June 2026

Release Note: QIAcuityDx® System Software v1.2

The QIAcuityDx Software Suite version 1.2 is now available for users of the QIAcuityDx System.

Upgrading to QIAcuity Software version 1.2 requires upgrading both the QIAcuityDx® Software Suite and the QIAcuityDx® Control Software to version 1.2. The upgrade also offers the option to upgrade the QIAcuityDx® Software Assay Plugin (SAP) SAP_UM v1.2.0. This latter option upgrades the Utility Mode in Software Suite to v1.2. Users who accept this upgrade can still access, set up, and run plates on Utility Mode v1.1 if they choose to do so.

Before requesting your QIAcuityDx System Software update, please read the following document to familiarize yourself with the update, and contact QIAGEN Technical Support if you have any questions prior to requesting your service-lead software upgrade visit.

1. Scope

This release of QIAcuityDx Software v1.2 introduces usability, robustness, and compliance-related improvements across the Software Suite, Control Software integration, and Utility Mode assay plugin.

2. Installation and Update Information

Installation and update procedures are described in the corresponding Instructions for Use. Please ensure system requirements are met before performing an update.

To verify installed version:

- **QIAcuityDx Software Suite**: Go to the login page of Software Suite web application. The version is visible in the footer. The displayed software version should be 1.2.0 once updated.
  Go to the Tools section and download a Software Support package, the downloaded file will contain the full software version (e.g., QIAcuityDx_1.2.0.X_SWSP_20240405_123409).
- **QIAcuityDx Control Software**: Go to the login page of the instrument. The version is visible in the header. The software version displayed should be 1.2.0.x once updated.
- **QIAcuityDx Software Assay Plugin** (Utility Mode): Log in to the Software Suite and navigate to **Configuration** > **Plugin management**. The software version displayed should be 1.2.0.3 once updated.

3. What's New and Improved in Version 1.2

3.1 Software Suite Improvements (Suite 1.2)

- Software Suite can now be installed from non-administrator accounts. This feature enables a connection from the Suite laptop (Notebook, QIAcuityDx Four w/Suite) to the users' company- or institute-owned internal network, and is configured to meet cybersecurity requirements (an admin account is not required to operate the software). Although some initial steps of the installation process require elevated privileges, a non-administrator can then configure and complete the installation process.
- The QIAcuityDx Suite software is now configured to support the supplied Notebook being set up as a server via a domain-connection (server) installation. Users are then able to connect to the Notebook (and, consequently, the Suite software via a web connection). Before attempting this connection, users are required to configure relevant ports, as per the advice in the updated Instructions for Use.

- More consistent reporting with increased number of workflow events captured via improved communication between Suite Software and Control Software, thus delivering improved analysis of Audit Trails with larger number of Instrument activities.
- Audit Trail events are now saved at the plate-level within the system, supporting the transfer of all relevant audit trail data during export/archive activities. This change also supports movement of plates (export or archive) without the need for additional action or user privileges (Administrator level) as with prior software releases.
- Whenever there are unsaved changes and the user clicks **Back** or **Forward** in the internet browser, closes the tab, refreshes the page, or clicks anywhere else that can redirect to a different screen, an “Unsaved changes” message is displayed to remind them to save their work if not already saved.
- Where attempted use overlaps with a previous action that is at odds with current action, a more informative message is shown to the user that better defines why their attempted tasks are not completed. For example, when a user tries to save changes in a plate template that has been edited in the meantime, a pop-up shows the message “Changes can't be saved. This plate template was edited in the meantime. Refresh the page to get the newest version”.
- Plate barcodes already assigned to a plate no longer need to be removed prior to updating a plate to a newly assigned barcode. Users can simply scan the new barcode and it will automatically overwrite the last scanned version.
- It is now clearer to users when unsupported characters have been entered into a data entry field. Whenever unsupported characters are entered into a field, the message indicating unsupported special characters appears so that the user can identify and rectify this more quickly.
- User now has the option to either enable or disable the expiration of passwords, as well as having the option to reconfigure the number of days before password expiration within a range of 1–360 days (software is set to 90 days by default).
- A small number of error messages popped up that did not give further guidance. These have been improved such that all remaining messages give clear guidance to user on how to proceed.
- Improved clarity has been added to system logs in Suite Software that should support easier understanding when in use.
- Users were previously restricted to running only a single lot of dPCR MasterMix on a Nanoplate but this has been updated so a user can switch from one MasterMix lot to another on a single plate.
- Where previously an error in the system may have only reported to the user as the last known error, any errors that occurred prior to the final error will also be recorded and displayed to support troubleshooting efforts, thus improving efficiency of troubleshooting either by the user or by technical support functions.
- On occasion, an instrument may move into an emergency state, indicating the user that an action needs to be completed before continued use. The latest software version supports communication of this emergency state displayed on the instrument user interface, such that is also visible on the Suite software (Notebook/domain access). This supports quicker recognition of potential instrument issues to user before they proceed further with any setup on Suite.

3.2 Control Software–Related Improvements

- Instrument Support Packages that were previously only downloadable from the instrument can now also be sent to or collected from a connected instance of the Suite Software (Notebook). If there are any technical difficulties with the use of the instrument, support packages, and troubleshooting activities by trained QIAGEN personnel, please refer to the Instructions for Use for further information.
- More consistent reporting with increased number of workflow events captured via improved communication between Suite Software and Control Software, thus delivering improved analysis of Audit Trails with larger number of Instrument activities.
- The internal plate handling has been optimized to reduce risks of failing plates due to expiration of the onboard stability function that is built in.

- An enhanced Nanoplate gripper handling algorithm has been implemented to reduce instrument errors that occasionally appear in continuous use.
- On occasion, an instrument may move into an emergency state, indicating to the user that an action needs to be completed before continued use. The latest software version supports communication of this emergency state displayed on the instrument user interface, such that is also visible on the Suite software (Notebook/domain access). This supports quicker recognition of potential instrument issues to user before they proceed further with any setup on Suite.
- Earlier software versions were not as accurate in estimating remaining processing time on plates running. This accuracy has been improved, as well as maintaining alignment on communicated timing between instrument (Control Software) and Suite (Notebook/Domain loaded software).
- An updated and improved StartUp screen now provides information about ongoing updates of software or firmware components. The User Interface on the instrument gives clear guidance to users to pause actions that may interfere with ongoing background tasks, e.g., asking the user to wait momentarily if attempting to open the drawer while plates are being imaged or moved between modules.
- Internal processing improvements have been implemented in the Control Software to increase robustness of plate processing within the instrument and further reduce occasional plate errors.
- Software components have been updated to the latest secure release to maintain and enhance already implemented cybersecurity functionality.

3.3 Software Assay Plugin – Utility Mode (v1.2.0)

- The display in the Concentration diagram in plate analysis was updated to improve display characteristics, including a clearer graphical output, that includes the correct grouping of samples, and hyperwelled samples.
- The x-axis on graphical data has been improved to deliver more easily readable information to the user, including more legible labels, and a newly added limit to range sliders (according to bars/points/data range).
- The option to Add to report has been hidden from users without Create report permission. This is to correctly reflect the expected options for different user levels.
- A new version of the algorithm library has been added, which delivers improvements to the total amount of data that is available to analyze. This update makes it less likely that the data would be flagged during quality control for further review, thus improving overall data integrity.
- The ability to view the reference channel signal map has been reinstated, as this helps users wishing to troubleshoot performance and improve data analysis.

4. Bug Fixes

QIAcuityDx Software version 1.2 includes fixes addressing data consistency, reporting accuracy, workflow behavior, and user interface robustness identified in previous software versions. All remaining bugs (residual deviations) were assessed to have no security impact, and this was captured and documented in a Software Deviation Summary Report.

- 15 of 16 bugs fixed (compared to QIAcuityDx software v1.0.0): All but one minor BUGS identified in the initial software release were fixed in this latest release. The remaining identified BUG not fixed was not reproducible following the move from v1.0 to v1.1. It was verified that this bug no longer affects the software.
- 18 BUGS fixed (compared to QIAcuityDx software v1.1.0), including the two bugs detailed below, that were previously communicated to customers.

QIACT-42749	Software bug corrected to align all data access options, and confirm that decimals (and therefore data integrity) are now accurate in all generated reports and exported CSV files
QIACT-32237	The update has removed occasional minor inconsistencies observed in the number of valid partitions and negative partitions in data export files

5. Known Issues

A small number of residual deviations remain in this release and are limited to rare, non-routine usage scenarios such as user interface behavior or system messaging. All known issues are classified as low risk and do not affect result accuracy, data integrity, or intended use of the system.