

Follow-up Customer Notification

AIMC 24-12.B.OUS

Atellica IM Analyzer
ADVIA Centaur XP System
ADVIA Centaur XPT System

Title **Resolution:** Atellica IM and ADVIA Centaur Folate (Fol) Invalid Calibration for Whole Blood Sample Types

Date Issued Oct-2024

Issue Description A calibrator deviation range has been implemented specific for whole blood sample types, starting with the lots listed in the table below, providing the resolution for potential invalid calibrations for whole blood sample types with the Atellica IM and ADVIA Centaur Folate Assay previously communicated in Customer Notification (CN) AIMC 24-12.A.OUS (released in Jun-2024).

Products	Assay	Test Code	Siemens Material Number/Unique Device Identification	Lot Number
	Atellica IM Folate (140 Test)	Fol	10995572 / 630414598963	Kit lot numbers ending in 368 and above
	Atellica IM Folate (700 Test)		10995573 / 630414598970	
	ADVIA Centaur Folate (100 Test)	FOL	10310308 / 630414204192	Kit lot numbers ending in 370 and above
	ADVIA Centaur Folate (500 Test)		10325366 / 630414450940	

- Customer Actions**
- Upon evaluation and implementation of the Atellica IM and ADVIA Centaur Folate lots listed in the table above, the actions outlined in initial Field Action Letter AIMC 24-12.A.OUS are no longer required.
 - **For ADVIA Centaur XP customers that receive ADVIA Centaur Folate kit lots ending in 370 only**, please perform the following steps for scanning the Master Curve Card for whole blood sample types only:
 - On the ADVIA Centaur XP system, at the workspace, select **Calibration**.
 - Select **Master Curve Definition**.
 - At the Calibration – Master Curve Definition window, select **Scan Data**.
 - Scan the barcodes on the ADVIA Centaur Folate Master Curve Card for whole blood sample types provided in the kit from top to bottom.
 - Using the keyboard, delete the checksum value “d3d7f056”
 - Using the keyboard, enter checksum value “**b9ddbc17**”.
 - **Note:** checksum values are case sensitive.

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- At the Calibration – Master Curve Definition window, select **Save**.

Please retain this letter with your laboratory records and forward this letter to those who may have received the product.

Resolution Atellica IM and ADVIA Centaur Folate lots listed in the table above are packaged with an updated calibration deviation range.

We apologize for the inconvenience this situation may have caused. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

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