

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. - Complete the Field Correction Effectiveness Check Form attached to this letter and return within 30 days.			

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- Credit will be issued for unexpired UAlb reagent (SMN 11537225), UAlb calibrator (SMN 11537247), and reaction cuvettes segments, as applicable.
 - For customers with Atellica CH analyzers, 2.5 boxes of reaction ring segments will be credited per system.
 - For customers with Atellica CI analyzers, 2 boxes of reaction ring segments will be credited per system.
 - 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.
 - 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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**Single Registration
Number (SRN)**

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

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue, Tarrytown, NY 10591
siemens-healthineers.com

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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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers **Urgent Field Safety Notice ACHC26-07.A.OUS** dated JUL-2026. Please read each question and indicate the appropriate answer.

If you have received any complaints of illness or adverse events associated with the products listed in the table on Page 1 immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Return this completed form as per the instructions provided at the bottom of this page.

- | | | |
|--|------------------------------|-----------------------------|
| 1. Have you read and understood the instructions provided in this letter? | Yes ☐ | No ☐ |
| 2. Do you have the affected product(s) on hand? Please check inventories before answering. | Yes ☐ | No ☐ |
| 3. Does your lab need to run additional studies to transition to μ ALB_2? | Yes ☐ | No ☐ |
| 4. Were affected Site Personnel notified? | Yes ☐ | No ☐ |
| 5. Was a copy of the letter retained? | Yes ☐ | No ☐ |

If the answer to Question #2 above is yes, please complete the table below to request credit. If the answer to question #3 above is yes, one box of Atellica CH μ Alb_2 reagent and calibrator will also be credited to complete these studies.

Number and Type of Analyzers Used to Process UAlb	Atellica CH			
	Atellica CI			
Product Description	Quantity of Affected Product in Inventory			
Atellica CH Urine Albumin (UAlb)				
Atellica CH Urine Albumin Calibrator (UAlb CAL)				
Name of person completing questionnaire:				
Title:				
Institution:				
Street:				
City:	State:	Zip Code:		
Phone:	Country:			
Customer Sold To #	Customer Ship To #			

Please send a scanned copy of the completed form via email to **CruinnFSNGroup@cruinn.ie**

Or to fax this completed form to the Customer Care Center at **016297401**

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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