

# Follow-up Urgent Field Safety Notice

AIMC 25-06.C-2.OUS

**Atellica CI Analyzer**

**Atellica IM Analyzer**

**ADVIA Centaur XP System**

**ADVIA Centaur XPT System**

**ADVIA Centaur CP System**

|                    |                                                                   |
|--------------------|-------------------------------------------------------------------|
| <b>Title</b>       | Atellica IM and ADVIA Centaur Homocysteine Calibrator Instability |
| <b>Date Issued</b> | 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       | 20-May-2025        | 20-May-2026     |
|                                              |                                                      | 52364A79       | 20-Jun-2025        | 20-Jun-2026     |
| ADVIA Centaur HCY Calibrator (2 Pack)        | 10310376 / 00630414468198                            | 44506A78       | 20-May-2025        | 20-May-2026     |
|                                              |                                                      | 52363A79       | 20-Jun-2025        | 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 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

**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:

|                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                         | <ul style="list-style-type: none"><li>○ 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.</li><li>○ Review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.</li><li>○ Review your current inventory to determine your laboratory's replacement needs and provide this information to Siemens Healthineers for reporting to the authorities.</li><li>○ Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.</li></ul> <ul style="list-style-type: none"><li>● Retain this letter for your laboratory records and forward to those who may have received the affected products.</li></ul> |
| <b>Resolution</b>                       | 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).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Single Registration Number (SRN)</b> | US-MF-000016560                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|                                         | <p>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.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

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

**FIELD CORRECTION EFFECTIVENESS CHECK**

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This response form is to confirm receipt of the enclosed Siemens Healthineers Follow Up Urgent Field Safety Notice AIMC 25-06.C-2.OUS dated Apr-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<br>SMN #/Lot #                                                        |  | Quantity of Affected Product in inventory<br>Discarded/Replacement Quantity Required |           |
|-------------------------------------------------------------------------------------------|--|--------------------------------------------------------------------------------------|-----------|
| Atellica IM Homocysteine Calibrator (2PK)<br>SMN: 10995498 Kit Lot: 44505A78 and 52364A79 |  |                                                                                      |           |
| ADVIA Centaur HCY Calibrator (2PK)<br>SMN: 10310376 Kit Lot: 44506A78 and 52363A79        |  |                                                                                      |           |
| 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.

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.

