CC to Chairman Medical Board and relevant Head of Departments

Urgent Field Safety Notice

ACHC20-01.A.OUS.CHC

December 2019

ADVIA® Chemistry systems

Phenindione Interference with Enzymatic Creatinine (ECRE_2) Assay

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

Table 1. ADVIA Chemistry Product affected by Phenindione

Assay	Test Code	REF Number	Siemens Material Number (SMN)	Lot Number
Enzymatic Creatinine_2	ECRE_2	04992596	10335869	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 reports of falsely depressed creatinine results for patients on phenindione therapy when using the enzymatic methodology. Interference has not been observed with the 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 ADVIA Chemistry ECRE_2 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 ADVIA Chemistry ECRE_2 IFU until the IFU is updated. It is anticipated that the IFU will be updated and available by April 2020.

511 Benedict Ave

Tarrytown, NY, 10591

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 Healthineers Customer Care Center or your local Siemens technical support representative.

511 Benedict Ave
Tarrytown, NY, 10591
www.siemens.com/diagnostics

FIELD CORRECTION EFFECTIVENESS CHECK

Phenindione Interference with the ADVIA Chemistry Enzymatic Creatinine_2 Assay

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice ACHC20-01.A.OUS.CHC dated December 2019 regarding Phenindione Interference with the Enzymatic Creatinine_2 Assay. Please read the question and indicate the appropriate answer. Return this completed form to Siemens Healthcare Diagnostics 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:

Customer Sold To #: Customer Ship To #:

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

511 Benedict Ave
Tarrytown, NY, 10591
www.siemens.com/diagnostics

CC to Chairman Medical Board and relevant Head of Departments

Urgent Field Safety Notice

ACHC20-01.A.OUS

December 2019

Atellica CH® Analyzer

Phenindione Interference with Enzymatic Creatinine (ECre_2) and Japan Enzymatic Creatinine (ECreJ) Assays

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

Table 1. Atellica CH Products affected by Phenindione

Assay	Test Code	REF Number	Siemens Material Number (SMN)	Lot Number
Enzymatic Creatinine_2	ECre_2	11097533	11097533	All
Japan Enzymatic Creatinine	ECreJ	11319121 (Japan only)	11319121 (Japan only)	

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 reports 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” sections of the Instructions For Use (IFU) for the Atellica CH ECre_2 and ECreJ assays 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’.*

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Phenindione Interference with Atellica CH Enzymatic Creatinine_2 and Japan Enzymatic Creatinine Assays

The information related to phenindione provided in this letter supersedes the information in the current Atellica CH ECre_2 and ECreJ IFUs until the IFUs are updated. It is anticipated that the IFU will be updated and available by April 2020.

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 Creatinine) 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 Healthineers Customer Care Center or your local Siemens technical support representative.

Atellica is a trademark of Siemens Healthcare Diagnostics.

511 Benedict Ave
Tarrytown, NY, 10591
www.siemens.com/diagnostics

FIELD CORRECTION EFFECTIVENESS CHECK

Phenindione Interference with the Atellica CH Enzymatic Creatinine_2 and Japan Enzymatic Creatinine Assays

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice ACHC20-01.A.OUS dated December 2019 regarding Phenindione Interference with the Enzymatic Creatinine_2 and Japan Enzymatic Creatinine Assays. Please read the question and indicate the appropriate answer. Return this completed form to Siemens Healthcare Diagnostics per the instructions provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice Correction instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Date:

Title:

Institution: Instrument Serial Number:

Street:

City: State:

Phone: Country:

Customer Sold To #: Customer Ship To #:

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

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Tarrytown, NY, 10591
www.siemens.com/diagnostics

CC to Chairman Medical Board
and relevant Head of
Departments

Urgent Field Safety Notice

ACHC20-01.A.OUS.DM

December, 2019

Dimension ® clinical chemistry systems

Phenindione Interference with Dimension® Enzymatic Creatinine (EZCR) Assay

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.

PO Box 6101
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 is a trademark of Siemens Healthcare Diagnostics.

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

FIELD CORRECTION EFFECTIVENESS CHECK

Phenindione Interference with the Dimension® clinical chemistry system Enzymatic Creatinine (EZCR) Assay.

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice ACHC20-01.A.OUS.DM dated December 2019 regarding phenindione Interference with the Dimension ® Enzymatic Creatinine (EZCR) 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:

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

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