

## Urgent Field Corrective Action

BR-03216\_OUS

May 2016

### Dimension Vista System

### Dimension Vista Flex Homocysteine (HCYS) reagent cartridge with reduced open well stability

---

Dear valued customer,

Our records indicate that your facility may have received the following product:

**Table 1. Affected Product(s)**

Assay	Catalog Number	Siemens Material Number (SMN)	Lot Number	Date of First Shipment	Expiration Date
Dimension Vista® Flex HCYS reagent cartridge	K7044	10445897	15243MA	2015-10-09	2016-05-31

### Reason for Corrective Action

Siemens Healthcare Diagnostics has confirmed that the reagent lot mentioned in Table 1 shows a reduced open well stability that does not meet the claimed time frame. As a consequence QC recoveries can be found below the assigned ranges, giving invalid runs that may prompt customers to a new calibration.

### Risk to Health

QC and patient samples may show a lower precision based on the reduced open well stability. The magnitude of the effect has been assessed as neither being likely to affect patient management of vitamin deficiencies nor will it impact the detection of patients with overt homocysteinuria that typically have plasma concentrations greater than eight to tenfold of the reference interval. Due to this, it is not necessary to review previous test results or to repeat testing.

### Actions to be Taken by the Customer

Please discontinue use of the affected lot referenced in Table 1 and discard any remaining inventory.

Please review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens for reporting to the authorities. Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.

Please review this letter with your Medical Director.

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 Customer Care Center or your local Siemens technical support representative.

Sincerely yours,

*Original Signature is on file*

Dr. Norbert Dedner  
Director Quality Systems & Compliance

*Original Signature is on file*

Dr. Lenard Müller  
Global Marketing Plasma Proteins

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

**FIELD CORRECTION EFFECTIVENESS CHECK**

Dimension Vista System

Dimension Vista Flex HCYS reagent cartridge with reduced open well stability

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Corrective Action BR-03216 dated May 2016 regarding Dimension Vista Flex HCYS reagent cartridge with reduced open well stability. 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 Urgent Field Corrective Action 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.

Product Description Product Catalog #/SMN #/Lot #	Please specify Lot and Quantity of Affected Product in inventory that has been discarded	Replacement Quantity Required
Dimension Vista Flex HCYS Reagent Cartridge; SMN 10445897, Lot 15243MA		

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 the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.