

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

### Aliquot Well Double Dispense

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 3.6.

<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 and 3.6.

Siemens Healthcare Diagnostics has confirmed that, under specific rare conditions which require a system reset, there is a potential for a sample to be dispensed into an aliquot well that has previously been used for a QC or calibrator product from a Vista vial. If two samples are dispensed into the same aliquot well, the first sample will always be QC or calibrator from a Vista vial. Patient sample will never be dispensed into an aliquot well that contains another patient sample. The possible combinations are:

- Patient sample dispensed on QC or calibrator from a Vista Vial
- QC from a Vista vial or any other sample container dispensed on QC or calibrator from a Vista vial
- Calibrator from a Vista vial or any other sample container dispensed on QC or calibrator from a Vista vial

---

### Siemens Healthcare Diagnostics Inc.

P.O. Box 6101  
Newark, DE 19714-6101

[800-441-9250]  
[www.siemens.com/diagnostics](http://www.siemens.com/diagnostics)

Page 1 of 3

## Aliquot Well Double Dispense

### **Risk to Health**

Aliquot well reuse can lead to out of range QC, poor calibrations or erroneous but believable results under rare specific conditions associated with instrument reset. The probability of this to occur and impact test results is extremely unlikely.

This bulletin should be brought to the attention of your laboratory director.

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

Please use the actions below to prevent the issue from occurring until further notice:

1. In the event that an instrument Reset is required for any reason, review the Current Activities Screen to determine if there are any pending QC or Calibration tests.
2. If there are no pending QC or Calibration tests, Reset the instrument or troubleshoot the instrument per the Operators Guide.
3. If there are pending QC or Calibration tests, restarting the software is necessary before resuming patient processing. Go to Operation ->Shutdown, confirm Yes, then on the blue console menu screen select Start Vista.

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

Complete the Field Effectiveness Check form attached to this letter.

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

Siemens is continuing to investigate the root cause of the issue, and will be implementing a correction in a future revision of Vista software.

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 is a trademark of Siemens Healthcare Diagnostics.

Aliquot Well Double Dispense

**FIELD CORRECTION EFFECTIVENESS CHECK**

Aliquot Well Double Dispense

**VSW 13-03**

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 13-49 dated June 2013 regarding Aliquot Well Double Dispense. Please Fax or email this completed form to Siemens Healthcare Diagnostics at the fax number/email listed.

PLEASE FAX THIS COMPLETED FORM TO: 0845 605 6800 or email to robert.davies@siemens.com

I have read and understood the Urgent Field Safety Notice Instructions provided in the June 2013 letter.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Name of person completing questionnaire: Block Capitals	Date:	

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

PLEASE FAX THIS COMPLETED FORM TO:  
0845 605 6800 or email to robert.davies@siemens.com