SIEMENS

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.

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Table 2. Dimension Enzyme II Calibrator Reassigned Bottle Values

	Updated BV (U/L)			Updated BV (µkat/L)		
Lot #	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.**

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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 14 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.

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FIELD CORRECTION EFFECTIVENESS CHECK

Dimension® clinical chemistry system

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

Ref: DC 16-03 [C/3499]

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter.	Yes ☐	No ☐
2. Signed:	Date:	

Name of person completing questionnaire:	
Title:	
Institution:	Instrument Serial Number:
Street:	
City:	Post Code:
Phone:	Email:

It is important that your organisation takes the actions detailed in the UFSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to this UFSN. Your organisations reply is evidence which, Siemens Healthcare, and subsequently the MHRA, needs to monitor the progress of the UFSN. Without your reply Siemens Healthcare cannot verify the completeness of the UFSN and the MHRA may need to issue a Medical Device Alert.

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