

# Urgent Field Safety Notice

AIMC 24-17.A-1.OUS

## Atellica IM Analyzer

|                          |  |
|--------------------------|--|
| <b>Title</b>             | Atellica IM Anti-Thyroid Peroxidase (aTPO) Bias  |
| <b>Date Issued</b>       | Aug-2024   |
| <b>Issue Description</b> | <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     |
|          | Atellica IM Anti-Thyroid Peroxidase (500 Test) |           | 10995467 / 00630414587837                            | 26099336       |                    |                 |

|                          |  |
|--------------------------|--|
| <b>Impact to Results</b> | <ul style="list-style-type: none"><li>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.</li></ul>  |
| <b>Customer Actions</b>  | <ul style="list-style-type: none"><li>Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.</li><li>Perform the actions provided below:<ul style="list-style-type: none"><li>Discontinue use of and discard the kit lots listed in the table above (Products Section).</li><li>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.</li><li>Complete and return the Field Correction Effectiveness Check and indicate product replacement needs on the form attached to this letter within 30 days.</li></ul></li></ul> |

- 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.

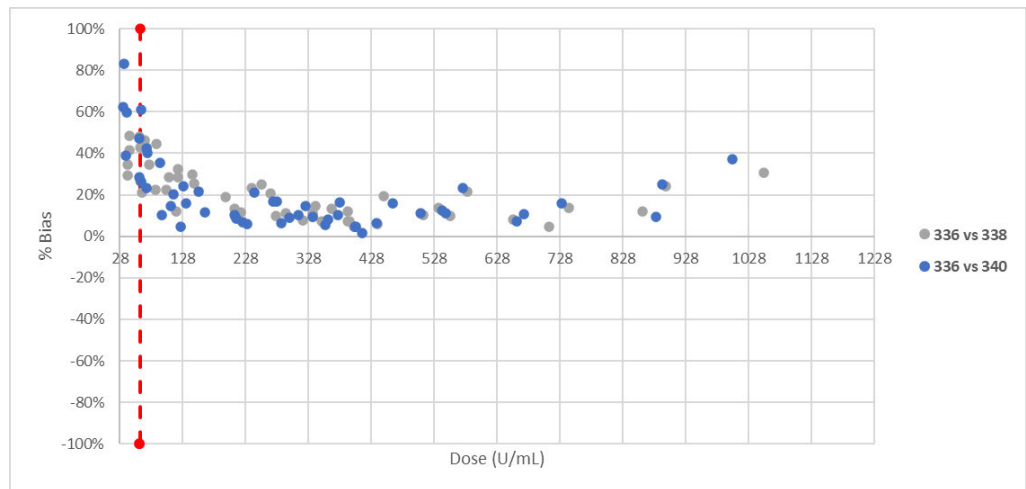
We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

**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 CO08 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  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<br>Product Catalog #/SMN #/Lot #             | Quantity of Affected Product in inventory<br>Discarded/Replacement Quantity Required |                 |                  |
|--|--|-----------------|------------------|
| Atellica IM aTPO (100 Test)<br>SMN: 10995466 Kit Lot #: 26098336 |  |                 |                  |
| Atellica IM aTPO (500 Test)<br>SMN: 10995467 Kit Lot #: 26099336 |  |                 |                  |
| <b>Name of person completing questionnaire:</b>                  |  |                 |                  |
| <b>Title:</b>  |  |                 |                  |
| <b>Institution:</b>  |  |                 |                  |
| <b>Street:</b>   |  |                 |                  |
| <b>City:</b>   |  | <b>State:</b>   | <b>Zip Code:</b> |
| <b>Phone:</b>  |  | <b>Country:</b> |                  |

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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**Siemens Healthineers**  
Siemens Healthcare Diagnostics Inc.

