



Urgent Field Safety Notice

ACHC20-05.A.US

January 2020

Atellica® CH Analyzer

Atellica® CH 930 Analyzer – Potential for Inaccurate Test Results Associated with Reaction Cuvette Segments

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

Table 1. Atellica CH 930 Affected Product(s)

Product	Siemens Material Number (SMN)	Kit lots
Atellica CH Reaction Cuvette Segment	11099326	ONLY kit lots ending in “17” or “18” are potentially impacted

Reason for Correction

The purpose of this communication is to inform you of an issue associated with Atellica CH Reaction Cuvette Segments and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. through the investigation of customer complaints has determined that a small percentage (<0.5%) of Atellica CH Reaction Cuvette Segment kit lots ending in “17” or “18” may have cuvette defects allowing water from the water bath to contaminate the interior of the cuvette. Not all cuvette positions within an affected cuvette segment are impacted.

There were no reports of illnesses or adverse events due this issue in the customer complaints received by Siemens.

There is a potential that sample results obtained at the impacted cuvette positions can be falsely elevated or depressed to varying degrees depending on the assay and the amount of water bath contamination.

Quality control samples may or may not detect this issue.

Please note: The supply of the Atellica CH reaction cuvette segments will be closely monitored. In order to ensure inventory for all customers; allocation may be required thus delaying full replacement orders.

Risk to Health

When an affected cuvette is used for testing, the potential exists to report erroneous results depending on the analyte. Mitigations include correlation to clinical history and presentation as well as to other diagnostic laboratory testing and/or serial testing. As the likelihood of an affected cuvette and a subsequent clinically significant effect is unlikely, Siemens Healthineers is not recommending a lookback.

Please review this letter with your Medical Director.

Actions to be Taken by the Customer (Detailed instructions provided in Appendices)

- **NOTE: Appendices 1 and 2 will need to be followed for each Atellica CH 930 analyzer in your laboratory. (Appendix 3 is only needed in some cases.)**
 - Appendix 1: Required of all customers to determine if impacted Reaction Cuvette Segment lots are in use on your Atellica CH 930 analyzer(s)
 - Appendix 2: Required of all customers to resume operations: If reaction cuvette segments are not impacted OR you have replaced all 13 reaction cuvette segments with kit lots ending in “19” or above.
 - Appendix 3: **Required only** if the analyzer does not return to Standby or Ready mode after step 6 in Appendix 2
- Review the inventory in your laboratory and discard all reaction cuvette kits ending in “17” or “18”.
- 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 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.

Appendix 1: Required of all customers.

Determine if your system is using impacted Atellica CH 930 Reaction Cuvette Segment lots.

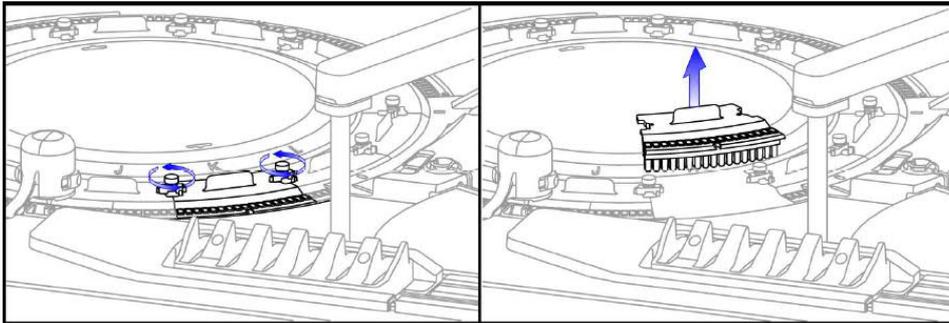
Enter the system into Operator Diagnostic State:

1. Select **System > Operator Diagnostics > CH Icon > Enter Diagnostics > Yes**

Wait for analyzer to enter Operator Diagnostics

2. Select **Subsystems > Cuvette > Emptying the Cuvettes > Perform > Yes**
3. Wait for the analyzer to prepare for maintenance (Do not select Cancel or Close)
4. Select **Continue** and wait for the window to automatically close in approximately 9 minutes.
5. Select **Replacing the CH Reaction Ring Cuvette Segments > Perform > Yes**
6. Wait for the analyzer to prepare for maintenance. (Do not select Cancel or Close)
7. Open the CH front cover. (The cover automatically unlocks. If the cover is locked, select **Unlock Covers.**)
8. Rotate the reaction ring to access the required reaction cuvette segment.
9. To unlock a segment, turn the thumbscrews and washers counterclockwise so the locking tabs are at the 12 or 6 position and the segment lifts out.
10. Individually lift each cuvette segment (Figure 1). DO NOT remove all reaction cuvette segments from the ring at the same time.

Figure 1. Unlock and lift up the cuvette segment

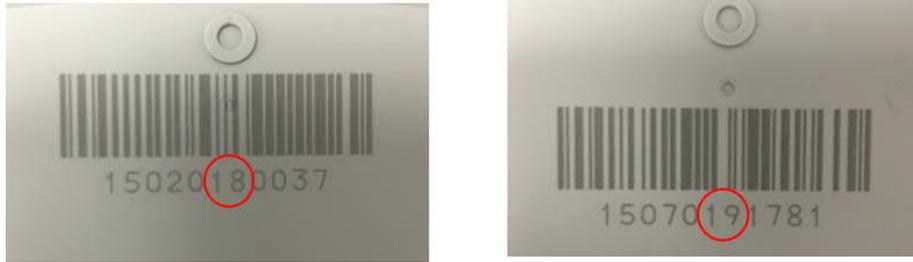


Inspect the reaction cuvette segment barcode

Note: Please take proper precaution when handling reaction cuvette segments. If you must place the cuvette segment down, ensure that you place the segment on a lint-free tissue.

11. Turn cuvette segment upside down to view the barcode (See Figure 2).

Figure 2. Example of 6th and 7th digit positions on the barcode sequence



Potentially impacted

Not impacted

- If the 6th and 7th digits are “19” or above for all 13 segments, the reaction cuvette segments are not impacted. Return each segment to the reaction ring by aligning the pins to the appropriate holes in the segment. Go to Appendix 2 for directions to resume your operations.
- If the 6th and 7th digits are “17” or “18,” for any one of the 13 segments no further inspection is required. If you have sufficient reaction cuvette inventory replace all 13 reaction cuvette segments with a lot number “19” or above. Go to Appendix 2 for directions to resume your operations.
- If you do not have sufficient reaction cuvette inventory to replace ALL 13 segments with kit lot numbers “19” or above:
 - Call Customer Service Center to order replacement cuvette inventory.
 - Follow steps 1-6 in Appendix 2.
 - **DISABLE Patient Sample Processing > Yes**
 - Follow steps 8 and 9 in Appendix 2.
 - Do NOT run any patient samples until reaction cuvettes have been replaced.
 - When new lots arrive, **replace** all 13 reaction cuvette segments. Enable Patient Sample Processing. Go to Appendix 2 for directions to resume your operations

Appendix 2: Required of all customers

Once all your Atellica CH 930 Reaction Cuvettes Segments onboard are lot “19” or above:

1. Tighten the thumbscrews clockwise to lock the segment in place.
2. Close the CH front cover. **Make sure CH front cover is securely closed.**
3. Select **Continue** (Do not select Cancel or Close)
4. Wait for the analyzer to complete process. The window will automatically close and return to Operator Diagnostics screen.
5. Select **Exit Diagnostics > Yes** (Wait for the analyzer to Exit Diagnostics)
6. **Status > CH Icon > Play** (Startup mode will prompt)

NOTE: If the analyzer does not return to Standby or Ready mode, perform the protocol “*Quickly drain and fill the reaction ring bath with water and WBA*” listed in Appendix 3.

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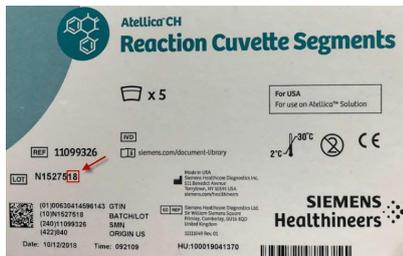
7. To ensure consumable tracking accuracy of your segments,
 - **If you do not have impacted inventory, onboard your Atellica CH 930 analyzer, DO NOT MARK** “Replacing the CH Reaction Ring Cuvette Segments” as completed under Maintenance

OR

 - **If you have replaced all 13 reaction** cuvette segments with a lot that is “19” or above, **MARK** “Replacing the CH Reaction Ring Cuvette Segments” as COMPLETED.
 - On the Command Bar, select **Maintenance > Schedule**
 - Under Filter, in Module, select your **CH** analyzer from the drop-down menu.
 - Select **Replacing the CH Reaction Ring Cuvette Segments > Mark as Completed > Yes > Yes**

8. Perform **CH Weekly Maintenance** (*Performing CH Weekly Maintenance* in Atellica® Solution Online Help).
 - Ensure analyzer is in Ready, Processing, or Standby state
 - Ensure water bath additive (WBA) and RPC4 packs are onboard.
 - On the Command bar, select **Maintenance > Schedule**.
 - Under Filter, in Module, select your **CH** analyzer from the drop-down menu.
 - Select **CH Weekly Maintenance > Perform > Yes > Yes**
 - Wait 65–75 minutes for maintenance to complete.
 - You can now proceed to run patient samples.

9. Review the inventory in your laboratory. If you have reaction cuvette kits ending in “17” or “18” (See Figure below) please note the number of kits in the FIELD CORRECTION EFFECTIVENESS CHECK form to determine your laboratory’s replacement needs and to provide information to Siemens Healthineers for reporting to the authorities. All other lots are not impacted.



10. Please discard all reaction cuvette kits ending in “17” or “18” in your laboratory.
11. Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

Appendix 3: If the analyzer does not return to Standby or Ready mode after step 6 in Appendix 2 (**Status > CH Icon > Play** (Startup mode will prompt) perform the protocol for “*Quickly drain and fill the reaction ring bath with water and WBA*” as indicated below:

1. Ensure water bath additive (WBA) is onboard.
 2. Enter Diagnostic State - Select **System > Operator Diagnostics > CH Icon > Enter Diagnostics > Yes**
 3. Select **Subsystems > Fluid > Quickly drain and fill the reaction ring bath with water and WBA > Perform > Yes**
 4. Wait for the analyzer to prepare for maintenance (Do not select Cancel or Close)
 5. Select **Continue** and wait for the window to automatically close in approximately 12 minutes.
 6. Select **Exit Diagnostics > Yes** (Wait for the analyzer to Exit Diagnostics)
 7. **Status > CH Icon > Play** (Startup mode will prompt)
- Once above steps are complete refer to Appendix 2, step 7

FIELD CORRECTION EFFECTIVENESS CHECK

Atellica® CH 930 – Potential for Inaccurate Test Results Associated with Reaction Cuvette Segments

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice ACHC20-05.A.US dated January 2020 regarding Atellica® CH 930 – Potential for Inaccurate Test Results Associated with Reaction Cuvette Segments. 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
- 2. Do you now have any of the noted product(s) on hand? Please check inventories before answering. Yes No

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory Discarded/ Replacement Quantity Required
11099326, Lots ending in "17" or "18"	

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Customer Sold To #: _____ Customer Ship To #: _____

Please send a scanned copy of the completed form via email to XXXX@XXXX

Or to fax this completed form to the Customer Care Center at XXXXXX

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