

Customer Notification

AIMC 26-02.A-1.OUS

Atellica CI Analyzer
Atellica IM Analyzer
ADVIA Centaur XP System
ADVIA Centaur XPT System

Title	Atellica IM and ADVIA Centaur Free Prostate-Specific Antigen (fPSA) Invalid Calibrations
Date Issued	Mar-2026

Products	Product	Test Code	Siemens Material Number/Unique Device Identification	Kit Lot Number	Manufacturing Date	Expiration Date
	Atellica IM Free Prostate-Specific Antigen Assay	fPSA	10995577 / 00630414599014	64480127	11-Jul-2025	11-Jul-2027
				64481127		
				65386127		
				65387127		
				65388127		
	ADVIA Centaur Free PSA	fPSA	10283414 / 00630414553344	64482127	11-Jul-2025	11-Jul-2027

Issue Description Siemens Healthineers has confirmed through the investigation of customer complaints the potential for invalid calibrations with the fPSA assay kit lots listed in the table above due to the “low calibrator deviation” parameter resulting outside of the defined specification range.

1. When a valid calibration is achieved and quality controls (QC) results are within defined ranges, patient results are considered accurate and acceptable for reporting, and no further action is required.
2. If a valid calibration is not achieved, QC and patient sample testing cannot be performed.

Customer Actions For the product(s) listed in the table above, please perform the following steps:

- Patient results can continue to be reported when a valid calibration is achieved, and QC results are within defined ranges.
- 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.
- Please review this letter with your Medical Director.

	<ul style="list-style-type: none">• 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	Unaffected Atellica IM and ADVIA Centaur fPSA kit lots are available at Siemens Distribution Center(s) or in transit to local distribution center.
Single Registration Number (SRN)	US-MF-000016560

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.

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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 26-02.A-1.OUS dated Mar-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. Do you have the affected product(s) on hand? Please check inventories before answering. Yes No
- 2. Were affected Site Personnel notified? Yes No
- 3. Was a copy of the letter 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 # and Kit Lot #	Quantity of Affected Product in inventory Replacement Quantity Required	
<i>Atellica IM Free Prostate-Specific Antigen Assay SMN: 10995577 Kit Lots: 64480127, 64481127, 65386127, 65387127, 65388127</i>		
<i>ADVIA Centaur Free PSA Assay SMN: 10283414 Kit Lot: 64482127</i>		
Name of person completing questionnaire:		
Title:		
Institution:		
Street:		
City:	State:	Zip Code:
Phone:	Country:	
Customer Sold To #	Customer Ship To #	

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

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