

Urgent Field Safety Notice

AIMC 25-06.A.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	Apr-2025

Products	Product	Siemens Material Number/Unique Device Identification	Kit Lot Number	Manufacturing Date	Expiration Date
	Atellica IM Homocysteine Calibrator (2 Pack)	10995498 / 00630414598253	86236A74	14-May-2024	14-May-2025
			44206A75	25-Sep-2024	25-Sep-2025
	ADVIA Centaur HCY Calibrator (2 Pack)	10310376 / 00630414468198	86237A74	14-May-2024	14-May-2025
			44207A75	25-Sep-2024	25-Sep-2025

Issue Description Siemens Healthineers has confirmed through the investigation of customer complaints that the Atellica IM Homocysteine Calibrator and ADVIA Centaur HCY Calibrator Lots listed in the table above do not meet the assay Instructions for Use (IFU) reference interval due to calibrator instability. As the calibrator ages, homocysteine results were observed to increase with bias up to 19.2% at 8 months post manufacture.

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

Impact to Results Erroneously elevated homocysteine may occur as a result of this issue. A positive drift may impact both QC and patient results in all sample matrices. Figure 1 of the Appendix provides representative data that may be observed.

Based on customer complaints and investigation results, users may observe elevated homocysteine results as compared to historical patient results and/or the published or laboratory-defined reference interval.

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

Customer Actions

- Perform the instructions provided below:

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.
- Discontinue use of and discard the kit lots listed in the table above (Products Section).
- Review your inventory of these products to determine your laboratory’s replacement needs and to provide 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.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

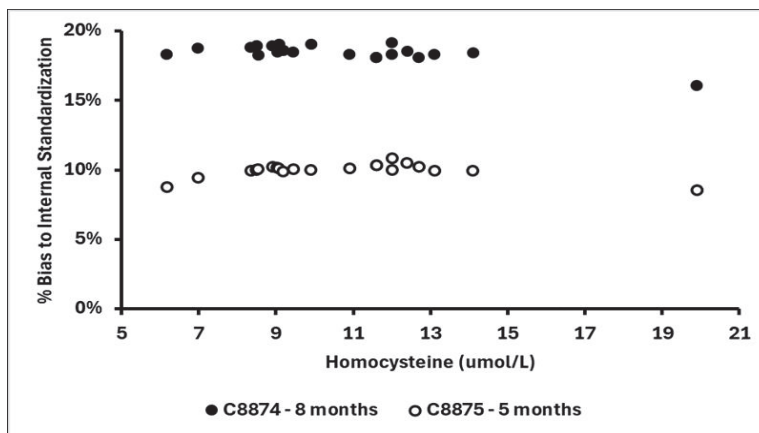
Resolution Atellica IM and ADVIA Centaur Homocysteine Calibrator Lots ending in 74 and 75 are not available for purchase. Alternate Atellica IM and ADVIA Centaur Homocysteine Calibrator lots are available at Siemens Distribution Center(s).

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.

Appendix Additional Data

Figure 1. Atellica IM Homocysteine Calibrator Lots ending in 74 and 75 as compared to Siemens Internal Standardization, using EDTA patient samples and commercial Quality Control (QC) Material – Percent (%) Bias Plot



Atellica IM Homocysteine Calibrator Lots ending in 74 and 75 contain Homocysteine Calibrator Level Lots C8874 and C8875, respectively.

The number of months next to the calibrator lot represents the calibrator age at the time of testing.

These data are representative of Atellica CI, ADVIA Centaur XP, ADVIA Centaur XPT, and ADVIA Centaur CP performance.

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