Urgent Field Safety Notice

VC-20-02.A.OUS

August 2020

Dimension Vista® System

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	19247AB 19282BB 19330BD	2019-09-18 2019-11-12 2020-01-02	2020-09-03 2020-10-08 2020-11-25

Reason for Urgent Field Safety Notice

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

Siemens Healthcare Diagnostics Inc. has observed a rare occurrence of low outlier results generated with Alkaline Phosphatase (ALPI) Flex® reagent cartridge lots listed in Table 1.

The maximum difference observed with a patient sample was approximately -27% at a concentration of 129 U/L (2.15 ukat/L) with the ALPI lots listed in Table 1.

Not all ALPI flexes listed in Table 1 nor all wells within the ALPI flex are impacted by this issue. The low outlier results are generated from the last five (5) tests of the 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.

The frequency of this issue is 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

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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 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.

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FIELD CORRECTION EFFECTIVENESS CHECK

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.A.OUS, dated August 2020 regarding low outliers on Dimension Vista Alkaline Phosphatase (ALPI) Flex® reagent cartridge.

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 in this letter. Yes ☐ No ☐
2. Do you now have any of the noted product(s) on hand? Please check inventories before answering. Yes ☐ No ☐

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 #19247AB**	
Catalog# K2115/ SMN#10642444 **Lot #19282BB**	
Catalog# K2115/ SMN#10642444 **Lot #19330BD**	

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 #:

Please send a scanned copy of the completed form via email to XXXX@XXXX

Or to fax this completed form to the Customer Care Center at xxxxxx

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

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