



Urgent Field Safety Notice Follow Up Letter

14-08A

February 2014

Dimension Vista® Systems Enzyme 1 Calibrator (KC310 SMN 10445179)

Update Information:

Siemens is releasing a lot of Dimension Vista® Enzyme 1 Calibrator (ENZ 1 CAL) (4AD061) that can be used to calibrate Amylase (AMY), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LDH), and Lipase (LIPL) and Pseudocholesterase (PCHE).

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 has caused. If you have any questions, please contact your Siemens Customer Care Center – Technical Solutions or your local Siemens technical support representative.

Background:

Siemens previously communicated, in Urgent Field Safety Notice 14-01, the potential for Quality Control (QC) shifts with Pseudocholesterase (PCHE) and imprecision during PCHE calibration with Dimension Vista® Enzyme 1 Calibrator (ENZ 1 CAL) lots 3FD034 and 3HD012. Investigation by Siemens confirms a loss of PCHE activity in the affected lots of Enzyme 1 Calibrator, causing an elevation of QC by as much as 80% and in some instances, imprecision of replicates during calibration.

With Urgent Field Safety Notice 14-01, instructions were provided to not use Dimension Vista® ENZ 1 CAL (Catalog # KC310) lots 3FD034 and 3HD012 to calibrate PCHE. Dimension Vista® ENZ 1 CAL (Catalog # KC310) lots 3FD034 and 3HD012 could be used to calibrate Amylase (AMY), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LDH), and Lipase (LIPL). Siemens has confirmed acceptable performance of these enzymes with lots 3FD034 and 3HD012.

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