

## Urgent Field Safety Notice

15-24

April 2015

### Dimension Vista® System

### Dimension Vista® Phenytoin Flex® reagent cartridge Abnormal Assay Errors

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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 Numbers        |
|----------------------------------|-----------|----------------|-------------------------------|--------------------|
| Phenytoin Flex reagent cartridge | PTN       | K4064          | 10445125                      | 14163AB<br>14181AC |

### Reason for Recall

Siemens Healthcare Diagnostics has confirmed an increase in the rate of Abnormal Assay errors (E143: Outside absolute results monitoring limits) with the Dimension Vista Phenytoin (PTN) Flex reagent cartridge lots 14163AB and 14181AC. The errors can occur on calibration, QC and/or patient samples. Any result produced with the Abnormal Assay error is deemed non-reportable as stated in the Dimension Vista Operator's Guide (section 5-49).

### Risk to Health

The risk to health as a result of this issue is negligible. If an acceptable calibration, QC or patient result has been obtained previously with no error flag reported, results are acceptable. A laboratory look back is not recommended.

### Actions to be Taken by the Customer

Please discontinue use and discard any remaining inventory of Dimension Vista Phenytoin Flex reagent cartridge lots 14163AB and 14181AC.

Please complete the attached effectiveness check form and fax it to your local Siemens Healthcare Technical Support representative to indicate that you have received this information and to facilitate your no-charge replacement needs.

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 local Siemens Technical Support representative.

Dimension Vista® and Flex® are trademarks of Siemens Healthcare Diagnostics.

**FIELD CORRECTION EFFECTIVENESS CHECK  
Dimension Vista Phenytoin Flex reagent cartridge  
Abnormal Assay Errors Lots 14163AB and 14181AC**

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 15-24 dated April 2015 regarding Dimension Vista Phenytoin Flex reagent cartridge Abnormal Assay Errors. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I have read and understood the Customer Notification instructions provided in this letter. Yes  No
  
2. Do you now have any of the noted product on hand? Please check inventories before answering. Yes  No

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

| Phenytoin Flex reagent cartridge (PTN)<br>K4064/10445125 | Quantity of Affected Product in inventory that has been discarded | Replacement Quantity Required |
|----------------------------------------------------------|-------------------------------------------------------------------|-------------------------------|
| Lot 14163AB                                              |                                                                   |                               |
| Lot 14181AC                                              |                                                                   |                               |

Name of person completing questionnaire: \_\_\_\_\_

Title: \_\_\_\_\_

Institution: \_\_\_\_\_ Instrument Serial Number: \_\_\_\_\_

Street: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_

Phone: \_\_\_\_\_ Country: \_\_\_\_\_

Customer Sold To #: \_\_\_\_\_ Customer Ship To #: \_\_\_\_\_

Please fax this completed form to your local Siemens Technical Support representative. If you have any questions, contact your local Siemens technical support representative.