

Dimension Vista® System

**Dimension Vista® LOCI CA 15-3 (CA15-3) Flex® reagent cartridge
Negative Bias with Patient Samples**

Our records indicate that your facility may have received the following product:

Table 1. Dimension Vista® Affected Products

Assay	Siemens Material Number (SMN)/REF (Catalog Number)	Unique Device Identification (UDI)	Lot Number	Expiration Date (YYYY-MM-DD)	Date of Manufacture (YYYY-MM-DD)
LOCI CA 15-3	10464344/K6456	0084276802852621340BB22120610464344840	21340BB	2022-12-06	2021-12-06
LOCI CA 15-3	10464344/K6456	0084276802852622049BC23021810464344840	22049BC	2023-02-18	2022-02-18
LOCI CA 15-3	10464344/K6456	0084276802852622112BF23042210464344840	22112BF	2023-04-20	2022-04-25

Reason for Urgent Field Safety Notice

The purpose of this communication is to inform you of an issue for the products indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthineers has received customer complaints for negative patient bias with the Dimension Vista LOCI CA 15-3 assay. Siemens has confirmed the Dimension Vista LOCI CA 15-3 lots listed in Table 1 show a negative bias with patient samples. The mean patient sample bias for the lots listed in Table 1 range from -26% to -33% as shown in Figures 1, 2 and 3. Patient bias is consistent across the Analytical Measurement Range (AMR). The highest bias observed on a patient sample (56 U/mL) was -47%. Quality Control does not detect this issue.

Siemens Healthineers is working to restore assay performance and until such time, subsequent lots of Dimension Vista LOCI CA 15-3 may contain an Alert Card within the carton listing lot specific correlation factors.

Figure 1. LOCI CA 15-3 % Bias Lot 21340BB

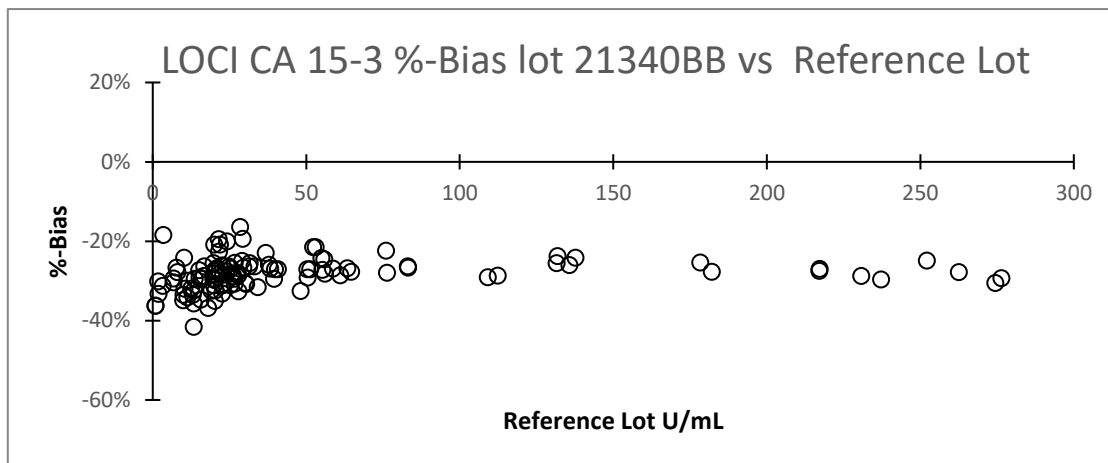


Figure 2. LOCI CA 15-3 % Bias Lot 22049BC

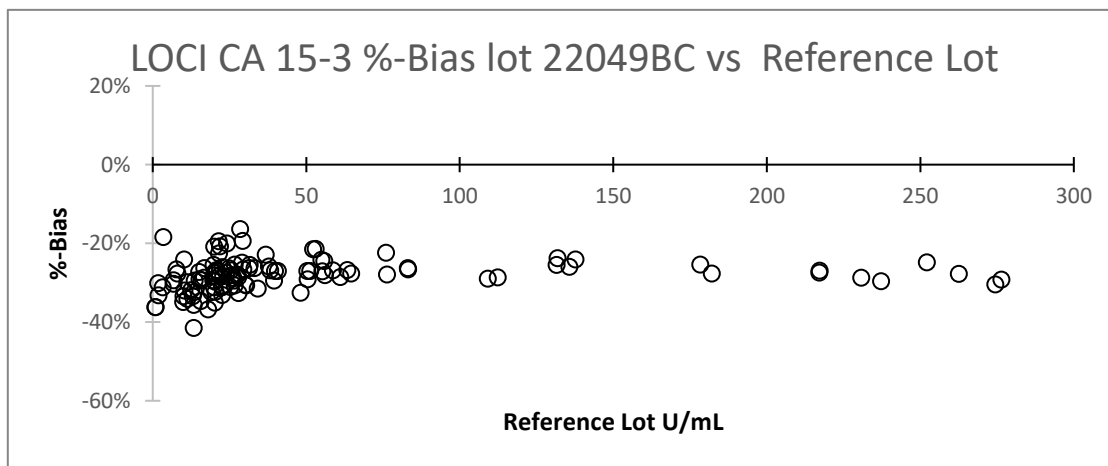
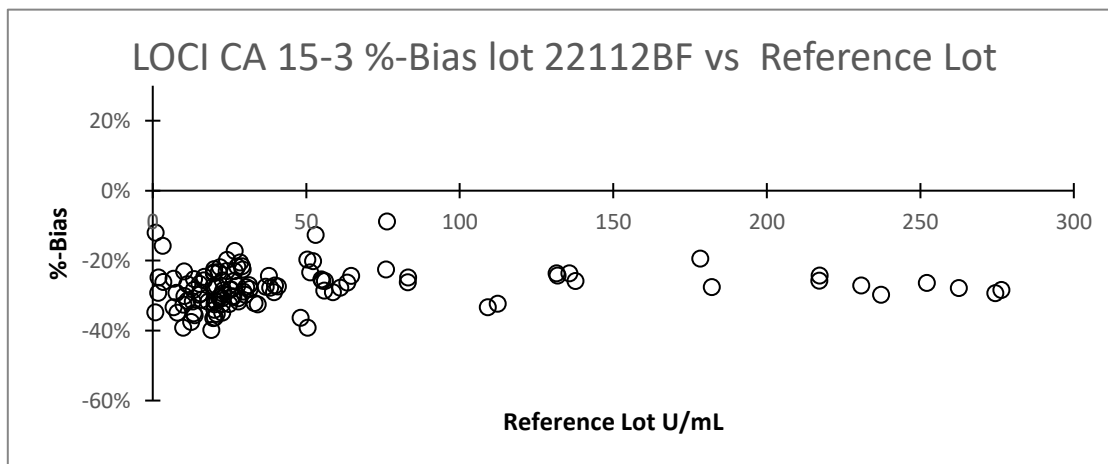


Figure 3. LOCI CA 15-3 % Bias Lot 22112BF



Risk to Health

Worst case, this issue poses a risk of delay in appropriate treatment and management decisions for patients in whom the CA 15-3 values are rising due to the relapse or progression of breast cancer, and the increase is masked by the negative bias. Per good clinical practice serial testing with CA 15-3 would occur, with multiple measurements needed to confirm a rising or falling pattern, indicating potential progression/recurrence or regression of breast cancer.

The risk is mitigated by use of CA15-3 in conjunction with other clinical indicators (such as signs and symptoms) and diagnostic procedures (such as imaging) that are also assessed during monitoring. Serial CA 15-3 testing to confirm a rising or falling pattern would reveal the true pattern of disease, after the initial use of an affected lot. Due to this, Siemens is not recommending a review of previously generated results

Actions to be Taken by the Customer:

- Calibrate/Recalibrate Dimension Vista LOCI CA 15-3 lots listed in Table 1 using any in date lot of Dimension Vista LOCI 7 Calibrator (SMN 10488446/ REF KC605).
- Enter lot specific correlation factors **C0** and **C1** in the Method Configuration screen per Flex reagent Lot listed below in Table 2. After applying correlation factors to the specified lot, product claims listed in the Instructions For Use (IFU) are met.

Table 2. Lot Specific Correlation Factors for Dimension Vista LOCI CA 15-3 Lots

LOCI CA 15-3 Lot	C0	C1
21340BB	0.0000	1.4932
22049BC	0.0000	1.3903
22112BF	0.0000	1.3876

- For instructions on entering correlation factors please refer to the Dimension Vista System Operator's Guide Rev A 2017-03 or online iGuide (Advanced Functions Section); Method Configuration, Section 9, page 9-25.
- Process Quality Control (QC) after recalibration and entry of lot specific correlation factors.
- The correlation factors may create an upward QC shift. Please follow your current laboratory process for adjusting QC ranges. Siemens is providing some examples of CA15-3 lot specific QC values calculated for the three in-date lots of Dimension Vista LOCI CA15-3. CA 15-3 lot specific bottle values for representative sets of QC materials are shown in Table 3.

Table 3. Example of QC Bottle Value Adjustment After Application of Correlation Factors to Dimension Vista LOCI CA 15-3 Lots.

Table 3.a. Quality Control Target Values and Acceptance Range for Dimension Vista LOCI CA 15-3 Flex Lot 21340BB

Quality Control Materials	QC Level	BioRad Insert Sheet Target Value (U/mL)	Siemens Target Value (U/mL) with Application of Correlation Factors	Acceptance Range (U/mL)
BioRad Liquichek Control - Tumor Marker Lot 94900	QC1 - 94901	21.3	31.8	25.4 to 38.2
	QC2-94902	57.2	85.4	68.3 to 102.5
	QC3-94903	100.0	149.3	119.5 to 179.2
BioRad Liquichek Control - Tumor Marker Lot 24010	QC1-24011	25.0	37.3	29.9 to 44.8
	QC2-24012	50.8	75.9	60.7 to 91.0
	QC3-24013	93.0	138.9	111.1 to 166.6
BioRad Lyphohek Control - Tumor Marker Plus Lot 54690	QC 1 - 54691	19.1	28.5	22.8 to 34.2
	QC2-54692	47.8	71.4	57.1 to 85.6
	QC3-54693	97.7	145.9	116.7 to 175.1
Thermofisher Liquid Assayed Tumor Marker Control 22100	QC1-22101	10.8	16.1	12.9 to 19.4
	QC3-22102	26.8	40.0	32.0 to 48.0
	QC3-22103	55.1	82.3	65.8 to 98.7

Table 3.b. Quality Control Target Values and Acceptance Range for Dimension Vista LOCI CA 15-3 Flex lot 22049BC

QC Materials	QC Level	BioRad Insert Sheet Target Value (U/mL)	Siemens Target Value (U/mL) with Application of Correlation Factors	Acceptance Range (U/mL)
BioRad Liquichek Control - Tumor Marker Lot 94900	QC1-94901	21.3	29.6	23.7 to 35.5
	QC2-94902	57.2	79.5	63.6 to 95.4
	QC3-94903	100.0	139.0	111.2 to 166.8
BioRad Liquichek Control - Tumor Marker Lot 24010	QC1-24011	25.0	34.8	27.8 to 41.7
	QC2-24012	50.8	70.6	56.5 to 84.8
	QC3-24013	93.0	129.3	103.4 to 155.2
BioRad Lyphohek Control - Tumor Marker Plus Lot 54690	QC 1-54691	19.1	26.6	21.2 to 31.9
	QC2-54692	47.8	66.5	53.2 to 79.7
	QC3-54693	97.7	135.8	108.7 to 163.0
Thermofisher Liquid Assayed Tumor Marker Control 22100	QC1-22101	10.8	15.0	12.0 to 18.0
	QC3-22102	26.8	37.3	29.8 to 44.7
	QC3-22103	55.1	76.6	61.3 to 91.9

Table 3.c. Quality Control Target Values and Acceptance Range for Dimension Vista LOCI CA 15-3 Flex lot 22112BF

QC Materials	QC Level	BioRad Insert Sheet Target Value (U/mL)	Siemens Recovery With Application of Correlation Factors	Acceptance Range (U/mL)
BioRad Liquichek Control - Tumor Marker Lot 94900	QC1-94901	21.3	29.6	23.6 to 35.5
	QC2-94902	57.2	79.4	63.5 to 95.2
	QC3-94903	100.0	138.8	111.0 to 166.5
BioRad Liquichek Control - Tumor Marker Lot 24010	QC1-24011	25.0	34.7	27.8 to 41.6
	QC2-24012	50.8	70.5	56.4 to 84.6
	QC3-24013	93.0	129.0	103.2 to 154.9
BioRad Lyphocheck Control - Tumor Marker Plus Lot 54690	QC1-54691	19.1	26.5	21.2 to 31.8
	QC2-54692	47.8	66.3	53.1 to 79.6
	QC3-54693	97.7	135.6	108.5 to 162.7
Thermofisher Liquid Assayed Tumor Marker Control 22100	QC1-22101	10.8	15.0	12.0 to 18.0
	QC3-22102	26.8	37.2	29.8 to 44.6
	QC3-22103	55.1	76.5	61.2 to 91.7

- In order to calculate your own QC bottle values you may apply the correlation factors directly to the Bottle Value of the QC using the equation below:

$$QC \text{ Target Value with correlation factors} = (C_1 * QC \text{ Target Value}) + C_0$$

NOTE:

- Correlation Factors will remain in the LOCI CA 15-3 Method configuration until removed manually or revised by the user.
 - You may receive future shipments of lots listed in Table 1. Be sure to retain this letter in order to apply correlation factors to CA15-3 lots listed in Table 1.
 - Subsequent lots may require correlation factors. An Alert Card will be included in the subsequent lots with the lot specific correlation factors and lot specific QC.
- Please review this letter with your Medical Director.
 - If you received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Remote Services Center or your local Siemens Technical Support Representative.
 - Complete and return the Field Correction Effectiveness Check 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.
 - If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers Technical Support Representative.

We apologize for the inconvenience this situation may cause.

Dimension Vista is a trademark of Siemens Healthineers.