SIEMENS

Urgent Field Safety Notice

VS-17-01.A.OUS

March 2017

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

Elevated Enzymatic Creatinine (ECREA) Results Following Dimension Vista Acid Clean (ACLN) Routine

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**

The following information only applies if your laboratory is processing enzymatic creatinine (ECREA: Enzymatic Creatinine Cat No. K1270A, SMN 10700444) and the automated Acid Clean (ACLN) maintenance routine has been implemented.

Reason for Correction:

Siemens Healthcare Diagnostics has confirmed that in isolated cases when ECREA is processed immediately after the weekly automated Acid Clean routine during Probe Test, there is the remote potential for an elevation of greater than 15 percent in the ECREA result.

While Siemens understands that customers routinely run Quality Control (QC) after system maintenance, it is particularly important to run ECREA QC after the Probe Test to identify a potential elevated ECREA result.

Risk to Health

Due to the remote probability of this issue occurring, the potential for misinterpretation of creatinine levels which may affect consideration of intervention is also remote. Clinical impact would be mitigated by correlation to clinical symptomology, continued monitoring of creatinine values, and additional investigations to confirm the initial result when clinically discordant and/or to assess kidney function. Siemens is not recommending a review of previously generated results.

Actions to be Taken by Customer:

If your laboratory is processing enzymatic creatinine (ECREA) and the Acid Clean (ACLN) maintenance routine has been implemented, Siemens recommends the following steps:

1. Replace the appropriate Reagent Probe:
   NOTE: If the ECREA Reagent probe indicated below has been replaced since the activation of ACLN, the probe does not need to be replaced again. (skip to step 2)
   - If running a Dimension Vista 1500 Intelligent Lab System, replace Reagent Probe 2 and Reagent Probe 3.
   - If running a Dimension Vista 500 Intelligent Lab System, replace Reagent Probe 2.

2. Siemens recommends processing QC which includes ECREA immediately after routinely scheduled Off Peak Activities including Probe Test.
   NOTE: If your laboratory does not schedule Probe Test as part of Off Peak Activities, QC should be processed after the manually ordered Probe Test.

3. After replacement of the reagent probe, if you experience elevated ECREA QC results directly after Off Peak Activities which includes the Probe Test or after manually processing the Probe Test contact your Siemens Customer Care Center - Technical Solutions or your local Siemens Technical Support Representative.

Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.

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

We apologize for the inconvenience this situation has caused. If you have any questions, please contact Siemens Customer Care Center - Technical Solutions or your local Siemens Technical Support Representative.

Siemens Healthcare Diagnostics
P.O.Box 6101
Newark, Delaware 29714-6101
www.siemens.com/diagnostics

FIELD CORRECTION EFFECTIVENESS CHECK

Elevated Enzymatic Creatinine (ECREA) Results Following Dimension Vista Acid Clean (ACLN) Routine

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Medical Device Correction VS-17-01.A.OUS dated March 2017 regarding Elevated Enzymatic Creatinine (ECREA) Results Following Dimension Vista Acid Clean (ACLN) Routine. Please read and indicate the appropriate answer to the question below. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

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 #: _____

Please fax this completed form to the Customer Care Center – Technical Solutions at XXX-XXX-XXXX. If you have any questions, contact your local Siemens Technical Support Representative.