

Urgent Field Safety Notice

ACHC26-07.A.OUS



Atellica CH Analyzer Atellica CI Analyzer

Title	Atellica CH Urine Albumin (UAlb) Impact to Urea Nitrogen, Enzymatic Hemoglobin A1c, and Reaction Cuvettes			
Date Issued	JUL-2026			
Products	Assay	Test Code	Siemens Material Number/ Unique Device Identification	Lot Numbers
	Atellica CH Urine Albumin	UAlb	11537225 / 00630414611099	All in-date lots
Issue Description	Siemens Healthineers has confirmed, through the investigation of customer complaints, the potential for the following issues associated with processing Atellica CH Urine Albumin (UAlb) tests on Atellica CH and Atellica CI analyzers. - Falsely depressed Atellica CH Urea Nitrogen (UN_c) results - Falsely depressed Atellica CH Enzymatic Hemoglobin A1c (A1c_E) results - Increased rate of reaction cuvette QC failures These issues may impact quality control (QC), calibrators, and patient results for the UN_c and A1c_E assays across all sample types. Internal studies indicate that frequent use of the UAlb assay increases the rate at which reaction cuvettes reach a “Needs Replacement” status, resulting in more frequent replacement of the reaction cuvette segments. The continued use of the UAlb assay may contribute to falsely depressed UN_c and A1c_E results. Consequently, customers should discontinue UAlb testing and replace all reaction cuvette segments before proceeding with further testing.			
Impact to Results	Erroneously depressed UN_c and A1c_E results may occur across the measuring interval due to the issues described above. Representative data is shown in Appendix Tables 1 & 2. The observed maximum bias may occur at any point within the A1c_E and UN_c measuring intervals. Results of these assays should always be interpreted in conjunction with the patient’s medical history, clinical presentation, and other findings.			
Customer Actions	- Discontinue Atellica CH Urine Albumin (UAlb) testing and transition to the Atellica CH Microalbumin_2 (μALB_2) reagent, SMN 11097610, and Atellica CH Microalbumin_2 Calibrator (μALB_2 CAL), SMN 11099435, as an alternate test solution. - Replace all reaction cuvette segments following discontinuation of UAlb testing. Refer to the Atellica Solution Online Help for instructions on replacing reaction cuvette segments. - Please review this letter with your Medical Director to determine the appropriate course of action, including whether review of any previously generated results is warranted.			

**Single Registration
Number (SRN)**

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- Please retain this letter with your laboratory records and forward this letter to those who may have received the affected product.
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US-MF-000016560

We apologize for the inconvenience this situation may cause and recognize that the transition to an alternate test solution may require planning. Siemens Healthineers is committed to supporting you through this process. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Siemens Healthineers

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Appendix Table 1: Impact of UAlb on UN_c Test Results

Sample Type	mg/dL	mmol/L	Worst Case % Bias
Urine QC	437	156.0	-39%
Urine QC	784	279.9	-56%
Serum QC	41	14.6	-10%
Serum QC	69	24.6	-16%

Table 2: Impact of UAlb on A1c_E Test Results

Sample Type	NGSP Unit (%HbA1c)		IFCC Unit (mmol/mol)	
	Control	Worst Case % Bias	Control	Worst Case % Bias
QC	5.41	-10%	35.63	-16%
QC	9.33	-3%	78.47	-3%

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