Urgent Field Safety Notice

ACHC26-09.B.OUS

Atellica CH Analyzer
Atellica CI Analyzer

Title Atellica CH Apolipoprotein B (APO B) Lot 252670 Low End Imprecision

Date Issued OCT-2026

Products

Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number	Manufacturing Date	Expiration Date
Atellica CH Apolipoprotein B	APO B	11097626 / 00630414596235	252670	01-Oct-2025	01-Jan-2027

Issue Description

Siemens Healthineers has confirmed through the investigation of customer complaints that the Atellica CH Apolipoprotein B (APO B) Lot 252670 does not meet the specification for within-lab precision of ≤ 7.0% Coefficient of Variation (CV) when used on the Atellica CH and Atellica CI Analyzers.

Increased within-lab imprecision may be observed with Quality Control (QC) and patient samples with APO B concentrations at or below 75 mg/dL (0.75 g/L). Samples with a concentration above 75 mg/dL (0.75 g/L) remain within expected performance.

Depending on the QC material and acceptance ranges established by the laboratory, the issue may be detected before patient samples are processed.

Repeatability within an individual run is not affected.

Impact to Results

Increased imprecision may result in erroneously depressed or elevated APO B patient results. In a five-day Analysis of Variance (ANOVA) within-lab precision study, a maximum CV of 15.1% was observed at concentrations ranging from approximately 30 to 75 mg/dL. Imprecision decreased as APO B concentration increased. Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Customer Actions

- Discontinue use and discard Atellica CH Apolipoprotein B (APO B) Lot 252670.
- Review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Review your current inventory to determine your laboratory's replacement needs and provide this information to Siemens Healthineers for reporting to the authorities.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- Retain this letter with your laboratory records and forward this letter to those who may have received the affected product(s).

Resolution	Unaffected alternate lots of Atellica CH Apolipoprotein B (APO B) are available.
Single Registration Number (SRN)	US-MF-000016560
	We apologize for the inconvenience this situation may cause. Siemens Healthineers is committed to product quality, patient safety, and transparent communication. 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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Siemens Healthineers
Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591
siemens-healthineers.com

FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice ACHC26-09.B.OUS dated OCT-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 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 ☐

Please complete the information requested below. If the answer question #2 above is yes, please also complete the Product Description and Quantity Affected section in the table below.

Name of person completing questionnaire:		
Title:		
Institution:		
Street:		
City:	**State:**	**Zip Code:**
Phone:	**Country:**	
Customer Sold To #	**Customer Ship To #**	
Product Description **Product Catalog #/SMN #/Lot #**	**Quantity of Affected Product in inventory** **Discarded/Replacement Quantity Required**	
Atellica CH Apolipoprotein B (APO B) *SMN 11097626 / Lot 252670*		

Please send a scanned copy of the completed form via email to **XXXX@XXXX.**

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

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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