

ADVIA® Chemistry XPT

Auto Rerun Issues

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

Table 1. ADVIA Chemistry XPT Affected Product

Product	Siemens Material Number (SMN)
ADVIA Chemistry XPT Software Version 1.0.2	11219493

Reason for Correction

Siemens Healthcare Diagnostics has confirmed an issue with ADVIA® Chemistry XPT software version 1.0.2. The system may cause samples to remain in an “Inprocess” state. Test results on a sample that is held Inprocess will not transmit to the LIS. Manual intervention is necessary to complete the processing of the samples that are held Inprocess. Event message 02 981 8728 is generated as part of this software issue.

Risk to Health

Under very rare circumstances, there is the potential for a delay in confirming a critical result. No look back is required.

Actions to be Taken by the Customer

The system status light and event log will blink red when event message 02 981 8728 is generated. In order to react promptly to the event, users should monitor the status light and event log frequently while processing samples.

To locate Inprocess samples that require manual intervention, perform the following steps:

1. Navigate to the **Dashboard** icon located at the lower center of the workstation monitor.
2. Single-select the icon to open the **Dashboard**.
3. Select the counter field next to the **Inprocess** label.
4. Allow the **Dashboard: Patient and QC tab of the Test Results** window to open and refresh.
5. Minimize the Dashboard.

6. A test result with a clock icon but no estimated time to completion (ETC) is an indication that a sample is stuck in the Inprocess state. Samples that are held Inprocess may have some completed tests. After laboratory review the completed test results may be manually transmitted to an LIS.
7. To manually transmit sample results to an LIS, select the record then select the **Transmit** button.
Note: Only completed test results will transmit to the LIS. The test results that are Inprocess are not available for transmission to the LIS.
8. To complete the processing of all tests on a sample held Inprocess, select the record and delete it.
9. Locate the sample and reprocess it.

In addition, please perform the following:

- 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 this situation may cause. If you have any questions about Inprocess samples, the event message 02 981 8728, or need assistance with mitigation solutions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

ADVIA is a trademark of Siemens Healthcare Diagnostics.

FIELD CORRECTION EFFECTIVENESS CHECK

Auto Rerun Issues

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 11219912, Rev. A dated February 2015 regarding Auto Rerun Issues. Please read the 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.

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: _____

Please fax this completed form to the Customer Care Center at (###) ###-####. If you have any questions, contact your local Siemens technical support representative.