

Dimension Vista® 1500 System

Server Designation for Dimension Vista® Enzymatic Creatinine (ECREA), Total Protein (TP), Acetaminophen (ACTM) and Phosphorus (PHOS) Flex® reagent cartridges

Our records indicate that your laboratory uses Dimension Vista® Enzymatic Creatinine (ECREA) Flex® reagent cartridges and Total Protein (TP), Acetaminophen (ACTM) or Phosphorus (PHOS) Flex® reagent cartridges on the Dimension Vista® 1500 System. **Siemens recently confirmed an issue which may cause ECREA results to be falsely depressed up to 0.4 mg/dL [35.3 µmol/L] or falsely elevated up to 0.6 mg/dL [53.0 µmol/L] across the assay range.** This bias is most significant in the clinical decision range of 1.0 - 1.5 mg/dL [88.4 - 132.6 µmol/L]. The issue may or may not be detected by quality control (QC), as the degree and onset of elevated/depressed results may vary and is likely dependent on multiple factors such as method mix or instrument maintenance.

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

Method	Server Designation
Enzymatic Creatinine (ECREA)	2
Total Protein (TP)	1
Acetaminophen (ACTM)	1
Phosphorus (PHOS)	1

To check the current Server Designations for ECREA, TP, ACTM, PHOS please follow the instructions below which can be found in the Dimension Vista® Operator's Guide, Section 9 page 35.

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.

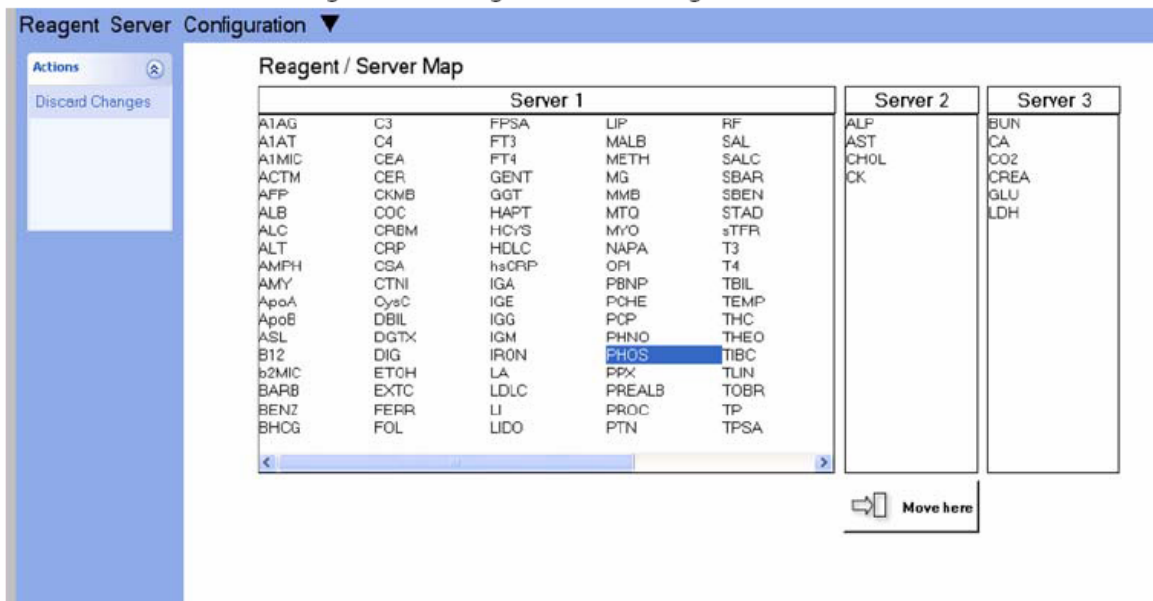
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If any of these methods are assigned to a different server than listed, please reassign the assays to the server designations listed in the above chart. You may contact your local technical support, or call the Siemens Technical Solutions Center at TSC at 800-441-9250 for help with reassignment, or follow the instructions below:

Note: Any method that is reassigned must be recalibrated and QC should be run according to laboratory practice. Remove any open ECREA Flex® reagent cartridge from inventory on your Dimension Vista® 1500 System and load a fresh cartridge.

1. Select **Modify Servers** from the Actions menu

Figure 9-20: Reagent Server Configuration Screen



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.

Any method that is reassigned 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 800-441-9250.

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FIELD CORRECTION EFFECTIVENESS CHECK

Server Designation for Dimension Vista[®] Enzymatic Creatinine (ECREA), Total Protein (TP), Acetaminophen (ACTM) and Phosphorus (PHOS) Flex[®] reagent cartridges

Dear Customer,

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated June 2010 Server Designation for Dimension Vista[®] Enzymatic Creatinine (ECREA), Total Protein (TP), Acetaminophen (ACTM) and Phosphorus (PHOS) Flex[®] reagent cartridges. Please read each question below and indicate the appropriate answer. Please fax this completed form to Siemens Healthcare Diagnostics at the fax number indicated at the bottom of this page.

1. Does your institution use Enzymatic Creatinine (ECREA) and/or Total Protein (TP), Acetaminophen (ACTM) and Phosphorus (PHOS)? Yes No
2. If the answer to Question 1 is Yes, do you intend to follow the recommendations as requested in the Urgent Field Safety Notice and discard the product as requested? Yes No

3. If the answer to Question 3 is No, please explain your intentions.

Name of person completing questionnaire: _____

Title: _____ Date: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____ Phone: _____

**FAX COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER (TSC) AT
THIS FAX NUMBER: (302) 631-8467.**
