SIEMENS Healthineers

Siemens Healthcare Diagnostics Inc.

Urgent Field Safety Notice

VC-18-07.A.OUS

October 2018

Dimension Vista® System

Lactate Dehydrogenase (LDI) Flex® reagent cartridge

Potential Cuvette Carryover from Lactic Acid (LA) reagent

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

Table 1. Dimension Vista® Affected Product:

Assay	Catalog Number	Siemens Material Number	Lot Number
Lactate Dehydrogenase (LDI)	K2054	10464323	All in-date LDI lots including future lots until the updated Dimension Vista Software Version is implemented

Reason for Field Action

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

Siemens Healthcare Diagnostics has confirmed that Dimension Vista® Lactate Dehydrogenase (LDI) may exhibit an erroneously elevated result when the preceding assay in the reaction cuvette is Lactic Acid (LA). The magnitude of the elevation may be variable. Both quality control and patient samples may be impacted. Incomplete removal of residual lactate dehydrogenase, a component of the LA reagent, has been identified as the cause of the potentially elevated result. Table 2 summarizes the maximum positive bias that was observed during Siemens investigation:

Table 2. Maximum Positive Bias Observed for Patient Samples

	Erroneously Elevated LDI Result U/L	LDI Result upon Repeat U/L	% Bias
Siemens data	189	123	54%
Customer data	523	224	133%

Siemens is working to provide an updated software version which will resolve this issue. Until the updated software version is installed, please refer to the “Actions to be Taken by the Customer” section in this letter.

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Risk to Health

A falsely elevated result for lactate dehydrogenase may lead to additional investigations to determine the etiology of tissue damage. Results would be correlated with clinical history and presentation in addition to other diagnostic laboratory testing. The risk to health is negligible. Siemens is not recommending a review of previous LDI results.

Actions to be Taken by the Customer

- If both LDI and LA assays are not being used on your Dimension Vista System, no action is required.
- If both LDI and LA assays are being used on your Dimension Vista System, Siemens recommends the following steps to prevent the potential for inaccurate LDI test results:
    - Dimension Vista 1500 System
        - Laboratories must separate LDI and LA assays onto different servers by configuring LDI onto Server 2 (refer to Dimension Vista Operator's Guide or iGuide, Chapter 9: Advanced Functions Section). LA can only be processed on Server 1.
    - Dimension Vista 500 System
        - Laboratories with an additional instrument must process LDI and LA assays on separate instruments.
        - If your laboratory only has one Dimension Vista 500 System instrument, configure LDI testing to run in duplicate (refer to Dimension Vista Operator's Guide or iGuide, Chapter 9: Advanced Functions Section). If the LDI results are discordant with each other, contact your local Siemens Technical Support Representative for further guidance. Alternatively, you can choose to process either lactate dehydrogenase or lactic acid using an alternate methodology.
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse events associated with the product listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Siemens Technical Support Representative.

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

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.

Dimension Vista is a trademark of Siemens Healthcare Diagnostics

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FIELD CORRECTION EFFECTIVENESS CHECK
Dimension Vista® Lactate Dehydrogenase (LDI) Flex® reagent cartridge
Potential Cuvette Carryover from Lactic Acid (LA) reagent

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice,VC-18-07.A.OUS, dated October 2018 regarding Dimension Vista Lactate Dehydrogenase (LDI) Flex® reagent cartridge with Potential Cuvette Carryover from Lactic Acid (LA) Reagent. Please read each 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:

Customer Sold To #: Customer Ship To #:

To fax this completed form please send it to your local Siemens Technical Support Representative. If you have any questions, contact your local Siemens Technical Support Representative.

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