SIEMENS Healthineers
Siemens Healthcare Diagnostics Inc.

Urgent Field Safety Notice

ASW18-02.A.OUS

June, 2018

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

Multiple Issues Identified in Atellica Solution System Software V 1.13 and lower

Our records indicate that your facility may have received the following product:

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
Atellica Sample Handler Connect	11069018
Atellica Sample Handler Additional	11069004

Reason for Urgent Field Safety Notice

Siemens Healthcare Diagnostics has identified the following issues with the Atellica Solution products listed in Table 1, that are running on Atellica Solution software (SW) version (V) 1.13 (SMN 11314885) or lower.

These issues are corrected in SW version 1.14.

Table 2. Description of Observed Behaviors

Issue Number	Observed Behavior	Description of Observed Behavior
1	The Atellica IM 1300 Analyzer and Atellica IM 1600 Analyzer Reagent lot locking may not work as	Reagent lot locking is not working as intended with Primary Reagent ReadyPacks® and Ancillary Packs when more than one (1) lot of the Reagent kits listed in Table 3, below, are loaded on the analyzer at the same time.

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	intended	This behavior can occur in SW version 1.13 and all previous versions.
2	The Sample Handler may misread Intervleaved 2 of 5 (i2of5) barcodes	The check digit feature for the i2of5 barcode symbology is disabled by default. As a results, if i2of5 barcode labels are applied to sample tubes at an angle, the camera may read the label incorrectly and not trigger a barcode misread error. This behavior can occur in SW version 1.13 and all previous versions.
3	The Atellica IM 1300 Analyzer and Atellica IM 1600 Analyzer may not run CEA dilutions at 50x and 100x	The Analyzer may post a “Sample Integrity Error” when 50x or 100x dilutions are ordered for Carcinoembryonic Antigen (CEA). Dilution factors lower than 50x and neat samples are not affected by this behavior. This behavior can occur in SW version 1.13 and all previous versions.
4	The Atellica CH 930 Analyzer may continue to display the default reporting units after the reporting units have been changed	If assay reporting units are changed from the default units in the Atellica Chemistry (CH) Test Definition (TDef), the default reporting units will still be displayed in numerous screens of the User Interface Workstation (UIW). All calculations and flagging will use the appropriate conversion factor for the units selected in the TDef Screen. This behavior only occurs in SW V 1.13. IMT tests are not impacted by this behavior.
5	The Atellica CH 930 Analyzer may not display results for sample if certain assays are configured to auto-dilute results above or below the assay measuring interval	If the Atellica CH 930 Analyzer is configured to perform Auto-Dilutions or Re-Analysis for samples that generate system flags, such as, “> Measuring Interval” or “< Measuring Interval”, the final result will not be displayed in the UIW or be transmitted to the LIS for the assays listed in Table 4, below. This behavior only occurs in SW V 1.13.

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Table 3. Atellica Solution Immunoassay Reagent Kits Affected:

NOTE: All reagent lot numbers of the assays listed below can be impacted by the software behavior described in Issue number 1, in Table 2.

Assay	Test Code
Hepatitis A IgM	aHAVM
Hepatitis A Total	aHAVT
Hepatitis B core Antigen	aHBcM
Hepatitis B core Total	HBcT
Hepatitis C	aHCV
Hepatitis B surface Antigen II	HBsII
Hepatitis B surface Antigen II Confirmatory	HBs Conf
Procalcitonin	PCT
Progesterone	PRGE
Syphilis	SYPH
Testosterone II	TSTII
Vitamin D Total	VitD

Table 4. Atellica Solution Chemistry Reagent Kits Affected:

NOTE: All reagent lot numbers of the assays listed below can be impacted by the software behavior described in Issue number 5, in Table 2.

Assay	Test Code
Alanine Aminotransferase P5P (liquid) Reagents	ALTPLc
Anti-Streptolysin-O_2	ASO_2
Immunoglobulin A_2	IgA_2
Immunoglobulin G_2	IgG_2
Immunoglobulin M_2	IgM_2
Inorganic Phosphorus	IP
Total Protein_2 (Urine)	UPro

Risk to Health

Issue Number	Risk to Health

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1	Siemens internal investigation is ongoing. There is a potential, though remote, that use of an incorrect combination of reagent and ancillary across different lots may cause a misinterpretation of Hepatitis B surface Antigen (HBsAg) results. For HBsAg, the risk to health is remote and limited to a falsely non-reactive HBsAg result when truly reactive, which may lead to delayed investigation of HBsAg infection. The risk to health is reduced by correlation with clinical presentation and clinical history, as well as concurrent or consequent testing with other biomarkers of Hepatitis B infection. A lookback is recommended for previously generated non-reactive results of ≥0.5 and <1.0 Index Value only where different lots may have been combined (see Question and Answer below). Retesting may be performed with the system on software version 1.13 and lower provided only one lot of reagent is on the system at a time. For all other assays affected, the risk to health is negligible.
2	The potential exists, though remote, for misidentification of a patient sample due to this issue. This only would occur if the misread barcode matches the sample ID of another sample with pending orders and the erroneously read sample is scanned first. Siemens is not recommending a laboratory look back of previously generated results as a duplicate barcode reader error will be generated by the system and due to the remote possibility of this event.
3 – 5	As these issues would be apparent to the user, the risk to health is negligible. Siemens is not recommending a laboratory look back of previously generated results.

Actions to be Taken by the Customer

1. For the assays listed in Table 3, please load only one (1) Reagent kit lot on the Atellica IM 1300 Analyzer or Atellica IM 1600 Analyzer at a time.
    - As per the assay specific Instructions For Use, “The Ancillary Reagent provided in this kit is matched to the Solid Phase and the Lite Reagent. Do not mix Ancillary Reagent lots with different lots of Solid Phase and Lite Reagent”.
    - Multiple ReadyPacks and Ancillary packs of the same Reagent kit lot can be on the system at the same time.
    - Any assay kit not listed in Table 3, is not affected.
2. The Atellica Solution Software disables the check digit feature on the interleaved 2 of 5 (i2of5) symbology by default. Consider using an alternate barcode symbology.
    - If your system posts a, “Duplicate Barcode Error” message in the Sample Handler Event Log, please inspect the sample tubes that caused the error. Call Siemens Technical Support if you need assistance troubleshooting the occurrence.
3. If you experience Sample Integrity Errors on CEA dilutions, run samples that require CEA dilutions of 50x and 100x on an alternate platform. As stated in the IFU, if using an alternate platform the laboratory must perform additional serial testing to confirm baseline values.
4. If your Atellica CH 930 Analyzer is operating on SW V 1.13, and any assay reporting units were changed, verify results are reported with the properly configured units.
    - No action is required if reporting units were changed on your system prior to being upgraded to SW V 1.13, they will continue to be displayed correctly.

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5. If your Atellica CH 930 Analyzer shows results with system flag that require dilutions, the dilution can be ordered manually.
    - Any assay not listed in Table 4, is not affected.

- 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 3, immediately contact your local Siemens Customer Care Center or your local Siemens 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 Customer Care Center or your local Siemens technical support representative.

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Question and Answer for Issue Number 1 only

Question: Why are only results of ≥0.5 and <1.0 included in the lookback?

Answer: Based on the predicted worst case differences that may be possible when combining different lots of reagent and ancillary packs, a difference of no more than 0.5 Index is expected between lots.

Question: Can Siemens Healthcare Diagnostics assist customers with determining whether two different lots were in-use on the Atellica IM 1300 Analyzer or Atellica IM 1600 Analyzer at the same time?

Answer: Please contact your local Siemens Healthcare Diagnostics Customer Care Center or Technical representative for assistance determining whether two lots of reagent were in use on the Atellica IM 1300 Analyzer or Atellica IM 1600 Analyzer at the same time.

Question: If potentially affected patients are identified, how can I communicate this issue to healthcare provider?

Answer: Siemens suggests the following wording:

Siemens Healthcare Diagnostics has confirmed through internal investigation that between [*dates affected in your laboratory*], there was a possibility for incorrect results for some patient samples for the Hepatitis B surface Antigen assay. Results may have been reported as non-reactive when truly reactive, though the probability is remote.

Please consider retesting in cases where all of the following events have occurred:

1. You have had HBsAg testing performed on your patient(s) during the dates listed above,
2. Your patient's HBsAg result was negative,
3. Your patient was not otherwise diagnosed with Hepatitis B infection due to repeat or additional Hepatitis B testing,
4. There is high clinical suspicion for disease.

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FIELD CORRECTION EFFECTIVENESS CHECK

Multiple Issues Identified in Atellica Solution System Software V 1.12.1 and 1.13

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) ASW18-02.A.OUS, dated June, 2018 regarding multiple issues identified in Atellica Solution System software V 1.12.1 and 1.13. 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 XXXX@XXXX (**for the US ONLY letter** use the following e-mail address: uscctsfcaecfax.team@siemens-healthineers.com, **for the OUS letter** the information will be filled in by the region).

Or to fax this completed form to the Customer Care Center at XXXXXX (**For US ONLY letter,** use the following phone number: (312) 275-7795, **for the OUS letter** the information will be filled in by the region) delete the Not Applicable text in yellow prior to sending.

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

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