Urgent Field Safety Notice

ACHC21-01.A.OUS.DV

November 2020

Dimension Vista® Systems

Etamsylate Interference with Dimension Vista® Assays

Our records indicate that your facility may have received the following products:

Table 1. Dimension Vista® Affected Products

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
Enzymatic Creatinine	ECREA	K1270A	10700444	ALL
Triglycerides	TRIG	K2069	10445093	ALL

Reason for Correction

The purpose of this communication is to inform you of an interference identified with the products indicated in Table 1 above and to provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has become aware that falsely depressed results may be observed in the presence of etamsylate, a hemostatic drug, with the assays listed in Table 1.

Siemens performed spiking studies to assess the magnitude of interference with etamsylate. Results of the testing are summarized in Table 2 below for the highest evaluated level of etamsylate.

Table 2: Etamsylate Interference testing results

Etamsylate Concentration	Assay	Analyte Concentration	Bias (%)
6 mg/dL [228 µmol/L]	ECREA	0.98 mg/dL [87 µmol/L]	-39%
	TRIG	142 mg/dL [1.6 mmol/L]	-16%
		208 mg/dL [2.4 mmol/L]	-14%

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The Instructions for Use (IFU) for the assays will be updated with the interference information. Please see “Actions Being Taken by Siemens” below.

Risk to Health

In scenarios where creatinine is measured in the presence of etamsylate, the potential exists to report falsely depressed values for patient samples, leading to an underestimation of kidney disease and/or the misinterpretation of an increased estimated glomerular filtration rate (eGFR). Creatinine values are not used in isolation, but are correlated with clinical history and symptomology, as well as to other diagnostic laboratory testing such as blood urea nitrogen, electrolytes, albumin, and/or microalbumin.

The magnitude of interference observed in the presence of etamsylate when measuring triglycerides would have negligible clinical impact.

Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer:

- Be aware of the limitations indicated below in “Actions Being Taken by Siemens”.
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Siemens technical support representative.

Actions Being Taken by Siemens:

The “Limitations of the Procedure” section of the Dimension Vista ECREA assay IFU will be updated to indicate that: *‘In the presence of etamsylate at 0.4 mg/dL [15 µmol/L], falsely depressed results ≥10% for enzymatic creatinine may be observed. Use of this assay is not recommended for patients being treated with etamsylate.’*

The “Limitations of the Procedure” section of the Dimension Vista TRIG assay IFU will be updated to indicate that: *‘In the presence of etamsylate at 2 mg/dL [76 µmol/L], falsely depressed results ≥10% for triglyceride may be observed.’*

The information related to etamsylate provided in this letter supersedes the information in the current Dimension Vista IFUs until each is updated.

The updated IFUs will be uploaded into Document Library where all registered users who opt in to receive alerts will be notified of the updated IFU.

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

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We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens Technical Support representative.

Dimension Vista is a trademark of Siemens Healthcare Diagnostics.

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Frequently Asked Questions:

1. **Is the Jaffe Creatinine (CRE2) assay impacted by the presence of etamsylate?**
   The Jaffe CRE2 assay is not impacted by etamsylate interference. The Jaffe methodology uses different reagents and parameters than the ECREA assay.

2. **Why was testing performed using 6 mg/dL of etamsylate?**
   This level of etamsylate tested correlates to the C_{max} of approximately 5 mg/dL reported during pharmacokinetic studies following a single dose of 500 mg of etamsylate. Titration experiments were subsequently performed to characterize the potential for interference at decreasing concentrations of etamsylate.

3. **Is etamsylate prescribed worldwide?**
   Etamsylate is currently not available for use in the United States. In some countries etamsylate is approved only for veterinary use.

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