

Siemens Healthcare Diagnostics GmbH, SHS EMEA CEET QT, Siemensstrasse 90,
1210 Vienna

Name M.A. Roland Ertl
 Department SHS EMEA CEET QT
 Telephone +43 51707-38274
 Mobile +43 (664) 8011738274
 E-mail roland.re.ertl@siemens-healthineers.com
 Date May 18, 2020
 Document Ref# ACHC20-06.A.OUS

Urgent Field Safety Notice:

Dimension® clinical chemistry systems

N-acetyl-p-benzoquinone imine (NAPQI) Interference with Dimension® Enzymatic Creatinine (EZCR) Flex® reagent cartridge

Dear Sirs,

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

Table 1. Dimension® affected product

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
Enzymatic Creatinine	EZCR	DF270B	10471520	ALL

Reason for Correction

The purpose of this communication is to inform you of an interference identified with the product 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 Dimension EZCR of approximately -12% at a creatinine concentration of 1.02 mg/dL (90 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 to be Taken by Siemens:

The "Limitations of the Procedure" section of the Dimension EZCR 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 10 mg/L correlating to toxic levels of acetaminophen demonstrates a ≤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 Dimension EZCR IFU until it 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

There is negligible risk to health. At toxic levels of acetaminophen, NAPQI interference may lead to falsely depressed creatinine values, however 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 limitation 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.

Frequently Asked Questions:

1. Which other assays have been evaluated for NAPQI interference?

The assays indicated below were tested on the Siemens ADVIA Chemistry and Atellica CH systems. These assays have identical principles of procedure to the equivalent assays on the Dimension® clinical chemistry system. No significant interference is expected on the following Dimension assays: Cholesterol, Creatinine (Jaffe), Direct HDL, Lactic Acid, Lipase, Triglyceride, and Uric Acid.

Additionally, Direct and Total Bilirubin (DBI and TBI) assays were tested on the Dimension system and showed show no interference ($\leq 10\%$ bias) for NAPQI concentrations of >15 mg/L (101 $\mu\text{mol/L}$) at sample concentrations similar to those published in each product's IFU.

2. Is the Jaffe Creatinine assay impacted in the presence of NAPQI?

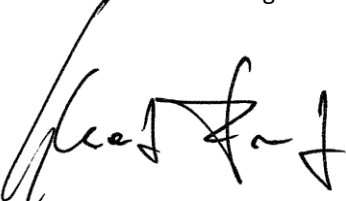
Siemens testing has shown that the Jaffe methodology is not impacted by NAPQI interference as the Jaffe methodology uses different reagents and parameters than the EZCR assay.

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.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH



i.V. Dipl. Ing. Franz Schwarz
Quality Management CEE



i.A. Dr.ⁱⁿ Brigitte Gassner
Product Manager Austria & SEE