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 Date August 09, 2024  
 Document Ref# AIMC 24-14.A.OUS

**Urgent Field Safety Notice:**

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

To whom it may concern,

**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
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 Result**

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.

We apologize for any inconvenience that this situation has caused. Thank you for your patience and continued support.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

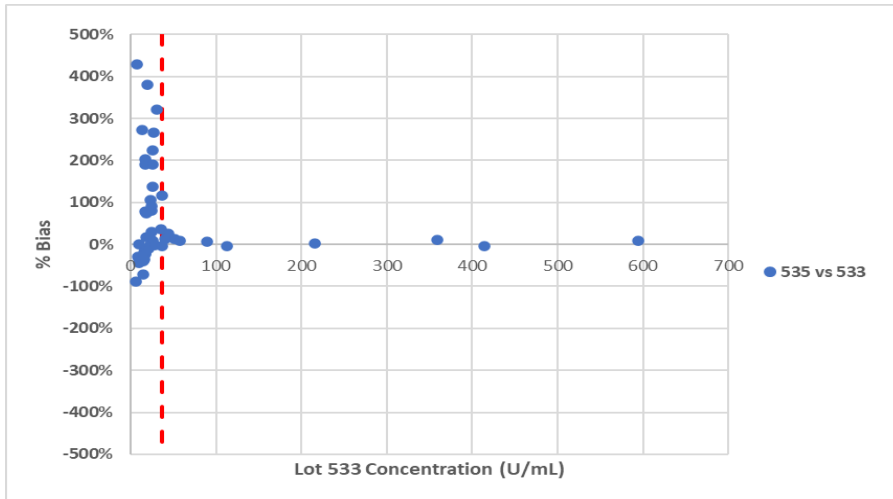
i.V. Dipl.-Ing. Gudrun Kapl

i.A. Dipl.-Ing. Carina Viehböck

**Appendix**

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

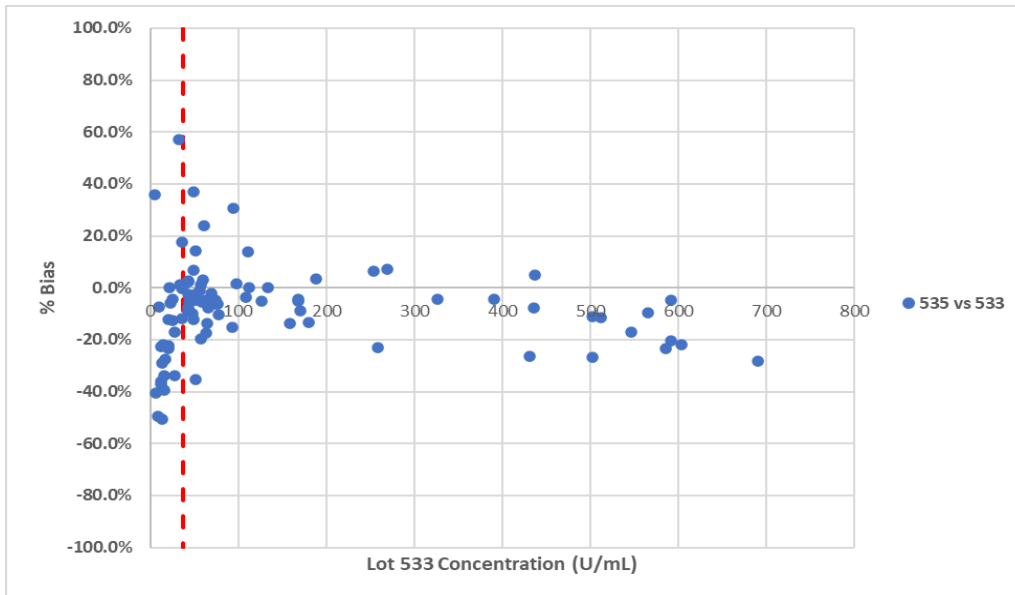
Figure 1. Asia Pacific Sample Population: ADVIA Centaur XPT CA 19-9 Lot 535 vs Lot 533 – Percent (%) Bias Plot



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.

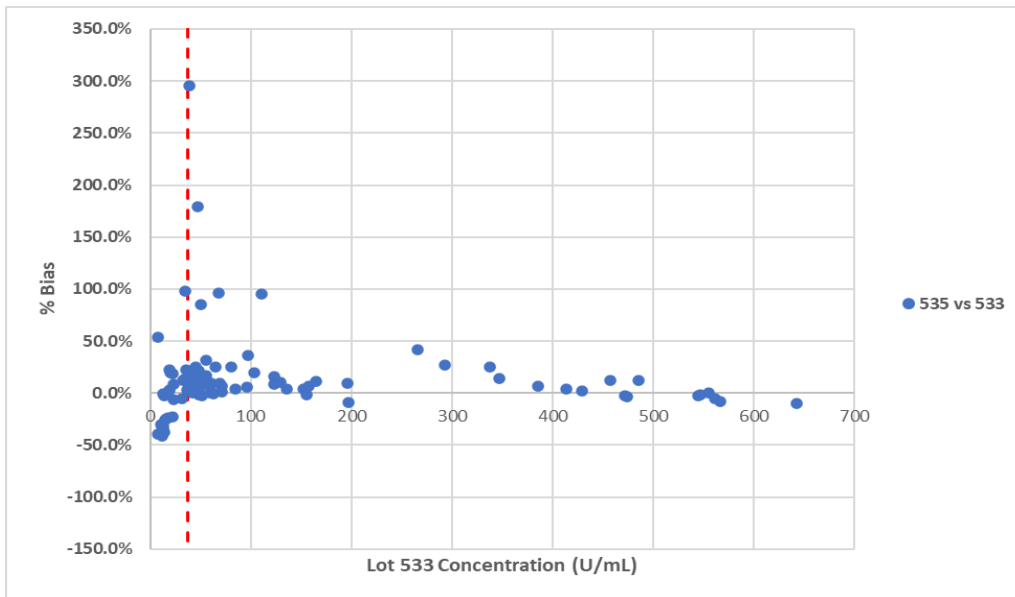
Figure 2. General Sample Population: Atellica IM CA 19-9 Lot 535 vs Lot 533 – Percent (%) Bias Plot



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

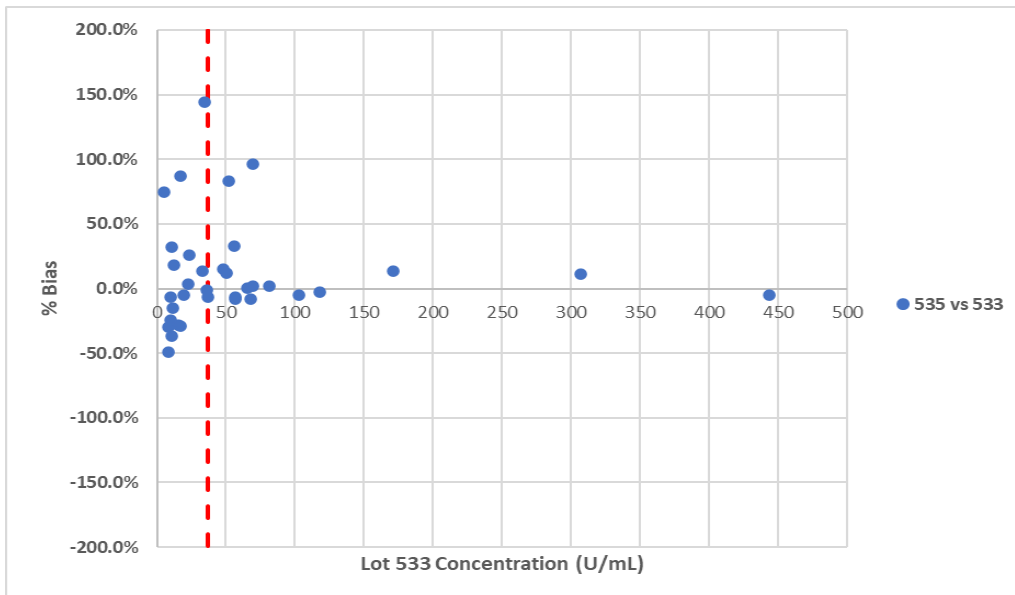
These data are representative of Atellica CI performance.

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.