

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

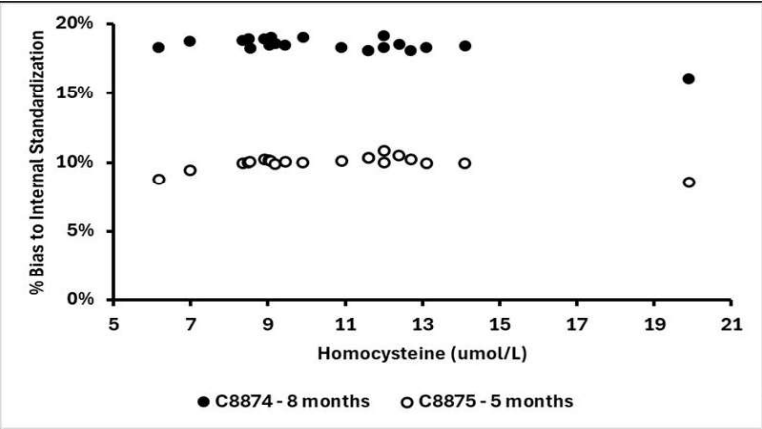
Title	Atellica IM and ADVIA Centaur Homocysteine Calibrator Instability																									
Date Issued	Apr-2025																									
Products	<table><tr><th>Product</th><th>Siemens Material Number/Unique Device Identification</th><th>Kit Lot Number</th><th>Manufacturing Date</th><th>Expiration Date</th></tr><tr><td rowspan="2">Atellica IM Homocysteine Calibrator (2 Pack)</td><td rowspan="2">10995498 / 00630414598253</td><td>86236A74</td><td>14-May-2024</td><td>14-May-2025</td></tr><tr><td>44206A75</td><td>25-Sep-2024</td><td>25-Sep-2025</td></tr><tr><td rowspan="2">ADVIA Centaur HCY Calibrator (2 Pack)</td><td rowspan="2">10310376 / 00630414468198</td><td>86237A74</td><td>14-May-2024</td><td>14-May-2025</td></tr><tr><td>44207A75</td><td>25-Sep-2024</td><td>25-Sep-2025</td></tr></table>					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
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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.

Atellica and ADVIA Centaur are a registered trademark of Siemens Healthcare Diagnostics Inc. © Siemens Healthcare Diagnostics Inc. 2025.

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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice AIMC 25-06.A.OUS dated Apr 2025. 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		
Atellica IM Homocysteine Calibrator (2PK) SMN: 10995498 Kit Lot: 86236A74			
Atellica IM Homocysteine Calibrator (2PK) SMN: 10995498 Kit Lot: 44206A75			
ADVIA Centaur HCY Calibrator (2PK) SMN: 10310376 Kit Lot: 86237A74			
ADVIA Centaur HCY Calibrator (2PK) SMN: 10310376 Kit Lot: 44207A75			
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 **XXXX@XXXX**.

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

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