

Release Note: QIAcuityDx[®] Software Suite (v1.1.1)

The QIAcuityDx Software version 1.1.1 is now available for download and installation.

Upgrading to QIAcuityDx Software version 1.1.1 requires the upgrade of both the QIAcuityDx Software Suite and the QIAcuityDx Control Software (CSW) to version 1.1.1, which is performed by your local QIAGEN service team or by QIAGEN-trained and approved commercial partners in dedicated countries.

This release (QIAcuityDx Software v1.1.1) is designed for new installations as well as updates to existing installed instruments. QIAcuityDx Software v1.1.1 will replace the prior version, QIAcuityDx Software v1.0.0 that will no longer be maintained. Installing v1.1.1 is mandatory to ensure the latest cybersecurity enhancements are implemented. It targets the following QIAcuityDx subsystems:

QIAcuityDx Software Assay Independent (SAI) v1.1.1:

- QIAcuityDx Control Software (CSW) v1.1.1
- QIAcuityDx Software Suite (Suite) v1.1.1
- UTL Plugin (Suite) v1.1.0

The software package contains three installation packages with the following components:

- The QIAcuityDx Software Suite application software (runs on provided Notebook), including the functionality to set up plates, manage users and permissions, manage software plugins and configure archiving
- The QIAcuityDx Control Software application software (runs on instrument user interface screen), including the functionality to manage and perform plate runs

The QIAcuityDx Control Software is an integral part of the QIAcuityDx instrument. It offers a GUI (graphical user interface) for basic functionalities such as plate setup, changing the order of plates to be processed, and monitoring the status of runs in real time while in front of the instrument. As each nanoplate run is active, the data are temporarily stored in the instrument's memory before being streamed to the QIAcuityDx Software Suite in real time, ready for plate analysis on completion of a run.

The QIAcuityDx Software Suite enables the user to set up plates, analyze results, and monitor the status of runs in real time. This software is also used for the configuration of the system and provides access to the QIAcuityDx user management. The QIAcuityDx Software Suite is designed to be installed on a Windows 11 PC with a specific configuration that is connected to the QIAcuityDx instrument(s).

The QIAcuityDx Software v1.1.1 (application software) has been successfully verified at the software level by performing and documenting tests in line with applicable regulatory requirements.

Installation and update instructions

The software installation or update is managed by your local QIAGEN service team or by QIAGEN-trained and approved commercial partners in dedicated countries. Please contact them to arrange for your software update.

New / updated functionality (compared to QIAcuityDx software 1.0.0)

Suite (v1.1.1) plus UTL v1.1.0

- **Added:** Import/Export plate csv. (plates can be exported as zip files to other software instances)
- **Added:** Import / Export Plate Layout in Utility Mode
- **Added:** Utility Mode Result Reports (default and customizable) with UTL Plug-in 1.1.0
- **Added:** Updates in IVD Plate Configurator to ready the system for IVD software plugin integration
- **Added:** LIMS Connectivity added (IVD + Utility Modes)
- **Added:** Internationalization
- **Added:** Support Package extended with RFU values
- **Updated:** Estimated completion time in Suite
- **Updated:** FDA-compliant cybersecurity improvements implemented
- **Updated:** Software Suite general upgrade

CSW (v1.1.1)

- **Added:** Language packs / Internationalization
- **Added:** Periodic Maintenance updates
- **Added:** Periodic Self-test / restart out of working hours function

A number of identified bug fixes were applied to both Suite and CSW.

A new version of QIAidentity (v2.0.2) was integrated into the software to mitigate risk associated with connection stability.

If you have further questions, please contact your local QIAGEN representative or contact our Technical Support Center at www.qiagen.com/support/technical-support