
   - Step 1: Determine how many replicates failed with a 'signal error'.
   - Step 2: Determine the minimum required replicates from the Test Definition screen: (Setup > Test Definition > IM Test Definition) by selecting the assay from the Test list and choosing the Calibration tab.
   - Step 3: Set the number of replicates on the Calibration Order screen: (Calibration->Create Calibration Orders->Edit Cal Order) to the total of (Step 1 + Step 2).
4. Do not order H, I, or L serum indices in the same order with ALT, AST, LDLP, or UN_c tests. In order to get correct serum indices values, order the serum indices on the system or from the LIS, in a separate order without any of the donor methods (ALT, AST, LDLP, or UN_c). Alternatively, automatic HIL ordering can be turned off from the settings screen: (Setup->Settings->General Setup->Patient->HIL Ordering) by selecting "Never Automatically order.

- 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 Customer Care Center or your local technical support provider.

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 Customer Care Center or your local technical support provider.

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FIELD CORRECTION EFFECTIVENESS CHECK

Multiple Issues Identified in Atellica Solution System Software in V 1.14.2 and lower

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) ASW18-03.A.OUS, dated September, 2018 titled "Multiple Issues Identified in Atellica Solution System Software in V 1.14.2 and lower". 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 U instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

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

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