Urgent Field Safety Notice

ACHC22-06.A.OUS

June 2022

Atellica® CH 930 Analyzer

Falsely Elevated Atellica CH Microalbumin_2 (µALB_2) Results due to Reagent Carryover from the Iron_2 Assay

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

Table 1. Atellica CH Affected Product

Assay	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Lot Number
Atellica CH Iron_2	11097601	00630414596402	All lots

Reason for Correction

The purpose of this communication is to inform you of an issue with the product indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed the potential for Atellica CH Iron_2 reagent carryover to impact Microalbumin_2 (µALB_2) results. Falsely elevated µALB_2 results are observed when the assay is processed immediately following an Iron_2 test on the Atellica CH analyzer (See Table 2). This issue can impact µALB_2 results for quality control (QC), patient samples and calibrators.

Investigation of this issue indicates that use of Reagent Probe Cleaner 2 (RPC2) wash is an effective mitigation in preventing Iron_2 reagent carryover into µALB_2.

For customers operating with Atellica Software v.1.25.2 and lower, the resolution of this issue will be implemented in Atellica Software v1.25.3 which will be available soon. In the interim, please follow the instructions in the “Additional Information” section.

Customers who are operating with Atellica Software v1.26 will receive further information when a software update to resolve the issue is available.

For laboratories operating with Atellica Software v1.25.2 and below and Atellica Software v1.26 follow the workaround instructions in the “Additional Information” section until a future version of software is available.

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Table 2. Impact of Iron_2 Carryover on µALB_2 Results

Sample	µALB_2 Result mg/dL (mg/L)	µALB_2 Result after Iron_2 mg/dL (mg/L)	% Bias
Bio-Rad Microalbumin Urine QC Level 1	2.9 (29.0)	3.3 (33.0)	14%
Bio-Rad Microalbumin Urine QC Level 2	5.2 (52.0)	5.5 (55.0)	6%
Bio-Rad Urine Chemistry QC Level 1	1.2 (12.0)	1.7 (17.0)	42%
MAS Urine Chemistry QC Level 2	6.1 (61.0)	7.0 (70.0)	15%

Note: Since urine QC samples tested are a human based urine matrix, patient urine samples were not tested.

Risk to Health

The potential exists for this issue to cause erroneously elevated microalbumin results with negligible potential for injury. Mitigations include increased patient monitoring, correlation of test results with patient's clinical signs and symptoms, repeat and additional testing. A review of previously generated results is not recommended as the issue would not lead to a clinically significant impact in patient management.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Perform the instructions provided in Additional Information.
- 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.

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Additional Information

- If your laboratory has multiple Atellica CH 930 Analyzers, Siemens recommends testing the Atellica CH µALB_2 assay on a separate analyzer from the Iron_2 assay.
- If you choose not to separate the assays as indicated above, batch testing of Atellica CH µALB_2 may be considered.
- If Iron_2 and µALB_2 will be processed on the same Atellica CH analyzer, an RPC2 wash mitigation must be initiated after processing Iron_2 and prior to processing µALB_2.

  Note: Any of the following will initiate the RPC2 wash:

  - After the Atellica CH 930 Analyzer has been in standby for 12 minutes.
  - After completion of any Open Channel assay.
  - Restarting the Atellica CH 930 Analyzer. Refer to the Atellica Solution Online Help for instructions on system restart.

Atellica is a trademark of Siemens Healthcare Diagnostics Inc.

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FIELD CORRECTION EFFECTIVENESS CHECK

Falsely Elevated Atellica CH Microalbumin_2 (µALB_2) Results due to Reagent Carryover from the Iron_2 Assay

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice (UFSN) ACHC22-06.A.OUS dated June 2022 regarding Falsely Elevated Atellica CH Microalbumin_2 (µALB_2) Results due to Reagent Carryover from the Iron_2 Assay.

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. Is your laboratory currently running Iron_2 on the Atellica CH 930? 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

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.

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