

Urgent Field Safety Notice

ACHC26-05.A.OUS

Atellica CH Analyzer Atellica CI Analyzer

Title	Atellica CH Creatine Kinase (CK_L): Potential for Falsely Elevated Results with Lot Numbers 252591, 252602 and 252612																						
Date Issued	MAR-2026																						
Products	<table border="1"><thead><tr><th>Assay</th><th>Test Code</th><th>Siemens Material Number/Unique Device Identification</th><th>Lot Number</th><th>Manufacturing Date</th><th>Expiration Date</th></tr></thead><tbody><tr><td rowspan="3">Atellica CH Creatine Kinase</td><td rowspan="3">CK_L</td><td rowspan="3">11097640/ 00630414006642</td><td>252591</td><td>01-Jul-2025</td><td>01-Aug-2026</td></tr><tr><td>252602</td><td>01-Jul-2025</td><td>01-Aug-2026</td></tr><tr><td>252612</td><td>01-Aug-2025</td><td>01-Sep-2026</td></tr></tbody></table>	Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number	Manufacturing Date	Expiration Date	Atellica CH Creatine Kinase	CK_L	11097640/ 00630414006642	252591	01-Jul-2025	01-Aug-2026	252602	01-Jul-2025	01-Aug-2026	252612	01-Aug-2025	01-Sep-2026				
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Issue Description	Siemens Healthineers has confirmed, through investigation of customer complaints, the potential for falsely elevated patient, quality control (QC), and/or calibrator results when using Atellica CH Creatine Kinase (CK_L) lot numbers 252591, 252602 and 252612 on the Atellica CH and Atellica CI Analyzers. This issue may be observed with both serum and plasma sample types. QC results may or may not detect the issue. Siemens Healthineers is actively investigating the root cause of this issue.																						
Impact to Results	<ul style="list-style-type: none">Customers have reported initial results above the measuring interval (>1300 U/L) or above the extended measuring interval (>39,000 U/L) where the true result is lower. True results may be below, within or above the measuring interval.																						
Customer Actions	<ul style="list-style-type: none">Immediately discontinue use of and discard the kit lots listed in the Products Section above.Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens Healthineers for regulatory reporting.Complete and return the Field Correction Effectiveness Check Form attached to this letter within 10 days.Please retain this letter with your laboratory records and forward a copy to any personnel who may have received or used this product.																						
Resolution	Alternate, unaffected Atellica CH CK_L kit lots are available.																						
Single Registration Number (SRN)	US-MF-000016560																						
	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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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice ACHC26-05.A.OUS dated MAR-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. Were affected Site Personnel notified? Yes No
- 4. Was a copy of the letter retained and posted with the current product labeling? Yes No

If the answer to question #2 above is yes, please complete the table below to indicate the quantity of affected products in your laboratory and replacement product required.

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory Discarded/Replacement Quantity Required	
Atellica CH Creatine Kinase (CK_L)/ SMN 11097640/ Lot Numbers 252591, 252602, 252612		
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 fscreportingunit.my@siemens-healthineers.com.

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.