

# Customer Notification

AIMC 24-03.A.OUS

**Atellica IM Analyzer**  
**ADVIA Centaur XP System**  
**ADVIA Centaur XPT System**

<b>Title</b>	Potential for Invalid Calibrations with Atellica IM and ADVIA Centaur Systems Rubella IgG Assay
<b>Date Issued</b>	Aug-2024
<b>Issue Description</b>	<p>Siemens Healthineers has investigated customer complaints and confirmed the potential for invalid calibrations with Atellica® IM and ADVIA Centaur® XP/XPT Rubella IgG (Rub G) assay due to low calibrator %CV failures.</p> <ul style="list-style-type: none"><li>• If a valid calibration is achieved and Quality Control (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 %CV failure is intermittent.</li><li>• Per the Instruction for Use (IFU), if an invalid calibration is obtained, QC and patient sample testing cannot be performed. Further action is defined below in the “Customer Actions” section.</li></ul> <p>Siemens Healthineers is currently investigating the root cause of the invalid calibration due to low calibrator %CV failures.</p>

Products	Assay	Siemens Material Number / Unique Device Identification	Kit Lot Number	Manufacturing Date	Expiration Date
	Atellica IM Rubella IgG (Rub G)	10995670 / 00630414600529	25432250 25433250 73268252 and higher	10/2/2023 10/2/2023 3/13/2024	10/2/2024 10/2/2024 3/13/2025
ADVIA Centaur Rubella G	10310283 / 00630414201412	25434249 73267251 and higher	10/2/2023 3/13/2024	10/2/2024 3/13/2025	

<b>Customer Actions</b>	<p>For the product(s) listed in the table above, please perform the following steps:</p> <ul style="list-style-type: none"><li>• Patient results may continue to be reported only when a valid calibration and within range Quality Control results are obtained.</li><li>• If you are unable to obtain a valid Rub G calibration after multiple re-calibration attempts, you may request no-charge replacement product(s) from your local Siemens Healthineers or distributor office.<ul style="list-style-type: none"><li>○ Please review your inventory of these product(s) and assess your laboratory’s replacement needs.</li><li>○ Complete and return the Product Replacement Form attached to this letter to request your no-charge replacement product(s).</li></ul></li><li>• Please retain this letter with your laboratory records and forward this letter to those who may have received the product(s).</li></ul>
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<b>Resolution</b>	Once more information is available, a follow-up communication will be provided.
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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.

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**PRODUCT REPLACEMENT FORM**

This response form is to request no-charge replacement product(s) for the enclosed Siemens Healthineers Customer Notification **AIMC 24-03.A.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 product(s) 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 been unable to obtain a valid Rub G calibration with the Atellica IM and ADVIA Centaur Rub G assay due to low calibrator %CV failures? 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

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

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in Inventory Discarded/Replacement Quantity Required
<i>Atellica IM Rub G 100T / SMN 10995670 / Kit Lot 25432250</i>	
<i>Atellica IM Rub G 100T / SMN 10995670 / Kit Lot 25433250</i>	
<i>Atellica IM Rub G 100T / SMN 10995670 / Kit Lot 73268252</i>	
<i>ADVIA Centaur Systems Rub G / SMN 100T 10310283 / Kit Lot 25434249</i>	
<i>ADVIA Centaur Systems Rub G 100T / SMN 10310283 / Kit Lot 73267251</i>	
<b>Name of Person Completing Questionnaire:</b>	
<b>Title:</b>	
<b>Institution:</b>	
<b>Street:</b>	
<b>City:</b>	<b>State:</b> <span style="float: right;"><b>Zip Code:</b></span>
<b>Phone:</b>	<b>Country:</b>

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

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