

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	<p>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.</p> <p>This issue is isolated to the product listed in the table below. See Appendix for data in Figures 1 - 4.</p>

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
	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
	ADVIA Centaur CA 19-9 (250 Test)		10491244 / 00630414574028	55972535 55973535		

Impact to Results	<ul style="list-style-type: none">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.
 - 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.

siemens-healthineers.tld/keyword

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.

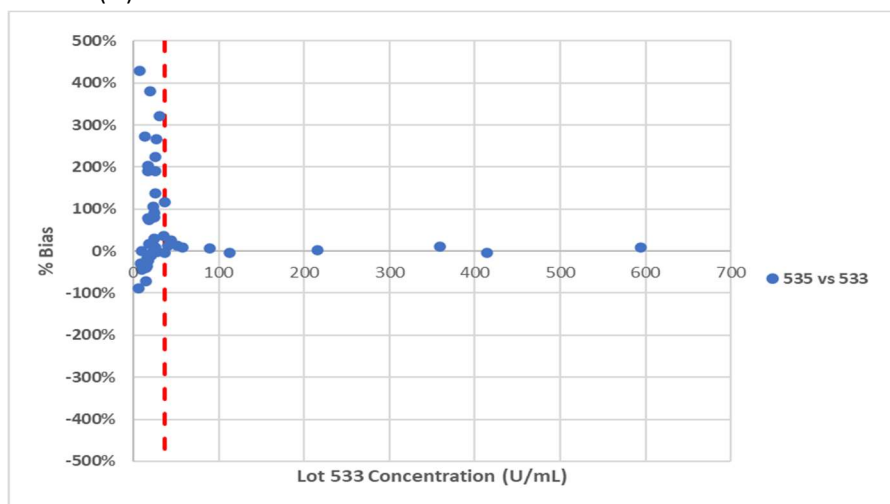
Single Registration Number (SRN)

US-MF-000016560

Appendix

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

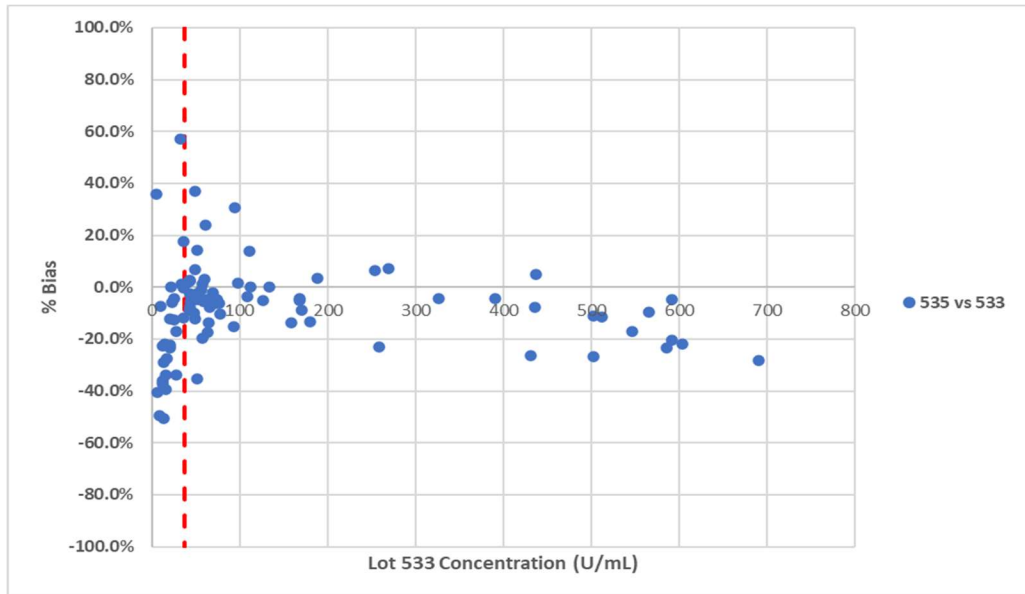
Figure 1. Asia Pacific Sample Population: ADVIA Centaur XPT CA 19-9 Lot 535 vs Lot 533 – Percent (%) Bias Plot



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.

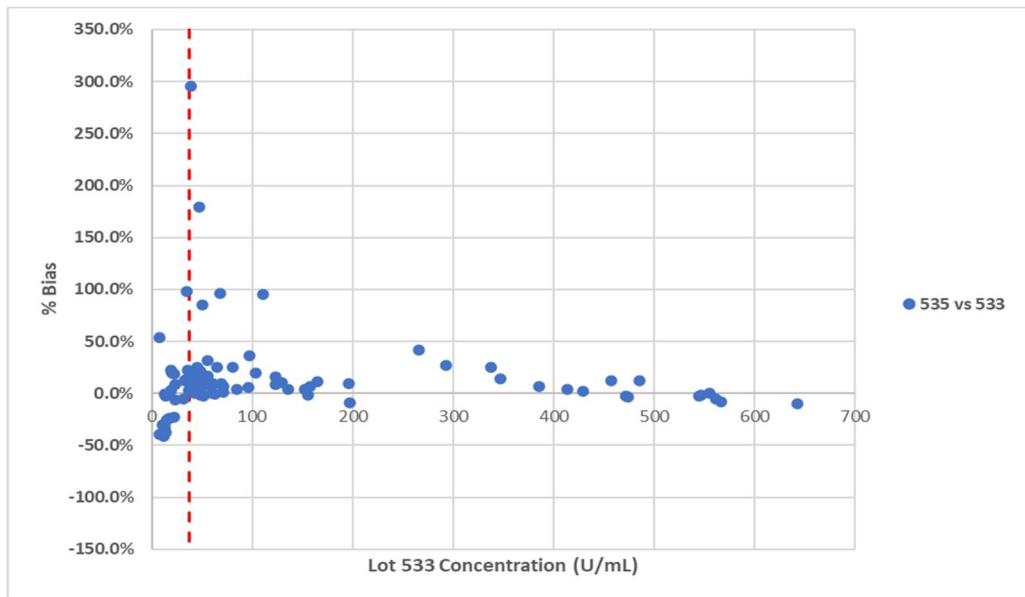
Siemens Healthineers
 Siemens Healthcare Diagnostics Inc.
 333 Coney Street
 Walpole, Massachusetts 02032
 siemens-healthineers.com

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



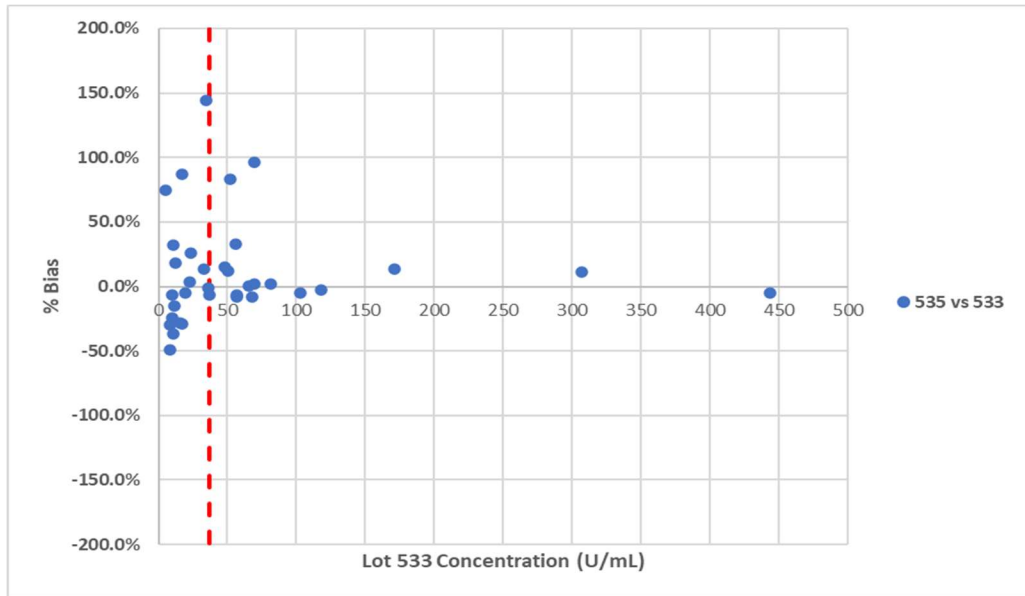
Note: Red dotted line represents concentration at 37 U/mL.
These data are representative of Atellica CI performance.

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.

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.

Atellica and ADVIA Centaur are registered trademarks of Siemens Healthcare Diagnostics Inc. © Siemens Healthcare Diagnostics Inc. 2024

CA 19-9 is a trademark of Fujirebio Diagnostics, Inc.

Siemens Healthineers

Siemens Healthcare Diagnostics Inc.

333 Coney Street

Walpole, Massachusetts 02032

siemens-healthineers.com

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 #: 55974535 and 55975535			
Atellica IM CA 19-9 (250 Test) SMN: 10995489 Kit Lot #: 55977535			
ADVIA Centaur CA 19-9 (50 Test) SMN: 10491379 Kit Lot #: 55970535 and 55971535			
ADVIA Centaur CA 19-9 (250 Test) SMN: 10491244 Kit Lot #: 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.

Siemens Healthineers
 Siemens Healthcare Diagnostics Inc.
 333 Coney Street
 Walpole, Massachusetts 02032
 siemens-healthineers.com