

ADVIA® Chemistry systems

N- Acetylcysteine (NAC) and Metamizole Interference with Trinder and Trinder-like reaction Assays

Our records indicate that your facility may have received the following products listed in Tables 1, 2 and 3 that can be processed on Siemens instruments:

Table 1. ADVIA Chemistry Products affected by N- Acetylcysteine (NAC) and Metamizole

| Assay | Test Code | Catalog Number | Siemens Material Number (SMN) | Lot Number |
|----------------------------------|-----------|----------------|-------------------------------|------------|
| Cholesterol_2 | CHOL_2 | 74719 | 10376501 | All |
| Cholesterol_c | CHOL_c | 74718 | 10335874 | All |
| Enzymatic Creatinine_2 | ECRE_2 | 74330 | 10335869 | All |
| Glucose Oxidase | GLUO | 74020 | 10492319 | All |
| Triglycerides_2 | TRIG_2 | 74082 | 10335892 | All |
| Triglycerides_2 Concentrated | TRIG_c | 74084 | 10697575 | All |
| Uric Acid | UA | 74021 | 10309492 10341133 | All |
| Uric Acid, Concentrated Reagents | UA_c | 74715 | 10335873 | All |
| Fructosamine | FRUC | 74080 | 10361941 | All |

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Table 2. ADVIA Chemistry Products affected by Metamizole only

| | | | | |
|------------------------|-------|-------|----------------------|-----|
| LDL Cholesterol Direct | DLDL | 74028 | 10311891 | All |
| Direct HDL Cholesterol | D-HDL | 74073 | 10309507 10283089 | All |

Table 3. ADVIA Chemistry Products affected by N- Acetylcysteine (NAC) only

| | | | | |
|----------------------------------------|--------|-------|----------|-----|
| Lactate | LAC | 74051 | 10325776 | All |
| Glucose Oxidase, Concentrated Reagents | GLUO_c | 74721 | 10335872 | All |

Reason for Correction

Siemens Healthcare Diagnostics has become aware of N- Acetylcysteine (NAC) and Metamizole (Dipyrone) interference with Trinder and Trinder-like reaction assays. The Trinder reaction is a reaction where hydrogen peroxide is formed and subsequently reacts with a phenol derivative and aminoantipyrine in the presence of peroxidase to form a colored quinone product.

Siemens has confirmed that falsely depressed results may occur on samples drawn from patients receiving N- Acetylcysteine (NAC) or Metamizole as indicated in Tables 1, 2 and 3. NAC is the accepted antidote for acetaminophen toxicity and is justified in patients at significant risk for hepatotoxicity. Metamizole is an anti-inflammatory anti-pyretic drug banned in most countries because of the potential for nephrotoxicity.

The Instructions For Use (IFU) for the ADVIA Chemistry assays listed in Table 1 (in the Limitations of the Procedure section) will be updated to indicate that: Venipuncture should occur prior to N-Acetyl Cysteine (NAC) or Metamizole administration due to the potential for falsely depressed results.

The Instructions For Use (IFU) for the ADVIA Chemistry assays listed in Table 2 (in the Limitations of the Procedure section) will be updated to indicate that: Venipuncture should occur prior to Metamizole administration due to the potential for falsely depressed results.

The Instructions For Use (IFU) for the ADVIA Chemistry assays listed in Table 3 (in the Limitations of the Procedure section) will be updated to indicate that: Venipuncture should occur prior to N-Acetyl Cysteine (NAC) administration due to the potential for falsely depressed results.

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Risk to Health

The potential exists for reporting falsely depressed results for the assays listed above from patients who have been administered NAC or Metamizole. Baseline values before administration of the NAC or Metamizole therapy would not be affected. It is extremely unlikely these assays would be requested during assessment of acetaminophen overdose and NAC treatment.

The potential impact on results due to this issue is limited to only the assays outlined in this communication. Siemens is not recommending a laboratory look back as a result of this issue.

Actions to be Taken by the Customer:

- Please review this letter with your Medical Director.
- Venipuncture should occur before drug administration of NAC or Metamizole; as indicated above under Reason For Correction. Baseline assay values before administration of NAC or Metamizole therapy would not be affected.
- 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, 2 or 3, 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.

ADVIA is a trademark of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

N- Acetylcysteine (NAC) and Metamizole Interference with Trinder and Trinder-like reaction Assays

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CHC16-01.A.OUS dated March, 2016 regarding N- Acetylcysteine (NAC) and Metamizole Interference with Trinder and Trinder-like reaction Assays. 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.

1. 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: _____

Customer Sold To #: _____ Customer Ship To #: _____

Please fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.