

# 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** 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.

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.

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
	Atellica IM Anti-Thyroid Peroxidase (500 Test)		10995467 / 00630414587837	26099336		

**Impact to Results**

- 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**

- 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:
  - 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.
  - 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.

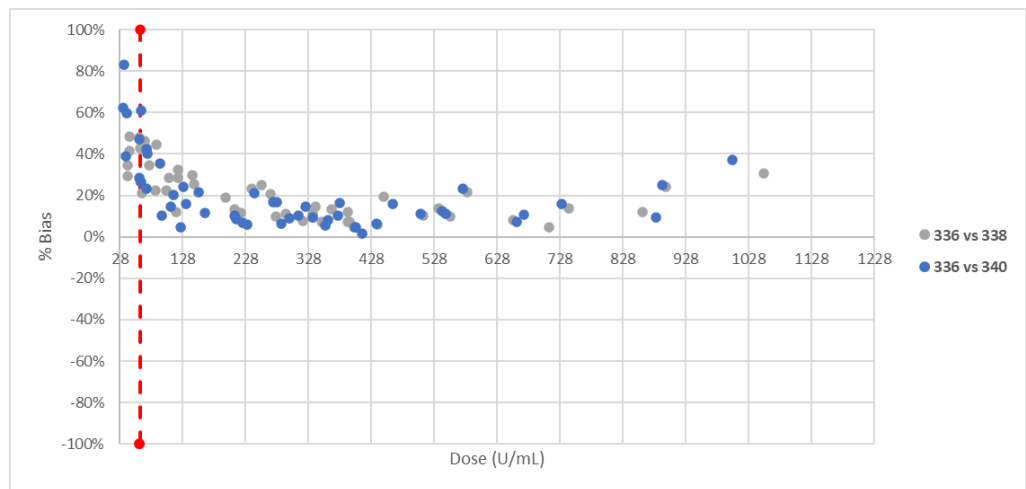
We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

**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.

Atellica is a registered trademark of Siemens Healthcare Diagnostics Inc. © Siemens Healthcare Diagnostics Inc. 2024  
**FIELD CORRECTION EFFECTIVENESS CHECK**

**Siemens Healthineers**  
 Siemens Healthcare Diagnostics Inc.  
 333 Coney Street  
 Walpole, Massachusetts 02032  
 siemens-healthineers.com