



Customer Notification

AIMC 24-01.A.OUS

October 2023

**Atellica® Solution
ADVIA Centaur® XP
ADVIA Centaur® XPT**

Atellica IM, Atellica CI, and ADVIA Centaur Free Prostate-Specific Antigen (fPSA) Invalid Calibrations

Reason for Customer Notification

Our records indicate that your facility may have received the product(s) **listed in Table 1**. Siemens Healthcare Diagnostics Inc. has confirmed the potential for invalid calibrations with the fPSA assay due to the “low calibrator deviation” parameter resulting outside of the defined specification range.

- If a valid calibration is achieved and quality controls (QC) meet defined ranges, then patient results are considered accurate and acceptable for reporting and no further action is needed.
- 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 low calibrator deviation failures. The low calibrator deviations are limited to the fPSA kit lots listed in Table 1.

Table 1. Atellica IM, Atellica CI, and ADVIA Centaur Affected Product(s)

Assay	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Kit Lot	Date of Manufacture (YYYY-MM-DD)	Expiration Date (YYYY-MM-DD)
Atellica IM and Atellica CI Free Prostate-Specific Antigen (fPSA) Assay (50 Test)	10995577	(01)00630414599014(10)44989114(17)20250616	44989114	2023-06-16	2025-06-16
		(01)00630414599014(10)44990114(17)20250616	44990114		
		(01)00630414599014(10)44991114(17)20250616	44991114		
		(01)00630414599014(10)44992114(17)20250616	44992114		
		(01)00630414599014(10)44993114(17)20250616	44993114		
		(01)00630414599014(10)44994114(17)20250616	44994114		

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Assay	Siemens Material Number (SMN)	Unique Device Identification (UDI)	Kit Lot	Date of Manufacture (YYYY-MM-DD)	Expiration Date (YYYY-MM-DD)
ADVIA Centaur Free Prostate-Specific Antigen (fPSA) Assay (50 Test)	10283414	(01)00630414553344(10)43728115(17)20250616	43728115	2023-06-16	2025-06-16
		(01)00630414553344(10)43729115(17)20250616	43729115		

Actions to be Taken by the Customer

For the products listed in Table 1, please perform the following steps:

- Patients results can continue to be reported when a valid calibration and in range quality control results are obtained.
- When valid calibration cannot be obtained due to low calibrator deviation, you may request no-charge replacement product from your local Siemens Healthineers 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).
 - Stock of the fPSA assay is limited. Requests for replacement product via the product replacement form may be fulfilled at a future date.

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

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

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PRODUCT REPLACEMENT FORM

Atellica IM, Atellica CI, and ADVIA Centaur Free Prostate-Specific Antigen (fPSA) Invalid Calibrations

This form is to be used to request no-charge replacement product for the enclosed Siemens Healthcare Diagnostics Customer Notification AIMC 24-01.A.OUS dated October 2023 regarding Atellica IM, Atellica CI, and ADVIA Centaur Free Prostate-Specific Antigen (fPSA) Invalid Calibrations.

Return this completed form to Siemens Healthcare Sdn Bhd as per the instructions provided at the bottom of this page.

Have you been unable to obtain a valid calibration of the Atellica IM, Atellica CI, and ADVIA Centaur fPSA assay due to low calibrator deviation? Yes No

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product and Kit Lot #	Quantity of Affected Product Returned/ Replacement Quantity Required
Atellica IM and Atellica CI fPSA Assay Kit Lot 44989114	
Atellica IM and Atellica CI fPSA Assay Kit Lot 44990114	
Atellica IM and Atellica CI fPSA Assay Kit Lot 44991114	
Atellica IM and Atellica CI fPSA Assay Kit Lot 44992114	
Atellica IM and Atellica CI fPSA Assay Kit Lot 44993114	
Atellica IM and Atellica CI fPSA Assay Kit Lot 44994114	
ADVIA Centaur fPSA Assay Kit Lot 43728115	
ADVIA Centaur fPSA Assay Kit Lot 43729115	

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Customer Sold To #: _____ Customer Ship To #: _____

Please send a scanned copy of the completed form via email to fscareportingunit.my@siemens-healthineers.com

If you have any questions, contact your local Siemens Healthineers technical support representative.