

Urgent Field Safety Notice

Follow-up Communication

VC-20-02.B.OUS

March 2021

Dimension Vista® System

Follow-up Information Regarding Alkaline Phosphatase (ALPI) Flex® Reagent Cartridge Potential for Low Outlier Results with Quality Control and Patient Samples

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

Table 1. Dimension Vista® affected product

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number	Date of First Distribution	Expiration Date
Alkaline Phosphatase	ALPI	K2115	10642444	20078AB	2020-04-25	2021-03-18
				20125BA	2020-06-23	2021-05-04
				20170AA	2020-07-13	2021-06-18
				20203BA	2020-09-02	2021-07-21
				20218AA	2020-09-21	2021-08-05
				20275AA	2020-10-25	2021-10-01
				20311BA	2020-12-01	2021-11-06
				20337AB	2021-01-04	2021-12-02

Reason for the Follow-up Communication

Siemens had issued Urgent Field Safety Notice VC-20-02.A.OUS distributed in August 2020 to inform customers who had received Dimension Vista ALPI lots 19247AB, 19282BB and 19330BD of a potential for low outlier results with quality control and patient samples. The low outlier results could be generated from the last five (5) tests of a well. Quality Control (QC) will only detect the issue if the QC is processed within the last five (5) tests of an impacted well set. Not all Dimension Vista ALPI flexes listed in Table 1, nor all wells within an ALPI flex are impacted by this issue. The maximum difference observed with a patient sample was approximately -27% at a concentration of 129 U/L (2.15 ukat/L).

The purpose of this communication is to provide instructions on actions that your laboratory must take with the products listed in Table 1 above. The supplier has identified a buffer reagent as the source of the issue. Siemens is actively working with the supplier for a solution. Siemens has also implemented mitigations to prevent this issue from impacting future Dimension Vista ALPI lots, including a reagent screening process and addition of ultra-filtration of the buffer reagent. Furthermore, the next version of Dimension Vista system software will include a calculation to flag a potential sporadic low ALPI outlier result. Siemens is instructing customers to discontinue and discard the Dimension Vista ALPI lots listed in Table 1 that were manufactured prior to implementation of the mitigations.

The frequency of this issue remains very low.

Risk to Health

When this issue occurs, the potential exists for misinterpretation of alkaline phosphatase levels which may confound differential diagnosis of bone, liver, intestinal, or parathyroid disease. Alkaline phosphatase is generally ordered as part of a liver panel but may also be ordered with other laboratory tests for investigations of a bone disorder. In addition to other laboratory testing, alkaline phosphatase would also be correlated with imaging as well as with clinical history and presentation. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer:

- Discontinue use of and discard the Dimension Vista ALPI lots listed in Table 1.
- Review your inventory of these products to determine your laboratory's replacement needs. Complete and return the attached form to this letter to request your no-charge replacement product(s).
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days to Siemens Healthineers for reporting to the Authorities.
- Please review this letter with your Medical Director.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers 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 Healthineers Customer Care Center or your local Siemens Healthineers Technical Support Representative.

Dimension Vista is a trademark of Siemens Healthcare Diagnostics Inc.

*Follow-up Dimension Vista® Alkaline Phosphatase (ALPI) Flex® Reagent Cartridge
Potential for Low Outlier Results with Quality Control and Patient Samples*

FIELD CORRECTION EFFECTIVENESS CHECK

Follow-up Dimension Vista Alkaline Phosphatase (ALPI) Flex® Reagent Cartridge
Potential for Low Outlier Results with Quality Control and Patient Samples

This response form is to confirm receipt of the enclosed Urgent Field Safety Notice, VC-20-02.B.OUS, dated March 2021 regarding low outlier results with Dimension Vista Alkaline Phosphatase (ALPI) Flex® reagent cartridges.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided Yes ☐ No ☐
in this letter.
2. Do you now have any of the noted product(s) on hand? Please check Yes ☐ No ☐
inventories before answering.

If the answer to the question 2 above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description Product Catalog #/SMN #/Lot #	Quantity of Affected Product in inventory Discarded/ Replacement Quantity Required
Catalog# K2115/ SMN#10642444 Lot #20078AB	
Catalog# K2115/ SMN#10642444 Lot #20125BA	
Catalog# K2115/ SMN#10642444 Lot #20170AA	
Catalog# K2115/ SMN#10642444 Lot #20203BA	
Catalog# K2115/ SMN#10642444 Lot #20218AA	
Catalog# K2115/ SMN#10642444 Lot #20275AA	
Catalog# K2115/ SMN#10642444 Lot #20311BA	
Catalog# K2115/ SMN#10642444 Lot #20337AB	

Name of person completing questionnaire:

Title:

Date (YYYY-MM-DD):

Institution:

Instrument Serial Number:

Street:

City:

State:

Phone:

Country:

Customer Sold To #:

Customer Ship To #:

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Please send a scanned copy of the completed form via email to uscctsfaecfax.team@siemens-healthineers.com Or to fax this completed form to the Customer Care Center at (312) 275-7795.

If you have any questions, contact your local Siemens Healthineers Technical Support Representative.