Siemens Healthcare Diagnostics GmbH, SHS EMEA CEET QT, Siemensstrasse 90,
1210 Vienna

Name M.A. Roland Ertl
Department SHS EMEA CEET QT

Telephone +43 51707-38274
Mobile +43 (664) 8011738274
E-mail roland.re.ertl@siemens-healthineers.com

Date September 2nd, 2019

Document Ref# POC 19-020.A.OUS

Urgent Field Safety Notice:

Atellica® UAS 800 Analyzer
Atellica® 1500 Automated Urinalysis System

A Downloaded Dilution Factor from LIS may not be Applied Correctly by the System.

Dear Sirs,

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

Table 1. Affected Product

Product	Siemens Material Number (SMN)	Software Version
Atellica® UAS 800 Analyzer Atellica® 1500 Automated Urinalysis System	11065004	V4.0.200 and V4.0.220

Reason for this Urgent Field Safety Notice

Siemens Healthcare Diagnostics has confirmed a mismatch between the LIS specification and the way the system application software interprets the dilution factor in a host query response message. When the three conditions below are all met, the system application software will not apply the dilution factor sent by the LIS, mistakenly providing results for the sample as if it was not diluted. The three conditions are:

1. The system application software 'LIS protocol' is set to '**ASTM**'
2. The system application 'Criteria for measuring samples' is set to '**Measure by Host Query'**
3. A dilution factor >1 has been downloaded from the LIS in the host query response message

Risk to Health

When this issue occurs, the potential exists for erroneously depressed urine sediment results, which may delay the detection of renal injury. Mitigations include correlation to clinical history and presentation as well as other urine and blood laboratory results. Siemens is not recommending a lookback of previously generated results due to this issue.

Actions to be Taken by the Customer

- Determine whether your system meets all three of the conditions above. If not, there is no action needed. If it does, Siemens recommends entering the dilution factor on the analyzer user interface instead of the LIS. The steps can be found in the User's Guide under "Rerunning a sample" or "Modifying sample information".
- Please review this letter with your Medical Director.
- Keep this notification document with your User's Guide for reference, as needed.
- Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

The LIS specification document guide will be updated to reflect the correct field for the dilution factor in the host query response message.

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.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

i.V. Dipl. Ing. Franz Schwarz
Quality Management CEE

i.A. Mag. Thomas Hufnagl
Product Manager Austria & SEE