

Customer Notification

AIMC 25-02.A.OUS

Atellica IM Analyzer

Title	Atellica IM Total Triiodothyronine (T3) Calibration Interval Reduction											
Date Issued	Nov-2024											
Issue Description	<p>Siemens Healthineers has confirmed through the investigation of customer complaints, the Atellica IM Total Triiodothyronine (T3) assay does not meet the Pack Calibration Interval of 21 days as stated in the Instructions for Use for the kit lot numbers listed in the table below.</p> <p>Please follow the 'Customer Actions' section to reduce the Pack Calibration Interval in order to mitigate the issue.</p> <p>When valid calibration is achieved and Quality Control (QC) meet defined ranges, patient results are acceptable for reporting.</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>Kit Lot Number</th></tr></thead><tbody><tr><td rowspan="2">Atellica IM Total Triiodothyronine</td><td rowspan="2">T3</td><td>10995679 / 00630414599922</td><td rowspan="2">23047272, 28261272, 23046272, 78082274, 78083274, 78084274, 78145274, and higher</td></tr><tr><td>10995678 / 00630414599915</td></tr></tbody></table>	Assay	Test Code	Siemens Material Number / Unique Device Identification	Kit Lot Number	Atellica IM Total Triiodothyronine	T3	10995679 / 00630414599922	23047272, 28261272, 23046272, 78082274, 78083274, 78084274, 78145274, and higher	10995678 / 00630414599915		
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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 3 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											

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Addendum As a temporary mitigation for this issue, reduce the Pack Calibration Interval.

- Remove any open T3 reagent packs onboard the system.
- Navigate to **IM Test Definition**.
- Select the 'T3' assay from the list.
- Select the 'Calibration' option.
- Change the Pack Calibration Interval frequency from 21 days to 3 days and save.
- Load one new T3 reagent pack onto the system.
- Perform **Lot** Calibration and ensure QC is in range.

Note: Load and run only one T3 reagent pack on the system at a time. With every fresh T3 reagent pack that is loaded onto the system, ensure QC is in range. Recalibrate if QC results do not meet acceptance ranges.
