Urgent Field Safety Notice

ASI19-04.A.OUS

August 2019

Cc to Chairman Medical Board and relevant Head of Departments

Atellica® Solution

Atellica CH 930 Analyzer – Three issues identified in Atellica Solution Software V 1.19.2 and below

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

Table 1. Atellica® Solution Affected Product:

Product	Siemens Material Number (SMN)
Atellica CH 930 Analyzer	11067000

Reason for Urgent Field Safety Notice

The purpose of this communication is to inform you of issues with the Atellica CH 930 Analyzer listed in Table 1 above, installed with Atellica Solution software (SW) versions V1.19.2 or lower and to provide instructions on actions that your laboratory must take. These issues will be fixed in software version 1.20.

Siemens Healthcare Diagnostics Inc. has confirmed three issues:

Assays	Issue observed
Issue #1: Ecstasy (SMN# 11097518)	The test definitions allow for 20 day pack calibration interval instead of 15 days. Based on Siemens Healthineers' investigation, there is **no impact to the performance** of the Ecstasy assay due to the extended pack calibration.
Issue #2: Total Protein (SMN# 11097604)	The test definition allows for a 185 day lot calibration interval instead of 181 days. Based on Siemens Healthineers' investigation, there is **no impact to the performance** of the Total Protein assay due to the extended lot calibration.
Issue #3: Rheumatoid Factor (SMN# 11097618)	The test definition allows for a 30 days Onboard Stability (OBS) interval instead of 21 days. Based on Siemens Healthineers' investigation, there is no impact to performance of the Rheumatoid Factor (RF) assay concentrations of approximately 7 IU/mL and 45 IU/mL due to the extended OBS. At a RF concentration of 75 IU/mL, a maximum decrease in recovery of 9% was observed due to the extended OBS.

Risk to Health

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Ecstasy and Total Protein	The risk to health due to this issue is negligible. There is no impact to assay performance for Ecstasy and Total Protein.
Rheumatoid Factor	The risk to health due to this issue is negligible. Patient samples with results above the reference interval for Rheumatoid Factor would have similar clinical interpretation. Mitigations include correlation to clinical history and presentation as well as to other laboratory diagnostic evaluation. Siemens Healthineers' is not recommending a review of previously generated results.

Actions to be Taken by the Customer

Issue #1: Atellica CH 930 Ecstasy (Xtc300 & Xtc500) Pack Calibration Workaround

1. Load Atellica CH Ecstasy (Xtc300/500) reagent packs onto the CH Analyzer. Refer to the Atellica Solution Online Help Section ***Loading CH Reagents*** for instructions.
2. Immediately perform a lot calibration. Refer to the Atellica Solution Online Help Section ***Creating Assay Reagent Lot Calibration Orders*** for instructions.
3. Upon completion and acceptance of the lot calibration, record the date and time the calibration was performed by navigating to **Calibration > Calibration Results** and filtering on the appropriate assay and analyzer. (Reference Figure 1. Calibration Results Screen)
4. If the test count in the well reaches zero before the 15 days elapses no additional action is required.
5. If the test count in the well does not reach zero before 15 days elapses, 15 days after the lot calibration was performed, a pack calibration must be performed. Refer to the Atellica Solution Online Help Section ***Creating Assay Reagent Pack Calibration Orders*** for instructions.
6. Upon completion and acceptance of the pack calibration, record the date and time the pack calibration was performed by navigating to **Calibration > Calibration Results** and filtering on the appropriate assay.
7. Perform steps 5 – 6 until either the well has zero tests left or has insufficient tests to perform another pack calibration upon expiration.
8. When the system switches wells, the already established lot calibration will be applied to the newly punctured well. When this happens, Navigate to **Inventory > Reagent Overview** select the onboard Xtc pack and under Reagent Details record the date and time that the second well was punctured. Fifteen days after the second well is punctured, a pack calibration must be performed. This process must be repeated until the well test count reaches zero.

Figure 1. Calibration Results Screen

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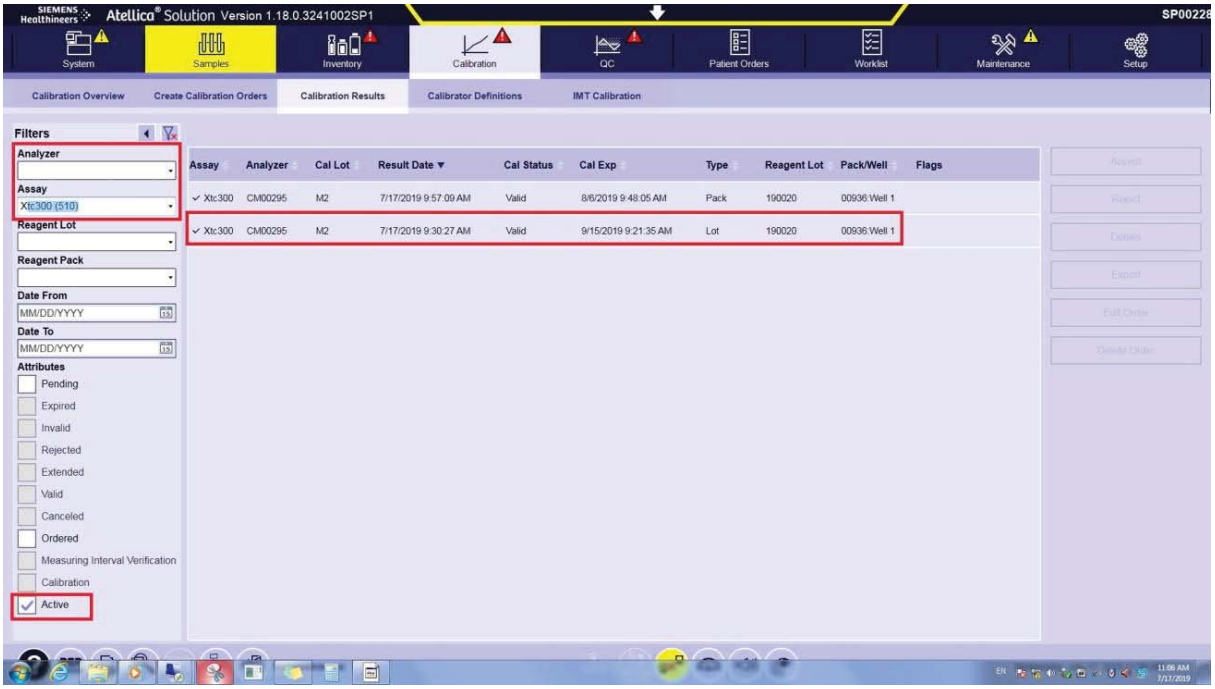

Issue #2: Atellica CH 930 Total Protein (TP) Lot Calibration Workaround

1. Navigate to **Calibration > Calibration Results** and select the TP Assay. (Reference Figure 1. Calibration Results Screen)
2. Record the date and time of the TP Lot calibration. A lot calibration will need to be performed 181 days from the recorded date.

Issue #3: Atellica CH 930 Rheumatoid Factor (RF) Onboard Stability Workaround

Reagent loading and Onboard Stability Recording

1. Load Atellica CH Rheumatoid Factor (RF) reagent packs onto the CH Analyzer. Refer to the Atellica Solution Online Help Section ***Loading CH Reagents*** for instructions.
2. Navigate to **Inventory > Reagent Overview** and select RF to view the Reagent Details. (Reference Figure 2. Reagent Overview Screen)
3. Record the date and time the reagent pack well(s) is opened. Please check status of each well in “Reagent Details”.
    a. Condition #1: If both wells are punctured upon loading the reagent pack and/or the Atellica Software Version is <1.19, the entire pack must be unloaded after 21 days. Refer to the Atellica Solution Online Help Section ***Unloading Reagents*** for instructions.
    b. Condition #2: If only the first well is punctured upon loading the reagent pack and the Atellica software version is 1.19 and greater, please follow steps below for

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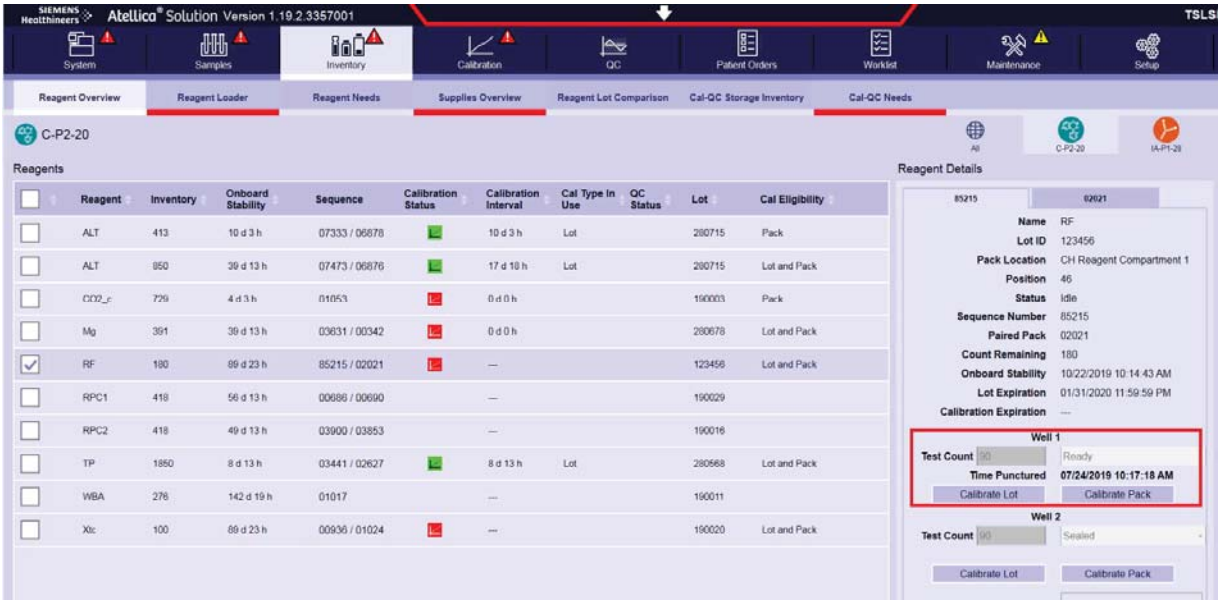
manually disabling a reagent pack well to utilize the second well. Once the second well is open for 21 days the entire pack must be unloaded from the CH analyzer.

c. **NOTE:** If either Well 1 or Well 2 test count reaches zero before the 21 onboard stability expires, no additional action is required.

Figure 2. Reagent Overview Screen



Manually Disabling a Reagent Pack Well or Unloading a Reagent Pack from the CH Analyzer

For Atellica software versions 1.19 and greater:

1. Log in as Lab Manager
2. Navigate to **Inventory > Reagent Overview** (Reference Figure 3. Reagent Overview Screen)
3. Locate and select the RF reagent.
4. Select the P1 Reagent Pack in Reagent Details
5. Select Disable Well 1

For Atellica Software Versions <1.19:

1. Remove the Reagent Pack from the CH Analyzer. Refer to the Atellica Solution Online Help Section ***Unloading Reagents*** for instructions.
2. Discard the reagent pack.

Figure 3. Reagent Overview Screen

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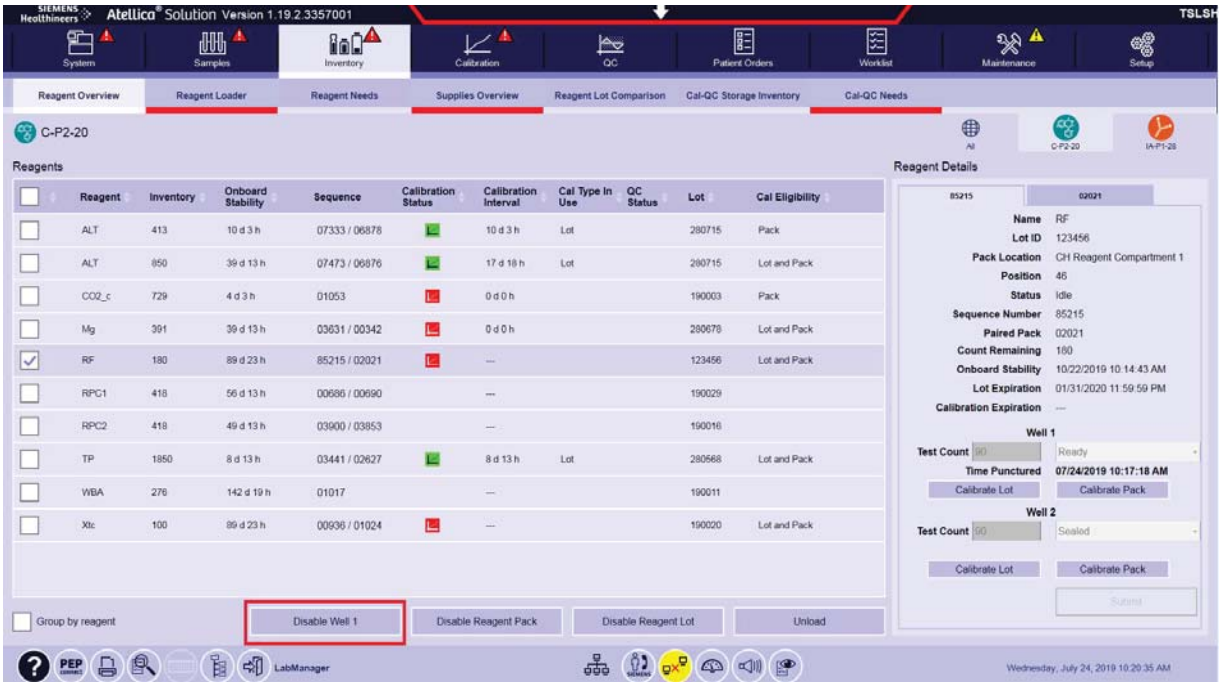

- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse health events associated with the product listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers 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 Siemens Healthineers technical support representative.

Atellica is a trademark of Siemens Healthcare Diagnostics. Inc.

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FIELD CORRECTION EFFECTIVENESS CHECK

Atellica® CH 930 Analyzer

Multiple issues identified in Atellica Solution Software V 1.19.2 and below

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) ASI19-04.A.OUS, dated August 2019 regarding “Atellica® CH 930 Analyzer Three issues identified in Atellica Solution Software V 1.19.2 and below”.

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.

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: _____

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

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