SIEMENS
Healthineers
Siemens Healthcare Diagnostics Inc.

Urgent Field Safety Notice
POC 19-021.A.OUS
September 2019

Atellica® UAS 800 Analyzer
Atellica® 1500 Automated Urinalysis System

Potential LIS Communication Loss When Using ASTM Protocol

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	All versions up to and including V4.0.220

Reason for this Urgent Field Safety Notice

Siemens Healthcare Diagnostics has confirmed that a communication error could be generated on the system application software when using the ASTM interface protocol to connect with Laboratory Information System (LIS). The following error messages, "LIS Connection Lost (412)" or "LIS communication Error (224)", may potentially be generated when the Host Query response or the Worklist entry message from the LIS and the result message from system application software occur simultaneously.

Risk to Health

When this issue occurs, the potential exists for an apparent delay in result transmission from the instrument to the LIS. The results can be resent after re-establishing the connection to the LIS. Siemens is not recommending a lookback of previously generated results due to this issue as results are accurate.

Actions to be Taken by the Customer

- If you do not use the "**Measure by Host Query**" or **Worklist** option and/or you do not use ASTM interface protocol, no action is needed.

- If you use the ASTM interface protocol and "**Measure by Host Query**" option, Siemens recommends to proactively use "**Run Sample**" option under "**When Host Query is not Available**" setting as referred in the Operators Guide to allow the instrument to process the sample in case the error occurs. Also, when the error occurs, Siemens recommends resetting the LIS or rebooting the instrument. To reset the LIS, an administration level user would select **Disable** followed by **Enable** under **Settings / Transfer / LIS Connection.**

- If you use the ASTM interface protocol and "**Worklist**" option, Siemens recommends resetting the LIS or rebooting the instrument. To reset the LIS, an administration level user would select **Disable** followed by **Enable** under **Settings / Transfer / LIS Connection.**

- 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.

This issue will be addressed in the next system application software version. Affected customers will be contacted regarding the installation of the next system application software version when it is available.

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

Atellica UAS 800 is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK AND PRODUCT DISCARD FORM

Potential LIS Communication Loss When Using ASTM protocol

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice POC 19-021.A.OUS dated September 2019, Potential LIS Communication Loss When Using ASTM Protocol. Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions 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 send a scanned copy of the completed form via email to XXXX@XXXX or fax this completed form to the Customer Care Center at XXXXXX.

If you have any questions