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 CA 19-9 (50 Test)
Device Model	10995490
Lot No.	55974535 55975535
Manufacturer	Siemens Healthcare Diagnostics Inc.
Country of Origin	US
Reference	Attached
Reason of Recall	NHRA initiates this FSN due to identifying a positive bias in CA 19-9 assay results for certain Atellica lots.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative Wael Pharmacy Co. W.L.L at sharmi@waelpharmacy.com to take the necessary action for recall.

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

Urgent Field Safety Notice

AIMC 24-14.A.OUS

Atellica CI Analyzer
Atellica IM Analyzer
ADVIA Centaur XP System
ADVIA Centaur XPT System
ADVIA Centaur CP System

Title

Atellica CI, Atellica IM and ADVIA Centaur CA 19-9 Bias

Date Issued

Jul-2024

Issue Description

Siemens Healthineers has confirmed, through the investigation of customer complaints, a positive bias for some samples around a concentration of 37 U/mL with the lots listed in the table below as compared to the previous lot. The sample bias observed was greatest in the Asia Pacific sample population. The observed bias is not proportional across the assay measuring interval and is less pronounced for sample results above a concentration of 110 U/mL.

This issue is isolated to the product listed in the table below.

See Appendix for data in Figures 1 - 4.

Products

Assay	Test Code	Siemens Material Number/Unique Device Identification	Kit Lot Number	Manufacturing Date	Expiration Date
Atellica IM CA 19-9 (50 Test)	CA 19-9	10995490 / 00630414598178	55974535	14-Nov-2023	14-Sep-2024
			55975535		
Atellica IM CA 19-9 (250 Test)		10995489 / 00630414598161	55977535		
ADVIA Centaur CA 19-9 (50 Test)	CA 19-9	10491379 / 00630414574257	55970535	14-Nov-2023	14-Sep-2024
			55971535		
ADVIA Centaur CA 19-9 (250 Test)		10491244 / 00630414574028	55972535		
			55973535		

Impact to Results

- Falsely elevated CA 19-9 assay results may occur. The data from internal studies show a positive bias as shown in Appendix Figures 1 - 4. Results of this assay should be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Customer Actions

- Please review this letter with your Medical Director to determine the appropriate course of action, including for any previously generated results, if applicable.

SIEMENS Healthineers

- Perform the instructions provided below:
    - Discontinue use of and discard the kit lots listed in the table above (Products Section).
    - If you experience this issue, you may request no-charge replacement product from your local Siemens Healthineers or distributor office. Please review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens Healthineers for reporting to the authorities.
    - Complete and return the Field Correction Effectiveness Check and indicate product replacement needs on the form attached to this letter within 30 days.
    - Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

Resolution

CA 19-9 kit lots ending in 535 are not available for purchase or use. You may request no-charge replacement product from your local Siemens Healthineers or distributor office.

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.

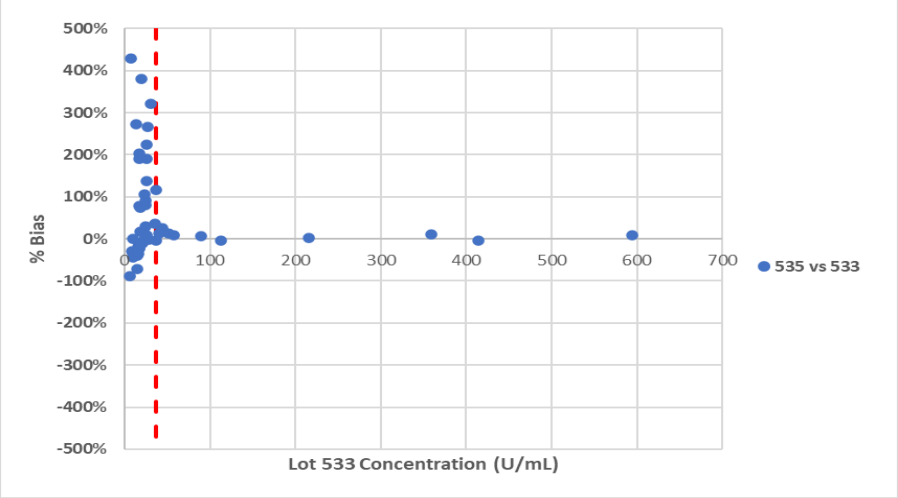
Single Registration Number (SRN)

US-MF-000016560

Appendix

Additional Data (Note: The y-axis is different among Figures 1 - 4.)

Figure 1. Asia Pacific Sample Population: ADVIA Centaur XPT CA 19-9 Lot 535 vs Lot 533 – Percent (%) Bias Plot



Note: Red dotted line represents concentration at 37 U/mL.
These data are representative of Atellica IM, Atellica CI, ADVIA Centaur XP, and ADVIA Centaur CP performance.

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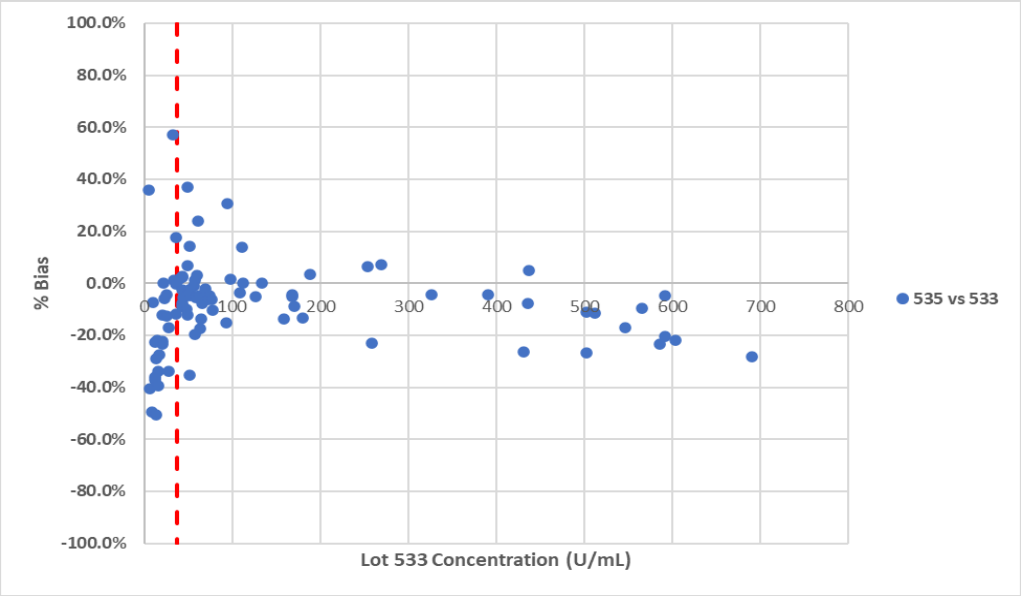
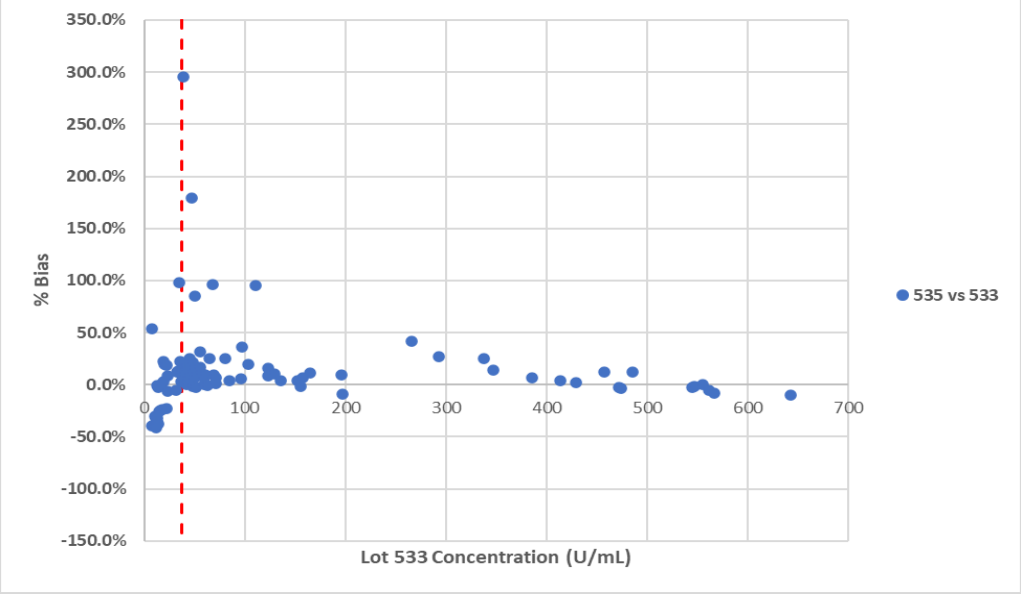
Figure 2. General Sample Population: Atellica IM CA 19-9 Lot 535 vs Lot 533 – Percent (%) Bias Plot



Note: Red dotted line represents concentration at 37 U/mL.
These data are representative of Atellica CI performance.

Figure 3. General Sample Population: ADVIA Centaur XPT CA 19-9 Lot 535 vs Lot 533 – Percent (%) Bias Plot



Note: Red dotted line represents concentration at 37 U/mL.
These data are representative of ADVIA Centaur XP performance.

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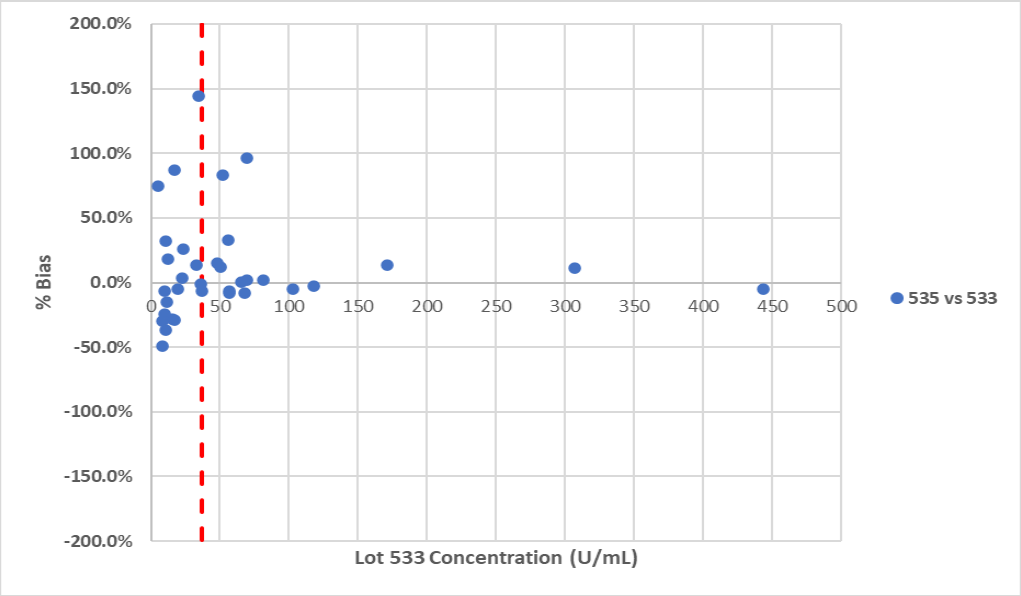
Figure 4. General Sample Population: ADVIA Centaur CP CA 19-9 Lot 535 vs Lot 533 – Percent (%) Bias Plot



Note: Red dotted line represents concentration at 37 U/mL.

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FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Siemens Healthineers Urgent Field Safety Notice (UFSN) AIMC 24-14.A.OUS dated Jul-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.	Do you have the affected product on hand? Please check inventories before answering.	Yes ☐	No ☐
3.	Were affected Site Personnel notified.	Yes ☐	No ☐
4.	Was a copy of the letter retained and posted with the current product labeling.	Yes ☐	No ☐

If the answer to the question #2 above is yes, please complete the table below to indicate the quantity of affected product 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 CA 19-9 (50 Test) *SMN: 10995490 Kit Lot #s: 55974535 and 55975535*	
Atellica IM CA 19-9 (250 Test) *SMN: 10995489 Kit Lot #s: 55977535*	
ADVIA Centaur CA 19-9 (50 Test) *SMN: 10491379 Kit Lot #s: 55970535 and 55971535*	
ADVIA Centaur CA 19-9 (250 Test) *SMN: 10491244 Kit Lot #s: 55972535 and 55973535*	
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 to 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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