

## Urgent Field Safety Notice

**ACHC20-06.A.OUS**

**May 2020**

### Atellica CH® Analyzer

#### **N-acetyl-p-benzoquinone imine (NAPQI) Interference with Atellica® CH Fructosamine (Fruc) and Enzymatic Creatinine\_2 (ECre\_2) Assays**

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

**Table 1. Atellica® CH Affected Product(s)**

Assay	Test Code	Siemens Material Number (SMN)	Lot Number
Fructosamine	Fruc	11097637	ALL
Enzymatic Creatinine_2	ECre_2	11097533	ALL
Japan Enzymatic Creatinine	ECreJ	11319121 (Japan only)	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 has become aware that the presence of N-acetyl-p-benzoquinone imine (NAPQI), a metabolite of acetaminophen, may cause interference in certain chemistry assays when testing patient samples. Through spiking studies of NAPQI at 15 mg/L [101 µmol/L], Siemens observed a bias with the Fruc assay of approximately -34% at a fructosamine concentration of 336 µmol/L, and a bias with the ECre\_2 assay of approximately -17% at a creatinine concentration of 0.81 mg/dL (72 µmol/L). This level of NAPQI correlates to a toxic level of acetaminophen. Titration experiments were subsequently performed to characterize the potential for interference at decreasing concentrations of NAPQI.

### Actions being Taken by Siemens:

The "Limitations of the Procedure" section of the Atellica CH Fruc assay Instructions for Use (IFU) will be updated to indicate that '*N-acetyl-p-benzoquinone imine (NAPQI) is a metabolite of acetaminophen. NAPQI concentrations of approximately 3 mg/L correlating to supratherapeutic levels of acetaminophen demonstrates a ≤10% change in results. NAPQI concentrations greater than this may lead to falsely depressed results for patient samples. Use of this assay is not recommended for patients being treated for an overdose of acetaminophen.*

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The "Limitations of the Procedure" section of the Atellica CH ECre\_2 assay IFU will be updated to indicate that '*N-acetyl-p-benzoquinone imine (NAPQI) is a metabolite of acetaminophen. NAPQI concentrations of approximately 8 mg/L correlating to toxic levels of acetaminophen demonstrates a  $\leq 10\%$  change in results. NAPQI concentrations greater than this may lead to falsely depressed results for patient samples.*'

The information related to NAPQI provided in this letter supersedes the information in the current Atellica CH Fruc and ECre\_2 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.

### **Risk to Health**

In a patient being treated for acetaminophen toxicity, the potential exists to report a falsely depressed fructosamine which may affect consideration for intervention. It is extremely unlikely, however, that fructosamine would be used to assess glycemic status in an acetaminophen overdose situation. For a patient being treated for acetaminophen toxicity, glucose would be used to inform the physician of a patient's glycemic status.

At toxic levels of acetaminophen, NAPQI interference may lead to falsely depressed creatinine values. The magnitude of the bias would not be expected to lead to a clinically significant difference in patient management.

### **Actions to be Taken by the Customer:**

- Be aware of the limitations indicated above.
- 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.

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.

## **N-acetyl-p-benzoquinone imine (NAPQI) Interference with Atellica® CH Fructosamine (Fruc) and Enzymatic Creatinine\_2 (ECre\_2) Assays**

### **Frequently Asked Questions:**

**1. Which other assays have been tested for NAPQI interference?**

Cholesterol\_2 (Chol\_2), Creatinine\_2 (Crea\_2, Jaffe method), Direct Bilirubin\_2 (DBil\_2), Direct HDL Cholesterol (D\_HDL), Glucose Oxidase (GluO), Lactate (Lac), Lipase (Lip), Total Bilirubin\_2 (TBil\_2), Triglycerides concentrated (Trig), and Uric Acid (UA) have been tested on the Atellica CH and did not show any significant interference ( $\leq 10\%$  bias) up to NAPQI concentrations of 15 mg/L (101  $\mu\text{mol/L}$ ).

**2. Is the Jaffe Creatinine (CRE\_2c) assay impacted by the presence of NAPQI?**

Siemens testing has shown that the Jaffe CRE\_2c assay is not impacted by NAPQI interference. The Jaffe methodology uses different reagents and parameters than the ECre\_2 assay.

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**FIELD CORRECTION EFFECTIVENESS CHECK**

N-acetyl-p-benzoquinone imine (NAPQI) Interference with Atellica® CH Fructosamine (Fruc) and Enzymatic Creatinine\_2 (ECre\_2) Assays

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice ACHC20-06.A.OUS dated May 2020 regarding NAPQI Interference with Atellica® CH Fructosamine (Fruc) and Enzymatic Creatinine\_2 (ECre\_2) 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.