

**Dimension Vista[®] Systems
Enzyme 1 Calibrator (KC310 SMN 10445179)
Pseudocholinesterase QC shifts and Imprecision with lots 3FD034 and 3HD012**

Our records indicate that your laboratory received the following product:

Assay	Catalog Number	Siemens Material Number	Lot Number
Dimension Vista [®] Enzyme 1 Calibrator	KC310	10445179	3FD034
			3HD012

Reason for Field Action

Siemens Healthcare Diagnostics has received complaints regarding Quality Control (QC) shifts with Pseudocholinesterase (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.

Risk to Health

QC will detect elevated PCHE results following calibration, and in these cases no patient results will be reported. Although it is up to the Medical Director to decide, Siemens does not recommend a look back of previously generated patient results if a PCHE calibration has resulted in acceptable QC. Siemens recommends that this communication be reviewed with your laboratory Medical Director.

Actions to be taken by Customer

Please do not use Dimension Vista[®] ENZ 1 CAL (Catalog # KC310) lots 3FD034 and 3HD012 to calibrate PCHE. There is limited availability of an alternate lot of ENZ 1 CAL, lot 3CD078, to calibrate PCHE.

Dimension Vista[®] ENZ 1 CAL (Catalog # KC310) lots 3FD034 and 3HD012 can 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.

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.

Siemens Healthcare Diagnostics Inc.

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FIELD ACTION EFFECTIVENESS CHECK

**Dimension Vista® ENZ 1 CAL (KC310) QC Shifts and Imprecision
lots 3FD034 and 3HD012**

Ref: VC 14-02

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated January 2014 regarding Dimension Vista® ENZ 1 CAL (KC310) QC Shifts and Imprecision. Please read the question and indicate the appropriate answer. Fax/email this completed form to Siemens Healthcare Diagnostics at the fax number/email address indicated at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in the January 2014 letter.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2. Name of person completing the response form: Block Capitals	Date:	

Title:		Instrument Serial Number(s):	
Hospital:		Street:	
City:		Post Code:	
Email:		Signed:	

It is important that your organisation takes the actions detailed in the FSN and reply immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to the FSN.

Your organisations reply is evidence which Siemens Healthcare, and subsequently the MHRA, needs to monitor the progress of the FSN. Without your reply Siemens Healthcare Diagnostics cannot properly verify the completeness of the FSN and the MHRA may need to issue a Medical Device Alert

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