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Urgent Field Safety Notice:

Atellica® CH 930 Analyzer

Falsely Elevated Atellica CH Microalbumin_2 (μ ALB_2) Results due to Reagent Carryover from the Iron_2 Assay

To whom it may concern,

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 (μ ALB_2) results. Falsely elevated μ ALB_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 μ ALB_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 μ ALB_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.

Table 1. Impact of Iron_2 Carryover on μ ALB_2 Results

Sample	μ ALB_2 Result mg/dL (mg/L)	μ ALB_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.

Additional Information

- If your laboratory has multiple Atellica CH 930 Analyzers, Siemens recommends testing the Atellica CH μ ALB_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 μ ALB_2 may be considered.
- If Iron_2 and μ ALB_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 μ ALB_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.
- 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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