

Urgent Field Safety Notice

14-53

November 2014

Dimension Vista® 500 Intelligent Lab System
Dimension Vista® 1500 Intelligent Lab System

Vista Reagent Probe Integrity

Our records indicate that your laboratory has the Dimension Vista® 500 Intelligent Lab System or Dimension Vista® 1500 Intelligent Lab System.

Product	Siemens Material Number (SMN)
Dimension Vista® 500 Intelligent Lab System	US: 10284473 Outside US: 10488224
Dimension Vista® 1500 Intelligent Lab System	US: 10444801 Outside US: 10444802

Reason for Correction

Siemens has received customer complaints of discrepant flagged and/or unflagged patient and QC results on Dimension Vista® Intelligent Lab Systems. Siemens Healthcare Diagnostics has confirmed that reagent probe performance may decline more quickly than anticipated and have an effect on assays with similar formulations when processed sequentially on the same reagent server. Replacing an associated reagent probe can resolve this type of issue.

These assays have been observed with this issue.

Assay	Observations
Calcium	Flagged or Low Results
Creatinine	Flagged Results
Free Thyroxine	High Results
Glucose	Flagged Results
Lipase	High Results
Lithium	Flagged Results
Low Density Lipoprotein Cholesterol	Flagged Results
Microalbumin	High Results
Phosphorus	High Results
Total Bilirubin	High Results
Total Protein	High or Low Results
Uric Acid	Low Results
Urinary/Cerebrospinal Fluid Protein	High Results
Urine Amphetamine	False Positive
Urine Barbiturates	False Positive
Urine Cocaine	False Positive
Urine Opiates	False Positive
Vancomycin	Flagged Results

Risk to Health

The Vista system will generate error flags for most of the noted discrepant results. For test results that were not flagged no risk to health is expected. The screening method for some drugs of abuse tests were noted to be falsely positive, which requires confirmation. Look back of previous test results is not required.

Actions to be Taken by the Customer

Step 1: Verify that your Dimension Vista® System Check feature is set up prior to proceeding.

- Go to the: Advanced > Configuration > Systems Check Configuration screen.
- Verify that only the test names in the table below have a ✓ to the left of the test name:

Test Names:	
CS1N2	CS2C03*
CR1BS	CR3BS*
CR2BS	CR4BS*
CS1C03	CR5BS*
CS2N2*	CS3N2*
SAIR	CS3C03*
*Dimension Vista 1500 only.	

- If Systems Check is not set up, please contact the Customer Care Center - Technical Solutions at 1-800-441-9250 or your local Siemens technical support representative

Step 2: To maintain consistent performance of your Vista system, Siemens recommends that customers perform a monthly System Check with CHK solution (KS996) to assess your reagent probe performance using the steps outlined in:

- Dimension Vista® Operator's iGuide - Chapter 8 – Systems Check, or
- Dimension Vista® System Operator's Guide 2012 Section 8-51, or
- If you do not have the Vista® System Operator's Guide 2012 see Frequently Asked Questions (FAQ) # 3

Step 3: Once the System Check has been run, evaluate the accuracy and precision of reagent delivery for each combination of probes by determining if the percent difference is greater than 4% using this calculation:

$$[(\text{Highest CR\#BS MEAN} - \text{Lowest CR\#BS MEAN}) / \text{Highest CR\#BS MEAN}] \times 100 = \% \text{ Difference}$$

Note: # = reagent probe number

- Server 1: CR1BS compared to CR2BS
- Server 2: CR4BS compared to CR3BS (Vista 1500 only)
- Server 3: CR5BS compared to CR2BS (Vista 1500 only)

Step 4: For each of the 3 combinations in step 2, if the percent difference is greater than 4%, replace the associated reagent probe with the lowest CR#BS Result MEAN from that combination (see CR1BS/CR2BS Example below) using the steps outlined in:

- Dimension Vista® Operator's iGuide – Chapter 7 – Other Maintenance – “Maintaining Probes”, or
- Dimension Vista® System Operator's Guide 2012 Section 7-64 “Maintaining Probes”

The data in the table below outlines an example of when to replace the probe when using the CR1BS and CR2BS combinations.

CR1BS/CR2BS Example

CR1BS MEAN	CR2BS MEAN	% DIFFERENCE	PASS/ FAIL	REPLACE R1 PROBE	REPLACE R2 PROBE
384	400	4%	PASS	NO	NO
360	400	10%	FAIL	YES	NO
346	353	2%	PASS	NO	NO
353	326	8%	FAIL	NO	YES

Step 5: After completing the probe replacement, rerun the System Check to verify that the MEAN differences are within 4%.

NOTE: If step 5 fails, please contact the Customer Care Center – Technical Solutions at 800-441-9250 for further assistance.

Step 6: Please complete the following activities

- Discuss the content of this letter with your Medical Director.
- Retain this letter with your laboratory records and forward this letter to those who may have received this product.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter.

We apologize for the inconvenience this situation has caused. If you have any questions, please contact your local Siemens technical support representative.

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Customer Frequently Asked Questions

1. How can I assess if my results may have been impacted by this issue?

If your laboratory has experienced unexplained QC outliers which upon repeat testing recover within limits without explanation, or if you have observed a higher frequency of delta check flags or results inconsistent with the clinical picture, then this issue may have occurred.

2. What action is Siemens taking to correct this issue?

Siemens is working to resolve the issue. Please follow the recommendations specified in this letter until further notice.

3. What should I do if my Dimension Vista® System Operator's Guide does not have information regarding System Check?

Please use the instructions below, taken from the latest Vista Operator's Guide 2012 Section 8-51, for running a System Check.

Running a System Check - Complete this procedure using the following supplies:
One surplus sample rack with a sample cup filled with one Flex® wells worth of Red CHK solution (part # KS996).

1. Press the Advanced icon, then the Diagnostics icon.
2. Select System Check from the Diagnostics menu.
3. Load CHK Flexes onto the instrument:
Dimension Vista 1500 requires 3 CHK Flexes
Dimension Vista 500 requires 1 CHK Flex
4. Scan the sample rack barcode and verify the correct numbers are displayed in the sample rack barcode field.
5. Verify that the correct position is displayed in the sample rack position field.
6. Place a sample cup filled with red CHK fluid onto the sample rack in the designated position. NOTE: red fluid is found in wells 1, 3, 5 & 7 only
7. Select Order System Check from the screen.
8. Place the rack in the sample lane and wait for tests to complete.
9. Tests results can be viewed on the System Check screen when completed (also viewable from the Results screen: Advanced > Results). These results can be printed.
10. Any failures are displayed in red on the System Check screen, contact the Customer Care Center - Technical Solutions at 1-800-441-9250 or your local Siemens technical support representative.

FIELD CORRECTION EFFECTIVENESS CHECK

Vista Reagent Probe Integrity

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 14-53 dated November 2014 regarding Vista Reagent Probe Integrity. Please read and indicate the appropriate answer to the question below. Fax this completed form to your local Siemens Healthcare Diagnostics technical support representative.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes No

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Street: _____

City: _____ State: _____

Phone: _____ Country _____

Customer Sold To #: _____ Customer Ship To #: _____

If you have any questions, contact your local Siemens technical support representative.