Siemens Healthcare Diagnostics GmbH, SHS EMEA CEET QT, Siemensstrasse 90,
1210 Vienna

Name M.A. Roland Ertl
Department SHS EMEA CEET QT

Telephone +43 51707-38274
Mobile +43 (664) 8011738274
E-mail roland.re.ertl@siemens-healthineers.com

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Urgent Field Safety Notice:

Dimension Vista® System

Alkaline Phosphatase (ALPI) Flex® reagent cartridge
Potential for Low Outlier Results with Quality Control and Patient Samples

Dear Sirs,

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 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.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

i.V. Dipl. Ing. Franz Schwarz
Quality Management CEE

i.A. Dr.in Brigitte Gassner
Product Manager Austria & SEE