

Urgent Field Safety Notice

AIMC 24-17.A-2.OUS

ADVIA Centaur XP System ADVIA Centaur XPT System

Title	ADVIA Centaur anti-TPO (aTPO) Bias
Date Issued	Aug-2024
Issue Description	Siemens Healthineers has confirmed customer complaints of a positive bias in the patient results at and below the cut-off of 60 U/mL with the lots listed in the table below as compared to alternate lots on the ADVIA Centaur XP analyzer. ADVIA Centaur CP does not exhibit the same positive bias as observed with the ADVIA Centaur XP and ADVIA Centaur XPT analyzers. The observed bias is not proportional across the assay measuring interval and becomes less significant as sample concentration increases. The Expected Values cut-off of 60 U/mL has been verified with euthyroid patient samples on the ADVIA Centaur analyzers.

Please note this issue is limited to only the kit lots ending in 337 as listed in the table below.

Products	Assay	Test Code	Siemens Material Number/Unique Device Identification	Kit Lot Number	Manufacturing Date	Expiration Date
	ADVIA Centaur anti-TPO (100 Test)	aTPO	10630886 / 00630414587837	26053337	10-Dec-2023	10-Dec-2024
				26054337		
	ADVIA Centaur anti-TPO (500 Test)		10630887 / 00630414587844	26051337		
				26052337		

Impact to Results	<ul style="list-style-type: none">Falsely elevated aTPO results may be generated. Results from internal studies are shown in Figure 1 in the Appendix. Results of this assay should always be interpreted in conjunction with the patient’s medical history, clinical presentation, and other findings.
Customer Actions	<ul style="list-style-type: none">Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.Perform the actions provided below:<ul style="list-style-type: none">Discontinue use of and discard the kit lots listed in the table above (Products Section).You may request no-charge replacement product from your local Siemens Healthineers or distributor office. Please review your inventory of these products to determine your laboratory’s replacement needs and to provide information to Siemens Healthineers for reporting to the authorities.

- Complete and return the Field Correction Effectiveness Check and indicate product replacement needs on the form attached to this letter within 30 days.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

Resolution You may request no-charge replacement product from your local Siemens Healthineers or distributor office.

Unaffected reagent lots are available for ordering.

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.

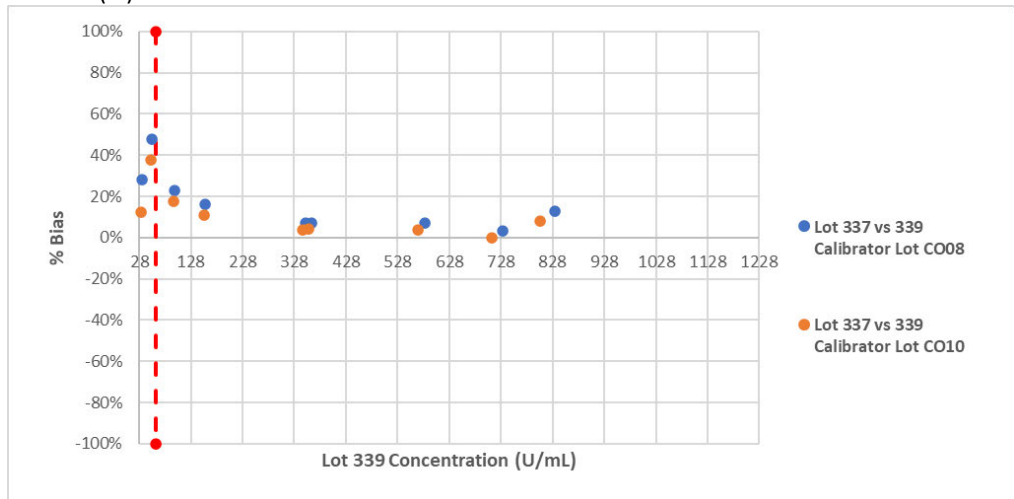
Single Registration Number (SRN)

US-MF-000016560

Appendix

Additional Data

Figure 1. ADVIA Centaur XP aTPO Lot 337 vs Lot 339, with Calibrator Lots C008 and C010 – Percent (%) Bias Plot.



These data are representative of ADVIA Centaur XPT performance.

Note: Red dotted line represents concentration at 60 U/mL.

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Siemens Healthineers

Siemens Healthcare Diagnostics Inc.



FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice (UFSN) AIMC 24-17.A-2.OUS dated Aug-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 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 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 Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory Discarded/Replacement Quantity Required		
ADVIA Centaur aTPO (100 Test) SMN: 10630886 Kit Lot #: 26053337 and 26054337			
ADVIA Centaur aTPO (500 Test) SMN: 10630887 Kit Lot #: 26051337 and 26052337			
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.

Siemens Healthineers
 Siemens Healthcare Diagnostics Inc.
 [Redacted]
 [Redacted]
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