Urgent Field Safety Notice

ACHC26-03.A.OUS

Atellica CH Analyzer
Atellica CI Analyzer

Title Atellica CH Urine Albumin (UAlb) – Potential for Falsely Depressed Results

Date Issued JAN-2026

Product

Assay	Test Code	Siemens Material Number / Unique Device Identification	Lot Number
Atellica CH Urine Albumin (UAlb)	UAlb	11537225/ 00630414611099	All lots

Issue Description

Siemens Healthineers has confirmed, through investigation of customer complaints, a potential for falsely depressed results for a small subset of samples above the measuring interval when using the Atellica CH Urine Albumin (UAlb) assay on the Atellica CH and Atellica CI analyzers.

The investigation determined that certain samples may report results within the UAlb measuring interval when expected to be above the UAlb measuring interval, when compared to the Atellica CH Microalbumin_2 (µALB_2) assay result. Based on global customer data and internal analysis, this subset represents approximately 0.3% of samples.

All current and future UAlb lots are considered impacted until further notice. Siemens Healthineers is actively investigating the root cause of this issue.

Impact to Results

Falsely depressed UAlb patient results may occur and may be reported due to this issue. In this case, affected samples with any urine albumin concentration above the UAlb measuring interval (>40.0 mg/dL; >400 mg/L) may report values between 6.2 mg/dL (62 mg/L) and 40.0 mg/dL (>400 mg/L).

Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Customer Actions

- Internal investigation has confirmed that diluting mitigates this behavior. A x10 dilution of an affected sample produces accurate UAlb results.
- **As a temporary mitigation, for any sample with a UAlb result above 5.0 mg/dL (50 mg/L), reanalyze the sample with a x10 dilution.**
    - If the diluted result is consistent with the initial result, either result may be reported.
    - If the diluted result is inconsistent with the initial result, the diluted result should be reported.
    - If you prefer to automate this dilution, please refer to your internal laboratory procedures.
- Please review this notification with your Medical Director to determine the appropriate course of action, including evaluation of any previously generated results, if applicable.
- Retain this letter with your laboratory records and forward it to others who may have received this product.

SIEMENS Healthineers

Resolution	A follow-up communication will be provided when “Customer Actions” are no longer required.
Single Registration Number (SRN)	US-MF-000016560
	We appreciate your continued partnership and apologize for the inconvenience this situation may cause. If you have any questions or require assistance, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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