Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	Atellica IM Rubella IgG
Material Number	10310283
Lot No.	25432250 25433250 73268252
Manufacturer	Siemens Healthcare Diagnostics Inc.
Country of Origin	US
Reference	Attached
Reason of Recall	NHRA initiates this FSN due to the potential for invalid calibrations with the Atellica IM and ADVIA Centaur Systems Rubella IgG assay, which could lead to inaccurate patient results and compromised diagnostic accuracy.
Action should be taken	Please refer to "Actions to be taken by Customer/ User" in the attached FSN And for more information please contact the authorized representative Wael Pharmacy Co.W.L.L. at sharon@waelpharmacy.com.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

Customer Notification

AIMC 24-03.A.OUS

Atellica IM Analyzer
ADVIA Centaur XP System
ADVIA Centaur XPT System

Title Potential for Invalid Calibrations with Atellica IM and ADVIA Centaur Systems Rubella IgG Assay

Date Issued Aug-2024

Issue Description

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.

- 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.
- If you are unable to obtain a valid calibration, you may attempt multiple re-calibrations.
- Investigation indicates the calibration failure rate due to %CV failure is intermittent.
- 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.

Siemens Healthineers is currently investigating the root cause of the invalid calibration due to low calibrator %CV failures.

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

Customer Actions

For the product(s) listed in the table above, please perform the following steps:

- Patient results may continue to be reported only when a valid calibration and within range Quality Control results are obtained.
- 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.
    - Please review your inventory of these product(s) 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(s).

Resolution Once more information is available, a follow-up communication will be provided.

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.

Siemens Healthineers
Siemens Healthcare Diagnostics Inc.
333 Coney Street
Walpole, Massachusetts 02032

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**	
Atellica IM Rub G 100T / SMN 10995670 / Kit Lot 25432250		
Atellica IM Rub G 100T / SMN 10995670 / Kit Lot 25433250		
Atellica IM Rub G 100T / SMN 10995670 / Kit Lot73268252		
ADVIA Centaur Systems Rub G / SMN 100T 10310283 / Kit Lot 25434249		
ADVIA Centaur Systems Rub G 100T / SMN 10310283 / Kit Lot 73267251		
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 **XXXX@XXXX**

Or fax this completed form to the Customer Care Center at **XXXXXX**

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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