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Urgent Field Safety Notice:

Atellica® UAS 800 Urine Sediment Analyzer
Atellica® 1500 Automated Urinalysis System

Results with "Invalid" Flag Erroneously Sent to LIS Due to Missing Centrifuge Arm

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 Urine Sediment Analyzer Atellica® 1500 Automated Urinalysis System	11065004	Up to and including v4.0.310

Reason for this Urgent Field Safety Notice

The purpose of this communication is to inform you of an issue with the product indicated in Table1 above and provide instructions on actions that your laboratory should take.

Siemens Healthcare Diagnostics Inc. has confirmed rare incidents of incorrectly sending false negative results (or "QC passed") to the LIS when the Atellica UAS 800/1500 system reports the sample (or the QC) as "Invalid". Usually, results with an "Invalid" flag are marked as "N/A" and are held in the software for further user review. These rare incidents of sending false negative results occur on only the first sample in the run after the system is rebooted or the centrifuge door is opened, and the centrifuge arm is either missing or improperly installed on the system. The system will then display the "Cuvette cannot be found under the microscope" message and subsequent samples will not run until the system is initialized.

Risk to Health

The issue has the potential to lead to reporting of a false negative result for urine particles (red blood cells; white blood cells; casts, etc.), leading to possible delays in recognition and treatment of various illnesses. Siemens is not recommending a retrospective review of test results. There have been no reports of injury.

Actions to be Taken by the Customer

- Always make sure to reseat the centrifuge arm in place on the system after it is removed for cleaning, as part of the monthly maintenance.
- When you get the message “Cuvette cannot be found under the microscope”, confirm that the results of the first sample/QC in the run match on both LIS and the Atellica database. If there is a mismatch, rerun the sample and send corrected results accordingly, if necessary.
- Complete and return the Field Correction Effectiveness Check form attached to this letter within 30 days.
- Please review this letter with your medical director or laboratory director. Keep this notification document with your User’s Guide for reference, as needed, and forward this letter to those who may have received this product.

This issue will be fixed in the next Atellica UAS 800 Software version.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

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