# Urgent Field Safety Notice

**ACHC20-01.A.OUS.DV**

**December 2019**

## Dimension Vista® Systems

## Phenindione Interference with Dimension Vista® Enzymatic Creatinine (ECREA) Assay

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

**Dimension Vista® System Flex® Reagent cartridge affected product**

| Assay | Test Code | Catalog Number | Siemens Material Number (SMN) | Lot Number |
|---|---|---|---|---|
| Enzymatic Creatinine | ECREA | K1270A | 10700444 | 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 Vista ECREA 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 Vista ECREA IFU until the IFU is updated. It is anticipated that the IFU will be updated and available by April 2020.




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Newark, DE 19714-6101
www.siemens.com/diagnostics

## 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.

Dimension Vista is a trademark of Siemens Healthcare Diagnostics.



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## FIELD CORRECTION EFFECTIVENESS CHECK

Phenindione Interference with the Dimension Vista® System Enzymatic Creatinine (ECREA) Assay.

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice ACHC20-01.A.OUS.DV dated December 2019 regarding phenindione Interference with the Dimension Vista® Enzymatic Creatinine (ECREA) Assay. 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 fax this completed form to the Customer Care Center at (###) ###-####.

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



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