

# Customer Notification

AIMC 24-09.A.OUS

**Atellica IM Analyzer**

**Atellica CI Analyzer**

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<b>Title</b>	Atellica IM and Atellica CI High-Sensitivity Troponin I (TnIH) Invalid Calibration
<b>Date Issued</b>	March 2024
<b>Issue Description</b>	<p>Siemens Healthineers has investigated customer complaints and confirmed the potential for invalid calibrations with the Atellica® IM and Atellica® CI High-Sensitivity Troponin I (TnIH) assay due to the “calibration signal ratio” parameter resulting outside of the defined specification range.</p> <ul style="list-style-type: none"><li>• If a valid calibration is achieved and quality controls (QC) meet defined ranges, then patient results are considered accurate and acceptable for reporting. No further action is needed.</li><li>• If you are unable to obtain a valid calibration, you may attempt multiple re-calibrations.</li><li>• Investigation indicates the calibration failure rate due to calibration signal ratio is intermittent. The calibrator does not contribute to the calibration ratio failure.</li><li>• Per the Instructions for Use (IFU), if an invalid calibration is obtained, QC and patient sample testing cannot be performed. Further action is defined below in the “Actions to be Taken” section.</li></ul> <p>Siemens is currently investigating the root cause of the calibration signal ratio failures. The calibration signal ratio issue is limited to the TnIH reagent in the kit lots listed in the table below.</p>

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Products	Assay	Test Code	Siemens Material Number/Unique Device Identification	Kit Lot Number	Manufacturing Date	Expiration Date
	Atellica IM and Atellica CI High-Sensitivity Troponin I (100 Test)	TnIH	10997840 / 00630414006703	11821101	23-Oct-2023	23-Jan-2025
				11822101		
				47365102	23-Jan-2024	23-Apr-2025
				47366102		
	Atellica IM and Atellica CI High-Sensitivity Troponin I (500 Test)	TnIH	10997841 / 00630414006758	11820101	23-Oct-2023	23-Jan-2025
				47204102	23-Jan-2024	23-Apr-2025

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- |                         |   |
|-------------------------|---|
| <b>Customer Actions</b> | <ul style="list-style-type: none"><li>• For the product(s) listed in the table above, please perform the following steps:</li></ul> |
|-------------------------|---|
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- Patient results may continue to be reported when a valid calibration and in range quality control results are obtained.
  - When a valid calibration cannot be obtained due to calibration signal ratio failure, you may request no-charge replacement product from your local Siemens Healthineers at 1800-815-508 or distributor office.
  - Please review your inventory of these products and assess your laboratory's replacement needs.
  - Complete and return the Product Replacement Form attached to this letter to request your no-charge replacement product(s).
  - Please retain this letter with your laboratory records and forward this letter to those who may have received the product.

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**Resolution** Atellica IM and Atellica CI TnIH Kit Lots ending in 103 are anticipated to start arriving at our distribution centers 20-Mar-2024.

Atellica IM and Atellica CI TnIH Kit Lots ending in 103 are packaged with TnIH Calibrator Lot ending in 102. For TnIH Kit Lots ending in 103 customers can expect to see reagent lot 103 and calibrator lot 102 in the kit. The TnIH Calibrator Lot 102 does not contribute to the calibration ratio failure. The calibrator values are not impacting the calibration ratio failure.

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**PRODUCT REPLACEMENT FORM**

This response form is to request no charge replacement product for the enclosed Siemens Healthineers Customer Notification **AIMC 24-09.A.OUS** dated March 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 at 1800-815-508 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 been unable to obtain a valid calibration of the Atellica IM and Atellica CI TnIH assay due to calibration signal ratio? Yes  No
- 2. All affected Site Personnel have been notified. Yes  No
- 3. A copy of the letter has been retained and posted with our current product labeling. Yes  No

If the answer to the question #1 above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description SMN #/Lot #	Quantity of Affected Product in inventory /Replacement Quantity Required
<i>Atellica IM and Atellica CI High-Sensitivity Troponin I (100 Test) SMN: 10997840 Kit Lot #: 11821101 and 11822101</i>	
<i>Atellica IM and Atellica CI High-Sensitivity Troponin I (100 Test) SMN: 10997840 Kit Lot #: 47365102 and 47366102</i>	
<i>Atellica IM and Atellica CI High-Sensitivity Troponin I (500 Test) SMN: 10997841 Kit Lot #: 11820101</i>	
<i>Atellica IM and Atellica CI High-Sensitivity Troponin I (500 Test) SMN: 10997841 Kit Lot #: 47204102</i>	
<b>Name of person completing questionnaire:</b>	
<b>Title:</b>	
<b>Institution:</b>	
<b>Street:</b>	
<b>City:</b>	<b>State:</b>
<b>Phone:</b>	<b>Country:</b>

Please send a scanned copy of the completed form via email to [fsreportingunit.my@siemens-healthineers.com](mailto:fsreportingunit.my@siemens-healthineers.com)

We apologize for the inconvenience this situation may cause.

If you have any questions, please contact your Siemens Healthineers Customer Care Center at 1800-815-508 or your local Siemens Healthineers technical support representative.

**Siemens Healthcare Sdn Bhd (201501001338)**  
 Level 16 - Wing1 & 2, CP Tower,  
 No 11, Jalan 16/11,  
 Pusat Dagang Seksyen 16,  
 46350 Petaling Jaya,  
 Selangor Darul Ehsan, Malaysia

Tel.: +60 (3) 7952 5555  
[www.siemens-healthineers.com/en-my](http://www.siemens-healthineers.com/en-my)