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Urgent Field Safety Notice:

Atellica CI Analyzer

Atellica IM Analyzer

ADVIA Centaur XP System

ADVIA Centaur XPT System

ADVIA Centaur CP System

Atellica IM and ADVIA Centaur Homocysteine Calibrator Instability

To whom it may concern,

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.

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

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.

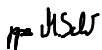
Resolution

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).

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.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH



Electronically signed by: Martina
Schreiber
Reason: I am approving this document
Date: Apr 28, 2025 13:12 GMT+2

ppa. Mag. Martina Schreiber

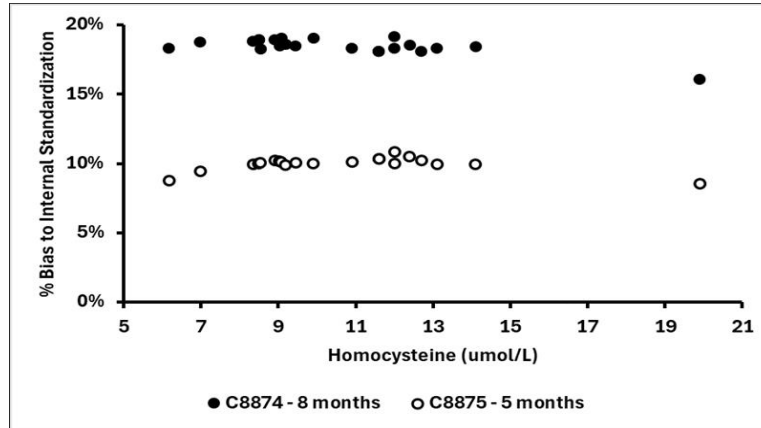


Electronically signed by: Carina Marie
Viehböck
Reason: I have reviewed this document
Date: Apr 28, 2025 12:53 GMT+2

i.A. Dipl.-Ing. Carina Viehböck

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.