

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 January 10, 2020  
 Document Ref# ACHC20-01.A.OUS.DM

**Urgent Field Safety Notice:**

**Dimension® clinical chemistry systems  
 Phenindione Interference with Dimension® Enzymatic Creatinine (EZCR) Assay**

Dear Sirs,

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

**Dimension® clinical chemistry system Flex® Reagent cartridge 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 issue with the product indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics has become aware of falsely depressed creatinine results for patients on phenindione therapy when using the enzymatic methodology. Interference has not been observed with the creatinine Jaffe methodology.

Phenindione is a vitamin K antagonist that acts as an anticoagulant. Phenindione therapy is no longer broadly prescribed due to known adverse side effects. Phenindione may be used if alternative anticoagulants are unavailable or not suitable for a patient.

Phenindione and/or phenindione metabolites are likely to play a significant role in the interference effect observed in samples from patients on phenindione therapy.

The "Limitations of the Procedure" section of the Instructions For Use (IFU) for the Dimension EZCR assay will be updated to indicate that *'Use of this assay is not recommended for patients undergoing treatment with phenindione, due to the potential for falsely depressed results'*.

The information related to phenindione provided in this letter supersedes the information in the current Dimension EZCR IFU until the IFU is updated. It is anticipated that the IFU will be updated and available by April 2020.

Siemens Healthcare Diagnostics GmbH  
 Management: Wolfgang Koepl, Stefan Scheidler

Siemensstrasse 90  
 1210 Vienna  
 Austria

Tel.: +43 51707 0  
 healthcare.siemens.com

## Risk to Health

Due to adverse side effects, phenindione is not widely prescribed. However, when creatinine is measured for a patient on phenindione therapy, the potential exists to report falsely depressed creatinine values that may lead 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. Discordance between these factors and the creatinine results would lead to questioning and further investigation. Siemens is not recommending a review of previously generated results.

## Actions to be Taken by the Customer:

- Please review this letter with your Medical Director.
- For patients on phenindione therapy an alternate creatinine methodology (i.e. Jaffe) is recommended.
- 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.

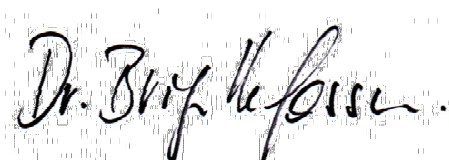
We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens Technical Support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH



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



i.A. Dr.<sup>in</sup> Brigitte Gassner  
Product Manager Austria & SEE