

Urgent Field Safety Notice

DC-16-03.B.OUS-Vista

MAY 2016

Dimension Vista® System

Alanine Aminotransferase (ALTI) High Bias when using certain Enzyme 2 calibrator lots

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

Table 1. Dimension Vista Affected Product

Product	Product Code	Catalog Number	Siemens Material Number (SMN)	Lot Number	Date of First Shipment	Expiration Date
Dimension Vista Enzyme 2 Calibrator	ENZ 2 CAL	KC321	10475527	4MD048	2015-03-19	2016-01-01*
				5DD026	2015-05-08	2016-04-01*
				5ED071	2015-06-22	2016-05-01*
				5GD004	2015-09-09	2016-08-01
				5JD058	2015-11-17	2016-10-01
				5LD061	2016-02-08	2016-12-01

* Expired

Reason for Urgent Field Safety Notice

Siemens Healthcare Diagnostics has received complaints of positive shift of patient and QC results when the ALTI assay is calibrated with the Dimension Vista Enzyme 2 Calibrator lots noted above. Internal investigation has confirmed that patients, quality control, and proficiency testing material all demonstrate a similar shift of up to 10% in comparison to results obtained using earlier calibrator lots. This shift began with Enzyme 2 calibrator lot 4MD048.

Siemens has reassigned the bottle values of all Enzyme 2 Calibrator lots currently in date. These reassigned values are listed in Table 2. Laboratories may expect to observe a downward shift of approximately 8% in QC, patient samples and proficiency testing material when reassigned bottle values are used for calibration. Beginning with lot 6CD052 all future Enzyme 2 Calibrator lots, will be assigned to ensure closer alignment of patient results with the IFCC reference method.

Table 2. Dimension Vista Enzyme 2 Calibrator Reassigned Bottle Values

Lot #	Updated BV (U/L)		Updated BV (µkat/L)	
	Level A	Level B	Level A	Level B
4MD048	Expired 2016-01-01			
5DD026	Expired 2016-04-01			
5ED071	Expired 2016-05-01			
5GD004	0	979	0	16.35
5JD058	0	994	0	16.59
5LD061	0	975	0	16.29

Risk to Health

Laboratories failing to successfully meet external quality assessment guidelines and that have ceased testing for ALT may experience a delay in reporting patient results. A delay of <24 hours has negligible clinical impact. The clinical impact of the bias observed for patient samples when this issue occurs is also negligible. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

Siemens recommends recalibration of existing Alanine Aminotransferase (ALTI) flexes and future calibrations using the reassigned calibrator bottle values for lots provided in Table 2 of this letter.

To edit the bottle values for a current lot of Enzyme 2 Calibrator programmed in the Dimension Vista® System, perform the following:

1. Select the **Advance** icon
2. Select the **Calibration** icon
3. Select **Calibrators** from the blue drop down menu
4. Select the Enzyme 2 Calibrator lot number to be edited
5. Under Actions, select **Edit**
6. Under the Bottle Value B column highlight the B value for ALTI
7. Press the delete key from the keyboard
8. Type in the new bottle value for Level B from Table 2 listed above
9. Under Actions, select **Save**
10. A pop-up window appears with the message "One bottle value or point value changed for the following ALTI" Select **YES**
11. Recalibrate any current ALTI reagent cartridge flex lots currently on board the Dimension Vista ® System

To edit the bottle values for a new lot of Enzyme 2 calibrator, perform the following:

1. Select the **Advance** icon
2. Select the **Calibration** icon
3. Select **Calibrators** from the blue drop down menu
4. Scan the Enzyme 2 Calibrator IFU for the new lot
5. Select the Enzyme 2 Calibrator lot number to be edited
6. Under Actions, select **Edit**
7. Under the Bottle Value B column highlight the B value for ALTI
8. Press the delete key from the keyboard
9. Type in the new bottle value for Level B from Table 2 listed above
10. Under Actions, select **Save**
11. A pop-up window appears with the message "One bottle value or point value changed for the following ALTI" Select **YES**

12. Calibrate or recalibrate ALTI reagent flex cartridge as needed

Please review this letter with your Medical Director.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens Technical Support representative.

Additional Information

- Recovery of available Quality Control Bio-Rad Multiqual lots 45680V and 45720V has been evaluated using the revised calibrator bottle values. The data shows that lot 45720V required target adjustment based on the bottle value reassignment recommended in this letter. The revised QC target values for lot 45720V are available on the Bio-Rad website at www.QCNet.com.
- Any additional requests for target updates for alternate QC products will be evaluated and the QC targets will be revised as needed. Any revised control values will be located on the Bio-Rad website at QCnet.com.

Dimension Vista® is a trademark of Siemens Healthcare Diagnostics.

Dimension Vista® System: Alanine Aminotransferase (ALTI) High Bias when using certain Enzyme 2 calibrator lots

FIELD CORRECTION EFFECTIVENESS CHECK

Dimension Vista® System

Alanine Aminotransferase (ALTI) High Bias when using certain Enzyme 2 calibrator lots
Catalog# KC321 / SMN# 10475527

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice DC-16-03.B.OUS-Vista dated May 2016 regarding Dimension Vista® System: Alanine Aminotransferase (ALTI) High Bias when using certain Enzyme 2 calibrator lots.

Please read the question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes No

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Please fax this completed form to the Customer Care Center at **XXX-XXX-XXXX**. If you have any questions, contact your local Siemens technical support representative.

Urgent Field Safety Notice

DC-16-03.B.OUS

May 2016

Dimension® clinical chemistry system

Alanine Aminotransferase (ALTI) High Bias when using certain Enzyme II calibrator lots

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

Table 1. Dimension Affected Product

Product	Product Code	Catalog Number	Siemens Material Number (SMN)	Lot Number	Date of First Shipment	Expiration Date
Dimension Enzyme II Calibrator	ENZ II CAL	DC143	10476170	4MD047	2015-03-11	2016-01-01*
				5CD052	2015-04-21	2016-03-01*
				5FD017	2015-06-29	2016-06-01
				5GD050	2015-08-05	2016-07-01
				5HD010	2015-10-01	2016-09-01
				5JD069	2015-11-12	2016-10-01
				5LD051	2016-01-22	2016-11-01
				6AD054	2016-02-19	2017-02-01

* Expired

Reason for Urgent Field Safety Notice

Siemens Healthcare Diagnostics has received complaints of positive shift of patient and QC results when the ALTI assay is calibrated with the Dimension Enzyme II calibrator lots noted above. Internal investigation has confirmed that patients, quality control, and proficiency testing material all demonstrate a similar shift of up to 10% in comparison to results obtained using earlier calibrator lots. The shift began with lot Enzyme II calibrator lot 4MD047.

Siemens has reassigned the bottle values of all Enzyme II calibrator lots currently in date. These reassigned values are listed in Table 2. Laboratories may expect to observe a downward shift of approximately 8% in QC, patient samples and proficiency testing materials when reassigned bottle values are used for calibration. Beginning with lot 6CD020, all future Enzyme II Calibrator lots produced will be assigned to ensure closer alignment of patient results with the IFCC reference method.

Dimension® clinical chemistry system: Alanine Aminotransferase (ALTI) High Bias when using certain Enzyme II calibrator lots

Table 2. Dimension Enzyme II Calibrator Reassigned Bottle Values

Lot #	Updated BV (U/L)			Updated BV (µkat/L)		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
4MD047	Expired 2016-01-01					
5CD052	Expired 2016-03-01					
5FD017	0	508	1011	0	8.48	16.88
5GD050	0	501	993	0	8.37	16.58
5HD010	0	492	979	0	8.21	16.35
5JD069	0	513	1013	0	8.56	16.91
5LD051	0	502	992	0	8.38	16.56
6AD054	0	507	1008	0	8.47	16.84

Risk to Health

Laboratories failing to successfully meet external quality assessment guidelines and that have ceased testing for ALT may experience a delay in reporting patient results. A delay of <24 hours has negligible clinical impact. The clinical impact of the bias observed for patient samples when this issue occurs is also negligible. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

Siemens recommends recalibration of existing Alanine Aminotransferase (ALTI) flexes and future calibrations using the reassigned calibrator bottle values for lots provided in Table 2 of this letter.

To edit the bottle values for a current lot of Enzyme II Calibrator programmed in the Dimension® System, perform the following:

Request a Calibration Manually From the Operating Menu

1. Press **F5: Process Control**.
2. Press **F1: Calibration** (Enter your Password).
3. Press **F2: Setup and Run**.
4. Select desired test key. Verify the reagent lot indicated is the one onboard. Press **F1: Other Lot** to change.
5. Enter the operator ID. Enter the calibrator lot number. Enter the segment position. Enter the calibrator values (provided in Table 2).
6. Press **F8: QC Yes/No**.
7. Press **F4: Assign Cups**.
8. Press **F7: Load/Run**.
9. Load the calibrators in assigned positions.
10. Place segment on sample wheel.
11. Press **Run**.

Utilizing QCC PowerPak™ to Define Calibrator Products

1. Press **Calib Alert** using the touch screen or (**ALT+C**).
2. Press **F5: Def Cal Product**.
3. Scan new calibrator product IFU with handheld barcode scanner. Calibrator information will populate screen.
4. Edit the Bottle Values with the updated values provided in Table 2.
5. Press **F7: Store**.

Editing Calibrator Product for a calibrator previously defined from the Operating Menu

1. Press **F5: Process Ctrl**.
2. Press **F1: Calibration**.
3. Enter your password.
4. Press **F6: Edt Cal Prodct**.
5. Select the product from the list of defined calibrator products.
6. Press **F1: Edit Product**.
7. Edit the Bottle Values with the updated values provided in Table 2.
8. Press **F7: Store**.

Please review this letter with your Medical Director.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

Additional Information

- Recovery of available Quality Control Bio-Rad Multiqual lots 45680 and 45700 has been evaluated using the revised calibrator bottle values. The evaluation demonstrated that a QC target value revision is not needed at this time.
- Any additional requests for target updates for alternate QC products will be evaluated and the QC targets will be revised as needed. Any revised control targets will be located on the Bio-Rad website at QCnet.com.

Dimension® is a trademark of Siemens Healthcare Diagnostics.

Dimension® clinical chemistry system: Alanine Aminotransferase (ALT) High Bias when using certain Enzyme II calibrator lots

FIELD CORRECTION EFFECTIVENESS CHECK

Dimension® clinical chemistry system

Alanine Aminotransferase (ALT) High Bias when using certain Enzyme II calibrator lots

Catalog# DC143/ SMN# 10476170

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice DC-16-03.B.OUS dated May 2016 regarding Dimension® clinical chemistry system: Alanine Aminotransferase (ALT) High Bias when using certain Enzyme II calibrator lots.

Please read the question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes No

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Instrument Serial Number: _____

Street: _____

City: _____

State: _____

Phone: _____

Country: _____

Please fax this completed form to the Customer Care Center at **XXX-XXX-XXXX**. If you have any questions, contact your local Siemens technical supports representative.