

Urgent Field Safety Notice

AIMC 24-17.A-1.OUS

Atellica IM Analyzer

Title	Atellica IM Anti-Thyroid Peroxidase (aTPO) Bias
Date Issued	Aug-2024
Issue Description	<p>Siemens Healthineers has confirmed customer complaints of a positive bias in patient results at and below the cut-off of 60 U/mL with the lots listed in the table below when compared to alternate lots on the Atellica IM analyzer. Atellica CI does not exhibit the same positive bias as observed with the Atellica IM analyzer.</p> <p>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 Atellica CI and Atellica IM analyzers.</p>

Please note this issue is limited to only the kit lots ending in 336 as listed in the table below.

Products	Assay	Test Code	Siemens Material Number/Unique Device Identification	Kit Lot Number	Manufacturing Date	Expiration Date
Atellica IM Anti-Thyroid Peroxidase (100 Test)	aTPO		10995466 / 00630414597935	26098336	10-Dec-2023	10-Dec-2024
			10995467 / 00630414587837	26099336		

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 of 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.

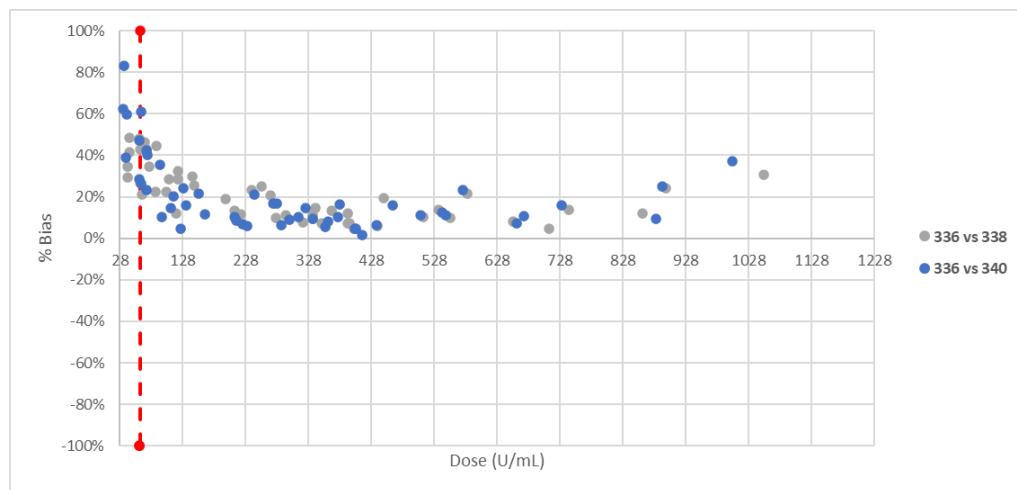
Single Registration Number (SRN)

US-MF-000016560

Appendix

Additional Data

Figure 1. Atellica IM aTPO Lot 336 vs Lots 338 and 340 with calibrator lot C008 Percent (%) Bias Plot.



Performance was also evaluated with calibrator lot C010 and a similar bias was observed.

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

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-1.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 <input type="checkbox"/>	No <input type="checkbox"/>
2. Do you have the affected product on hand? Please check inventories before answering.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3. Were affected Site Personnel notified.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4. Was a copy of the letter retained and posted with the current product labeling.	Yes <input type="checkbox"/>	No <input type="checkbox"/>

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		
Atellica IM aTPO (100 Test) SMN: 10995466 Kit Lot #: 26098336			
Atellica IM aTPO (500 Test) SMN: 10995467 Kit Lot #: 26099336			
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**

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