SIEMENS

Urgent Field Safety Notice

CHC-15-14.A.OUS

June 2015

ADVIA® Chemistry Systems

Acetaminophen N-acetylcysteine (NAC) Interference Change

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

Table 1. ADVIA Chemistry Systems Affected Product(s)

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number *	Expiration Date
Acetaminophen	ACET	07989138	10327381	46251 46564 46369 46370 46619 46782 47001 47157 47558	June 30, 2015 July 31,2015 Sept. 30, 2015 Sept. 30, 2015 Oct. 31, 2015 Dec. 31, 2015 Jan. 31, 2016 Mar. 31, 2016 April 30, 2016

***** This change also applies to all future ADVIA Chemistry Acetaminophen reagent lots.

Reason for Correction

Siemens Healthcare Diagnostics is issuing a field correction for a change in the concentration of N-acetylcysteine (NAC) that may cause interference for the ADVIA® Chemistry Systems Acetaminophen assay for the lots listed in Table 1 and all future lots. This issue applies to the ADVIA 1200, 1800, and 2400 Chemistry Systems and ADVIA Chemistry XPT Systems.

The previous maximum NAC concentration at which acceptable acetaminophen results were obtained was 800 mg/L. Siemens has revised the concentration of NAC at which acceptable results were obtained to 200 mg/L NAC in an acetaminophen sample of approximately 10 mg/dL(661µmol/L), as indicated in Table 2.

Table 2. ADVIA Chemistry Systems Interference Levels

Assay	Original Interference Level of N-acetylcysteine (NAC)	Revised Interference Level of N-acetylcysteine (NAC)
Acetaminophen	800 mg/L	200 mg/L

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Tarrytown, NY 10591
www.siemens.com/diagnostics

This change in (NAC) interference concentration for the ADVIA Chemistry Acetaminophen assay is effective immediately. The Instructions For Use (IFU) will be updated to reflect this change in interference. See representative ADVIA Chemistry NAC interference data provided in Table 3 in the Additional Information section.

Risk to Health

The change in NAC interference concentration due to the issue described above results in a negative bias in acetaminophen concentration, at a lower concentration of NAC than what is anticipated based on the current ADVIA Chemistry Acetaminophen assay IFU. Baseline acetaminophen values (obtained before administration of NAC) would not be affected. A review of previously generated results is not recommended due to this issue.

Actions to be Taken by the Customer

- Effective immediately, this communication will serve as temporary labeling for the updated N-acetylcysteine (NAC) interference level of the ADVIA Chemistry Systems Acetaminophen assay until IFU changes are made.
- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.

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.

Additional Information

Serum samples containing approximately 10 mg/dL (661µmol/L) acetaminophen were tested with increasing levels of NAC with the following results. This in vitro analysis was performed approximately two hours after the addition of NAC to a serum pool.

Table 3. Representative ADVIA Chemistry NAC Interference Data

NAC Concentration	Percent Bias
200 mg/L NAC	-3.0%
300 mg/L NAC	-5.7%
400 mg/L NAC	-10.3%
600 mg/L NAC	-27.5%
800 mg/L NAC	-40.5%

ADVIA is a trademark of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

Acetaminophen N-acetylcysteine (NAC) Interference Change

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CHC-15-14.A.OUS dated June 2015 regarding ADVIA Chemistry Systems Acetaminophen N-acetylcysteine (NAC) Interference Change. Please read the question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

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

Name of person completing questionnaire:

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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