

Cc to Chairman Medical Board
and relevant Head of Departments

Urgent Field Safety Notice

CHC18-04.A.OUS

April, 2018

ADVIA® Chemistry Systems

Urea Nitrogen (UN)

Increased Incidence of Calibration Failures or Falsely Elevated Results

Our records indicate that you have or may have received the following product:

Table 1. Affected Product

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number	Expiration Date	Manufacturing/1 st Distribution Date
Urea Nitrogen	UN	03040257	10309051	408143	2018-06-28	2017-03-28/2017-06-09
				418290	2018-06-28	2017-03-28/2017-07-17

Reason for Recall

Siemens Healthcare Diagnostics has confirmed that the Urea Nitrogen reagent kit lots listed in the table 1 above for use on ADVIA® 1800, 2400 and XPT Chemistry Systems demonstrate an increased incidence of Calibration Failures. Results cannot be generated by the system when calibration fails.

If calibration passes, there is a potential for falsely elevated patient and quality control results.

Internal testing has also shown that for the lots listed in table 1, results have the potential to be falsely increased by approximately 10 mg/dL (3.57 mmol/L) across the analytical range. Quality controls may not always detect the elevated results.

Siemens is currently investigating the root cause of this issue.

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Risk to Health

The positive bias of 10 mg/dl (3.57 mmol/L) has been observed across the analytical measuring range of Urea Nitrogen lots 408143/418290 for patients, calibrator and QC samples. This bias has the potential to impact the interpretation of elevated urea nitrogen, such as dehydration, renal failure, or increased urea load with negligible risk to health. Urea Nitrogen is not used in isolation but is correlated with clinical history and presentation, as well as additional diagnostic laboratory testing such as creatinine. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Discontinue use of and discard the kit lots listed in Table 1.
- Please review this letter with your Medical Director.
- 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.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens for reporting to the authorities.
- 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 that this situation has caused. If you have technical questions regarding this information, please contact your local Siemens Technical Support Personnel. Thank you for your patience and continuing support of Siemens Healthcare Diagnostics products.

ADVIA is a trademark of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

Urea Nitrogen (UN) Reagent Kit Lots 408143 and 418290 –
Increased Incidence of Calibration Failures or Falsely Elevated Results

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CHC18-04.A.OUS, Rev. A dated April, 2018 regarding Urea Nitrogen reagents kit lots listed in Table 1 above used on the ADVIA® 1800, 2400, and XPT Chemistry Systems may demonstrate an increased incidence of calibration failures or falsely elevated results.

Please read each 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 ☐
2. Do you now have any of the noted products on hand? Please check inventories before answering. Yes ☐ No ☐

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description Product Catalog #/SMN #/ Lot #	Quantity of Affected Product in inventory that has been discarded	Replacement Quantity Required
ADVIA Chemistry Urea Nitrogen 03040257/10309051/Lot 408143		
ADVIA Chemistry Urea Nitrogen 03040257/10309051/Lot 418290		

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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.