SIEMENS Healthineers

Urgent Field Safety Notice

ACHC21-01.A.OUS

November 2020

Atellica CH® Analyzer

Etamsylate Interference with Atellica® CH Assays

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

Table 1. Atellica® CH Affected Products

Assay	Test Code	Siemens Material Number (SMN)	Lot Number
Enzymatic Creatinine_2	ECre_2	11097533	ALL
Japan Enzymatic Creatinine	ECreJ	11319121 (Japan only)	ALL
Fructosamine	Fruc	11097637	ALL
Glucose Oxidase	GluO	11097621	ALL
Lactate	Lac	11097614	ALL
Lactate_2	Lac_2	11532568	ALL
Triglycerides (concentrated)	Trig	11097591	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.

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Table 2: Interference Testing Results

Etamsylate Concentration	Assay	Analyte Concentration	Bias (%)
6 mg/dL (228 µmol/L)	ECre_2/EcreJ	0.99 mg/dL (88 µmol/L)	-59%
	Fruc	187 µmol/L	-44%
		257 µmol/L	-44%
	GluO	44 mg/dL (2.4 mmol/L)	-9%
		111 mg/dL (6.2 mmol/L)	-5%
	Lac/Lac_2	16.5 mg/dL (1.8 mmol/L)	-12%
	Trig	135 mg/dL (1.5 mmol/L)	-13%
		196 mg/dL (2.2 mmol/L)	-9%

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 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.

In scenarios where fructosamine is measured in the presence of etamsylate, the potential exists to report falsely depressed values for patient samples, leading to delayed intervention of hyperglycemia. Clinical impact would be mitigated by continued correlation to clinical history and presentation, follow-up monitoring of glucose levels, and continued serial monitoring of fructosamine.

When glucose is measured in the presence of etamsylate, the potential exists to report falsely depressed values for patient samples possibly leading to inappropriate treatment for hypoglycemia. Mitigations for clinical impact include correlation to clinical history and presentation, as well as continued monitoring of blood glucose values.

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

Siemens is not recommending a review of previously generated results.

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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 Atellica CH ECre_2 and ECreJ assay IFUs will be updated to indicate that ‘*In the presence of etamsylate at 0.5 mg/dL (19 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 Atellica CH Fruc assay IFU will be updated to indicate that ‘*In the presence of etamsylate at 0.8 mg/dL (30 µmol/L), falsely depressed results ≥10% for fructosamine may be observed. Use of this assay is not recommended for patients being treated with etamsylate.’*

The “Limitations of the Procedure” section of the Atellica CH GluO assay IFU will be updated to indicate that *‘In the presence of etamsylate at 5 mg/dL (190 µmol/L), falsely depressed results ≥10% for glucose oxidase may be observed.*

The “Limitations of the Procedure” section of the Atellica CH Lac and Lac_2 assay IFUs will be updated to indicate that *‘In the presence of etamsylate at 5 mg/dL (190 µmol/L), falsely depressed results ≥10% for lactate may be observed.*

The “Limitations of the Procedure” section of the Atellica CH Trig assay IFU will be updated to indicate that *‘In the presence of etamsylate at 4.4 mg/dL (167 µmol/L), falsely depressed results ≥10% for triglycerides may be observed.*

The information related to etamsylate provided in this letter supersedes the information in the current Atellica CH 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.

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.

Atellica is a trademark of Siemens Healthcare Diagnostics.

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Frequently Asked Questions:

1. **Is the Jaffe Creatinine (Crea_2) assay impacted by the presence of etamsylate?**
   The Atellica CH Jaffe Crea_2 assay is not impacted by etamsylate interference. The Jaffe methodology uses different reagents and parameters than the ECre_2 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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FIELD CORRECTION EFFECTIVENESS CHECK

Etamsylate Interference with Multiple Atellica® CH Assays

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice ACHC21-01.A.OUS dated November 2020 regarding Etamsylate Interference with Atellica® CH Assays.

Please read the question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions 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:

Date:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Please send a scanned copy of the completed form via email to XXXX@XXXX

Or to fax this completed form to the Customer Care Center at XXXXXX

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

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