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Date May 18, 2021

Document Ref# ASI21-03.A.OUS

Urgent Field Safety Notice (ASI 21-03):
Atellica® CH 930 Analyzer
Photometer Lamp May Reach Saturation Without Flagging Results

Dear Sirs,

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 CH 930 Analyzer	11067000

Reason for Urgent Medical Device Correction

The purpose of this communication is to inform you of an issue with the product indicated in Table1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed that, as the Photometer Lamp reaches end of life, there is a potential for the Photometer Lamp (SMN 11075676), used in the Atellica CH 930 Analyzer, to increase in intensity on one or more of the eleven wavelengths used in testing. This unexpected increase in intensity can drive the photometer into saturation and may cause erroneous unflagged photometric test results.

If the Photometer Lamp does reach saturation on any of the wavelengths used for testing, the Analyzer will post event code “04 474 04 58”, in the Operator Event Log, with the message, “Photometer lamp intensity is low on at least 1 wavelength. Perform the Lamp Replacement routine in Operator Diagnostics”. Along with the event code an alert is posted to the operator in the Module Status screen with a red triangle. The operator event codes and alerts will be generated if the lamp intensity goes above or below the acceptable intensity range on any wavelength.

- Results generated after the event code and alert will **not** be flagged if the lamp intensity was above the acceptable intensity range.
- Results generated after the event code and alert **will be** flagged with, “Measurement Error”, and a numeric value will not be calculated, if the lamp intensity was below the acceptable intensity range.
- The event code will repeat every hour until the lamp is replaced and all wavelengths restored to their respective intensity ranges.

Lamp intensity is measured while the system is idle in standby mode, as well as when the analyzer is processing samples. If the user checks the Operator Event Log and alerts and replaces the lamp before processing samples, there is no potential for erroneous results. Risk to Health

When this issue occurs, the potential exists for the instrument to generate erroneously elevated or depressed patient results. Mitigations would include review of the Event Code in the Module Status screen, failed calibration, or QC due to this issue, 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.

Actions to be Taken by the Customer

- If the Atellica CH 930 Analyzer in your laboratory posts event code “04 474 04 58”, in the Operator Event Log, with the message, “Photometer lamp intensity is low on at least one wavelength. Perform the Lamp Replacement routine in Operator diagnostics”, stop the analyzer and replace the source lamp utilizing the Lamp Replacement routine, as prompted by the event message. Instructions for the Lamp Replacement routine are available by following the link in the event code message or by accessing the online help procedure, Replacing the Source Lamp.
- After the lamp has been replaced, any tests completed after the error message initially posted must be repeated.
- 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 Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Additional Information

The Atellica Solution software will be updated to flag results for this unexpected lamp failure mode to address cases where a user may delay in responding to the lamp intensity event codes and alerts. Version 1.25.0, which is under development, will be available for installation on your analyzer soon.

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.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Signature: *Electronically signed by: Roland Ertl*
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Date: May 17, 2021 17:24 GMT+2

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