

Urgent Field Safety Notice

June 30, 2008

Dimension Vista[®] System

Server Designation for Dimension Vista[®] Calcium (CA), Total Bilirubin (TBIL), Magnesium (MG) and Alkaline Phosphatase (ALP) Flex[®] reagent cartridges

Our records indicate that your laboratory uses Dimension Vista[®] Calcium (CA), Total Bilirubin (TBIL), Magnesium (MG) and Alkaline Phosphatase (ALP) Flex[®] reagent cartridges on the Dimension Vista[®] System. Siemens has confirmed two potential reagent interactions.

- **TBIL results** - The potential interactions between the TBIL and CA reagent may cause an elevation of TBIL results when both TBIL and CA are on the same Server. The TBIL elevation appears to be a constant positive bias averaging about 0.5 mg/dL and may thus cause normal TBIL values to be reported above the reference range. CA results are not impacted.
- **MG results** - The potential interactions between the MG and ALP reagent may cause an elevation of MG results when ALP is on Server 2 and MG is on Server 3. The elevation of the MG can be variable up to approximately 2.0 mg/dL. ALP results are not impacted.

The following server designations must be used for these reagents to eliminate any potential reagent interactions.

Method	Server Designation
Calcium (CA)	3
Total Bilirubin (TBIL)	1
Magnesium (MG)	1
Alkaline Phosphatase	2

To check the current Server Designations for CA, TBIL, MG and ALP please follow the instructions below which can be found in the Dimension Vista[®] Operator's Guide, Section 9 page 72.

1. Make sure the instrument is in idle. Press the **Advanced** icon, then the **Configuration** icon.
2. Select **Reagent Server Configuration** from the menu.

Siemens Healthcare Diagnostics Inc.

08-22

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If any of these methods are assigned to a different server than listed, please reassign the assays to the server designations listed in the above chart. You may contact your local technical support, or call the Siemens Technical Solutions Center at TSC at 800-405-6473 for help with reassignment, or follow the below instructions below:

Note: Any method that is re assigned will need to be recalibrated and QC should be run according to laboratory practice.

1. Select **Modify Servers** form the Actions menu
2. Highlight the method to be moved.
3. Press **Move Here** at the bottom of the list for the new server.
4. Select **Store Servers** from the Actions menu. Press **OK** on the dialog box.
5. Any method that is moved must be recalibrated.

We recommend discussing the content of this letter with your laboratory director regarding the need to review previous test results.

We apologize for the inconvenience that this situation has caused. If you have any technical questions regarding this information, please contact the Siemens Technical Solutions Center at 800-405-6473.

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