

## Urgent Field Safety Notice

13-77

October 2013

**Dimension Vista<sup>®</sup> 500**  
**Dimension Vista<sup>®</sup> 1500**

### User Defined Method Flex Assignment

Our records indicate that your laboratory has the Dimension Vista<sup>®</sup> 500 or Dimension Vista<sup>®</sup> 1500 System with software versions 3.5.1 or lower.

<b>Product</b>	<b>Siemens Material Number (SMN)</b>
<b>Dimension Vista<sup>®</sup> 500</b>	<b>Domestic: 10284473</b> <b>International: 10488224</b>
<b>Dimension Vista<sup>®</sup> 1500</b>	<b>Domestic: 10444801</b> <b>International: 10444802</b>

### Reason for Correction

Siemens Healthcare Diagnostics is conducting a field correction for Dimension Vista<sup>®</sup> 500 and Dimension Vista<sup>®</sup> 1500 systems using software versions 3.5.1 or lower with User Defined Methods. Instruments that utilize Vista Software Version 3.6 are not affected.

Siemens Healthcare Diagnostics has confirmed that under a rare set of conditions when utilizing the Routine Inventory screen to enter a User Defined Method (EMPTY) Flex the system may assign the User Defined Method Flex to a different Flex that is currently in inventory on the system, and then use the incorrect Flex cartridge to process the user defined method. Investigation of the issue has determined that this error will only occur if the Assign Empty Reagent Cartridge window has been left open and the Flex inventory on the system changes.

The error does not occur when assigning a User Defined Method Flex from the Advanced Inventory screen.

### Risk to Health

Use of an incorrect Flex, containing reagent intended for another assay, will typically result in low out of range values for QC, Calibrator and patient samples due to the differing chemistries between the two methods. In rare cases where the two methods have similar chemistries the

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**Siemens Healthcare Diagnostics Inc.**

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QC values may result in range. It is extremely unlikely that this issue will impact patient diagnosis, treatment or clinical outcome.

Following the instructions below will prevent this issue from occurring in the future. No action is required with respect to previously generated results.

### **Actions to be Taken by the Customer**

Please use the following actions if using Vista SW Versions 3.5.1 and below to prevent the issue from occurring:

1. When assigning a User Defined (EMPTY) Flex, use the Advanced Inventory Screen per the Operators Guide.
2. Verify that EMPTY Flex is no longer listed in the inventory before proceeding with any testing.
3. If the EMPTY Flex is still listed in the inventory, contact your Siemens Customer Care Center - Technical Solutions for assistance.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

Please complete the Field Effectiveness Check form attached to this letter.

Discuss the content of this letter with your Medical Director

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.

Dimension Vista and Flex are trademarks of Siemens Healthcare Diagnostics.

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### **FIELD CORRECTION EFFECTIVENESS CHECK**

#### User Defined Method Flex Assignment

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 13-77 dated October 2013 regarding User Defined Method Flex Assignment. Fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page.

I have read and understood the Urgent Field Safety Notice Instructions provided in the October 2013 letter.

Yes

No

Name of person completing questionnaire:

Title:

Institution:

Instrument Serial Number:

Street:

City:

State:

Phone:

Customer Sold To #:

Customer Ship To #:

PLEASE FAX THIS COMPLETED FORM TO SIEMENS CUSTOMER CARE CENTER - TECHNICAL SOLUTIONS AT xxxx-xxx.