

Customer Notification

AIMC 25-01.A.OUS

Atellica IM Analyzer

Title	Atellica IM Total Thyroxine (T4) Calibration Interval Reduction											
Date Issued	Oct-2024											
Issue Description	<p>Siemens Healthineers has confirmed through the investigation of customer complaints, the Atellica IM Total Thyroxine (T4) assay does not meet the Pack Calibration Interval of 21 days as stated in the Instructions for Use.</p> <p>When valid calibration is achieved and Quality Control (QC) meet defined ranges, patient results are accurate and acceptable for reporting.</p> <p>Please follow the 'Customer Actions' section to reduce the Pack Calibration Interval, in combination with standard QC practice, to mitigate the issue.</p> <p>Siemens Healthineers is currently investigating the root cause of this issue.</p>											
Products	<table border="1"><thead><tr><th>Assay</th><th>Test Code</th><th>Siemens Material Number / Unique Device Identification</th><th>Lot Number</th></tr></thead><tbody><tr><td rowspan="2">Atellica IM Total Thyroxine</td><td rowspan="2">T4</td><td>10995684 / 00630414599977</td><td rowspan="2">All in-date and future lots until further notification</td></tr><tr><td>10995685 / 00630414599984</td></tr></tbody></table>	Assay	Test Code	Siemens Material Number / Unique Device Identification	Lot Number	Atellica IM Total Thyroxine	T4	10995684 / 00630414599977	All in-date and future lots until further notification	10995685 / 00630414599984		
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Atellica IM Total Thyroxine	T4	10995684 / 00630414599977	All in-date and future lots until further notification									
		10995685 / 00630414599984										
Customer Actions	<p>For the products listed in the table above, perform the actions provided in the attached Addendum to reduce the Pack Calibration Interval from 21 days to 4 days.</p> <p>Please retain this letter with your laboratory records and forward this letter to those who may have received this product.</p>											
Resolution	<p>A follow-up communication with further instructions will be provided when available.</p> <p>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.</p>											
Single Registration Number (SRN)	US-MF-000016560											

Addendum As a temporary mitigation for this issue, in combination with standard Quality Control (QC) practice, reduce the pack calibration interval.

- Remove any open T4 reagent packs onboard the system.
- Navigate to **IM Test Definition**.
- Select the 'T4' assay from the list.
- Select the 'Calibration' option.
- Change the Pack Calibration Interval frequency from 21 days to 4 days and save.
- Load one new T4 reagent pack onto the system.
- Recalibrate and ensure QC is in range.

Note: Load and run only one T4 reagent pack on the system at a time. With every fresh T4 reagent pack that is loaded onto the system, ensure QC is in range. Recalibrate if QC results do not meet acceptance ranges.

FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers **AIMC 25-01.A.OUS** dated Oct-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. Were affected Site Personnel notified? Yes No
- 3. Was a copy of the letter retained and posted with the current product labeling? Yes No

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 fscareportingunit.my@siemens-healthineers.com

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