

Customer Notification

AIMC 24-12.A.OUS

Atellica IM Analyzer
ADVIA Centaur XP System
ADVIA Centaur XPT System

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

Date Issued June 2024

Issue Description Siemens Healthineers has investigated customer complaints and confirmed the potential for intermittent invalid red blood cell (RBC) Folate calibrations with the Atellica® IM and ADVIA Centaur® Folate (Fol) assay when using whole blood samples due to calibrator deviation outside of the defined specification range.

- The serum Folate calibration is not affected.
- If a valid RBC Folate calibration is achieved for the whole blood sample type and quality controls (QC) meet defined ranges, then patient results are considered accurate and acceptable for reporting. No further action is needed.
- If you are unable to obtain a valid RBC Folate calibration, you may attempt multiple re-calibrations.
- Per the Instructions for Use (IFU), if an invalid calibration is obtained, QC and patient sample testing cannot be performed. Further action is defined below in the “Actions to be Taken” section.

Siemens is currently investigating the root cause of the RBC Folate calibrator deviation failures. The following Folate kit lots listed in the table below are susceptible to an invalid RBC Folate calibration.

Products

Assay	Test Code	Siemens Material Number/Unique Device Identification	Kit Lot Number
Atellica IM Folate (140 Test)	Fol	10995572 / 630414598963	Kit lot numbers ending in 359 and above
Atellica IM Folate (700 Test)	Fol	10995573 / 630414598970	
ADVIA Centaur Folate (100 Test)	FOL	10310308 / 630414204192	Kit lot numbers ending in 358 and above
ADVIA Centaur Folate (500 Test)	FOL	10325366 / 630414450940	

Customer Actions

- For the product(s) listed in the table above , please perform the following steps for addressing a potential invalid RBC Folate calibration:

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- Patient results may continue to be reported when a valid calibration and in range quality control results are obtained.
 - When a valid calibration cannot be obtained after multiple attempts, you may request no-charge replacement product from your local Siemens Healthineers at 1800-815-508 or distributor office.
 - Please review your inventory of these products and assess your laboratory's replacement needs.
 - Complete and return the Product Replacement Form attached to this letter to request your no-charge replacement product(s).
 - Please retain this letter with your laboratory records and forward this letter to those who may have received the product.

Resolution A follow up communication will be provided when "Customer Actions" are no longer required.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center at 1800-815-508 or your local Siemens Healthineers technical support representative.

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PRODUCT REPLACEMENT FORM

This response form is to request no charge replacement product for the enclosed Siemens Healthineers Customer Notification **AIMC 24-12.A.OUS** dated June 2024. 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 at 1800-815-508 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 been unable to obtain a valid RBC Folate calibration of the Atellica IM and ADVIA Centaur Fol assay due to calibrator deviation? Yes No
- 2. All affected Site Personnel have been notified. Yes No
- 3. A copy of the letter has been retained and posted with the current product labeling. Yes No

If the answer to the question #1 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 #/Kit Lot #	Quantity of Affected Product in inventory / Replacement Quantity Required		
Atellica IM Folate (140 Test) SMN: 10995572 Kit Lot Numbers ending in 359 and above			
Atellica IM Folate (700 Test) SMN: 10995573 Kit Lot Numbers ending in 359 and above			
ADVIA Centaur Folate (100 Test) SMN: 10310308 Kit Lot Numbers ending in 358 and above			
ADVIA Centaur Folate (500 Test) SMN: 10325366 Kit Lot Numbers ending in 358 and above			
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 fscareportingunit.my@siemens-healthineers.com.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center at 1800-815-508 or your local Siemens Healthineers technical support representative.