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/1st Distribution Date
Urea Nitrogen	UN	03040257	10309051	408143 418290	2018-06-28 2018-06-28	2017-03-28/2017-06-09 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 across the analytical range. Quality controls may not always detect the elevated results.

Siemens is currently investigating the root cause of this issue.

Risk to Health

The positive bias of 10 mg/dl has been observed across the analytical measuring range of Urea Nitrogen lots 408143/418290 for patients, calibrator and QC samples. This bias has the

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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.

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