

Follow-up Urgent Field Safety Notice

AIMC 25-06.C-1.OUS

Atellica CI Analyzer
Atellica IM Analyzer
ADVIA Centaur XP System
ADVIA Centaur XPT System
ADVIA Centaur CP System

Title	Atellica IM and ADVIA Centaur Homocysteine Calibrator Instability
Date Issued	May-2026

Products	Product	Siemens Material Number/Unique Device Identification	Kit Lot Number	Manufacturing Date	Expiration Date
	Atellica IM Homocysteine Calibrator (2 Pack)	10995498 / 00630414598253	44505A78 52364A79 and above until further notice	20-May-2025 20-Jun-2025	20-May-2026 20-Jun-2026
ADVIA Centaur HCY Calibrator (2 Pack)	10310376 / 00630414468198	44506A78 52363A79 and above until further notice	20-May-2025 20-Jun-2025	20-May-2026 20-Jun-2026	

Issue Description

Siemens Healthineers is providing follow up information to Urgent Field Safety Notice (UFSN) AIMC 25-06.A.OUS regarding the reference range not being met due to instability observed in Atellica IM Homocysteine Calibrator and ADVIA Centaur HCY Calibrator.

Ongoing internal investigation has confirmed that the Atellica IM Homocysteine Calibrator and ADVIA Centaur HCY Calibrator Kit Lots ending in 78 and 79 do not maintain the calibrator stability across the full 12-month shelf life. As these calibrators age, a positive bias of up to 17.0% in homocysteine results was observed at approximately 9 months post-manufacture compared to Siemens Internal Standardization.

The calibrator instability impacts homocysteine results generated on the Atellica IM Analyzer, Atellica CI Analyzer, ADVIA Centaur XP System, ADVIA Centaur XPT System, and ADVIA Centaur CP System.

Ongoing investigations have shown that frozen storage (-15°C to -25°C, target -20°C) improves calibrator stability. Siemens Healthineers is actively implementing frozen storage as a permanent resolution, expected later this year. We will continue to monitor performance closely and provide updates as appropriate. In the interim, see Customer Action below.

Impact to Results

Erroneously elevated homocysteine may occur due to calibrator drift over time and may impact both QC and patient results across all sample types.

Laboratories may observe elevated homocysteine results exceeding historical patient results and/or the published or laboratory-defined reference intervals.

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

-
- Customer Actions**
- Please take the following actions:
 - For Atellica IM Homocysteine Calibrator and ADVIA Centaur HCY Calibrator Kit Lots ending in 78 and 79: discontinue use immediately and discard these kit lots.
 - For Atellica IM Homocysteine Calibrator and ADVIA Centaur HCY Calibrator Kit Lots ending in 80 and above (until further notice):
 - **Immediately** store your current unopened inventory and newly received shipments of these lots in a freezer (-15°C to -25°C).
 - Do not refreeze calibrator material after thawing.
 - Preparing the Calibrators: Allow the calibrator materials to thaw and bring to room temperature before use. Gently mix and invert the vials to ensure homogeneity of the material.
 - Opened calibrators are stable at 2-8°C for 8 weeks or 4 hours at room temperature.
 - 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 10 days.
 - Retain this letter for your laboratory records and forward to those who may have received the affected products.

Resolution Atellica IM and ADVIA Centaur Homocysteine Calibrator Kit Lots ending in 78 and 79 are no longer available for purchase. Alternate Atellica IM and ADVIA Centaur Homocysteine Calibrator lots are available at Siemens Distribution Center(s).

A temporary mitigation for continued product use has been provided for Atellica IM and ADVIA Centaur Homocysteine Calibrator Kit Lots ending in 80 and above.

A follow-up communication will be provided when "Customer Actions" are no longer required.

Single Registration Number (SRN) US-MF-000016560

We recognize the importance of consistent assay performance and appreciate your partnership as we work to resolve this issue. We apologize for the inconvenience this issue may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Atellica and ADVIA Centaur are a registered trademark of Siemens Healthcare Diagnostics Inc.

FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Follow Up Urgent Field Safety Notice AIMC 25-06.C-1.OUS dated May-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 the question #2 above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description SMN #/Lot #	Quantity of Affected Product in inventory Discarded/Replacement Quantity Required		
<i>Atellica IM Homocysteine Calibrator (2PK) SMN: 10995498 Kit Lot: 44505A78 and 52364A79</i>			
<i>ADVIA Centaur HCY Calibrator (2PK) SMN: 10310376 Kit Lot: 44506A78 and 52363A79</i>			
Name of person completing questionnaire:			
Title:			
Institution:			
Street:			
City:	State:	Zip Code:	
Phone:	Country:		

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.