

Urgent Field Safety Notice**13-13****February 2013****Dimension Vista[®] Systems****Vista Drug 4 Calibrator Lot 2KD052 (KC460 SMN 10472284)****Vista Drug 4 Calibrator Lot 2KD053 (KC460A SMN 10476171)****Digoxin QC and Patient Accuracy Shift**

Our records indicate that your laboratory received one of the following products:

Calibrator	Catalog Number	Siemens Material Number (SMN)	Lot Number
Drug 4 Cal	KC460	10472284	2KD052
Drug 4 Cal	KC460A	10476171	2KD053

Reason for Voluntary Recall

Siemens Healthcare Diagnostics is conducting a voluntary recall for Dimension Vista[®] Drug 4 CAL (KC460) lot 2KD052 and Drug 4 CAL (KC460A) lot 2KD053.

Siemens has confirmed complaints of low QC and patient recovery with the Dimension Vista[®] LOCI Digoxin (DIGXN) Flex[®] reagent cartridge when calibrating DIGXN with either Drug 4 Cal (KC460) lot 2KD052 or Drug 4 Cal (KC460A) lot 2KD053.

Internal testing has shown an average 15% low bias in the therapeutic range of 0.9 to 2.0 ng/mL.

Risk to Health

Falsely low Digoxin results may lead to the impression of inadequate dosing which may result in increased and/or unnecessary changes in dosing regimens. The increased dosing may lead to possible toxicity.

We recommend discussing the content of this letter with your laboratory director to determine if additional follow up is appropriate for patient tests conducted on Vista DIGXN when calibrated with Drug 4 CAL lot 2KD052 or 2KD053.

Siemens Healthcare Diagnostics

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Newark, DE 19714-6101

800-441-9250
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Dimension Vista[®] Drug 4 CAL (KC460) Lot 2KD052 and (KC460A) Lot 2KD053

Actions to be taken by Customer

Customers should immediately discard any remaining **Dimension Vista[®] Drug 4 CAL KC460 lot 2KD052 and/or KC460A lot 2KD053**.

Siemens will replace any un-used inventory of lots 2KD052 and/or 2KD053, at no charge. Please complete the attached form and fax it to your local Siemens technical support representative to indicate that you have received this information.

All replacement and future supply of Drug 4 CAL will be the KC460A/SMN 10476171. Siemens will no longer be producing the Drug 4 CAL KC460/SMN 10472284.

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 Technical Solutions Center or your local Siemens technical support representative.

**EFFECTIVENESS CHECK
REQUEST FOR REPLACEMENT PRODUCT**

Dimension Vista® Drug 4 CAL (KC460) Lot 2KD052

Dimension Vista® Drug 4 CAL (KC460A) Lot 2KD053

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Noticed dated February 2013 regarding Dimension Vista® Drug 4 Cal and Digoxin QC and Patient Accuracy Shift, letter #13-13.

Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics your local Siemens Technical Support Representative.

1. I have read and understood the information provided in the February 2013 letter # 13-13 Yes No
2. Do you now have any of the noted product on hand? (Please check inventories before answering.) Yes No
3. If the answer to the question above is yes, how much product do you have on hand and quantity to be replaced?

Vista Drug 4 CAL (KC460/SMN 10472284)	Quantity Discarded	Replacement Quantity
2KD052		
Vista Drug 4 CAL (KC460A/SMN 10476171)	Quantity Discarded	Replacement Quantity
2KD053		

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number(s):

Street:

City:

State:

Phone:

Customer Sold to #:

Customer Ship to #

PLEASE FAX THIS COMPLETED FORM TO YOUR LOCAL SIEMENS TECHNICAL SUPPORT REPRESENTATIVE