July 2024

QIAcuityDx® System User Manual

IVD For in vitro diagnostic use

CE

REF 911060

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Sample to Insight

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1. Introduction

Thank you for choosing the QIAcuityDx. We are confident it will become an integral part of your laboratory.

This user manual describes the QIAcuityDx System (abbreviated to QIAcuityDx), which has been developed using the architecture of the QIAcuityDx Four instrument, but with the required functionality, consumables, and overall compliance necessary to meet our diagnostic customers' requirements.

Before using the QIAcuityDx, it is essential that you read this user manual carefully and pay attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

Be aware that you may be required to consult your local regulations for reporting serious incidents that have occurred in relation to the device to the manufacturer and/or its authorized representative and the regulatory authority in which the user and/or the patient is established.

1.1. About this user manual

This user manual provides information about the QIAcuityDx in the following sections:

- Introduction
- Safety Information
- General Description
- Installation Procedures
- Operating Procedures
- Maintenance
- Troubleshooting
- Technical Specifications
- References
- Appendices

The appendices contain the following information:

- Appendix A – Legal
- Appendix B – QIAcuityDx Accessories

1.2. General information

1.2.1. Technical assistance

At QIAGEN®, we pride ourselves on the quality and availability of our technical support. Our Technical Services Departments are staffed by experienced scientists with extensive practical and theoretical expertise in molecular biology and the use of QIAGEN products. If you have any questions or experience any difficulties regarding the QIAcuityDx or QIAGEN products in general, do not hesitate to contact us.

QIAGEN customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to other scientists as well as to the researchers at QIAGEN. We therefore encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

For technical assistance, contact QIAGEN Technical Services.

Website: **support.qiagen.com**

When contacting QIAGEN Technical Services about errors, please have the following information ready:

- QIAcuityDx serial number, type, and version
- Error code (if applicable)
- Timepoint when the error occurred for the first time
- Frequency of error occurrence (i.e., intermittent or persistent error)
- Copy of log files

1.2.2. Policy statement

It is the policy of QIAGEN to improve products as new techniques and components become available. QIAGEN reserves the right to change specifications at any time. In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual. Please contact QIAGEN Technical Services.

1.3. Dual-use description

The QIAcuityDx System includes two modes of use: IVD mode and Utility mode. As a completely approved (IVDR and FDA) system, the IVD mode includes clinically validated and globally approved assays, with locked analytics and defined reporting; and the Utility mode, offering flexibility to the laboratories to develop their own laboratory-developed tests (LDT) workflows or use for translational (nonclinical) research purposes.

Note: Products intended for nonclinical laboratory research include products intended for use in discovering and developing medical knowledge related to human disease and conditions and products for molecular research, genotyping, forensic and human identity testing, food and animal feed safety and quality testing, cancer research, microbiological research, and animal pathogen research. They are not intended to produce results for clinical use and are not themselves the object of the research. These products do not have medical purpose, and thus they are not considered medical devices.

Note: The QIAcuityDx "Utility Mode" Software Assay Plugin can be used with the Utility mode. Utility Mode assay plugins are dedicated software components installed on the same PC as the QIAcuityDx Software Suite, allowing healthcare assay developers with Utility mode privileges to configure and execute digital PCR (dPCR) runs and perform analysis of data. These assay plugin(s) can be used also for nonclinical research purposes.

1.4. Intended use of the QIAcuityDx

The QIAcuityDx System is intended for in vitro diagnostic use for the examination of specimens derived from the human body, using automated multiplex quantification dPCR technology, for the purpose of providing diagnostic information concerning pathological states, as indicated in the corresponding available validated assays.

The QIAcuityDx System comprises of the following:

- QIAcuityDx Four instrument — a semi-automated dPCR instrument designed to perform partitioning, amplification, detection (qualitative and quantitative), and analysis of nucleic acid samples, isolated from biological specimens
- QIAcuityDx Software Assay Independent (SAI) unit — a dedicated software component installed in a PC that drives the QIAcuityDx Four instrument and provides a user interface to manage the system
- QIAcuityDx Software Assay Plugin/s — a dedicated software component installed same PC as the SAI allowing users to run dPCR analysis
- QIAcuity Nanoplate 26k 24-well — single-use disposables that partition samples and reaction mixes using a microfluidic plate-based technology
- QIAcuityDx Universal MasterMix Kit — a ready-to-use dPCR master mix reagent set for use within the QIAcuityDx System in conjunction with associated target specific reagents

The QIAcuityDx System is intended for use by trained laboratory professionals in clinical laboratories.

1.4.1. Utility mode

The QIAcuityDx System incorporates a Utility (open) mode to allow research applications and support for LDTs or in-house assays (IHA), manufactured and used within a health institution (i.e., same legal entity), under user-validated workflows or using the mode in the execution of nonclinical laboratory research.

Demarcation between Utility (open) mode and the IVD mode is ensured upon starting the Software Suite and is controlled through User Access Management (UAM). The user must choose between the IVD and the Utility mode as described in Section 5.9. In addition, IVD Software Assay Plugin(s) can only be used with approved assays and compliant components (Nanoplates and MasterMix). Similarly, the QIAcuityDx Software Assay Plugin(s) that are used for LDTs or IHA or nonclinical laboratory research purposes cannot be used with approved IVD assays.

Instrument malfunction and/or degradation

In the event that the instrument malfunctions and/or appears to be degrading as suggested by changes in its appearance that may affect performance, remove the power from the unit and contact QIAGEN Technical Services.

Exposure to external influences or environmental conditions

In the event that the instrument is exposed to external influences such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature outside of the operating range, remove the power from the unit and contact QIAGEN Technical Services.

Interference emitted by the device affecting other equipment

In the event that the instrument is affecting other equipment during the normal operation of the device, please ensure the minimum installation distances have been adhered to and contact QIAGEN Technical Services for further information.

Warnings and/or precautions related to potentially infectious material that is included in the device

The QIAcuityDx may be used for a wide range of applications, including infectious disease testing. From a biological risk perspective, the QIAcuityDx is a "closed" system once a top seal is applied to a nanoplate, thus significantly reducing the risk of instrument contamination and potential user infection. However, local health and safety measures should be adhered to when operating the system with potentially infectious agents.

1.5. Limitations of use

The QIAcuityDx System, when used in combination with QIAGEN kits indicated for use with the QIAcuityDx instrument, is intended for the applications described in the respective QIAGEN kit handbooks where relevant, requirements for special facilities, or special training, such as particular qualifications of the intended user.

1.6. Requirements for QIAcuityDx

The table below covers the general level of competence and expertise necessary for transportation, installation, use, maintenance, and servicing of the QIAcuityDx.

Task	Personnel	Level of competence and expertise
Delivery	No special requirements	No special requirements
Installation	QIAGEN service personnel or service technicians of an authorized agent	Trained and authorized by QIAGEN
Routine use (IVD mode)	Laboratory technicians or equivalent trained in the Diagnostic Assay being executed	Appropriately trained or experienced personnel familiar with use of computers and diagnostic instrumentation in general
Routine use (Utility mode)	Laboratory technicians or equivalent	Appropriately trained or experienced personnel familiar with use of computers and diagnostic instrumentation in general
Assay design and validation (Utility mode)	Scientist or equivalent	Appropriately trained or experienced personnel familiar with molecular biological techniques
Result Interpretation (IVD mode)	Clinician or equivalent	Appropriately trained or experienced personnel familiar with clinical interpretation of results
Dust Filter replacement	Laboratory technicians or equivalent	Appropriately trained or experienced personnel familiar with use of computers and automation in general
Preventative maintenance	QIAGEN service personnel or service technicians of an authorized agent	Trained and authorized by QIAGEN

1.7. Materials required

Note: Only use accessories supplied by QIAGEN.

1.7.1. IVD mode

When operating the QIAcuityDx System in IVD mode:

The following QIAGEN kits are required to perform dPCR using the QIAcuityDx System:

- QIAcuityDx Universal MasterMix Kit (1 mL)
- QIAcuityDx Universal MasterMix Kit (5 mL)

The following QIAGEN disposable kit is required to perform dPCR using the QIAcuityDx System:

- QIAcuity Nanoplate 26k 24-well (10)

1.7.2. Utility mode

When operating the QIAcuityDx System in **Utility mode**, the materials described in Section 1.7.1 are recommended.

Optionally, the following QIAGEN kits may be used to perform dPCR using the QIAcuityDx System:

- QIAcuity Probe PCR Kit (1 mL)
- QIAcuity Probe PCR Kit (5 mL)
- QIAcuity Probe PCR Kit (25 mL)

Optionally, the following QIAGEN disposables kits may be used to perform dPCR using the QIAcuityDx System in **Utility mode**:

- QIAcuity Nanoplate 26k 24-well (10)
- QIAcuity Nanoplate 8.5k 96-well (10)
- QIAcuity Nanoplate 8.5k 24-well (10)

Note: QIAcuity Nanoplate 26k 8-well (10) are not supported by the QIAcuityDx System.

A QIAcuityDx Notebook is required to perform dPCR using the QIAcuityDx System. This notebook must meet the following specifications:

Table 1. QIAcuityDx Notebook specifications

Description	Required specifications
Operating system	Microsoft® Windows 11 Professional Edition 64-bit version
Processor	x64 compatible processor with 4 physical cores and 2.5 GHz
Main memory	16 GB RAM
Hard disk space	At least 500 GB
Graphics interface	At least 1280 x 768 pixels

The QIAcuityDx notebook should be minimally installed with the following software components:

- QIAcuityDx Software Suite
- QIAcuityDx Utility Mode Software Assay Plugin

1.8. Materials required but not provided

- Calibrated pipettes (p2 – p1000)
- DNase/RNase free microtubes and/or microplates
- Vortex mixer
- Centrifuge
- Safety glasses
- Gloves
- Lab coat

2. Safety Information

Before using the QIAcuityDx, it is essential that you read this user manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

The following types of safety information appear throughout the *QIAcuityDx System User Manual*.

WARNING The term **WARNING** is used to inform you about situations that could result in personal injury to you or others.

Details about these circumstances are given in a box like this one.

CAUTION The term **CAUTION** is used to inform you about situations that could result in **damage to an instrument** or other equipment.

Details about these circumstances are given in a box like this one.

The guidance provided in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

Please be aware that you may be required to consult your local regulations for reporting serious incidents that have occurred in relation to the device to the manufacturer and/or its authorized representative and the regulatory authority in which the user and/or the patient is established.

2.1. Proper use

WARNING/ CAUTION **Risk of personal injury and material damage**

Improper use of the QIAcuityDx may cause personal injuries or damage to the instrument. The QIAcuityDx must only be operated by qualified personnel who have been appropriately trained. Servicing of the QIAcuityDx must only be performed by a QIAGEN Field Service Specialist.

Perform the maintenance as described in Section 6. QIAGEN charges for repairs that are required due to incorrect maintenance.

WARNING **Risk of personal injury and material damage**

The QIAcuityDx is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. The bottom plane shall be used for lifting. Do not lift at the touchscreen.

Contact QIAGEN Technical Services to relocate the instrument.

WARNING **Risk of personal injury and material damage**

Do not attempt to move the QIAcuityDx during operation.

CAUTION **Damage to the instrument**

Avoid spilling water or chemicals onto the QIAcuityDx. Instrument damage caused by water or chemical spillage will void your warranty.

In case of emergency, power OFF the QIAcuityDx using the power switch at the right, rear panel of the instrument and unplug the power cord from the power outlet.

CAUTION **Damage to the instrument**

Only use QIAcuityDx -specific consumables with the QIAcuityDx. Do not use the plates without applied top seals. Damage caused by use of other consumables will void your warranty.

CAUTION **Validity of results**

Only use QIAcuityDx -specific consumables that are within the expiration date stated on them.

CAUTION **Damage to the instrument**

Do not drop objects into the instrument when the plate tray is ejected.

WARNING **Risk of explosion**

The QIAcuityDx is intended for use with reagents and substances supplied with QIAGEN kits or others that are outlined in respective Information for Use. Use of other reagents and substances may lead to fire or explosion.

CAUTION **Damage to the instrument**

Do not stack instruments and do not place items on top of the QIAcuityDx.

CAUTION **Damage to the instrument**

Do not lean against the touchscreen when it is pulled out.

WARNING **Risk of personal injury and material damage**

The QIAcuityDx is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. The bottom plane shall be used for lifting. Do not lift at the touchscreen.

Contact QIAGEN Technical Services to relocate the instrument.

WARNING **Risk of personal injury and material damage**

Load nanoplate only in accordance with step-by-step instructions provided by the QIAcuityDx Software. Beware of moveable parts.

WARNING **Risk of personal injury and material damage**

Do not stare into the beam of the nanoplate barcode reader.

CAUTION **Risk of material damage**

Avoid moving the workbench and causing vibrations to the QIAcuityDx during operation to prevent disturbing sensitive optical measurements.

CAUTION **Damage to the instrument**

Avoid spilling water or chemicals onto the QIAcuityDx. Instrument damage caused by water or chemical spillage will void your warranty.

CAUTION **Damage to the instrument**

Do not place items on top of the QIAcuityDx.

CAUTION **Damage to the instrument**

Make sure that the nanoplate is inserted in the correct position. Incorrect insertion of the nanoplate can damage the instrument.

WARNING **Fire hazard**

Empty the liquid waste bottle before each run and make sure to place it in the correct orientation back in the QIAcuityDx instrument. Spilling of liquidwaste may cause an electrical short-circuit and fire.

2.2. Electrical safety

Disconnect the line power cord from the power outlet before servicing.

WARNING **Electrical hazard**

Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection of the protective conductor terminal is likely to make the instrument dangerous.

Intentional interruption is prohibited.

Lethal voltages inside the instrument

When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts.

WARNING **Damage to electronics**

Before powering ON the instrument, make sure that the correct supply voltage is used.

Use of incorrect supply voltage may damage the electronics.

To check the recommended supply voltage, refer to the specifications indicated in the type plate of the instrument.

WARNING **Risk of electric shock**

Do not open any panels on theQIAcuityDx.

Risk of personal injury and material damage

Only perform maintenance that is specifically described in this user manual. Any other maintenance or repair may only be carried out by an authorized Field Service Specialist.

To ensure satisfactory and safe operation of the QIAcuityDx, follow the advice below:

- The line power cord must be connected to a line power outlet that has a protective conductor (earth/ground).
- Place instrument in a location so that the power cord is accessible and can be connected/disconnected.
- Use only the power cord delivered by QIAGEN.
- Do not adjust or replace internal parts of the instrument.
- Do not operate the instrument with any covers or parts removed.
- If liquid has spilled inside the instrument, switch off the instrument, disconnect it from the power outlet and contact QIAGEN Technical Services.

If the instrument becomes electrically unsafe, prevent other personnel from operating it and contact QIAGEN Technical Services.

The instrument may be electrically unsafe when:

- It or the line power cord appears to be damaged.
- It has been stored under unfavorable conditions for a prolonged period.
- It has been subjected to severe transport stresses.
- Liquids come in contact directly with electrical components of the QIAcuityDx.

2.3. Biological safety

Specimens and reagents containing materials from humans should be treated as potentially infectious. Use safe laboratory procedures as outlined in publications such as Biosafety in Microbiological and Biomedical Laboratories, HHS (**https://www.cdc.gov/labs/BMBL.html**).

2.3.1. Samples

Samples may contain infectious agents. You should be aware of the health hazard presented by such agents and should use, store, and dispose of such samples according to the required safety regulations.

WARNING **Samples containing infectious agents**

Samples used with the QIAcuityDx may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations.

Always wear safety glasses, gloves, and a lab coat.

The responsible body (for example, a laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe, and that the instrument operators are suitably trained and not exposed to hazardous levels of infectious agents as defined in the applicable Material Safety Data Sheets (MSDSs) or the OSHA1,* ACGIH,† or COSHH‡ documents.

Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.

* OSHA — Occupational Safety and Health Organization (United States of America)
† ACGIH – American Conference of Government Industrial Hygienists (United States of America)
‡ COSHH – Control of Substances Hazardous to Health (United Kingdom)

2.4. Environment

2.4.1. Operating conditions

WARNING **Explosive atmosphere**

The QIAcuityDx is not designed for use in an explosive atmosphere.

WARNING **Risk of explosion**

The QIAcuityDx is intended for use with reagents and substances supplied with QIAGEN kits. Use of other reagents and substances may lead to fire or explosion.

CAUTION **Damage to the instrument**

Direct sunlight may bleach parts of the instrument, cause damage to plastic parts. The QIAcuityDx must be located out of direct sunlight.

WARNING **Infection or microbial hazard**

Damage to the instrument in operation may result in exposure to infection or microbial hazards, as consumables may be contaminated with potentially infectious substances of human origin.

2.5. Chemical safety

Universal MasterMix

Contains: 2-methylisothiazol-3(2H)-one. May be harmful in contact with skin or if inhaled. Causes serious eye damage. Wear protective gloves/protective clothing/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF exposed or concerned: Immediately call a POISON CENTER or doctor/ physician. Dispose of contents/ container to an approved waste disposal plant.

H361 — Contains components which are Suspected of damaging fertility or an unborn child. Take appropriate precautions if pregnant.

Emergency information

CHEMTREC

USA & Canada: 1-800-424-9300

Outside USA & Canada: +1 703-527-3887

WARNING **Hazardous chemicals**

Some chemicals used with the QIAcuityDxmay be hazardous or may become hazardous after completion of purification.

Always wear safety glasses, gloves, and a lab coat.

The responsible body (for example, a laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe, and that the instrument operators are suitably trained and not exposed to hazardous levels of infectious agents as defined in the applicable Material Safety Data Sheets (MSDSs) or the OSHA1,* ACGIH,† or COSHH‡ documents.

Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.

* OSHA — Occupational Safety and Health Organization (United States of America)

† ACGIH – American Conference of Government Industrial Hygienists (United States of America)

‡ COSHH – Control of Substances Hazardous to Health (United Kingdom)

2.6. Waste disposal

Used labware may contain hazardous chemicals. Such wastes must be collected and disposed of properly according to local safety regulations.

For more information about how to dispose of the QIAcuityDx, see “Waste Electrical and Electronic Equipment (WEEE) ”, page 242242242.

CAUTION **Hazardous chemicals and infectious agents**

The waste contains samples and reagents. This waste may contain toxic or infectious material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures.

2.7. Mechanical hazards

The door of the QIAcuityDx should remain closed during operation of the instrument. Only handle the QIAcuityDx Nanoplate loading station when the QIAcuityDx Nanoplate door has been released by the software.

Note: Only power OFF the instrument if the process has been properly terminated by the software and the QIAcuityDx Nanoplate door is closed. Otherwise, the instrument could initialize with the QIAcuityDx Nanoplate door open.

WARNING **Moving parts**

To avoid contact with moving parts during the operation of the QIAcuityDx, the instrument must be operated with the door closed.

If the door sensor is not functioning correctly, contact QIAGEN Technical Services.

WARNING **Risk of overheating**

To ensure proper ventilation, maintain a minimum clearance of 100 mm at the sides and rear of the QIAcuityDx.

Slits and openings that ensure the ventilation of the QIAcuityDx must not be covered.

2.8. Maintenance safety

WARNING/ CAUTION **Risk of personal injury and material damage**

Only perform maintenance that is specifically described in this user manual.

WARNING **Risk of fire**

When cleaning the QIAcuityDx with alcohol-based disinfectant, leave the QIAcuityDx door open to allow flammable vapors to disperse.

CAUTION **Damage to the instrument**

Do not use bleach, solvents, or reagents containing acids, alkalis, or abrasives to clean the QIAcuityDx.

WARNING **Hot surface**

Internal components of the instrument can reach very hot temperatures. Wait until the cool down cycle has finished before handling the Nanoplate to avoid skin burns.

2.9. Symbols on the QIAcuityDx

Symbol	Description
CE	This product fulfills the requirements of the European Regulation (EU) 2017/746 for in vitro diagnostic medical devices (IVDR).
IVD	In vitro diagnostic medical device
REF	Catalog number
MAT	Material number
LOT	Lot number
GTIN	Global Trade Item Number
UDI	Unique Device Identifier
CONT	Contains
COMP	Component
	Date of manufacture
Rn	R is for revision of the Product Sheet and n is the revision number
Vn	V is for version of the Product Sheet and n is the version number
	Use-by date

Symbol	Description
	Temperature limitations
	Legal manufacturer
	Consult instructions for use
 <N>	Contains reagents sufficient for <N> reactions
	Protect from light

3. General Description

The QIAcuityDx performs fully automated processing of QIAcuityDx Nanoplates, including all necessary steps of nanoplate priming, sealing of partitions, thermocycling, and image analysis. Depending on the plate type and operation mode, up to 96 samples per plate can be analyzed. For diagnostic applications, the QIAcuityDx Nanoplate 26K is available. A total of 4 nanoplates can be simultaneously processed, with continuous loading possible. The QIAcuityDx Software controls all integrated modules, including a robotic gripper for nanoplate handling, a partitioning module, a PCR thermocycler, and a fluorescence imaging module.

Digital PCR run configuration is performed on the Software Suite that should be installed on a QIAcuityDx Notebook. The Software Suite also provides the graphical user interface for analysis of a QIAcuityDx run. Dedicated analytical algorithms are contained in Software Assay Plugins (SAPs) depending upon the mode of operation and the assay being performed. The Software Suite and QIAcuityDx instrument can be connected via a direct Ethernet connection, or via a Local Area Network (LAN).

3.1. QIAcuityDx principle

The QIAcuityDx is designed as a walk-away instrument that integrates and automates all plate processing steps. Only the nanoplate must be prepared manually before starting the run. This includes the pipetting of the target-specific reagents (primers, probes, and nucleic acid template) and master mix into the input wells of the nanoplate and the sealing of the nanoplate wells with the top seal. Once this preparation is completed and the experiment is set up, the nanoplate is placed in a free plate slot of the instrument tray. By reading the barcode of the plate, the instrument links the nanoplate to the experimental parameters previously defined in the software and after pressing the play button, all further steps are performed in a fully automated workflow by the instrument.

This includes the following process steps which are performed sequentially:

- **Partitioning**: In the first instrument module, the microchannels and partitions of the plate are filled with the sample material and dPCR reaction mix. This is accomplished by plunger pins compressing the elastic top seal of the nanoplate over each well. This creates a positive pressure that pumps the input well liquid into the microchannels and partitions. Subsequentially, the connecting channels between the partitions are sealed by activation of a pressure sensitive adhesive through a pressure-controlled rolling process (see Figure 1).

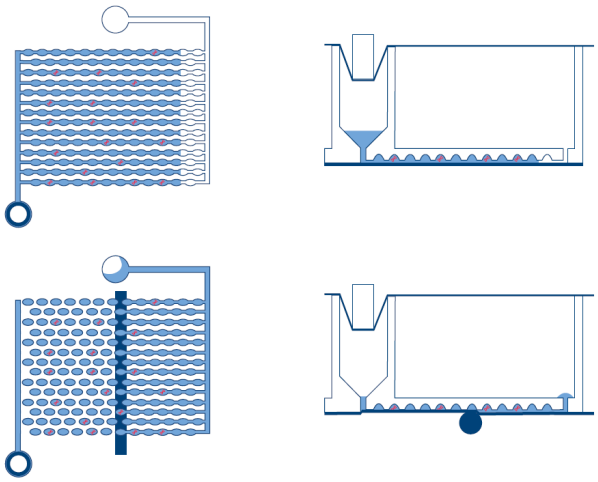


Figure 1. Scheme of filling and partitioning of a well.

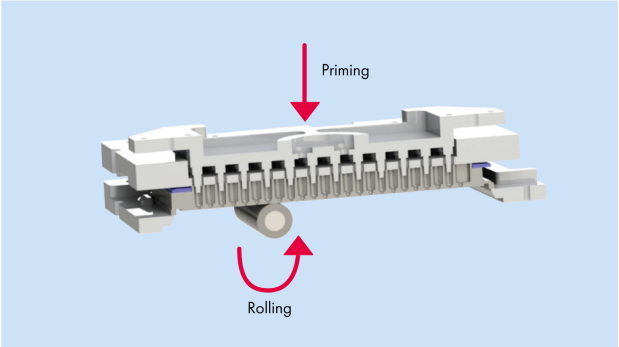


Figure 2. Principle of priming and rolling to allow partitioning of the wells.

- **Thermocycling**: During this second step of dPCR, a high-accuracy plate thermocycler performs the temperature cycling for the polymerase chain reaction. Within Utility mode, the cycling profile can be configured using the Software Suite. Within the IVD mode, the cycling profile is preset to optimized conditions, requiring no configuration by the user. For more details on the thermal cycler specification, see Section 8 Technical Specifications.
- **Imaging**: The final process step is the image acquisition, which captures the signal from each partition of the nanoplate wells. Within Utility mode, the user can configure the detection channels and imaging settings using the experiment setup functionality within the Software Suite. Within the IVD mode, the imaging settings are preset to optimized conditions, requiring no configuration by the user. The partitions which contain a target molecule will emit fluorescence with higher intensity than partitions without target (see Figure 1). For more details and specifications on the imaging system, see Section 8 Technical Specifications.

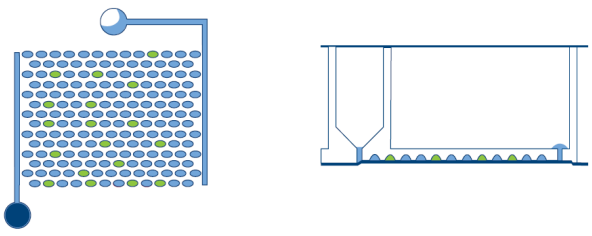


Figure 3. Scheme of positive (green) and negative (blue) partitions after imaging.

The concept of digital PCR has been around since 1992 when Sykes et al. (1) described it as "limiting dilution PCR." This general method used end-point analysis and Poisson statistics to quantify the absolute number of nucleic acid molecules present in a sample. This was followed by revolutionary work by Vogelstein and Kinzler in 1999, who developed a method whereby the sample was diluted and distributed into individual reactions called partitions, and single products with fluorescence signals were detected and analyzed after amplification. They then coined the term "digital PCR," as we all know it today.

Sample dilution and PCR reaction mix setup
Blue – Target
Red – Background (gDNA, cDNA; primers/probes; master mix)

PCR reaction partitioning into thousands of individual reactions

End-point PCR amplification of partitions
Green – Positive reactions
Blue – Negative reactions

Readout and absolute quantification

Figure 4. Absolute quantification in 4 steps.

While the sample is prepared in a similar manner for qPCR, sample partitioning, where a sample is divided into thousands of individual reactions before amplification, is unique to digital PCR. By random distribution of molecules into partitions, in contrast to the bulk analysis performed in qPCR, digital PCR minimizes the effects of competing targets and enhances precision and sensitivity to improve detection of rare targets in the researchers' or patients' sample.

Digital PCR allows researchers to:

- Quantify low-abundance targets or targets in complex backgrounds
- Detect and discriminate allelic variants (SNPs)
- Monitor small fold changes in target levels otherwise undetectable by qPCR

Contrary to real-time qPCR, dPCR does not rely on every amplification cycle to determine the relative amount of target molecule, which can be subject to differences in amplification efficiency. Rather, dPCR relies on Poisson and Binomial distribution statistics to determine the absolute target quantity following an end-point amplification, which reduces the impact of efficiency differences on the result.

As the target molecules are distributed randomly across all available partitions and all partitions contain the same volume of sample, the distribution of target genes encapsulated in the partitions of the well follows a Poisson distribution of parameter λ. In addition, the distribution of positive partitions in the well follows a binomial distribution of probability $1 - e^{-\lambda}$. This allows estimating the concentration of target in the sample, from the following equations:

$$\lambda = -\ln\left(\frac{\text{Number of valid partitions} - \text{number of positive partitions}}{\text{Number of valid partitions}}\right)$$

The 95% confidence interval of this distribution is a range given by:

$$\mathrm{Cl_{low}} = \lambda_{\mathrm{low}} = -\ln\left(1 - p + 1.96\sqrt{\frac{p(1-p)}{\text{Number of valid partitions}}}\right)$$

$$\mathrm{Cl_{high}} = \lambda_{\mathrm{high}} = -\ln\left(1 - p - 1.96\sqrt{\frac{p(1-p)}{\text{Number of valid partitions}}}\right)$$

Where:

$$p = \frac{\text{Number of positive partitions}}{\text{Number of valid partitions}}$$

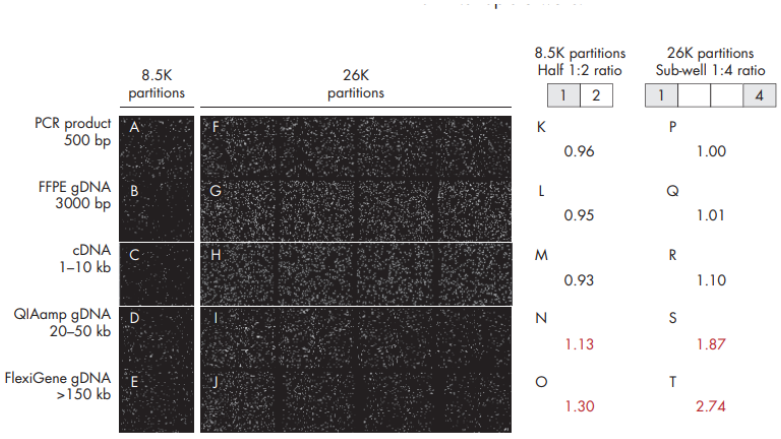
Poisson and Binomial–based statistical analysis of the number of positive and negative reactions yields a precise, absolute quantitation of the target sequence.

3.2. Sample input constraints

Digital PCR relies upon Poisson statistics for accurate quantification. During the partitioning process, template material, reaction mix, and assay components are pushed in a unilateral direction through the nanoplate partitions and connecting channels.

Any failure to uniformly distribute template material through the partitions violates the assumptions of Poisson law and results in calculation inaccuracies. To ensure that template is uniformly distributed, it is recommended to digest template material to 30 kb or less.

Enzymatic restriction digestion is the recommended approach for template digestion. This minimizes the likelihood of shearing regions of interest within target molecules that may occur in random shearing methods such as sonication or mechanical shearing.



For IVD applications, only the validated extraction methodology outlined in the application-specific Instructions for Use (IFU)/Handbook should be followed. Failure to do so may result in impaired performance.

3.3. External features of the QIAcuityDx

Front view (left side panel)

Rear view (left side panel)

1	Touchscreen display	5	Drawer eject button	9	Cooling air outlet
2	USB ports	6	RJ-45 Ethernet port	10	Transport screw
3	Power button	7	Mains inlet	11	Not shown – handheld barcode scanner
4	Drawer flap & LED status	8	Fuses		

3.3.1. Touchscreen display

The QIAcuityDx includes a swivel-mounted touchscreen. To adjust the angle of the touchscreen, pull gently at the bottom edge. The touchscreen enables the user to see an overview of all plate slots and the corresponding process steps and remaining times. Additionally, the touchscreen can be used to extend the plate tray, start/stop plate runs, and adjust the run schedule for loaded nanoplates. For all functions and instructions of the instrument software, see Section 5 Operating Procedures.

Figure 5. Touchscreen.

3.3.2. USB ports

The QIAcuityDx has two USB ports that are located at the front of the instrument in the upper left corner of the instrument housing. Additionally, a third USB slot is available behind the touchscreen in the upper right corner. To access this slot, extend the touchscreen as far as possible.

The USB ports allow connection of the QIAcuityDx to a USB stick. Data files, such as support packages and instrument log files, can be transferred via the USB port from the QIAcuityDx to the USB stick. The USB ports can also be used to plug in an external barcode reader or a mouse/keyboard.

Important: We recommend using QIAGEN USB sticks only to ensure full compatibility.

Important: Once a USB flash drive is plugged in, wait for approximately 15–20 seconds until the QIAcuityDx Software recognizes the storage drive.

Important: Do not remove the USB stick while downloading or transferring data or software to or from the instrument.

3.3.3. Power switch

The main power switch is located at the back of the QIAcuityDx. To power ON the QIAcuityDx, turn the power switch to "I" and press the blue soft-switch button at the front of the instrument. The startup screen appears, and the instrument automatically performs initialization tests.

To conserve energy, the QIAcuityDx can be powered OFF when not in use. To power OFF the QIAcuityDx, press the blue front soft switch.

Important: After powering OFF the QIAcuityDx, wait for a few seconds before switching ON the instrument again. The system might fail to start if you do not allow the QIAcuityDx to rest for a few seconds before powering ON.

3.3.4. Drawer flap and status LED

Once the drawer is ejected from the instrument, the flap will lower automatically. Upon placing a nanoplate in an available slot in the drawer and pressing the eject button once more, the drawer will retract and the internal barcode scanner will scan the nanoplate and will compare it with the database configured on the Software Suite. Depending on the plate status, the LED above the slot where the nanoplate was placed, will illuminate blue, green, or red.

LED color	Status
Green	Processing of the nanoplate in the instrument is completed.
Blue	The plate has been loaded and is in queue or processing.
Red	An error occurred during plate processing occurred or it is not possible to get plate information from the Software Suite.

3.3.5. Eject button

Pressing the drawer eject button either ejects or retracts the QIAcuityDx Four instrument drawer depending on its current position. This enables the operator to insert or remove nanoplates from the instrument.

3.3.6. RJ-45 Ethernet port

The RJ-45 Ethernet port is located at the back of the instrument beside the power cord socket. It is only used to connect the QIAcuityDx instrument to either a QIAcuityDx Notebook or local area network. Only the QIAGEN-provided ethernet cable should be used for this purpose.

Important: We recommend using QIAGEN-provided ethernet cable only to ensure stable connectivity between the QIAcuityDx and the Notebook/LAN.

3.3.7. Power cord socket

The power cord socket is located at the rear right of the QIAcuityDx and allows connection of the QIAcuityDx to a power outlet via the supplied power cord.

WARNING **Electrical hazard**

Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection of the protective conductor terminal is likely to make the instrument dangerous.

Intentional interruption is prohibited.

Lethal voltages inside the instrument

When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts.

WARNING **Damage to electronics**

Before powering ON the instrument, make sure that the correct supply voltage is used.

Use of incorrect supply voltage may damage the electronics.

To check the recommended supply voltage, refer to the specifications indicated in the type plate of the instrument.

WARNING **Risk of electric shock**

Do not open any panels on theQIAcuityDx.

Risk of personal injury and material damage

Only perform maintenance that is specifically described in this user manual. Any other maintenance or repair may only be carried out by an authorized Field Service Specialist.

3.3.8. Fuses

There is a position for two 12A replaceable fuses of size 5 x 20 mm [T12A L 250 V].

3.3.9. Cooling air outlet

Cooling air outlets are located at the rear side of the QIAcuityDx and allow cooling of the internal components of the QIAcuityDx.

WARNING **Risk of overheating**

To ensure proper ventilation, maintain a minimum clearance of 100 mm at the sides and rear of the QIAcuityDx.

Slits and openings that ensure the ventilation of the QIAcuityDx must not be covered.

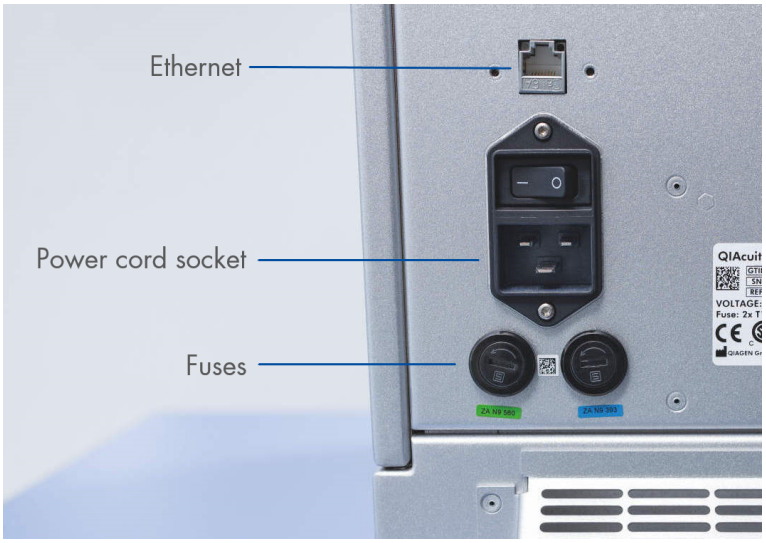


Figure 6. Back view of the QIAcuityDx.

3.3.10. Transportation screw

A transportation screw is used to hold the internal handling module arm in place. It will be removed by the field service upon installation. The screw must be retained with the instrument in case the instrument needs to be moved.

Important: The transport screw must be removed prior to powering on the QIAcuityDx Four instrument. Failure to do so may result in damage to the instrument.

3.3.11. External barcode scanner

The QIAcuityDx includes a barcode scanner as a provided accessory. This enables the user to scan the nanoplate ID before loading and decrease the likelihood of transcription errors.

WARNING **Risk of personal injury**

Hazard Level 2 laser light: Do not stare into the light beam when using handheld barcode scanner.

3.4. Internal features of the QIAcuityDx

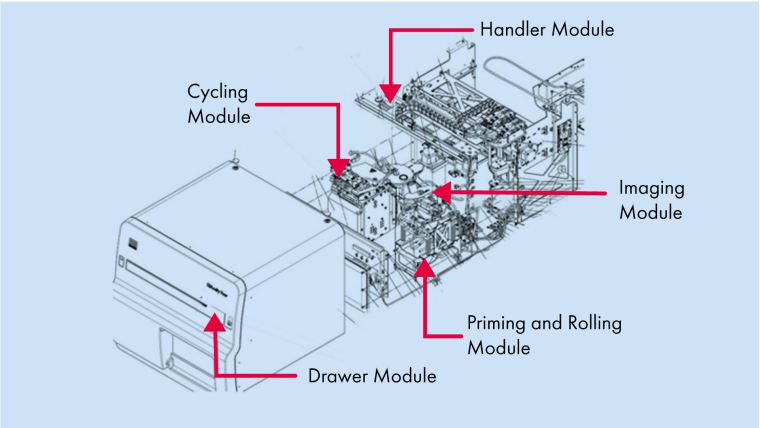


Figure 7. Internal view of the fluidic drawer.

1	Drawer module	**4**	PCR thermocycling module
2	Handling module	**5**	Imaging module
3	Priming and rolling module		

3.4.1. Drawer

The Drawer module acts as the human-to-instrument interface to insert and retrieve the nanoplates containing samples for analysis. There are four slots where nanoplates can be placed, and when the drawer is retracted into the instrument, above each nanoplate slot is a sensor to check for the presence of a nanoplate and to check loaded nanoplates have an affixed top seal.

The QIAcuityDx drawer includes a cutout design to support correct loading of nanoplates. In the event of loading a nanoplate in the incorrect orientation, the internal barcode scanner will not detect the loaded nanoplate and a run will not proceed. Please ensure that the nanoplates are correctly loaded into the drawer slot and are flat within the drawer prior to closing the drawer.

The QIAcuityDx drawer includes a sensor to detect the presence of loaded nanoplates that have a QIAcuityDx top seal attached. Inverted nanoplates or those without a top seal will not be detected by the QIAcuityDx drawer and a run will not proceed.

The handing module of the QIAcuityDx consists of a gripper assembly, rails, and motors along which the assembly can move to allow nanoplate movement within the instrument. Additionally, the handling module includes a 1D/2D barcode scanner that supports traceability of loaded nanoplates, and mitigates incorrect loading of nanoplates.

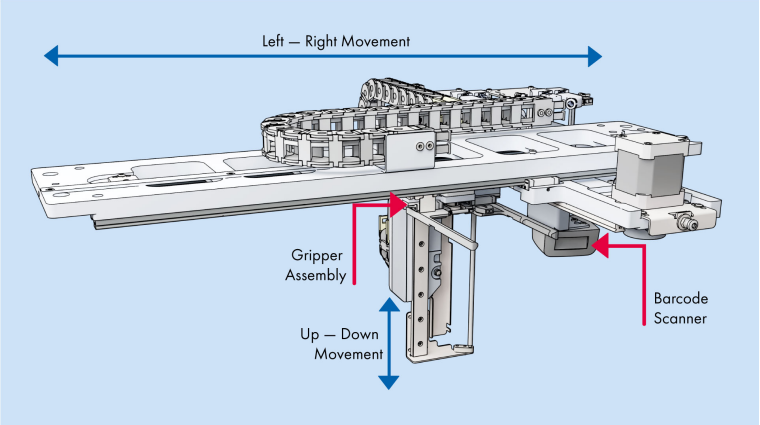


Figure 8. Handling module.

3.4.2. Priming and rolling module

The priming and rolling module is an internal hardware component that performs the following steps inside the instrument following plate loading:

- Sample partitioning
- Secondary nanoplate sealing

It consists of 3 motors, a priming pin-plate, a nanoplate clamp, rollers springs, and a load cell. The priming and rolling module functions to move sample and reaction mix into the partitioned area of a nanoplate for downstream amplification and imaging.

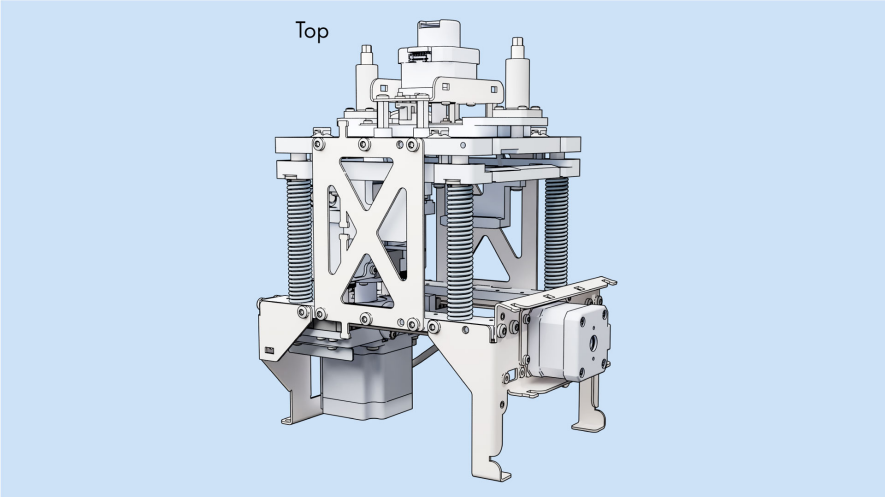


Figure 9. Priming and Rolling Module – Front view.

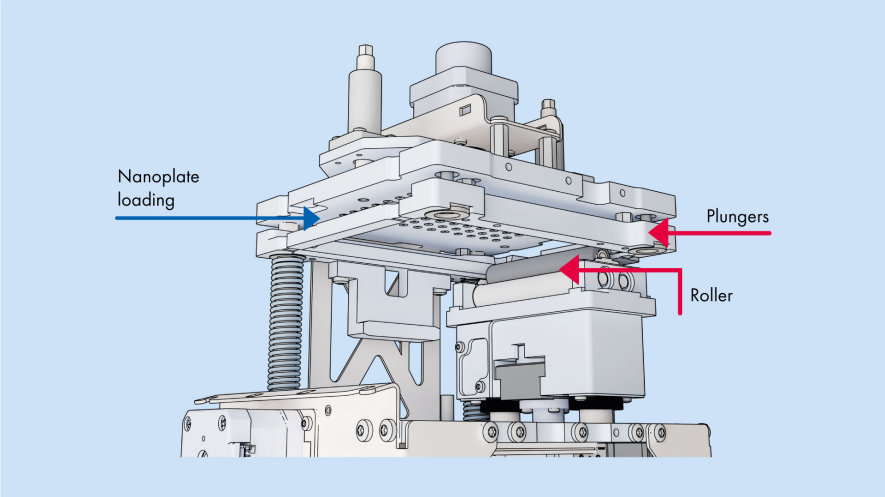


Figure 10. Priming and Rolling Module – Cross section.

3.4.3. PCR thermocycler module

The thermocycler of the QIAcuityDx is a plate thermocycler that features high speed and precision temperature control of the temperature cycling steps. Several Peltier elements are used for the temperature generation and control. For an optimal thermal contact between plate and thermocycler, the nanoplate is clamped on the heating surface during cycling.

The thermocycler has the following specification:

Process temperature:	40–99°C (Control overshoot to 110°C)
Ramp rate:	approx. 3.0°C/s
Accuracy:	±1°C
Homogeneity:	±1°C

3.4.4. Imaging module

The optical system of the QIAcuityDx is a camera-based fluorescence microscopy system. The excitation source for the fluorescence dyes is a high-power white LED. This source in combination with a specific excitation filter is used to illuminate one whole well at a time. The unquenched fluorophores in each partition absorb filtered light and subsequently emit light that is filtered by a detection filter prior to collection and imaging through an objective lens on a CMOS-camera chip (see Figure 11 for a detailed overview of the components). The QIAcuityDx includes five detection channels. Within the Utility mode users can configure QIAcuityDx dPCR runs to image in required channels. Within the IVD mode, the imaging settings are preset to optimized conditions, requiring no configuration by the user.

An additional channel is used for detecting filled partitions using a passive dye within the QIAcuityDx Universal MasterMix Kit. Reference signal is used to determine the exact number of valid partitions and to normalize fluorescence data.

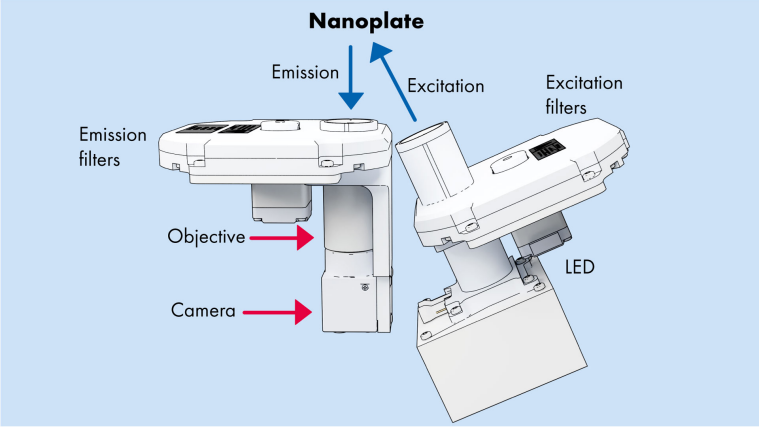


Figure 11. Schematic of Imaging module.

The QIAcuityDx is optimized for use with the following fluorophores in the corresponding optical channels.

Table 2. Optical channels for the QIAcuityDx

Channel	Excitation (nm)	Emission (nm)	Supported fluorophores
Green	463–503	518–548	FAM™
Yellow	514–535	550–564	HEX™
Orange	543–565	580–606	TAMRA™
Red	570–596	611–653	ROX™
Crimson	590–640	654–692	Cy5®

Important: An integrated crosstalk correction is applied to images generated by the QIAcuityDx. This correction is to minimize the effects of spectral overlap between neighboring optical channels and fluorophores. Use of nonsupported dyes may result in sub-optimal crosstalk correction leading to image artifacts.

4. Installation Procedures

The information provided here is needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer. Installation is performed by a certified QIAGEN Field Service Specialist on the QIAcuityDx Four instrument. Any installation instruction provided is for information purposes only to help you prepare for the installation.

4.1. System delivery and installation

The unpacking and installation of QIAcuityDx must be performed by a certified QIAGEN Field Service Specialist. A person who is familiar with the laboratory and computer equipment should be present during the installation.

The following items are delivered:

- QIAcuityDx instrument
- *QIAcuityDx System User Manual*
- QIAcuityDx Notebook
- QIAcuityDx Software (will be installed by QIAGEN Field Service during initial set up)

The manufacturer's warranty will be invalidated if the package has been opened prior to QIAGEN Field Service arrival.

4.2. Site requirements

The QIAcuityDx must be positioned away from direct sunlight, away from heat sources, and away from sources of vibration and excessive electrical interference. Refer to Section 8 Technical Specifications for the operating conditions (temperature and humidity). Be aware that ambient temperatures below 17°C (63°F) require an equilibration phase of approximately 30–60 minutes at the location where the instrument will be used before the instrument is powered on. The site of installation should be free from excessive drafts, excessive moisture, excessive dust and should not be subject to large fluctuations in temperature.

Use a level workbench that is large enough and strong enough to accommodate the QIAcuityDx. Refer to Section 8 Technical Specifications for the weight and dimensions of the QIAcuityDx. Allow at least 100 mm (5.9 in.) of free space behind and to the sides of the instrument for cooling and cabling.

Ensure that the workbench is dry, clean, vibration-proof and has additional space for accessories.

The QIAcuityDx must be placed within approximately 1.5 m of a properly grounded (earthed) AC power outlet. The power line to the instrument should be voltage-regulated and surge-protected. Ensure that the QIAcuityDx is positioned where it is easy to access the power connector and the power switch, at the back of the instrument, always to ensure that it is easy to power the instrument OFF and disconnect it.

Note: We recommend plugging the instrument directly into its own power outlet and not to share the power outlet with other laboratory equipment. Do not place the QIAcuityDx on a vibrating surface or near vibrating objects.

WARNING **Risk of overheating**

To ensure proper ventilation, maintain a minimum clearance of 100 mm at the sides and rear of the QIAcuityDx.

Slits and openings that ensure the ventilation of the QIAcuityDx must not be covered.

WARNING **Risk of personal injury and material damage**

The QIAcuityDx is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. The bottom plane shall be used for lifting. Do not lift at the touchscreen.

Contact QIAGEN Technical Services to relocate the instrument.

4.3. Power requirements

The QIAcuityDx operates at 100–240 V AC, 50/60 Hz, 900 VA (max.).

Ensure that the voltage rating of the QIAcuityDx is compatible with the AC voltage available at the installation site. Main supply voltage fluctuations should not exceed 10% of nominal supply voltages.

WARNING **Damage to electronics**

Before powering ON the instrument, make sure that the correct supply voltage is used.

Use of incorrect supply voltage may damage the electronics.

To check the recommended supply voltage, refer to the specifications indicated in the type plate of the instrument.

WARNING **Electrical hazard**

Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection of the protective conductor terminal is likely to make the instrument dangerous.

Intentional interruption is prohibited.

Lethal voltages inside the instrument

When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts.

4.4. Grounding requirements

To protect operating personnel, the National Electrical Manufacturers' Association (NEMA) recommends that the QIAcuityDx be correctly grounded (earthed). The instrument is equipped with a 3-conductor AC power cord that, when connected to an appropriate AC power outlet, grounds (earths) the instrument. To preserve this protection feature, do not operate the instrument from an AC power outlet that has no ground (earth) connection.

4.5. Workstation requirements

The QIAcuityDx Software Suite is designed to work with Windows® 11 operating system. The following browsers were tested in the QIAcuityDx Software Suite:

- Mozilla® Firefox®: version 122.0
- Microsoft Edge®: version 120.0.2210.77
- Google Chrome®: version 121.0.6167.85

The QIAcuityDx Four instrument is supplied with a notebook; see the following table for the recommended notebook requirements.

Table 3. Workstation system requirements

Description	Minimum requirement
Operating system	Microsoft® Windows 11 64-bit versions as follows: • Windows 11 21H2 Professional • Windows 11 21H2 Enterprise • Windows 11 22H2 Professional • Windows 11 22H2 Enterprise
Processor	x64 compatible processor with 4 physical cores and 2.5 GHz
Main memory	16 GB RAM
Hard disk space	At least 500 GB
Graphic card	Intel® UHD Graphics 630
Display	At least 1920 x 1080 pixels
Ports	2 USB 3.1 Gen 1 1 USB 3.1 Gen 1 (1 charging) 2 USB Type-C port with Thunderbolt 3, pass through support DisplayPort 1.4, USB 3.1 Gen 2, with BC 1.2 support

4.6. Unpacking the QIAcuityDx

WARNING **Risk of personal injury and material damage**

The QIAcuityDx is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. The bottom plane shall be used for lifting. Do not lift at the touchscreen.

Contact QIAGEN Technical Services to relocate the instrument.

Note: Before unpacking the QIAcuityDx, move the package to the site of installation and check that the arrows on the package point upward. In addition, check whether the package is damaged. In case of damage, stop here and contact QIAGEN Technical Services.

1. Cut the straps securing the packaging to the shipping pallet.
2. Open the top of the transportation box to remove the accessories set before lifting the box.
3. Remove the top and side protective black foam.
4. When lifting the QIAcuityDx, we recommend utilizing a minimum of 2 people. Lift the instrument by sliding your hands under both sides of the workstation and keeping your back straight.

   Important: Do not hold the touchscreen display while unpacking or lifting the QIAcuityDx as it might damage the instrument.
5. Check the packing list document is included after unpacking the QIAcuityDx.
6. Read the packing list to check that you have received all items. If anything is missing, contact QIAGEN Technical Services.
7. Check that the QIAcuityDx is not damaged and that there are no loose parts. If anything is damaged, contact QIAGEN Technical Services. Make sure that the QIAcuityDx has equilibrated to ambient temperature before operating it.
8. **Important**: Remove the transport screw prior to powering on the QIAcuityDx instrument.
9. Retain the packaging in case you need to transport the QIAcuityDx in the future. Refer to Section 4.7 for more details. Using the original packaging minimizes the possibility of damage during transportation of the QIAcuityDx.

4.7. Repackaging and shipping the QIAcuityDx

When repackaging the QIAcuityDx for shipping, the original packaging materials must be used. If the original packaging materials are not applicable, contact QIAGEN Technical Services. Make sure that the instrument has been properly prepared (see Section 6 Maintenance) prior to packing and ensure that the QIAcuityDx poses no biological or chemical hazard.

WARNING **Risk of personal injury and material damage**

The QIAcuityDx is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. The bottom plane shall be used for lifting. Do not lift at the touchscreen.

Contact QIAGEN Technical Services to relocate the instrument.

Note: Before transporting the QIAcuityDx, the instrument must first be decontaminated. Refer to Section 6 Maintenance for more details. Then, prepare the instrument as follows:

1. Turn off the instrument and unplug the power cord.
2. Reinstall the shipping fixation screw.
3. Prepare the packing material. Materials required are the cardboard carton, the pallet with foam blocks, and the foam lid.
4. Place the QIAcuityDx onto the pallet and put the black foam lid over the top of the instrument. Place the box onto the instrument.

   Important: When lifting the QIAcuityDx, slide your hands under both sides of the instrument and keep your back straight.

   Important: Do not hold the touchscreen display while lifting the QIAcuityDx, as this might damage the instrument.

   WARNING **Risk of personal injury and material damage**

   The QIAcuityDx is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. The bottom plane shall be used for lifting. Do not lift at the touchscreen.

   Contact QIAGEN Technical Services to relocate the instrument.

5. Place the accessories into the black foam lid.

   Important: The power cord must be packed in an air cushion bag.

6. Seal the outside edges of the carton with tape to protect against moisture.

   Note: Using the original package minimizes potential damage during transportation of the QIAcuityDx.

4.8. Installing the QIAcuityDx

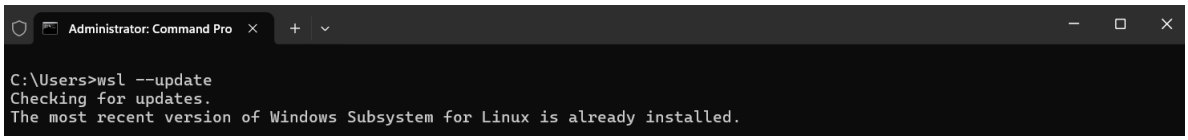
Installation is carried out by a certified QIAGEN Field Service Specialist for the QIAcuityDx Four instrument.

4.9. Installing the QIAcuityDx Software Suite

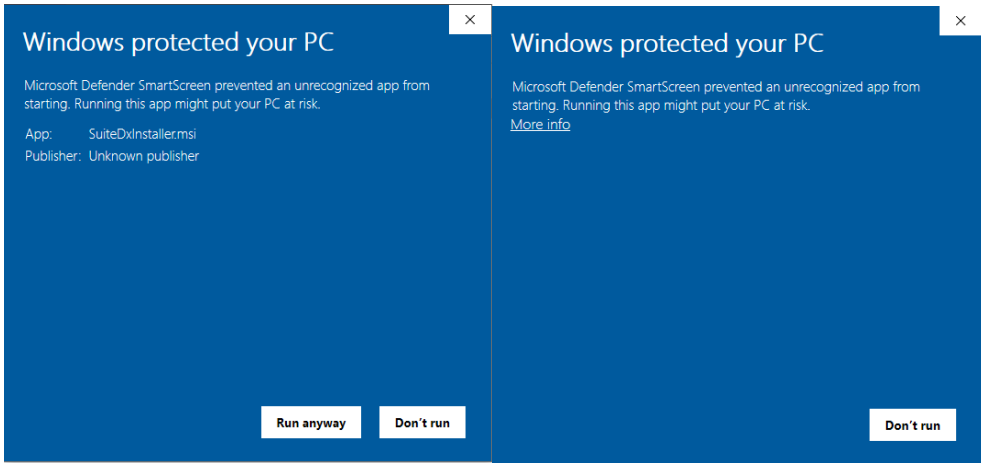
This section is optional; most customers will be supplied with a notebook preinstalled with the Software Suite.

To install Software Suite, it is required to have administration rights. Once it has been verified that the user has administration rights, the Software Suite can be installed following the next steps:

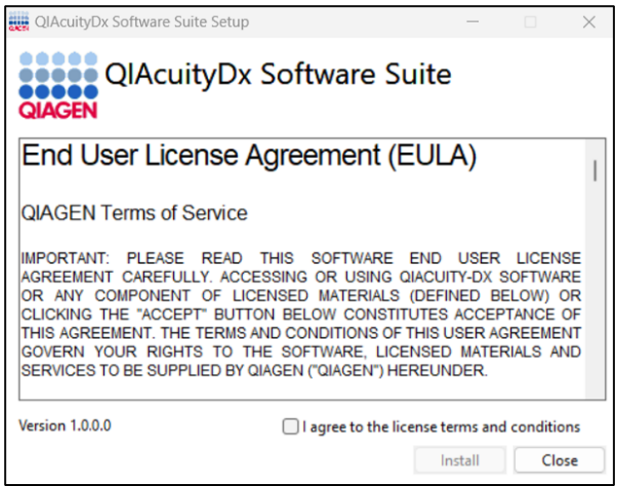
1. Hyper-V is installed and enabled in Control Panel's "Turn Windows features on or off".
2. Virtual Machine Platform is installed and enabled in Control Panel's "Turn Windows features on or off".
3. Windows Subsystem for Linux (WSL) is installed and enabled in Control Panel's "Turn Windows features on or off".
4. WSL is updated and running.
   a. Execute the following command in Command Prompt:



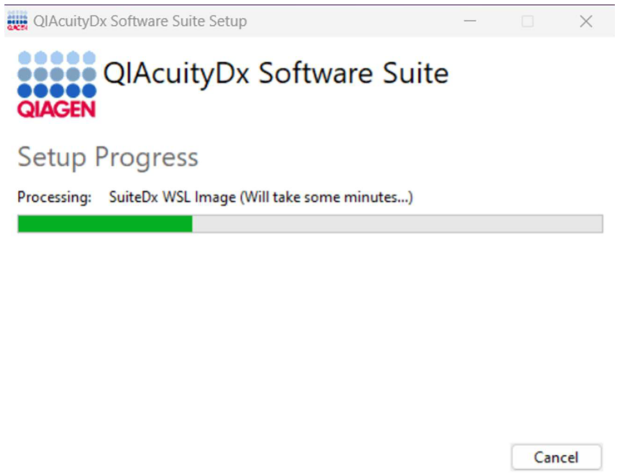
5. The Software Suite installer will be provided by a field service engineer.
6. Double-click the **SuiteDxInstaller.exe** file to start the installation process.
7. The installer will check whether the required software described in steps 1–4 are installed and enabled. In case the installation process fails, an error message will be displayed.
8. Afterwards, the following will be displayed (because the current installer is not certified by a valid Publisher). Click the **More info** link followed by the **Run Anyway** button:



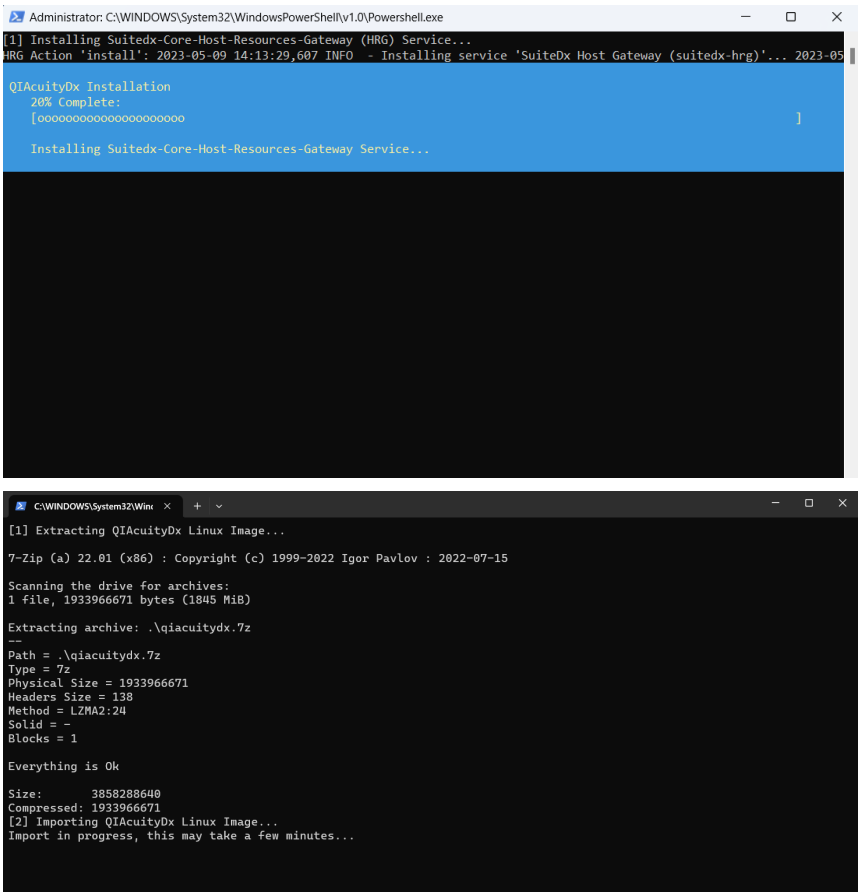
9. The Software Suite License Agreement will be displayed. Tick the checkbox and click the **Install** button.



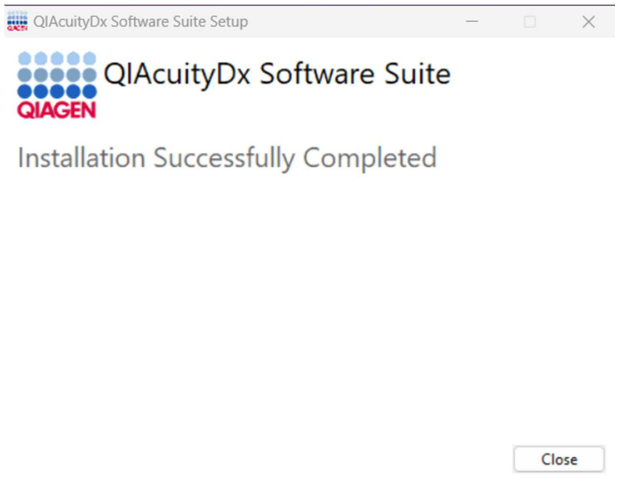
10. In case a prompt requesting Administrator rights is displayed, grant Administrator permission to continue.
11. The Software Suite installation will start.



12. During the process, some windows will be opened with the output of internal script executions. Do not interact with or close them.



13. Once the services' configuration has finished, then the installation is complete. Click **Finish**.

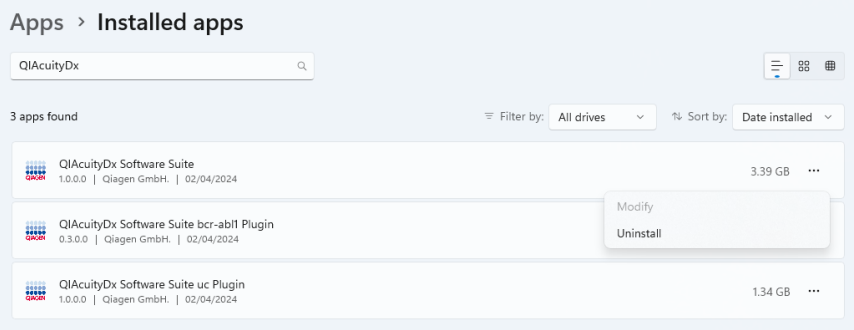


4.9.1. Uninstalling the QIAcuityDx Software Suite

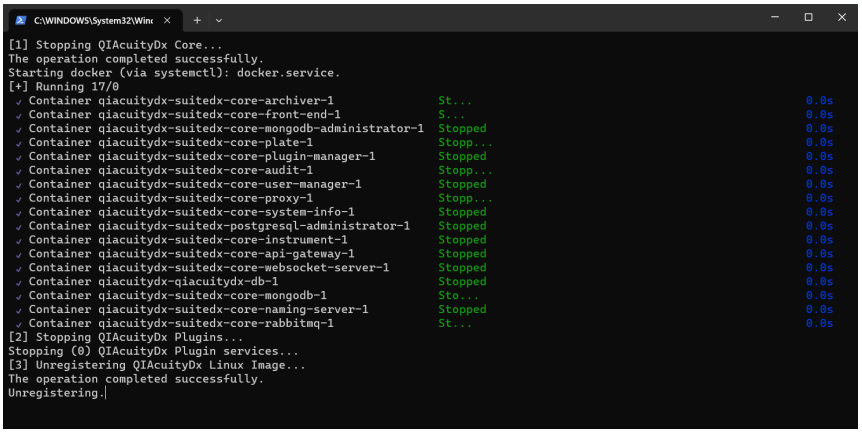
Note that all data will be deleted, including plate data, when the Software Suite is uninstalled. It is highly recommended to create a backup before uninstalling the Software Suite.

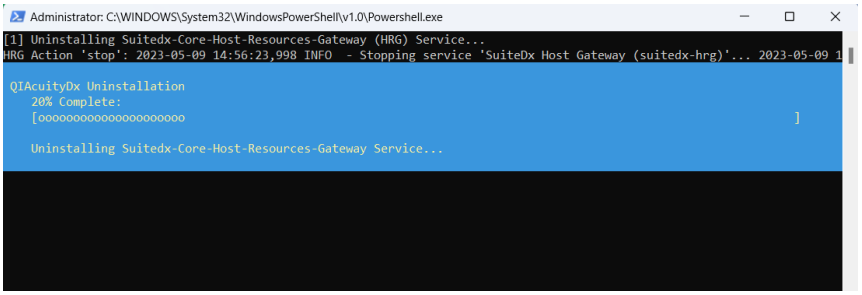
To uninstall the Software Suite, follow these steps:

1. Go to **Add or remove programs**, which is accessible from Windows' Control Panel or the **Start** menu.
2. Search "QIAcuityDx" in the Installed apps, click the 3-dot menu on Software Suite, and click **Uninstall** for each application installed.



During the process, some windows might be opened with the output of internal script executions. Do not interact with or close them:





No confirmation will be needed to finish the process.

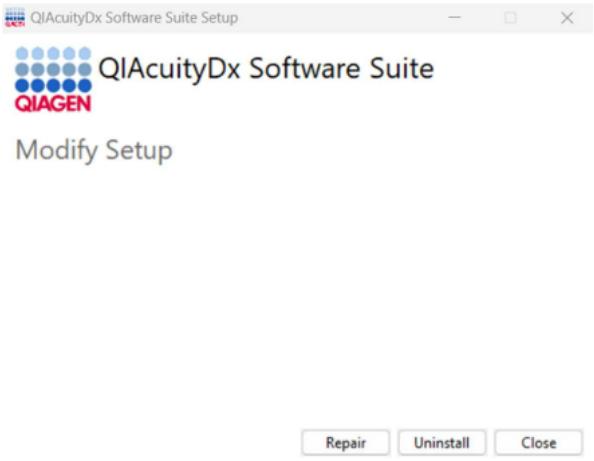
The installation wizard will be opened. Click **Uninstall** again to confirm uninstallation.

4.9.2. Repairing QIAcuityDx Software Suite installation

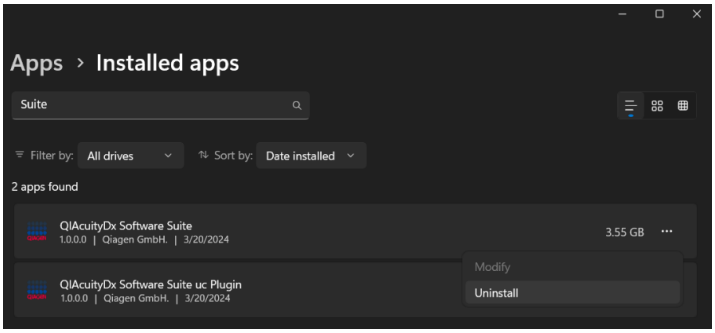
The installer's Repair feature will restore the Software Suite to a stable state with no data loss. All the installation files will be restored, and the scripts will be executed again to have the Software Suite running properly.

Repair feature can be accessed double-clicking directly in the Software Suite installer:

1. Double-click on the installer file, and select **Repair** option after the License agreement:
   a. In case the installer has been removed from the computer, click **Add or remove programs**, which can be found in Windows' Control Panel. If not, skip to step 2.



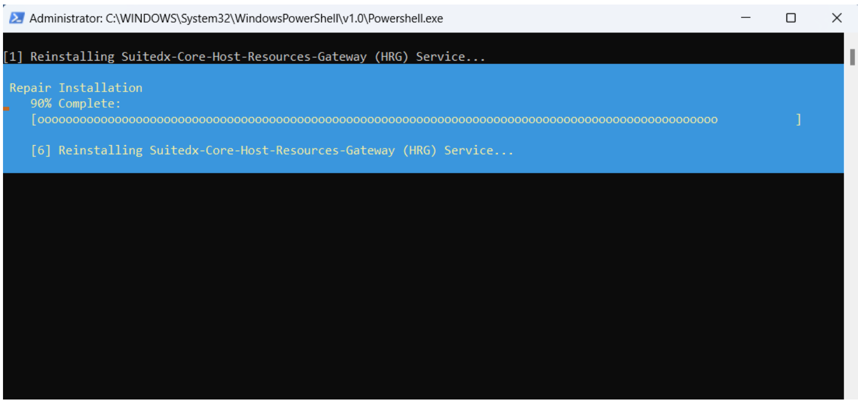
   b. Search "Suite" in the Installed apps, click the 3-dot menu on the Software Suite, and click **Uninstall**.

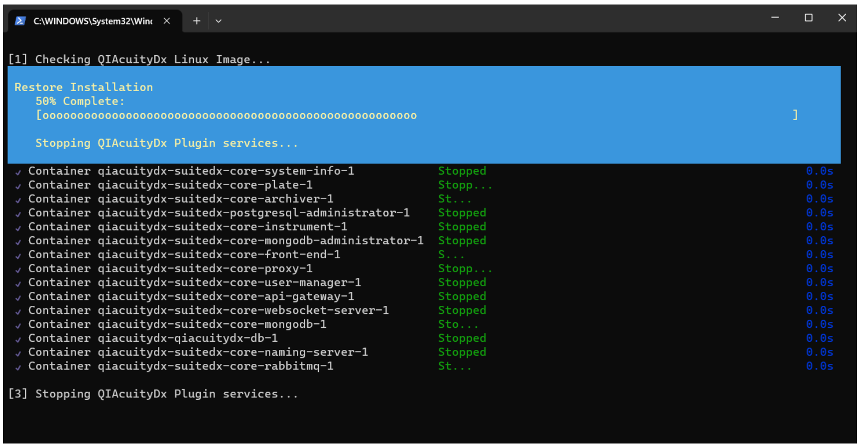


   The installation wizard will be displayed.

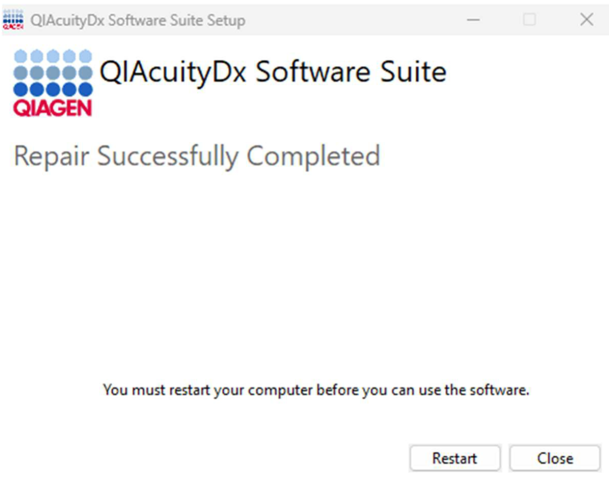
   c. There, click **Repair**.

2. During the process, some windows will be opened with the output of internal script executions. Do not interact with or close them.





3. Once completed, click on **Finish** to close the installer and finish the process.



4. Restart the computer as specified in the installation wizard to complete the repair process.

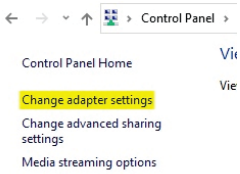
4.9.3. Establish direct connection between QIAcuityDxinstrument and QIAcuityDx Software Suite

When the connection has been established between a computer and the QIAcuityDxinstrument via Ethernet cable, a new Ethernet adapter network will appear when command “ipconfig” is executed using the Command Prompt (**.cmd**). Moreover, the Software Suite computer firewall should be configured to allow incoming connection on ports 8687 TCP, 8080 TCP, 44321 TCP, and 9595 UDP.

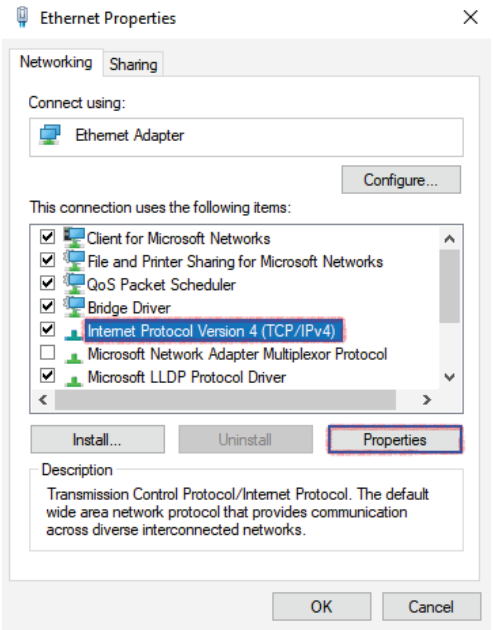
Modify IP address

The IP address of the new network must be modified to establish direct connection between the QIAcuityDx instrument and the computer running Software Suite. Follow these steps to modify the IP address:

1. Go to **Control Panel** > **Network and Internet** > **Network and Sharing Centre**.
2. Select **Change adapter settings**.



3. Right-click over the new Ethernet network adapter, and select the **Properties** option.
4. Ethernet Properties pop-up is displayed.
5. Select **Internet Protocol Version 4 (TCP/IPv4)**, and click **Properties**.

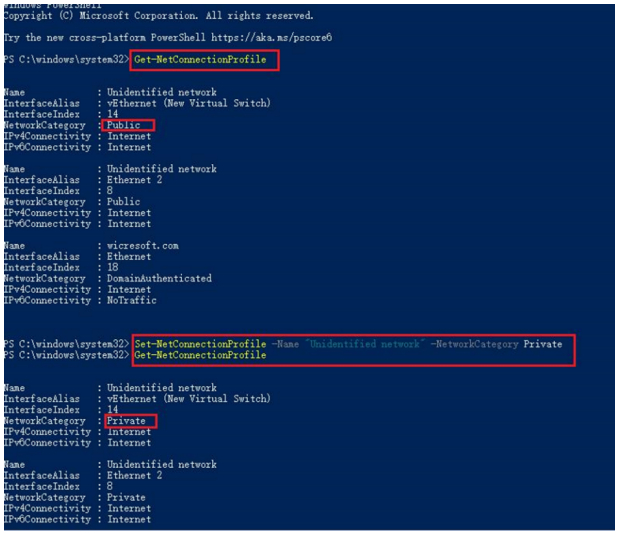


6. Select **Use the following IP address**. Enter the following information:
    - **IP address**: 192.168.1.1
    - **Subnet mask**: 255.255.255.0
    - **Default gateway**: 192.168.1.2
7. Click **OK**, then click **Close**.

Check NetworkCategory

The "NetworkCategory" of this new network on your computer must be set as Private instead of Public. To check and, if necessary, modify the networks "NetworkCategory", follow these steps:

1. Run PowerShell as administrator.
2. Enter the command "Get-NetConnectionProfile", and press **Enter**.
    - Information is shown for all active network connections.
3. Check if the "NetworkCategory" is set as Public or Private.
    - If it is set Private, no additional steps are required.
    - If it is set as Public, continue with the next step.
4. Enter the command "Set-NetConnectionProfile -Name NetworkName -NetworkCategory Private".
    - Replace "NetworkName" with the value of the Name field shared by the previous command (it might be "Unidentified network").
5. To double check that the network location was changed, run the **Get-NetConnectionProfile** command again and check the results.

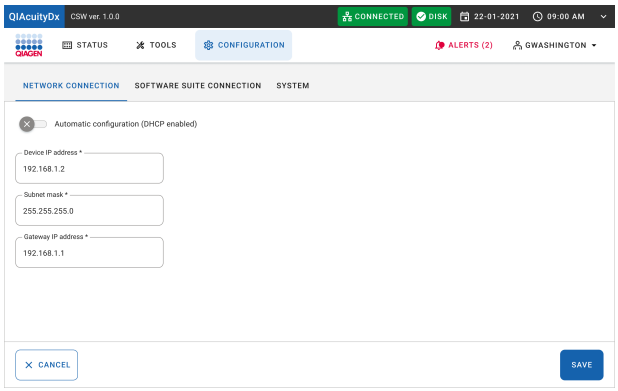


The "NetworkCategory" field should have a different value.

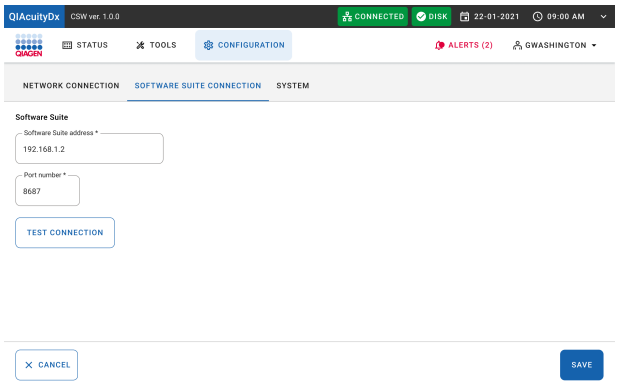
Instrument configuration

To make the instrument operative, it is necessary, at its first startup, to perform an initial configuration.

1. If it is not already running, power on the instrument by pressing the power button.
2. After an initial self-test, the Login screen appears.
3. On the status bar at the top, it is indicated that the instrument is not connected to the Software Suite.
4. Login using the “SetupUser”.
5. On the QIAcuityDx instrument toolbar, tap **Configuration**.
6. Select the **Ethernet** tab.
7. Ensure that the DHCP Enabled box is not checked. Enter the following information:



8. Select the **Software Suite Connection** tab, and enter the following information:



9. Click the **Test Connection** button.

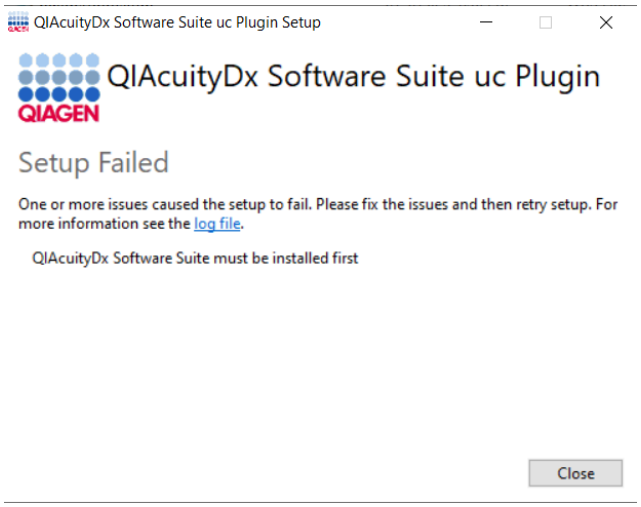
   A message stating that the connection has been established successfully is displayed onscreen.

10. Click the **Save** button.

    A pop-up window is displayed onscreen requesting user to restart the QIAcuityDx instrument; after restart, the instrument will be properly connected to the specified QIAcuityDx Software Suite.

4.10. Installing the QIAcuityDx Software Assay Plugin

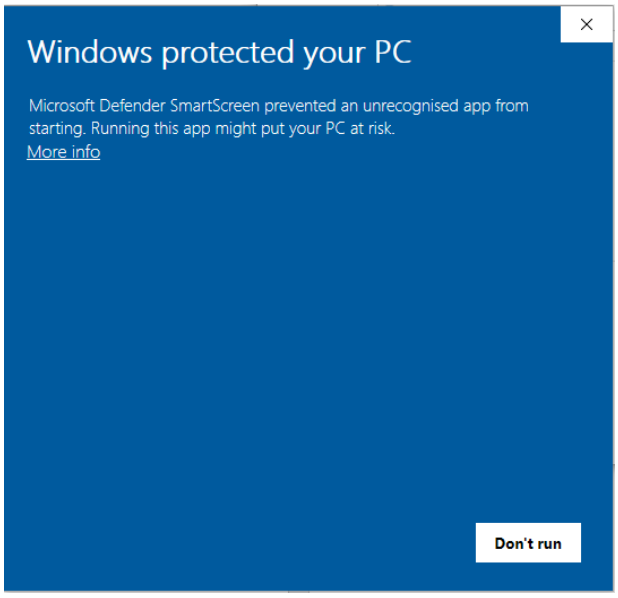
The Software Suite must be installed in the same environment (LAN) / Notebook where the QIAcuityDx Software Assay Plugin will be installed; otherwise, the following error will be displayed:



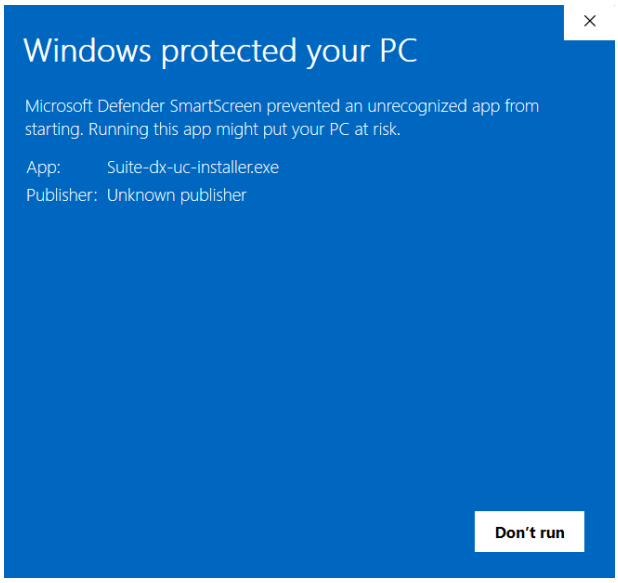
The following procedure is valid for all QIAcuityDx Software Assay Plugins currently available:

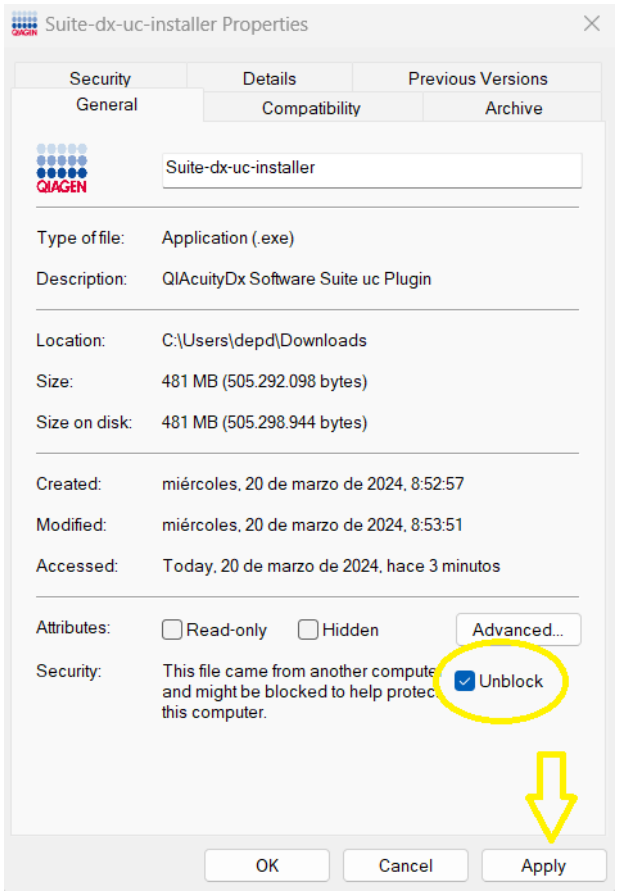
Note: The QIAcuityDx Software Assay Plugin installer(s) will be provided by a field service engineer.

1. Ensure that all the instructions described in Section 4.9 has been followed and that the Software Suite is currently running (execute script **Start-SuiteDx.bat**).
2. Double-click the plugin installer file to start the installation process.
3. The following pop-up will be displayed onscreen. Click the **More info** link, then click the **Run Anyway** button:

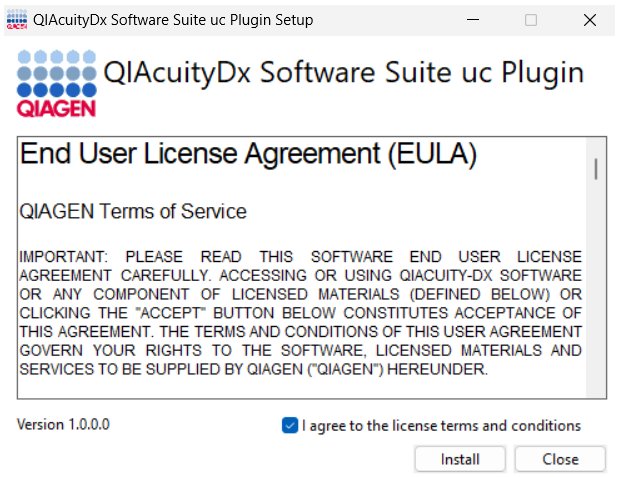


Note: If the option "Run anyway" is not displayed after clicking **More info**, check the **Suite-dx-uc-installer.exe** file properties and ensure that the Unblock checkbox is checked in the **General** tab > **Security**:

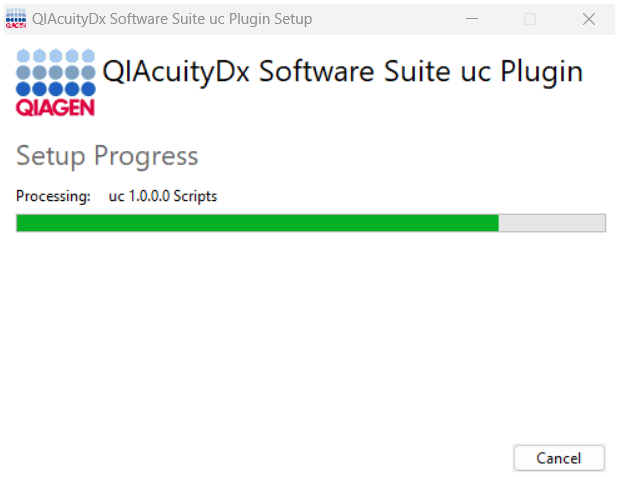




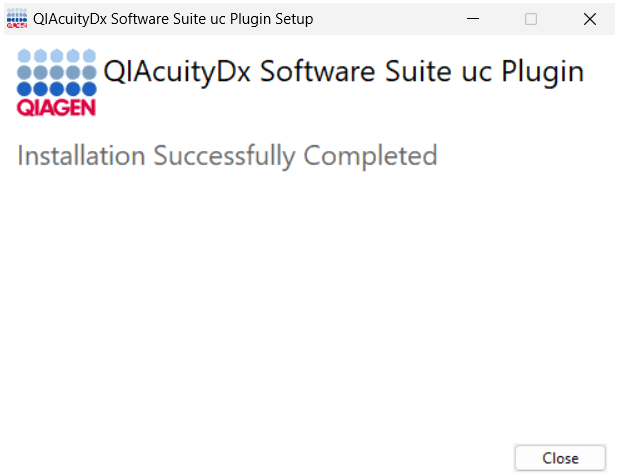
4. The QIAcuityDx Software Assay Plugin License Agreement will be displayed. Check the checkbox and click the **Install** button.



5. In case a prompt requesting Administrator rights is displayed, grant Administrator permissions to continue.
6. The QIAcuityDx Software Assay Plugin installation will begin.



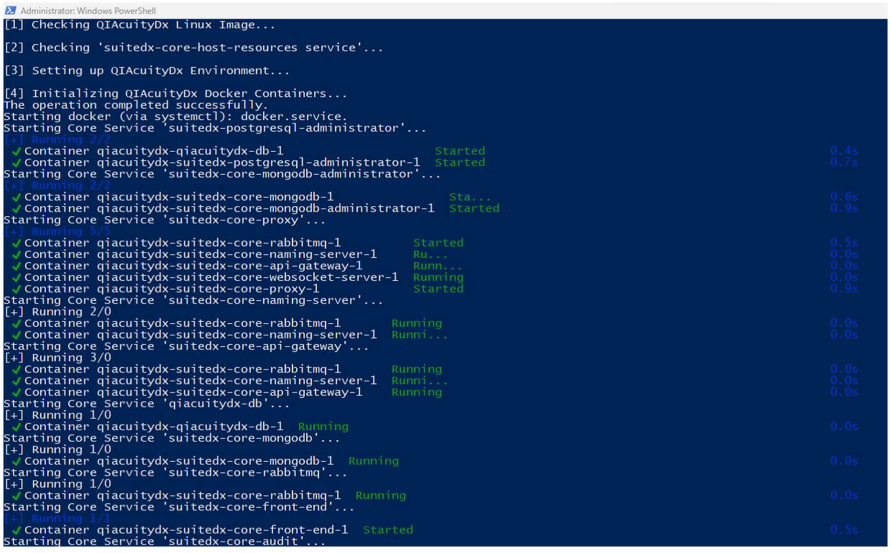
7. Once the services' configuration has finished, the installation is complete. Click **Finish**.



4.10.1. Start the QIAcuityDx Software Assay Plugin

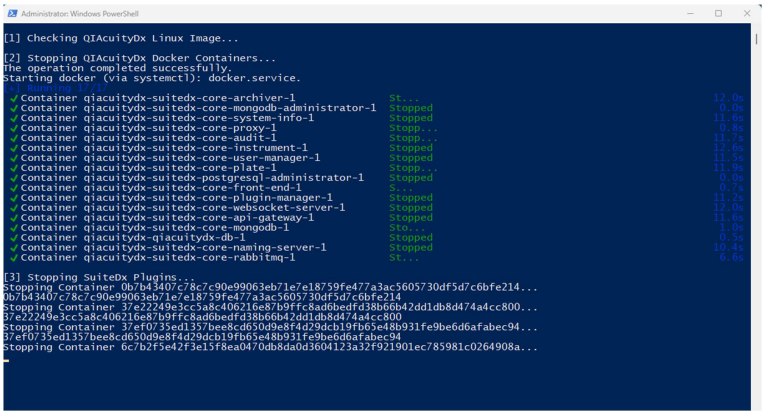
As part of the installation process, a new folder will be created for each assay plugin installed in the path `C:\Program Files\Qiagen\QIAcuityDx\[Plugin-Version]`.

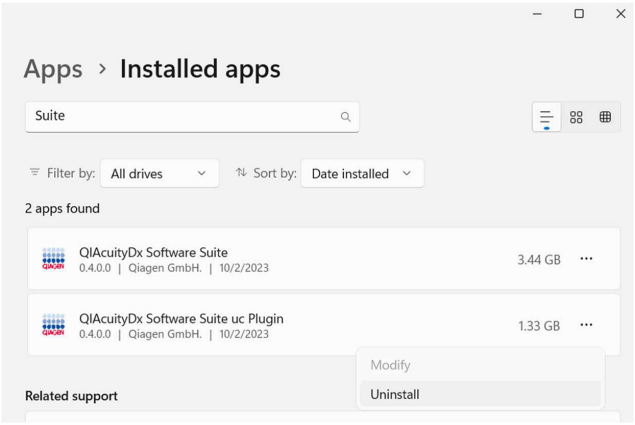
The QIAcuityDx Software Assay Plugin(s) are automatically initialized when running the Software Suite that can be performed by executing the **Start-SuiteDx.bat** script, which will check whether all services related to the Software Suite and Assay Plugins have been installed properly and start them.

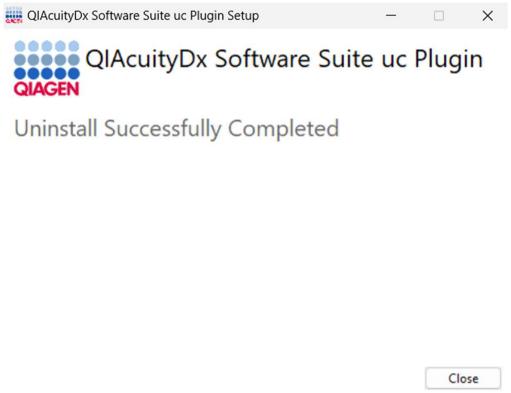


4.10.2. Stop the QIAcuityDx Software Assay Plugin

The QIAcuityDx Software Assay Plugin(s) are automatically stopped when the Software Suite is stopped, which can be performed by executing the **Stop-SuiteDx.bat** script. The shutdown implies the closure of some shared application services; therefore, all the assay plugins will have to be stopped as well. All the actions will be accomplished automatically by the execution of the script:







WARNING Never uninstall any QIAcuityDx Software Assay Plugin. This action may lead to software malfunctions.

4.11. Getting started

4.11.1. Powering ON the QIAcuityDx

Important: Before powering on for the first time, ensure the transport screw is removed from the back of the instrument.

Check that the QIAcuityDx operates properly:

1. Power on the device from the rocker switch at the back of the QIAcuityDx instrument.
2. Ensure that the drawer of the QIAcuityDx is closed.
3. Power ON the QIAcuityDx using the blue front power switch.
4. The startup screen appears. The instrument automatically performs initialization tests.

   Note: The main power switch in the back must be switched on as well.

   Note: If ambient temperature is below 17°C (63°F), an equilibration phase of 30–60 minutes might be required. After the equilibration phase, the error can be cleared and the instrument is operational after restart.

38. If there is an initialization error, retry the initialization process by turning the instrument off and on again. If the problem persists, see Section 7 Troubleshooting or contact QIAGEN Technical Services.

    Note: The instrument must be turned off at least once a week.

4.11.2. Managing users

The QIAcuityDx requires the users to log in before accessing instrument functionalities. Each user must have a user account with an appropriate role assigned to it. The QIAcuityDx supports various pre-designed user roles. Each role has different access rights to QIAcuityDx functions described in Section 5.10.2 User management.

5. Operating Procedures

Before proceeding, we recommend that you familiarize yourself with the features of the instrument by referring to the Section 3.

CAUTION **Damage to the instrument**

Only use QIAGEN Nanoplates and consumables with the QIAcuityDx. Damage caused by use of other types of Nanoplate or consumable will void your warranty.

CAUTION **Risk of material damage**

Avoid moving the workbench and causing vibrations to the QIAcuityDx during operation to prevent disturbing sensitive optical measurements.

5.1. Use and operation of QIAcuityDx Nanoplates

In the QIAcuityDx System, 1 reaction mix per sample well is partitioned into a large number of individual partitions prior to the amplification step, resulting in one or very few target molecules being present in each partition. QIAGEN offers different plate types according to specific user needs.

Plate type	Frame color	No. of wells	Input volume/well (µL)	No. of partitions	Partition volume (nL)
QIAcuity Nanoplate 26k 24-well Diagnostic	Red	24	40	Approx. 26,000	Approx 0.82
QIAcuity Nanoplate 26k 24-well	Blue	24	40	Approx. 26,000	Approx. 0.82
QIAcuity Nanoplate 8.5k 24-well	White	24	12	Approx. 8500	Approx. 0.34
QIAcuity Nanoplate 8.5k 96-well	Gray	96	12	Approx. 8500	Approx. 0.34

5.2. Continuous loading on the QIAcuityDx

The QIAcuityDx supports continuous loading of nanoplates. The QIAcuityDx Software is preconfigured to prevent the expiration of loaded nanoplates.

The following stability times have been determined for the QIAcuityDx:

Workflow Stage	Stability time (hours)
Time to apply top-seal to nanoplate	0.5
Time to begin partitioning process after loading	3
Time to begin cycling process after partitioning	9
Time to begin imaging process after cycling	240 (10 days)

Note: Completed nanoplates have a 10 day stability after cycling. If reimaging is required (Utility mode), it should be completed within 10 days of partitioning completing.

5.3. QIAcuityDx Nanoplate 26k 24-well (IVD mode)

For diagnostic applications requiring high sensitivity, QIAGEN offers the 26k Nanoplate. In this plate, 1 reaction mix is distributed over 4 sub-wells and separated into approximately 26,000 partitions. The plate may be used for up to 24 samples and has a red frame as a distinction from the other plates.

The key applications of the 26k Nanoplate are as follows:

- Absolute Quantification
- Copy Number Variation
- Gene Expression
- Rare mutation detection
- Liquid biopsy

Important: This nanoplate type is recommended for all diagnostic purposes including its use with LDT/IHA workflows. This Nanoplate is required for QIAGEN IVD applications.

5.4. QIAcuity Nanoplate 26k 24-well (Utility mode)

For applications requiring high sensitivity, QIAGEN offers the 26k Nanoplate. In this plate, 1 reaction mix is distributed over 4 sub-wells and separated into approximately 26,000 partitions. The plate may be used for up to 24 samples and has a blue frame as a distinction from the other plates.

The key applications of the 26k Nanoplate are as follows:

- Absolute Quantification
- Copy Number Variation
- Genome Editing
- Gene Expression
- Rare mutation detection

5.5. QIAcuity Nanoplate 8.5k 24-well

In this plate, 1 reaction mix is distributed in 1 well and separated into approximately 8500 partitions. The plate is recommended for applications using low input volumes and a small number of samples. The plate may be used for up to 24 samples and has a white frame as a distinction from the other plates.

The key applications of the 8.5k Nanoplate are:

- CNV detection
- NGS library quantification

5.6. QIAcuity Nanoplate 8.5k 96-well

In this plate, 1 reaction mix is distributed in 1 well and separated into approximately 8500 partitions. This plate is recommended for applications using low input volumes and large number of samples. The plate may be used for up to 96 samples and has a gray frame as a distinction from the other plates.

The key applications of this nanoplate are as follows:

- CNV detection
- NGS library quantification

5.7. Reaction setup

WARNING All liquid components of the QIAcuityDx Universal MasterMix Kit, PCR components (primers and probes), and template/sample material should be completely thawed prior to dispensing.

WARNING For diagnostic applications including LDTs and IHAs, the QIAcuityDx Universal MasterMix Kit is recommended.

WARNING It is not recommended to perform mixing steps within the nanoplate sample well. Such mixing may introduce air bubbles or cause pre-filling of partitions.

WARNING Failure to use the QIAcuity Roller to apply nanoplate top seal may result in incomplete sealing of the QIAcuityDx Nanoplate. Use of a non-QIAcuity Roller may result in pre-filling of partitions.

WARNING Once the nanoplate is loaded and the top-seal is applied, the nanoplate should remain upright and shaking should be minimized.

Note: Loaded nanoplates cannot be centrifuged as pre-filling of partitions may occur during this action.

WARNING Only use a dedicated QIAcuityDx top seal to seal QIAcuityDx Nanoplates.

Note: The QIAcuityDx reads fluorescence from the bottom of the plate, which is covered with a foil. For best results, keep the foil clean and avoid damages such as scratches. Keep the barcode on the side of the plate clean and intact. Ensure that you wear gloves when working with a plate and do not apply force to it.

Note: For recommended assay master mix set-up (Step 1), see the *QIAcuityDx Universal MasterMix Kit Product Sheet*. For IVD assays, the reaction mix composition will be clearly defined in the application instructions for use/handbook. For Utility Mode applications, assay optimization may be required.

Note: It is recommended that all pipettes used in the QIAcuityDx workflow are maintained and calibrated.

For better handling of the plate, you can place the plate into the Nanoplate tray that can be ordered as an accessory, see Appendix B – QIAcuityDx Accessories or the QIAcuityDx webpage on **www.qiagen.com**

For detailed guidance on master mix assembly and assay optimization, see the *QIAcuityDx Universal MasterMix Kit Product Sheet*, available on the QIAGEN website (**www.qiagen.com**).

To set up a plate, follow these steps:

1. Prepare your master mix according to your reaction setup. To prepare the reaction mix without sample, the QIAcuityDx Universal MasterMix Kit has to be mixed with magnesium chloride, primers, RNase-free water, and optionally restrictions enzyme and probes according to the kit manual. The final volume depends on the QIAcuityDx Nanoplate that is used.

   Note: To prevent non-homogeneous reaction mixes, the set up in a standard PCR pre-plate or microtubes are required. The calculated reagent volumes have to be pipetted into the PCR pre-plate/microtubes, and then the sample has to be added accordingly. For homogenous mixing of reaction mix, the pre-plate/microtubes have to be sealed/closed, shortly vortexed and briefly centrifuged.

   Note: Enzymatic fragmentation of DNA larger than 20 kb ensures even distribution of template throughout the QIAcuityDx Nanoplate, which in turn aids accurate and precise quantification. Therefore, adding a restriction enzyme depends on the size of the template used. In case of enzymatic fragmentation using the recommended restriction enzymes, the pre-plate has to be incubated at RT for 10 minutes. Refer to the Application Guide on **www.qiagen.com** for the recommended restriction enzymes.

   Important: Do not pipette master mix and sample separately into the nanoplate as this will lead to insufficient mixing.

2. Pipette each reaction mix from the pre-plate into a well of the nanoplate. If possible, use an electric 1-channel pipette. To ensure bubble-free pipetting, we recommend pipetting 40 µL for Nanoplate 26k 8/24-well and 12 µL for Nanoplate 8.5k 96/24-well of your prepared reaction mix to the bottom of the respective input well of the nanoplate. Ensure not to pipette into the output well instead of the input well.

   Note: To avoid damaging the optical surface and to reduce dust that will interfere with the imaging and analysis of results, we recommend placing the nanoplate into a nanoplate tray before pipetting the reaction mix into the nanoplate.

   Note: Do not centrifuge the nanoplate as this will lead to pre-priming and insufficient filling of the wells.

   Note: Do not vortex the nanoplate as this will lead insufficient filling of the wells.

   Note: To avoid introduction of air bubbles into the sample well, pipette only to the first stop when pipetting.

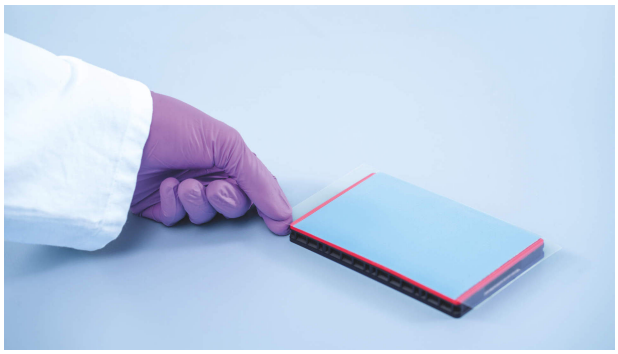
3. Apply the plate seal that comes with the nanoplates as follows to ensure good filling of the wells and to prevent evaporation and contamination:

   The stiff plate seal consists of a plate seal and 2 protective foils. The 3-layered foil should not be folded. Remove the bottom white protective foil carefully, center and align the plate seal (still containing the upper protective foil) with the lower edge of the colored frame of row H. The foil should not overlap on any side more than 1 mm; otherwise, the nanoplate may not be processed by the instrument. If the plate seal is incorrectly placed or the seal does not cover some parts of the nanoplate, carefully remove this seal and repeat sealing step with a new one. Correct sealing of the nanoplate prevents samples from not being fully processed.

   Note: It is recommended to cover the plate, within 30 minutes after pipetting, with the top seal to prevent subsequent filling issues.

   Note: Keep the plate seals stored in a dry, darkened, and air-sealed environment.

4. After correct placing, the plate seal has to be fixed with the QIAcuity Roller in the horizontal and vertical direction.



5. Afterwards, the upper protective foil is removed on the bottom left corner. We recommend that 1 finger holds the rubber foil on the plate corner in place while the upper transparent foil is pulled off. If the upper foil would be pulled off in another way, the plate seal might get loose.
6. Use the QIAcuity Roller with high force to fix the plate seal on the nanoplate by rolling at least 3 times forwards and backwards in horizontal and 3 times forwards and backwards in the vertical direction over the edge of the plate. Roll over the plate seal covering the nanoplate frame. The proper fixing of the plate seal is important for good filling of the wells.

   Note: For a properly sealed plate, the plate seal should cover the whole structure and no bubbles or strong depressions are visible, as this can also lead to bad filling of the wells.

7. The plate frame gives the option to mark the plate with a marker pen. Use the lane between the plate edge and the printed letters (next to column 1) as well as the mirrored part (from column 12 to the plate edge) only. Marking the plate seal above the wells is not recommended as it might lead to inadequate filling of the wells.

   Important: Do not mark the bottom side of the plate, as it is used to read fluorescence signals.

   Note: Ensure that overlapping parts of the plate seal are turned down and well attached to the plate frame and that the barcode is not covered. Do not apply pressure to the plate seal.

8. For the transport of the Nanoplate to the QIAcuityDx instrument, the plate should be held at the side edges or on the tray horizontally. Make sure that the plate is transported to the QIAcuityDx smoothly without shaking or rotating of the plate to ensure that the reaction mix is at the bottom of the input well.
9. The plate can now be used to start a run. For more information about starting a run on the QIAcuityDx, see Section 5.19 Performing a run.

   Note: Do not store the plate for more than 2 hours before the start of a run as this may lead to pre-partitioning of the reaction mix resulting in reduced number of analyzable partitions.

10. The QIAcuityDx Nanoplates can be stored in a dark, airtight container at room temperature or at 4°C for 1 week after the run is completed.

    Note: Storage time may vary due to dye/probe stability, master mix, and previous imaging step/settings.

    You can re-image a plate up to 6 times (7 total imaging steps), see the "Adding imaging steps after the completion of the experiment (reimaging) " section for more information on how to re-cycle and re-image a plate.

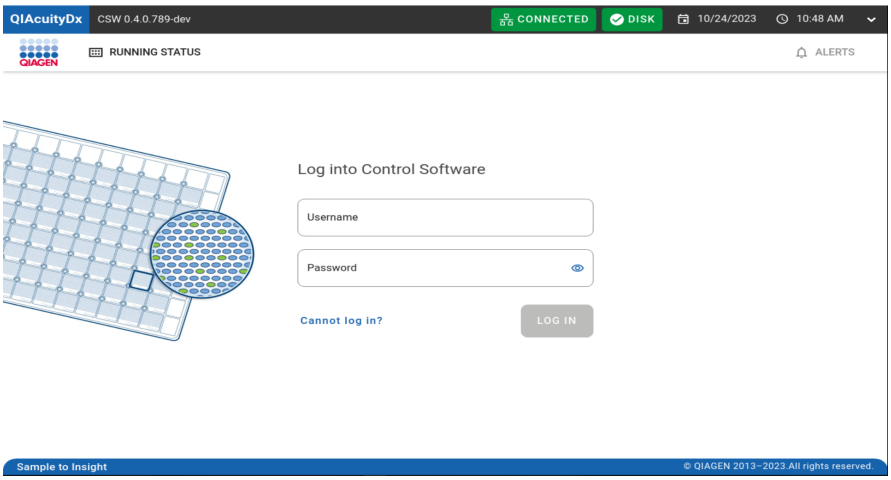
    Note: The fluorescent intensity and plate seal integrity can be affected for plates that are stored incorrectly, which could lead to contamination of the laboratory. Store processed plates according to these guidelines or dispose of them properly after processing.

    Note: The QIAcuityDx Nanoplates that have been stored at refrigeration temperatures should be equilibrated to room temperature for a minimum of 30 minutes before loading into the QIAcuityDx instrument.

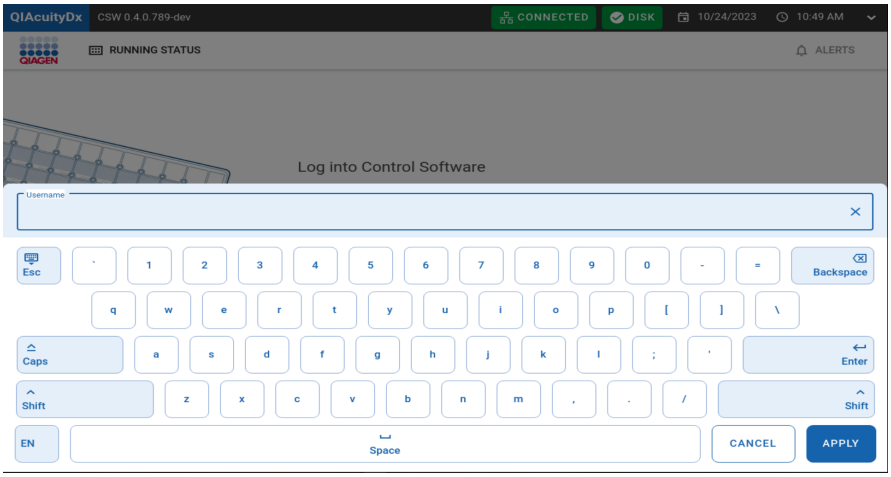
5.8. Instrument set-up

Press the power button to turn ON the QIAcuityDx instrument.

The start-up screen will appear on the touchscreen and the instrument automatically will perform initialization tests. After the initialization set-up is complete, the Login window will appear.

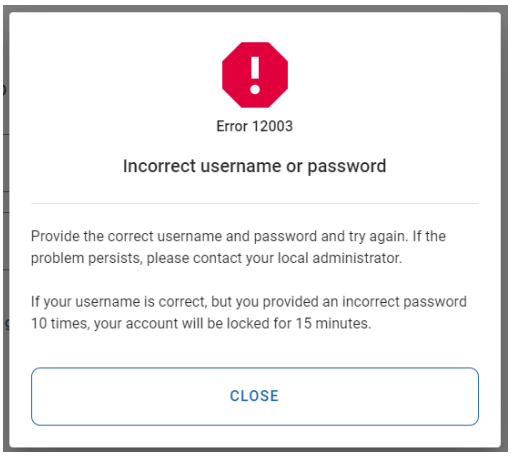


Log into the instrument. The QIAcuityDx is operated through a touchscreen pad.

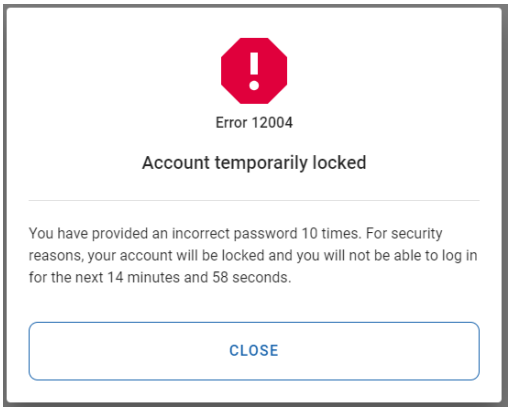


Enter your credentials in the Username and Password fields.

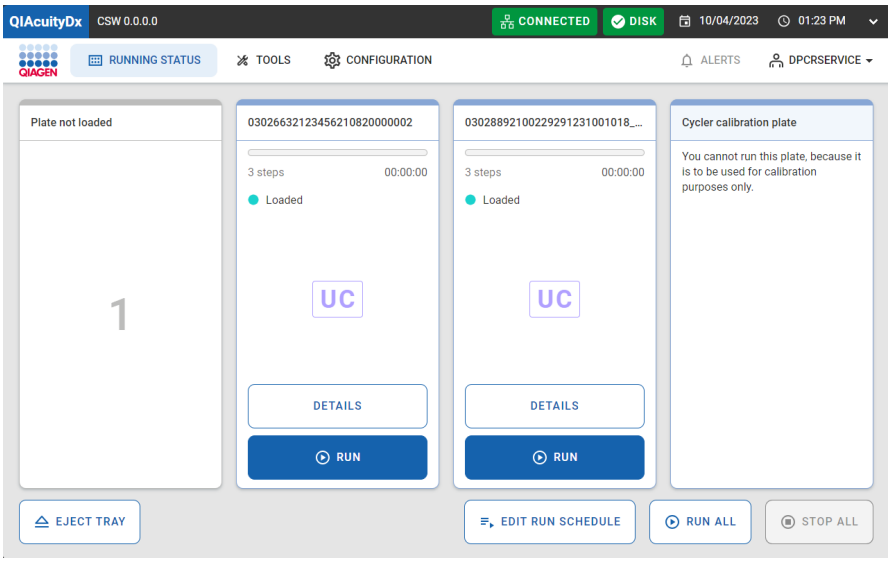
If the user enters the wrong login or password, they should receive information about incorrect login or password.



The user account will be blocked following 10 consecutive unsuccessful login attempts. If this occurs the user is informed when another login attempt can be performed. In such scenario the user is informed at which time can another login attempt be performed.



Following successful login, the Home screen will appear.



Before starting a run, at least 1 plate must be created and specific run requirements must be defined.

Note: A plate run can only be performed if the instrument is connected to the Software Suite through either a network or a direct cable connection to the QIAcuityDx Software Suite server.

The Home/Running status screen shows the current status of the loading tray and the slots inside. If there are no plates loaded in the instrument, the screen displays empty panes and each pane has the "Plate is not loaded" label. Users can load 4 plates.

Accessing the QIAcuityDx Software Suite

The Software Suite provides the user an interface to create Nanoplates. This allows the user to configure Nanoplates to be run on a QIAcuityDx instrument. Within the Software Suite the user can name a plate, configure the dPCR run parameters and define targets.

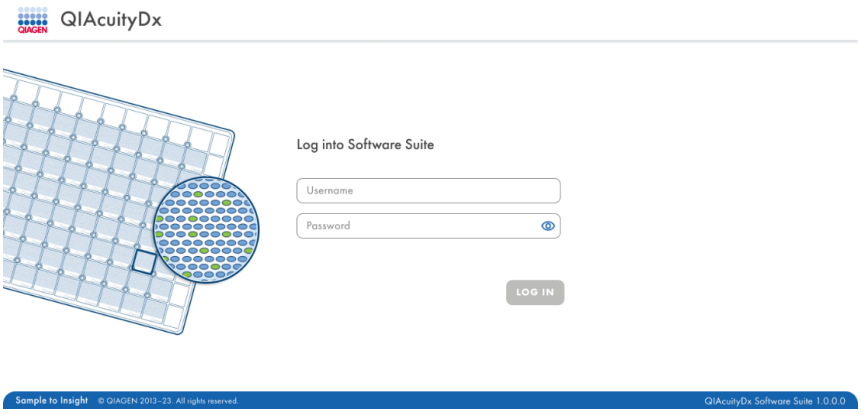
5.9. QIAcuityDx Software Suite set-up

The Software Suite is centrally installed on a designated QIAcuityDx server. To access the Software Suite, users should perform the following steps:

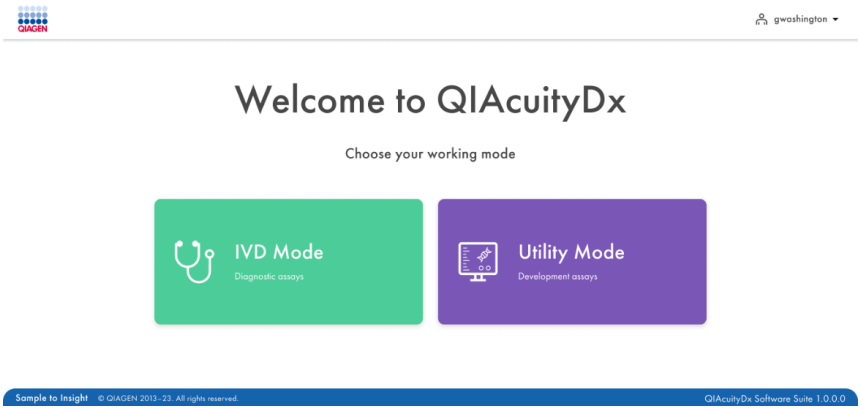
1. Open Google Chrome.
2. Type **https://<suiteServerIPAddress>:8687** (e.g., **https://10.99.240.62:8687**) into the address bar.

   Upon accessing the Software Suite, a security warning may be shown. Follow the prompt to proceed to website.

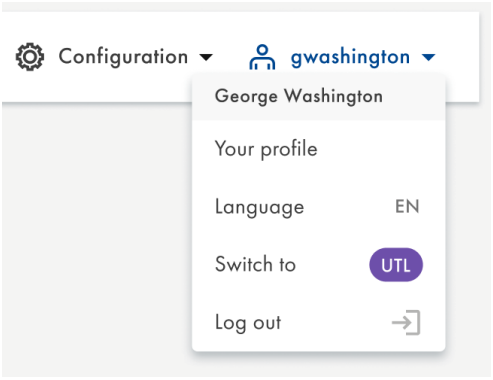
3. The website should proceed to the Software Suite sign-on page:



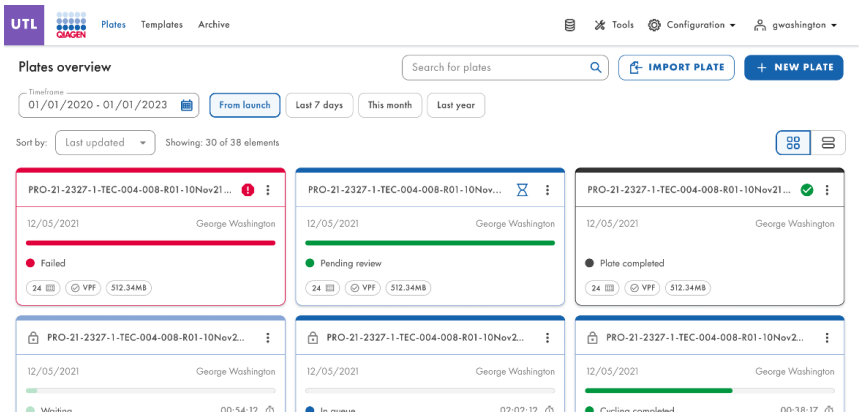
4. Enter the username and password. For the first log in, a Field Service Engineer will provide the user and password for the administrator user.
5. The mode should then be selected. This should be **Utility Mode**:



If the wrong mode is selected, click on the top right user icon and a drop-down list of options is shown. Click on the **Switch to UTL** option to navigate to the Utility mode.



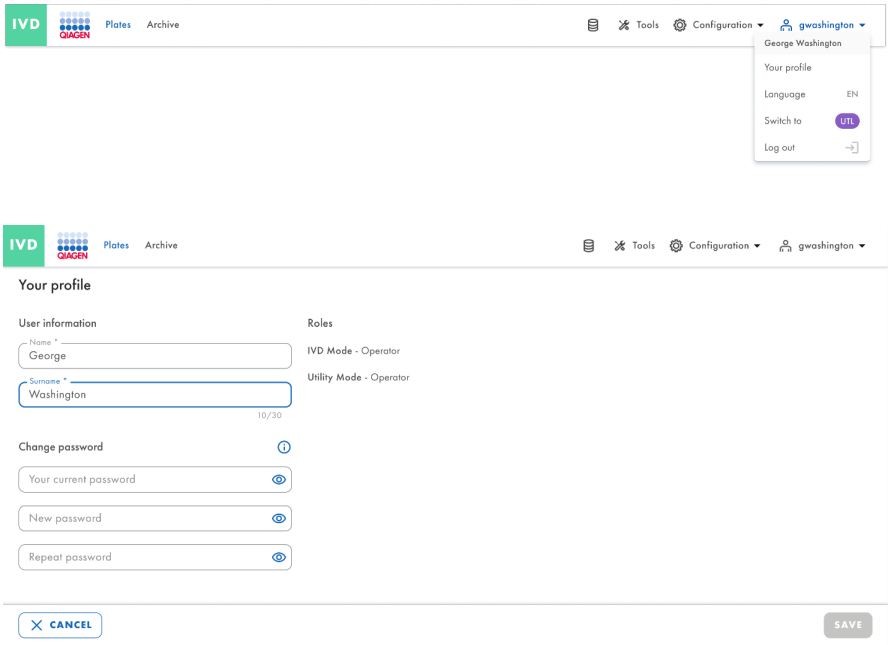
6. After navigating to the correct mode, the Plates overview page should then be displayed to the user.



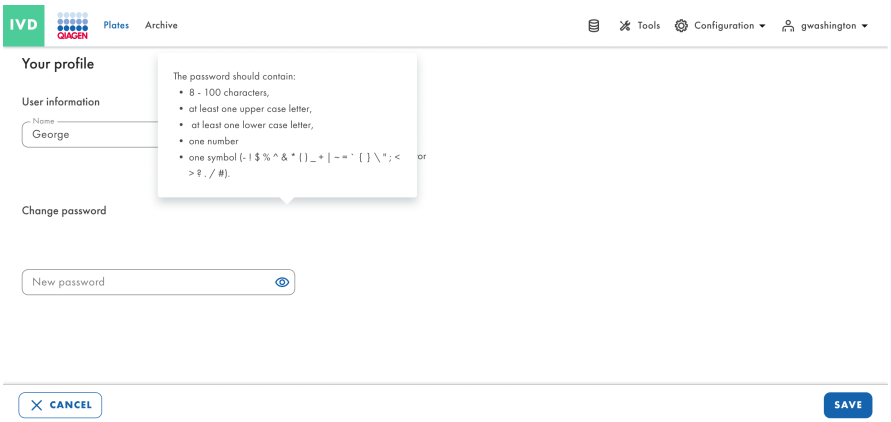
7. The Software Suite should be accessible via any PC/laptop/tablet that is connected to the internet.
8. Users should follow the guidance below to configure new plates.

5.9.1. Change own password

Each user can change their own password at any time before it expires.

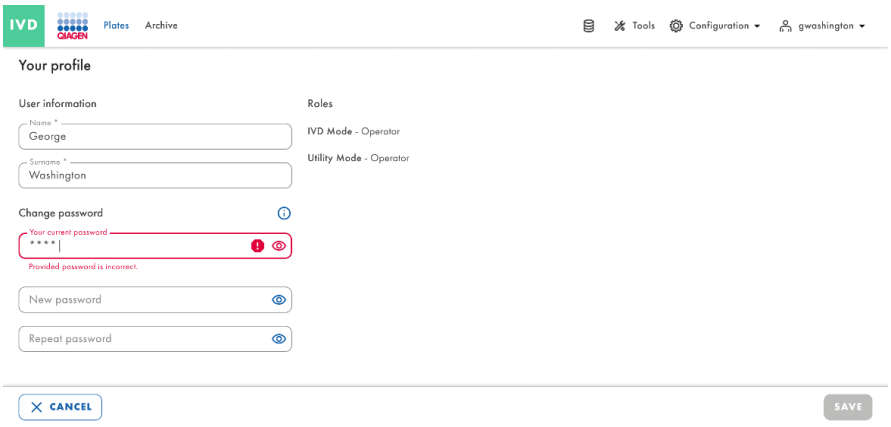


- The user must enter their current password for authentication.
- The user must enter a new password that is compliant to the current active password policy.
- The user must reconfirm their new password.
- Rules of the current password policy are displayed upon hovering over the info icon.

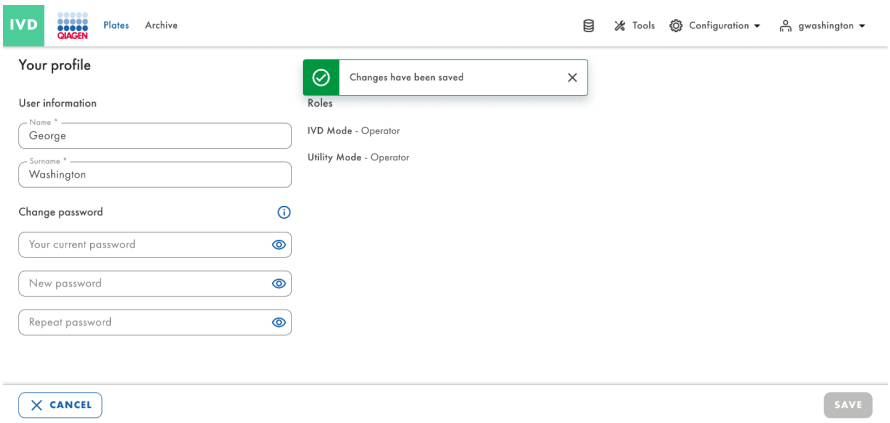


A password change will be denied if the Software Suite detects the following errors:

- Current password is not correct.
- New password differs from confirmation.
- New password is the same as a previously used password.
- New password does not comply with the password policy.



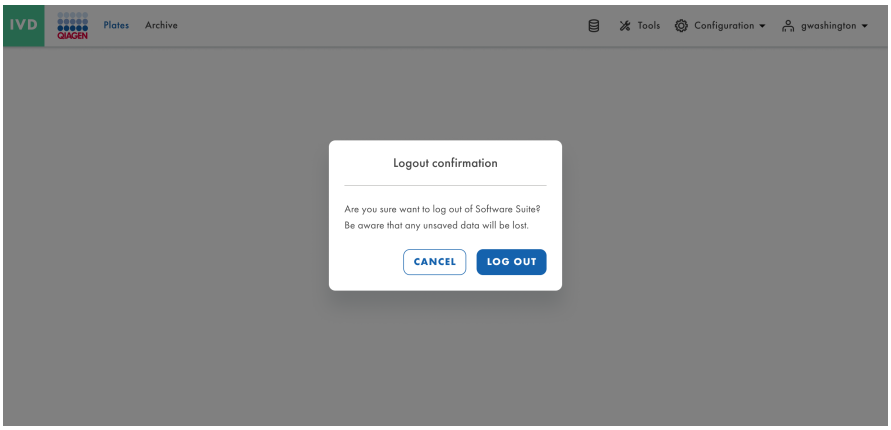
The Software Suite informs the user that changes have been saved.



5.9.2. User logout

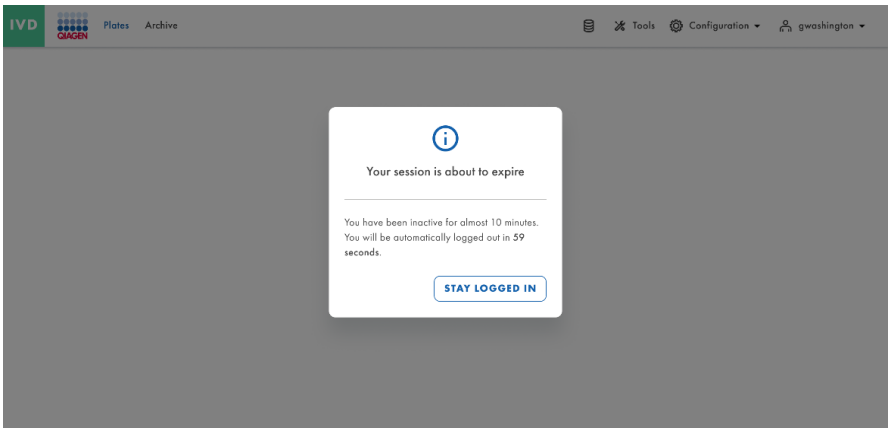
Each user can access the **Logout** option from any screen in the Software Suite.

Upon clicking the **Logout** button, a confirmation pop-up is displayed with the **Cancel** and **Logout** options for returning to the previous screen or confirming the logout and going to the Login page, respectively.



5.9.3. Automatic logout

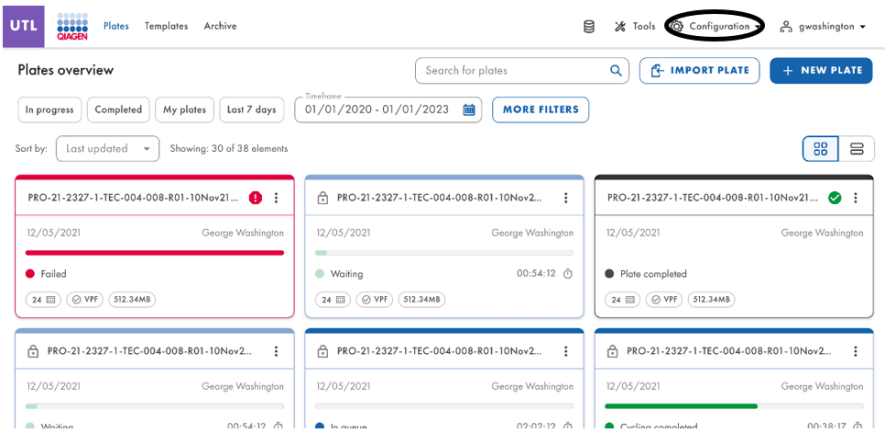
Each user will be logged out after 10 minutes of inactivity on Software Suite. The 10 minute counter restarts after every user action. After logging in, users are taken to the last screen they were in. After the automatic logout, the Login page is displayed. Any other user logging in (different from the last logged in user) will be taken to the landing page.



Important: Implementing network modifications may result in users being automatically logged out by the system, thereby posing a potential risk of loss for unsaved information. Ensure that no user is actively working on the system during the implementation of network modifications.

5.10. QIAcuityDx Software Suite configuration

To access to the Software Suite configuration, click on **Configuration** in the top bar.



The following options will be displayed:

- User Management
- Plugin Management
- Instruments
- Archive Configuration

- Languages & Formats
- Audit Trail

5.10.1. Software workspace

Main toolbar

The main toolbar shows navigation items. Clicking on the icon navigates to the overview of the selected area. Depending on the role, not all navigation areas might be visible.

IVD Mode toolbar

Utility Mode toolbar

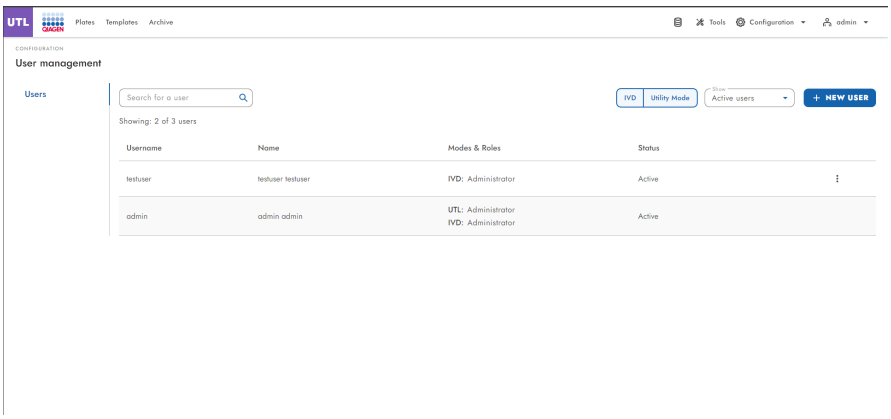
5.10.2. User management

The advanced User Management allows users to create, edit, activate, and deactivate users and provide unique usernames and passwords, for both the instrument and the Software Suite (PC). The username is entered only once and cannot be changed. In addition, each user is assigned to a specific user role (see the “Permissions depending on the role” section).

A user role is a set of permissions to features relating to the instrument or the Software Suite (PC).

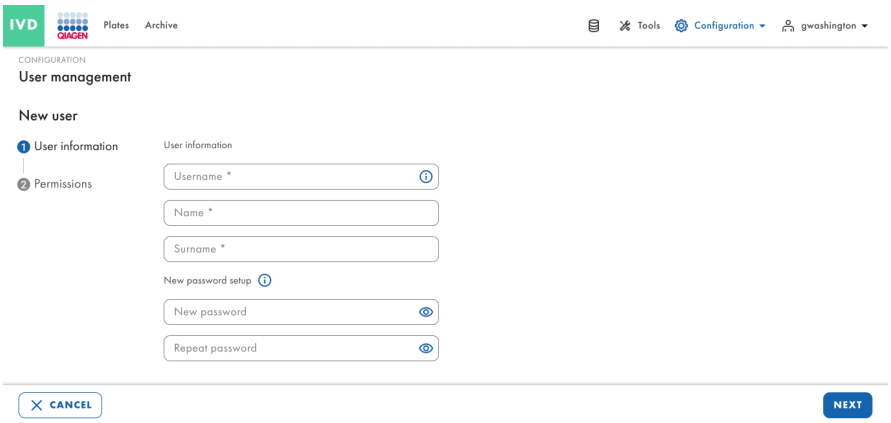
The centralized user management enables independent use of the instrument software and Software Suite. Regardless of which user is logged in with which role on the Suite software, another user can log in with a different role on the instrument. Both logins are completely independent from each other.

Users with Read Users and Roles permission can access the **Configuration** > **User Management** screen, which includes all registered users (active and inactive) in the system. Activation and editing of users is available for each individual user except for the logged-in user. It is possible to sort users in the user list by Username, Name, and Status.



Elements of user account

The user account contains username, name, surname, and password, all of which are mandatory fields.



The username has a minimum number of 5 characters and a maximum number of 30 characters. The following characters are not allowed: (, @ - ! $ % ^ & * ( ) _ + | ~ = ` { } [ ] : \ " ; < > ? /), and neither are spaces and dots as first and last characters.

Users must have 1 role. Possible default roles are Administrator, Operator, Lab Leader, Group Leader, Supervisor, and Quality Assurance. The list of permissions for each role and its description are available when assigning a role.

List of permissions

The available permissions and their description are the following:

- Log in [Instrument and PC software] section
  - **Instrument**: User can login to Instrument (username and password are needed).
  - **Suite Software**: User can login to the Software Suite (PC software) (username and password are needed).
- Instrument accesses [Instrument software] section
  - **Instrument Maintenance**: User can update Instrument and go to Data Management, Self-Check, Servicing and Configuration.
  - **Experiment Schedule**: User can change or set the order of plates processing.
  - **Create Support Package**: User can download and upload support packages.
  - **Clear module error**: User can clean module errors.
- Plates [Instrument and PC software] section
  - **Create Plate**: User can set up dPCR parameters (partitioning, cycling, imaging), reaction mixes (reagents), samples (control, non-control), and create plate layouts.

- **All Plates**
  - **Run Experiment**: User can run/stop an experiment and eject plate(s) from instrument.
  - **Edit Plate Data**: User can check and edit parameters of existing plates (dPCR parameters and plate layout — samples, reaction mixes (reagents), controls), and mark as primed.
  - **Edit Analysis Data**: User can change the threshold and use lasso selection on the Analysis page of all Plates to verify the accuracy of the results.
  - **Read Plate**: User can search for a specific plate, see all created plates, check plate details (dPCR parameters and plate layout — samples, reaction mixes, controls) and export a plate to CSV.
  - **Delete Plate**: User can delete any plate.

- Owned plates
  - **Edit Plate Data**: User can check and edit parameters of owned Plates (dPCR parameters, plate layout (samples, reaction mixes (reagents), controls), and mark as primed.
  - **Edit Analysis Data**: User can change the threshold and use lasso selection on the Analysis page of owned Plates to verify the accuracy of the results.
  - **Read Plate**: User can search for owned plates, see all created plates, check details about owned plates (dPCR parameters, plate layout — samples, reaction mixes, and controls), and export an owned plate to CSV.
  - **Delete Plate**: User can delete owned plates.

- Other permissions
  - **Import Plate**: User can import plates from a ZIP file.
  - **Export Plate**: User can export plates as a ZIP file.
  - **Set Plate Ownership**: User can set plate owners.
  - **Upload VPF**: User can upload Volume Precision Factor files.
  - **Create Support Package**: User can download and export support packages for plates.
  - **Create Report for Analysis**: User can create and generate a report using the charts and data from the Analysis of a plate.
  - **Sign Report**: User can add a signature to a report.
  - **Delete Report**: User can delete a report.

- Templates [Instrument and PC software]
  - **Create Template**: User can create a new template.
  - **Edit Template**: User can edit an existing template.
  - **Read Template**: User can read information about existing templates and use them while creating and editing plates (if also has appropriate plate permissions).

- Access to all created templates
  - **Delete Template**: User can delete existing templates.

- Archive [PC software] section
  - **Plate Archiving**: User can archive plates.
  - **Archive Overview**: User has access to list of archived plates. User can see all archived plates, search for archived plates, check general information about archived plates, and disk space usage for the Archive in the Disk Monitor.
  - **Recover the Plate from Archive**: User can restore archived plates.
  - **Delete the Plate from Archive**: User can delete any plate from Archive.
- User Management [PC software] section
  - **Read Users and Roles**: User can see the list of users and the list of roles in the system.
  - **Create and Edit Users and Roles**: User can create and edit a user, and create and edit a role.
  - **Activate and Deactivate User**: User can activate and deactivate a user.
- System configuration [PC software] section
  - **View registered Instruments**: User can see the list of registered instruments.
  - **Manage registered Instruments**: User can manage an instrument.
  - **Manage Archive**: User can edit Archive location, detach Archive, and turn on/off and configure automatic archiving.
  - **View Audit Trail**: User can see the list of Audit trail events, search for a specific event, check details of the event and export it to PDF.
  - **Manage Language and Format**: User can configure the language and formats of the system.
- Plugins [PC software]
  - **Manage Plugins**: User can see the list of installed plugins and manage IVD plugins.
  - **Review Plate Result**: User can approve or reject IVD plate results.

Permissions depending on the mode

Some permissions granted to the user will depend on the mode assigned.

General permissions mode-agnostic

The following permissions are applied across modes and can be manually selected during user creation and/or editing:

- Instrument accesses [Instrument software]
  - Instrument Maintenance
  - Create Support Package
  - Experiment Schedule
  - Clear module error
- Plates [Instrument and PC software]
  - Upload VPF
  - Create Support Package

- User Management [PC software]
  - Read Users and Roles
  - Create and Edit Users and Roles
  - Activate and Deactivate User
- System configuration [PC software]
  - View registered Instruments
  - Manage registered Instruments
  - Manage Archive
  - View Audit Trail
  - Manage Language and Format
- Plugins [PC software]
  - Manage Plugins
  - Review Plate Result

IVD Mode permissions

The following permissions are applied for IVD Mode users and can be manually selected during user creation and/or editing:

- Log in [Instrument and PC software]
  - Instrument
  - Suite Software
- Plates [Instrument and PC software]
    - Create Plate
  - All Plates
    - Run Experiment
    - Edit Plate Data
    - Edit Analysis Data
    - Read Plate
  - Owned plates
    - Edit Plate Data
    - Edit Analysis Data
    - Read Plate

    - Other permissions
        - Import Plate
        - Export Plate
        - Set Plate Ownership
        - Create Report for Analysis
- Archive [PC software]
    - Plate Archiving
    - Archive Overview
    - Recover the Plate from Archive

Note: The Sign Report permission is not available in the IVD mode because each IVD Plugin will include its own specific permission upon plugin installation.

Utility Mode permissions

The following permissions are applied for Utility Mode users and can be manually selected during user creation and/or editing:

- Log in [Instrument and PC software]
    - Instrument
    - Suite Software
- Plates [Instrument and PC software]
        - Create Plate
    - All plates
        - Run Experiment
        - Edit Plate Data
        - Edit Analysis Data
        - Read Plate
        - Delete Plate
    - Owned plates
        - Edit Plate Data
        - Edit Analysis Data
        - Read Plate
        - Delete Plate

    - Other permissions
        - Import Plate
        - Export Plate
        - Set Plate Ownership
        - Create Report for Analysis
        - Sign Report
        - Delete Report
- Templates [Instrument and PC software]
    - Create Template
    - Edit Template
    - Read Template
    - Delete Template
- Archive [PC software]
    - Plate Archiving
    - Archive Overview
    - Recover the Plate from Archive
    - Delete the Plate from Archive

Permissions depending on the role

Some permissions granted to the user will depend on the role assigned.

Administrator role permissions

The administrator is the role outside of the laboratory, responsible for configuring the system and providing individual user access and rights. Users with this role will have extensive access to the QIAcuityDx Control Software and QIAcuityDx Software Suite, including the user management and audit trail access rights.

The administrator role's default permissions are the following:

- Log in [Instrument and PC software]
    - Instrument
    - Suite Software
- Plates [Instrument and PC software]
        - Create Plate
    - All Plates
        - Run Experiment
        - Edit Plate Data

        - Edit Analysis Data
        - Read Plate
        - Delete Plate (*Utility Mode only*)
    - Owned plates
        - Edit Plate Data
        - Edit Analysis Data
        - Read Plate
        - Delete Plate (*Utility Mode only*)
    - Other permissions
        - Import Plate
        - Export Plate
        - Set Plate Ownership
        - Create Report for Analysis
        - Sign Report (*Utility Mode only*)
        - Delete Report (*Utility Mode only*)
- Templates [Instrument and PC software] (*Utility Mode only*)
    - Create Template
    - Edit Template
    - Read Template
    - Delete Template
- Archive [PC software]
    - Plate Archiving
    - Archive Overview
    - Recover the Plate from Archive
    - Delete the Plate from Archive (*Utility Mode only*)

Operator role permissions

The operator is the role inside the laboratory and is designed for Life Science projects. Users with this role will have access to all general Control Software and Software Suite functionalities required to process plates and analyze results. Deleting plates and access to user management is restricted for these users.

The operator role's default permissions are the following:

- Log in [Instrument and PC software]
  - Instrument
  - Suite Software
- Plates [Instrument and PC software]
    - Create Plate
  - All Plates
    - Run Experiment
    - Edit Plate Data
    - Edit Analysis Data
    - Read Plate
  - Owned plates
    - Edit Plate Data
    - Edit Analysis Data
    - Read Plate
  - Other permissions
    - Import Plate
    - Export Plate
    - Set Plate Ownership
    - Create Report for Analysis
    - Sign Report (*Utility Mode only*)
    - Delete Report (*Utility Mode only*)
- Templates [Instrument and PC software] (*Utility Mode only*)
  - Create Template
  - Edit Template
  - Read Template

- Archive [PC software]
    - Plate Archiving
    - Archive Overview
    - Recover the Plate from Archive

Lab leader role permissions

The lab leader role will have extensive access to all Control Software and Software Suite functionalities required to process plates and analyze results. This role also allows for basic user management functionalities to read user descriptions and their permissions.

The lab leader role's default permissions are the following:

- Log in [Instrument and PC software]
    - Instrument
    - Suite Software
- Instrument accesses [Instrument software]
    - Experiment Schedule
- Plates [Instrument and PC software] section
        - Create Plate
    - All Plates
        - Run Experiment
        - Edit Plate Data
        - Edit Analysis Data
        - Read Plate
        - Delete Plate (*Utility Mode only*)
    - Owned plates
        - Edit Plate Data
        - Edit Analysis Data
        - Read Plate
        - Delete Plate (*Utility Mode only*)
    - Other permissions
        - Import Plate
        - Export Plate
        - Set Plate Ownership
        - Create Report for Analysis

        - Sign Report (*Utility Mode only*)
        - Delete Report (*Utility Mode only*)
- Templates [Instrument and PC software] (*Utility Mode only*)
    - Create Template
    - Edit Template
    - Read Template
    - Delete Template
- Archive [PC software] section
    - Plate Archiving
    - Archive Overview
    - Recover the Plate from Archive
    - Delete the Plate from Archive (*Utility Mode only*)

Group leader role permissions

The group leader has access to Control Software and Software Suite functionalities required to process plates, analyze results, and manage archived plates, but only for the plates that such a user is assigned as owner. Users with this role will not be able to delete plates, templates and unlock plates, and will not be allowed to access the user management and audit trail.

The group leader role's default permissions are the following:

- Log in [Instrument and PC software]
    - Instrument
    - Suite Software
- Instrument accesses [Instrument software]
    - Experiment Schedule
- Plates [Instrument and PC software]
        - Create Plate
    - Owned plates
        - Edit Plate Data
        - Edit Analysis Data
        - Read Plate
    - Other permissions
        - Import Plate
        - Export Plate
        - Set Plate Ownership

        - Create Report for Analysis
        - Sign Report (*Utility Mode only*)
- Templates [Instrument and PC software] (*Utility Mode only*)
    - Create Template
    - Edit Template
    - Read Template
- Archive [PC software]
    - Plate Archiving
    - Archive Overview
    - Recover the Plate from Archive

Supervisor role permissions

The supervisor has extensive access to Control Software and Software Suite functionalities required to process plates and analyze results. Users with this role will not be able to delete plates or archived plates, and unlock plates, and will not be allowed access to the user management. The audit trail functionality is limited to view the list of events and view event details.

The supervisor role's default permissions are the following:

- Log in [Instrument and PC software]
    - Instrument
    - Suite Software
- Plates [Instrument and PC software]
        - Create Plate
    - All Plates
        - Run Experiment
        - Edit Plate Data
        - Edit Analysis Data
        - Read Plate
    - Owned plates
        - Edit Plate Data
        - Edit Analysis Data
        - Read Plate

    - Other permissions
        - Import Plate
        - Export Plate
        - Set Plate Ownership
        - Create Report for Analysis
        - Sign Report (*Utility Mode only*)
- Templates [Instrument and PC software] (*Utility Mode only*)
    - Create Template
    - Edit Template
    - Read Template
    - Delete Template
- Archive [PC software] section
    - Plate Archiving
    - Archive Overview
    - Recover the Plate from Archive

Quality Assurance role permissions

The quality assurance is the role outside the laboratory. The role has rights to check all plate information, import plates, create, and sign reports. Users with this role will have audit trail read access, consisting of viewing and searching events, showing event details and also exporting audit trail for external review.

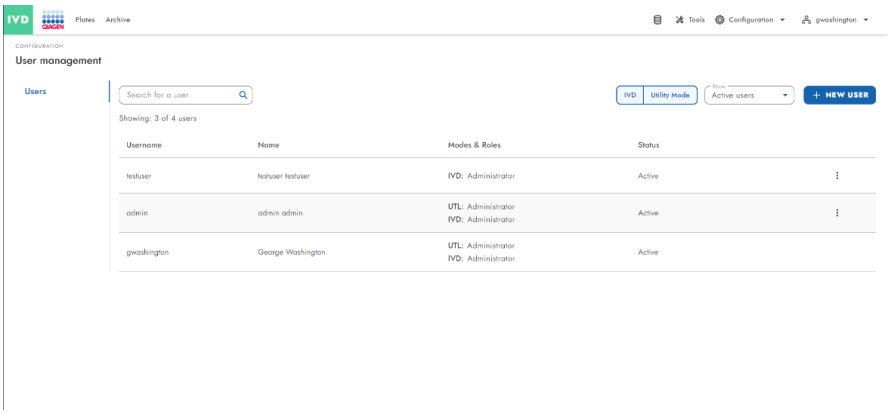
The quality assurance role's default permissions are the following:

- Log in [Instrument and PC software]
    - Instrument
    - Suite Software
- Plates [Instrument and PC software]
    - All Plates
        - Read Plate
    - Other permissions
        - Import Plate
        - Create Report for Analysis
        - Sign Report (*Utility Mode only*)
- Templates [Instrument and PC software] (*Utility Mode only*)
    - Read Template

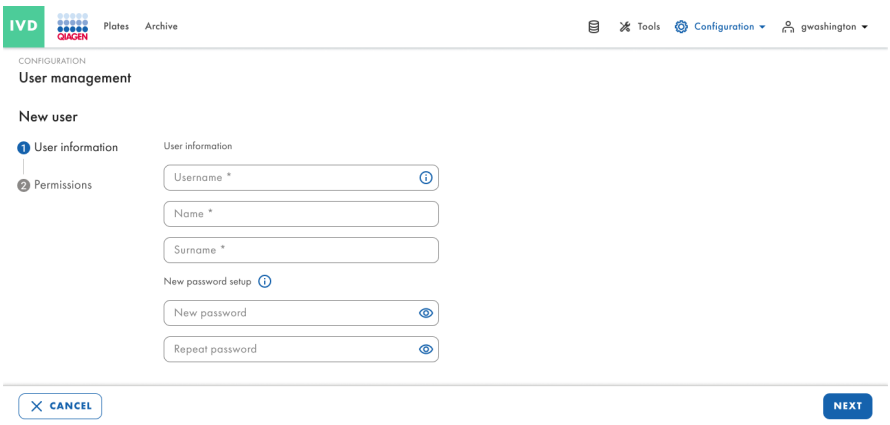
- Archive [PC software]
  - Archive Overview
  - Recover the Plate from Archive

User creation

Only users with Create and Edit Users and Roles permission can create and edit users.

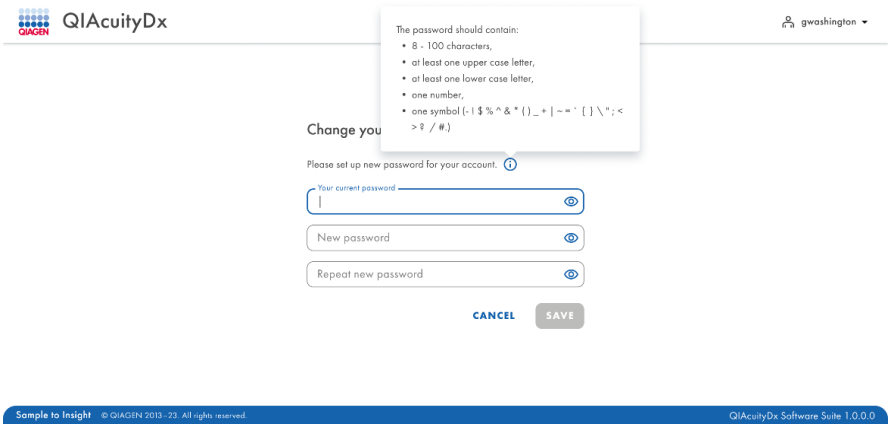


User creation consists of 2 steps: User information and Permissions. The User information step must include the user account elements (username, name, surname, and password), and the Permissions step must include the Role assignment for each applicable mode (IVD mode or Utility Mode). It is possible to switch steps before saving.

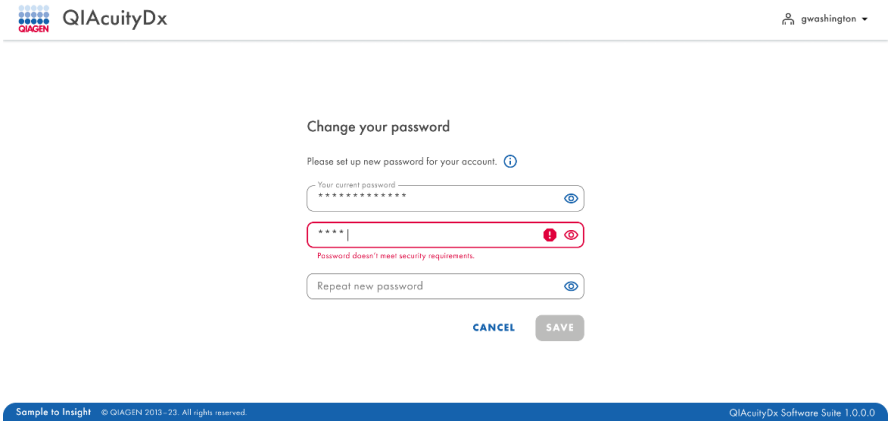


Password change

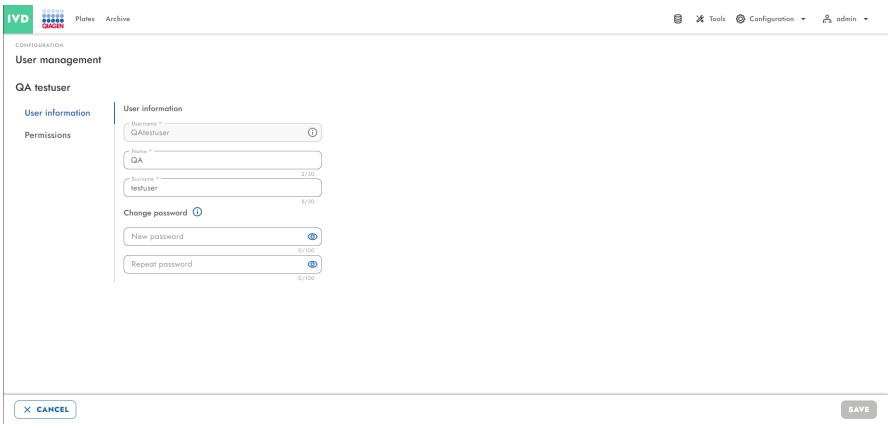
Initial password upon creation of a user has to be changed after the first login.



The system informs the user if the requirement criteria for assigning a password are not met.

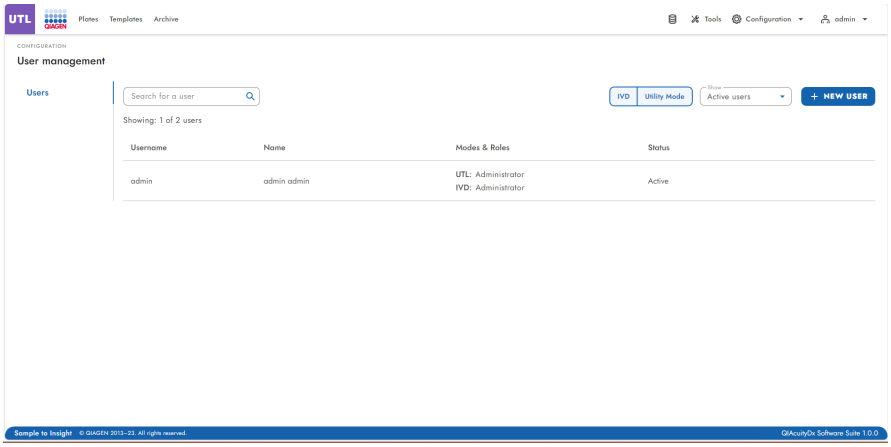


Users with Create and Edit Users and Roles permission can change the password of existing users from the **Configuration** > **User management** screen.

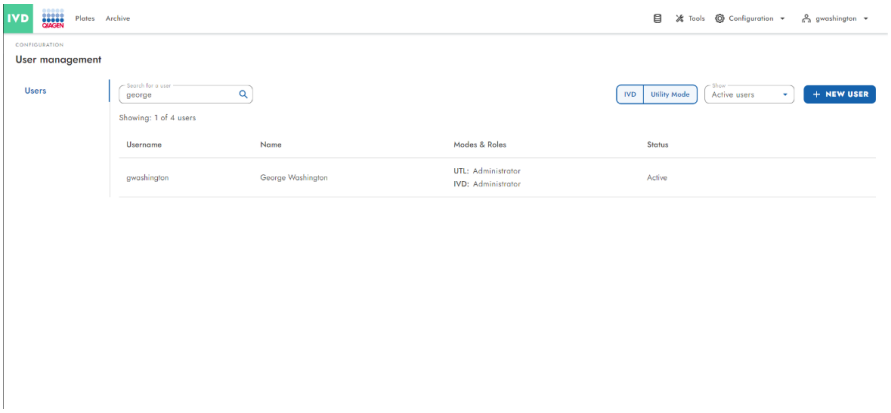


Search users

Users with Read Users and Roles permission can access the **Configuration** > **User management** screen, which includes all registered users (active and inactive) in the system. Activation and editing of users is available for each individual user, except for the logged-in user. It is possible to sort users in the user list by Username, Name, Modes & Roles, and Status.

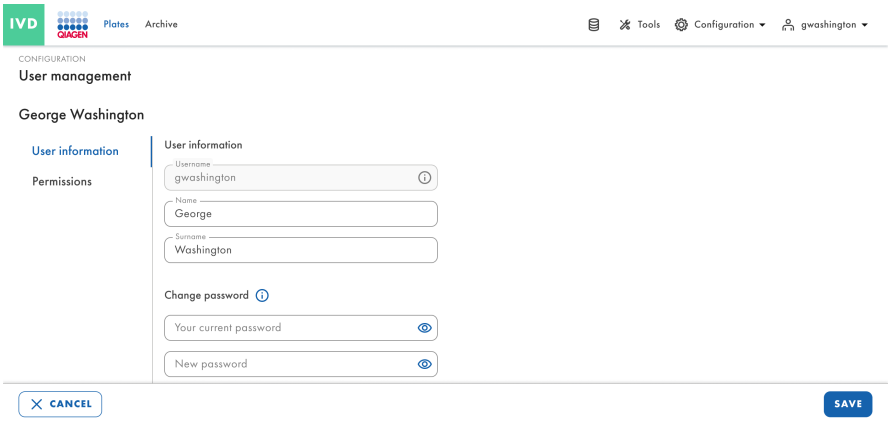


Users with Read Users and Roles permission can search users by Username, Name, and Surname in the search bar.



Edit user

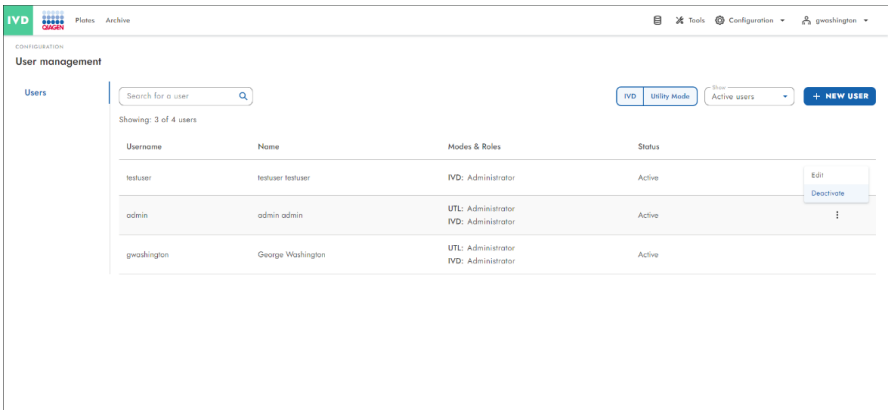
Users with Create and Edit Users and Roles permission can update a Username, Surname, and permissions from the **Configuration** > **User management** screen. The username cannot be updated. For users that are already logged in, the role change will be applied after the next login.



Only Active users can be edited from the **Configuration** > **User management** screen. Users cannot edit their account from the **Configuration** > **User management** screen.

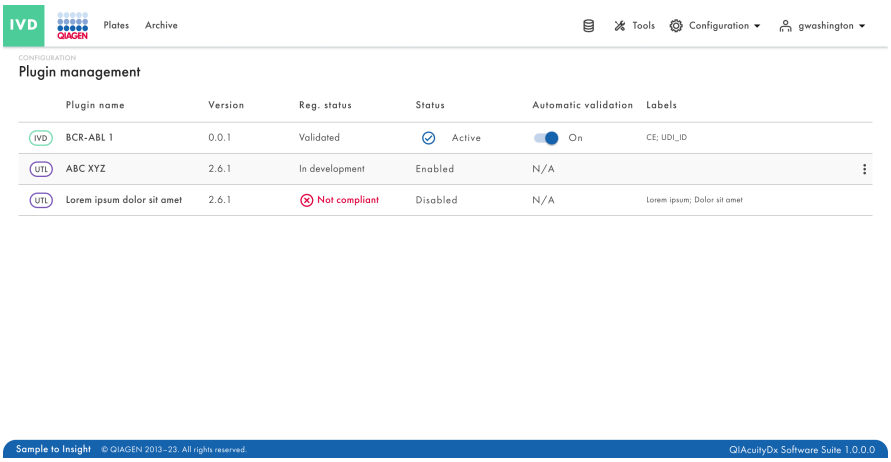
Activate/Deactivate users

Users with Activate and Deactivate User permission can deactivate and activate users to ensure that only certified users can access the system.



5.10.3. Assay plugin management

Users with the Manage Plugins permission can access the **Configuration** > **Plugin management** screen, which displays all the system's installed Assay Plugins (active and inactive). It is possible to see the Plugin name, the (Assay Plugin) version, the Regulatory status, the Mode, the (Assay Plugin) Status, the Automatic Validation, and the Labels for each Assay plugin. Any installed Assay Plugin that has not been properly registered due to incongruences with the contract is displayed with Reg. Status “Not compliant” with further details on the incompliance shown when hovering over the “Not compliant” status.

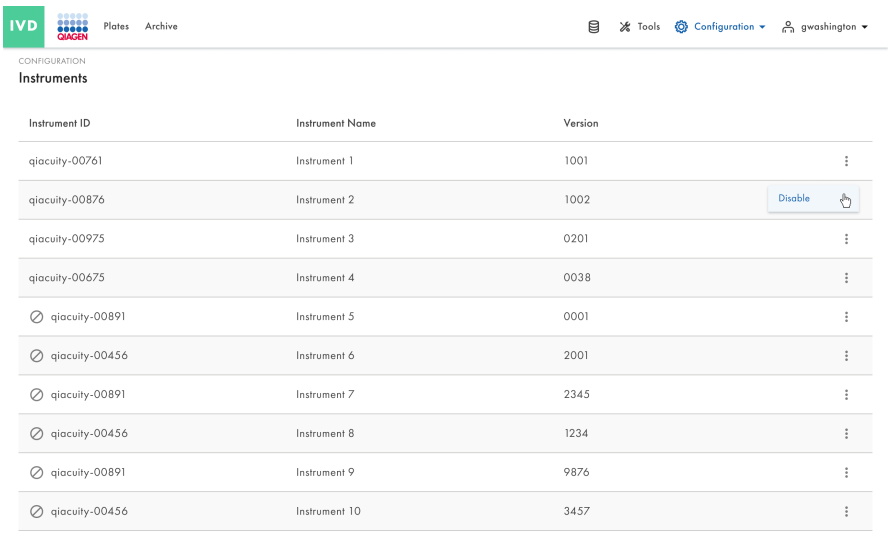


Users with the Manage Assay Plugins permission can access the Assay Plugin Management screen and see the Assay Plugin identification strings (Assay Plugin Name and Version) as well as the graphical labels required by the regulatory bodies (Labels) for IVD Assay plugins.

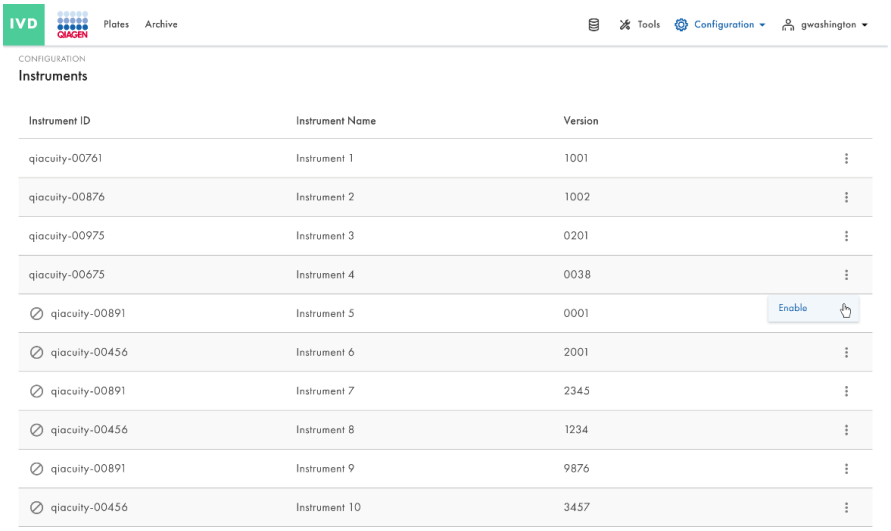
5.10.4. Instruments

Users with Registered Instruments permission can see the list of registered instruments, which consists of the instrument ID, the instrument name, and the version. The list is read-only.

Users with Manage Registered Instruments permission can enable/disable an instrument in the instruments screen if the registered instruments do not have any locked plates.

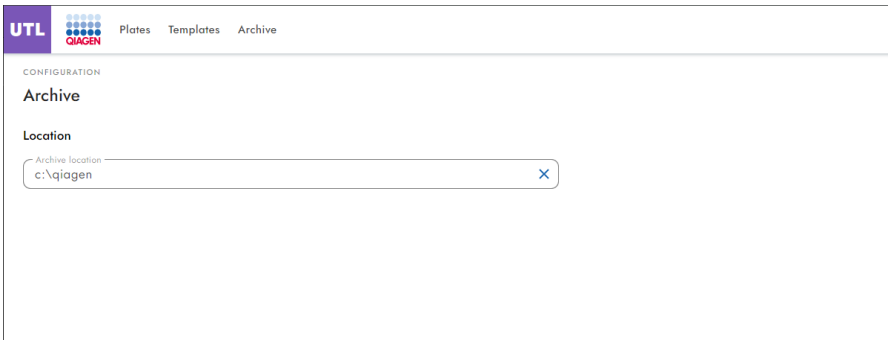


The authorized users can activate an instrument if there are fewer than 10 instruments enabled. Otherwise, at least one of the enabled instruments must be disabled first.

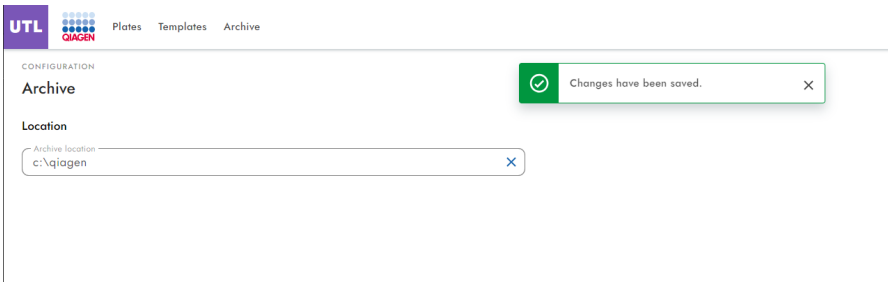


5.10.5. Archive location

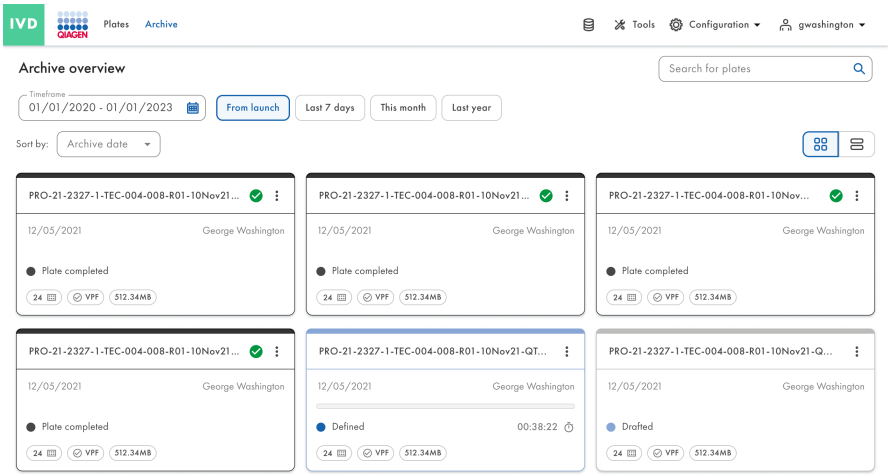
Users with Manage Archive permission user can configure the Archive location as either a local drive or a network drive. For local drives, the path begins with a drive letter. For network drives, the path begins with a server name and it is encoded as UNC.



The authorized user enters the path in the Archive location input field and confirms with the **Save** button. Upon correct configuration, the "Changes have been saved." message is displayed.



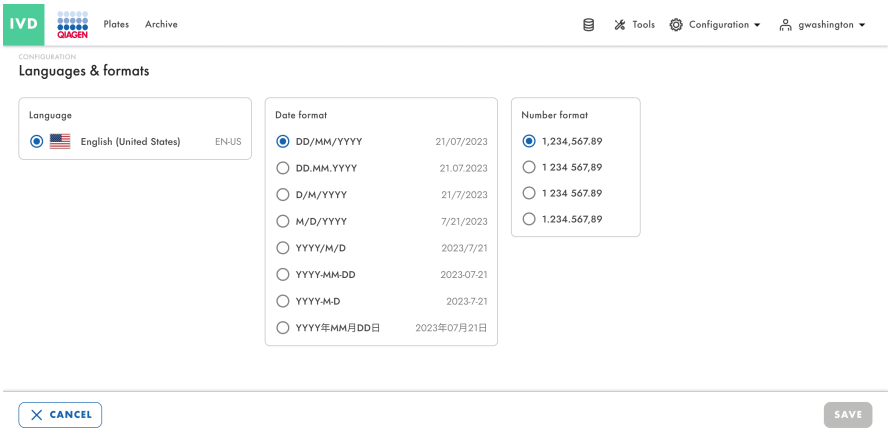
The Software Suite automatically reloads the plates displayed in Archive Overview every time the user changes the archive location so that the user instantly knows which plates can be restored.



5.10.6. Languages and formats

Users with Manage Language and Format permission can define which date format and number format they wish to use on each individual QIAcuityDx instrument.

Note: Currently, QIAcuityDx is only available in English.



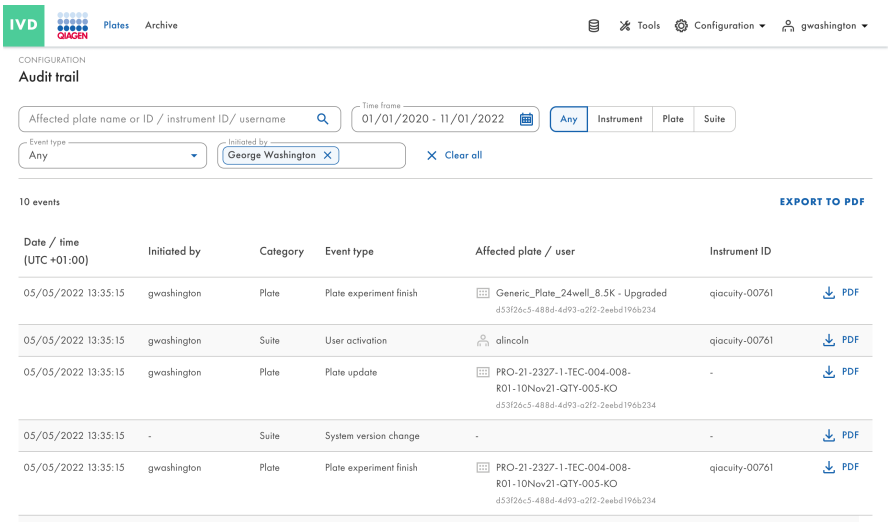
5.10.7. Audit Trail

The Audit Trail function in the Software Suite helps users to meet Good Manufacturing Practice (GMP)/Good Laboratory (GLP) regulations.

Audit Trail is always enabled and cannot be switched off.

Users with View Audit Trail permission can see the list of Audit Trail events with the following data:

- Date and time (with time zone)
- Initiated by (username)
- Category
- Event type
- Affected plate / user (Plate name + Plate ID / username)
- Instrument ID



The system stores the following event types in the audit trail:

- Create plate
- Update plate
- Delete plate
- Delete report
- Delete template
- Archive plate
- Restore plate
- Set plate ownership
- Plate experiment change
- Instrument enabled
- Instrument disabled
- Instrument language pack installed
- Instrument language pack uninstalled
- Plate schedule update
- Plate approved by user
- Plate rejected by user
- Support Package created
- Support Package download
- Drawer opening/closing during run
- Archive configuration update
- Edit user

- Instrument registration
- LIMS Connection Configuration
- LIMS Sent Results
- Labware file upload
- Calibration
- Experiment run (plate)
- Experiment canceled
- Clear error
- Archive configuration delete
- Upload VPF
- Apply VPF
- Create user
- Create report
- Create template
- Change password
- Log on - success
- Log on - failure
- Log off
- User activation
- User deactivation
- Plugin installed
- Thermocycler used
- Plate experiment finish
- Audit Trail Export
- Automatic log off
- Update started
- Update template
- Sign report
- Sign report failed
- Export plate
- Import plate
- Troubleshooting package download

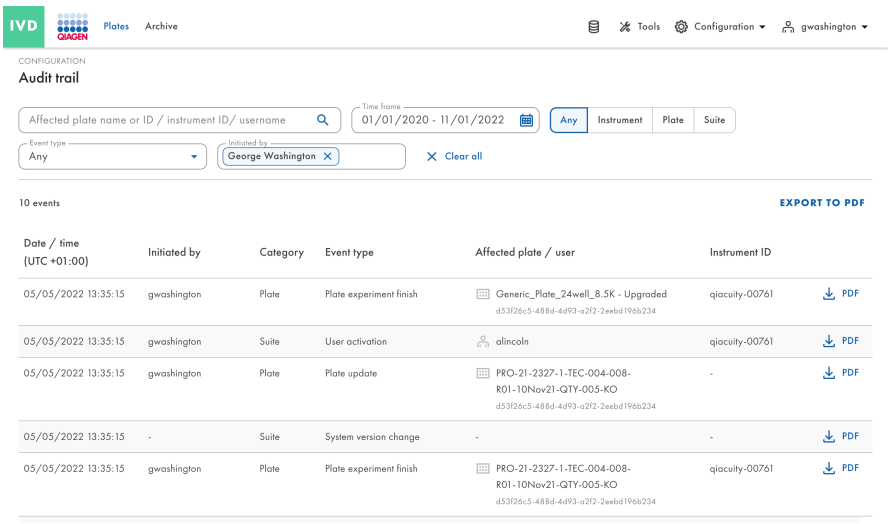
The Audit trail is compliant with the following conditions:

- The system stores the audit trail file in PDF format.
- The system stores the content in English.
- The system creates 1 file per download, each event is displayed on a separate page.

When an audit trail is exported to a file, it contains the following information:

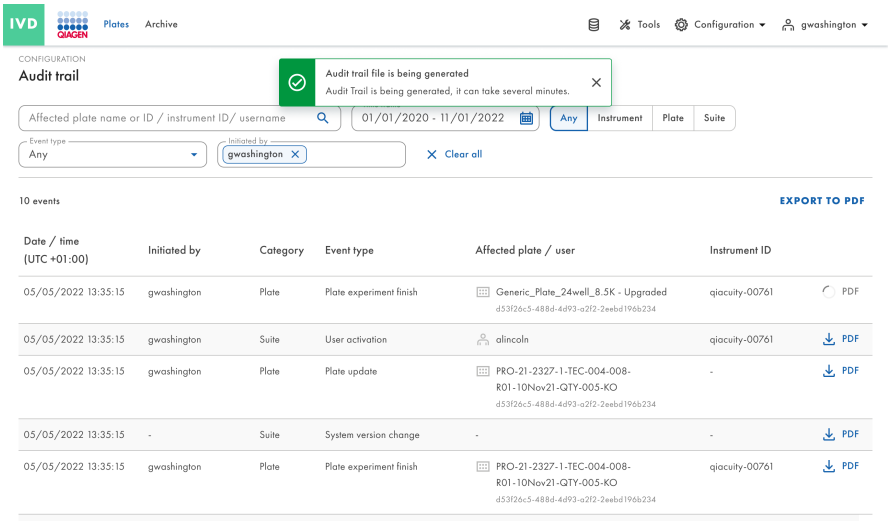
- An unambiguous time stamp (with the time zone)
- The meaning of the action (event details)
- Username (that performed the action)
- Affected user (if applicable)
- Affected entity (if applicable)
- Event category
- Instrument ID (if applicable)
- Event action

Users can filter Audit Trail events by several variables depending upon need.

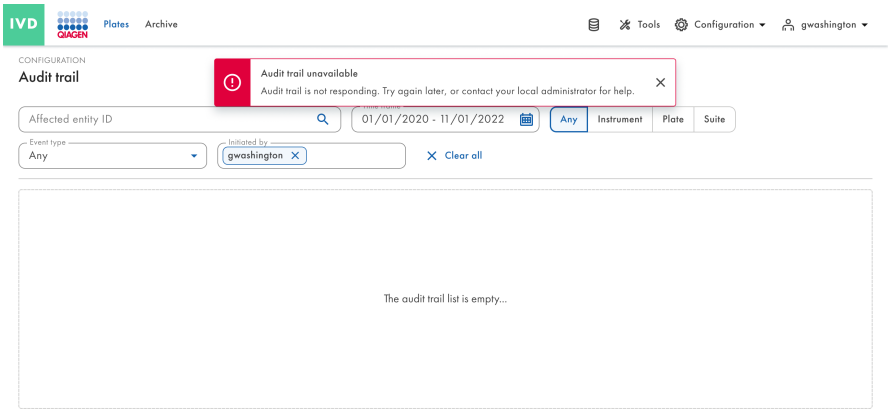


Export Audit Trail in PDF format

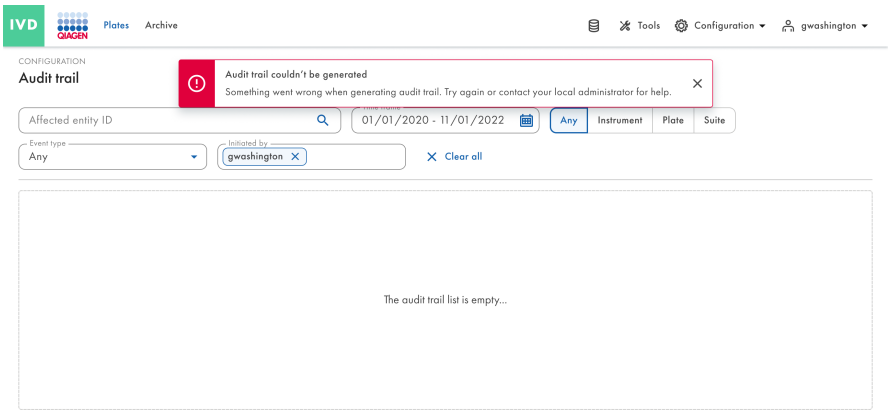
Users with the View Audit Trail permission can export Audit Trail events to a non-editable, printable PDF file. Whenever applicable, the PDF file shows both the current state and the state before the changes were made. A notification is displayed to the user whenever the Audit trail file is being generated.



An error notification is displayed to the user whenever the Audit trail is not available.



An error notification is displayed whenever the Audit Trail cannot be generated.



Before and after Audit Trail events

The Software Suite tracks both the current state of the impacted Audit Trail event and the state before the changes were made (whenever applicable).

Events that include the previous state and the current state as follows:

- Update plate
- Set plate ownership
- Plate experiment change
- Instrument plate schedule
- Drawer opening/closing during run
- Archive configuration update
- Edit user

WAS

Changed/removed

name	Generic_Plate_24well_8.5K - Upgraded					
barcode	-					
plateTypeName	-					
dpcrParams	-					
primingProfile	-					
dpcrParams						
index	cycles					
1	count	position	cycleStep			
	1	0	position	temperature	duration	rampingSpeed
			0	40	5	3.5
	1	1	position	temperature	duration	rampingSpeed
			1	55	10	3.5
			1	55	10	3.5
imaging						
index	imagingProfiles					
2	channel	durationOfExposure	gain			
	Green	700	8			
	Yellow	700	8			
	Orange	400	6			
	Red	300	4			
	Crimson	400	8			

IS

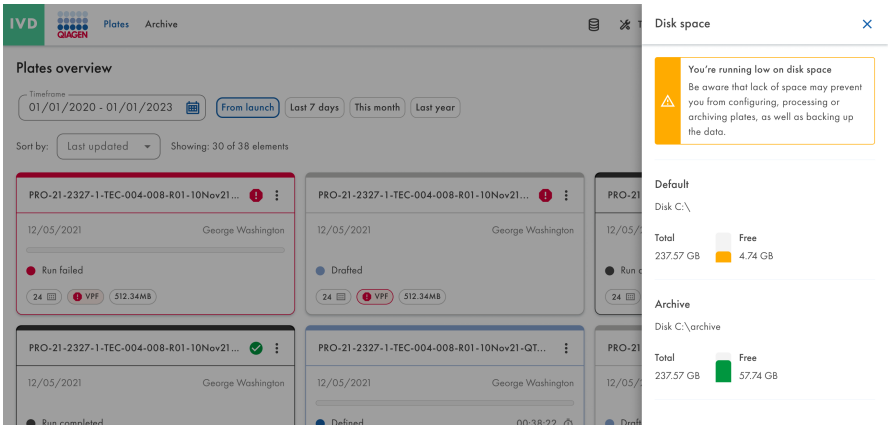
New value

name	Generic_Plate_24well_8.5K - Upgraded					
barcode	01234567890123456789012345					
plateTypeName	-					
dpcrParams	-					
primingProfile	-					
dpcrParams						
index	cycles					
1	count	position	cycleStep			
	1	0	position	temperature	duration	rampingSpeed
			0	40	5	3.5
	1	1	position	temperature	duration	rampingSpeed
			1	55	10	3.5
imaging						
index	imagingProfiles					
2	channel	durationOfExposure	gain			
	Green	700	8			
	Yellow	600	8			
	Orange	400	7			
	Red	300	4			
	Crimson	400	8			

5.11. QIAcuityDx Software Suite disk space monitoring

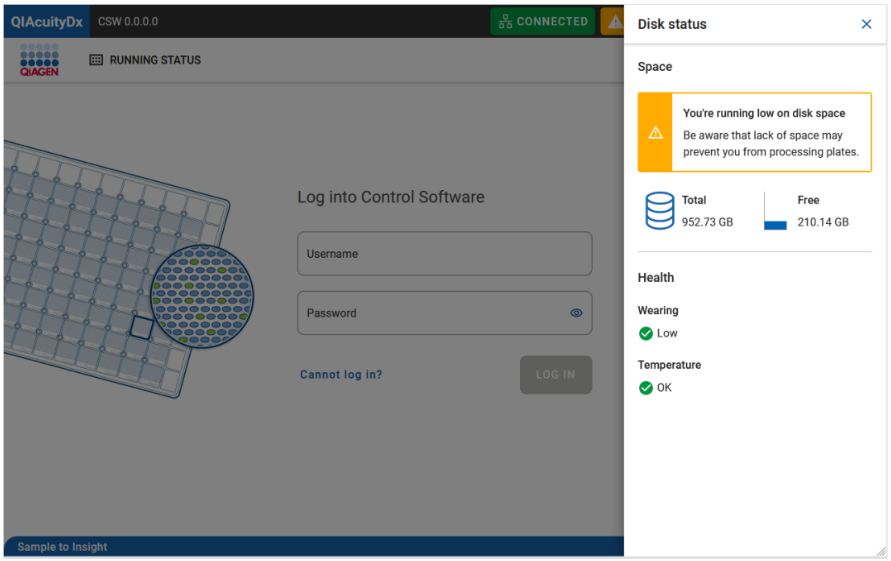
The Software Suite allows authorized users to monitor the disk space of the Software Suite storage and all external storage used for external files. The Software Suite notifies the user about insufficient storage space and prevents users executing any step of the IVD workflow (create plate, archive plate) if there is not sufficient storage available to complete it.

In event that 65% of the available disk space is occupied or whenever less than 10 GB of disk space is available, a Disk space warning is flagged on the Software Suite. In the event that 95% of the available disk space is occupied or whenever less than 5 GB of disk space is available, a Critical disk space warning is flagged on the Software Suite.



5.12. QIAcuityDx Control Software disk space monitoring

The instrument storage is also monitored to ensure sufficient disk space is available to generate and temporarily store raw image data prior to uploading it to the Software Suite. Disk space can be monitored directly in the instrument GUI on the right side of the top status bar, as shown in the below image:



If the instrument is unable to connect to the Software Suite, raw image data will be stored in the instrument storage. Once the connection is restored the instrument will automatically upload the stored images to the Software Suite. In some cases, the

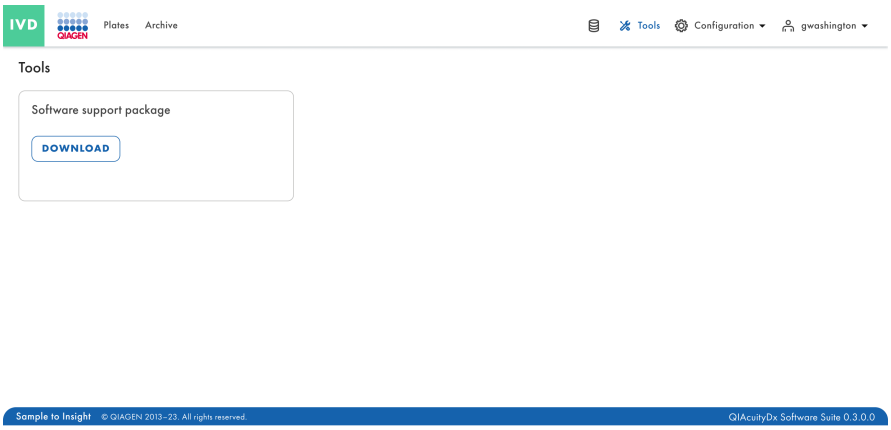
number of images temporarily stored in the instrument storage can drastically reduce the disk space available to store new images; in this case an error dialog will inform the user and suggest to clean up space by deleting images not yet uploaded to the Software Suite.

The Laboratory administrator user can delete images as required via the **Tools** > **System support** > **Disk Space**.

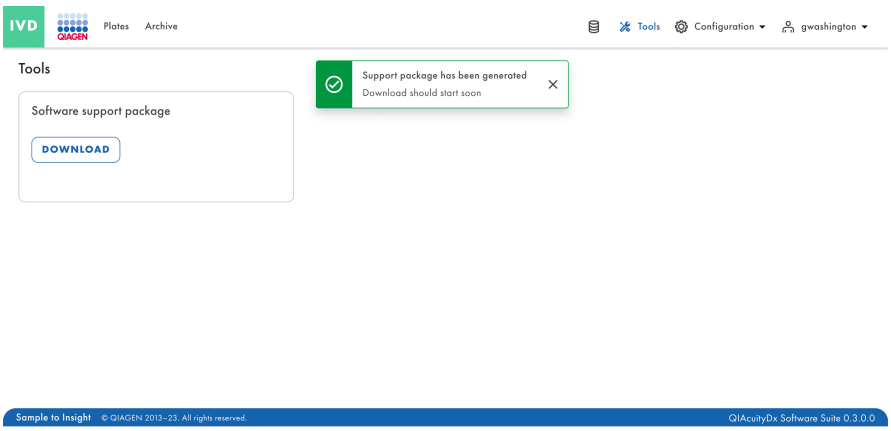
5.13. QIAcuityDx support packages

5.13.1. QIAcuityDx Software Suite support packages

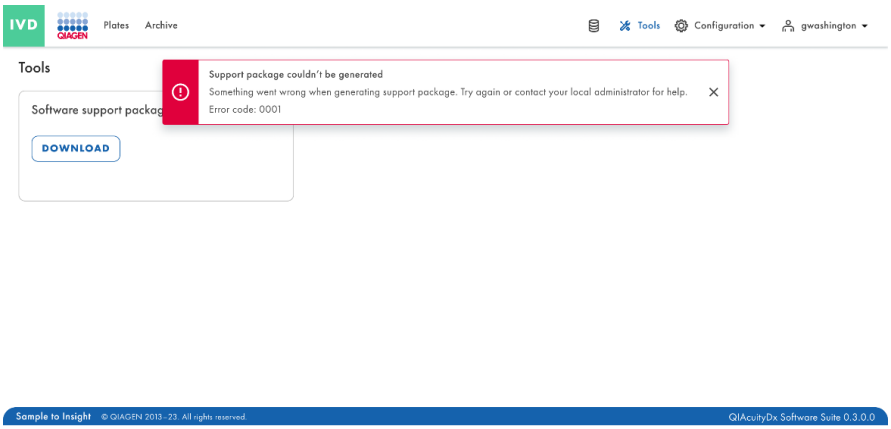
Any user logged into the Software Suite is able to create and download support packages containing the system logs by clicking the **Download** button in **Tools** > **Support Package**. The generated zip file is password protected and contains the log file(s).



The GUI informs the user about the successful creation of support packages.



An error notification is displayed whenever the support package cannot be generated.

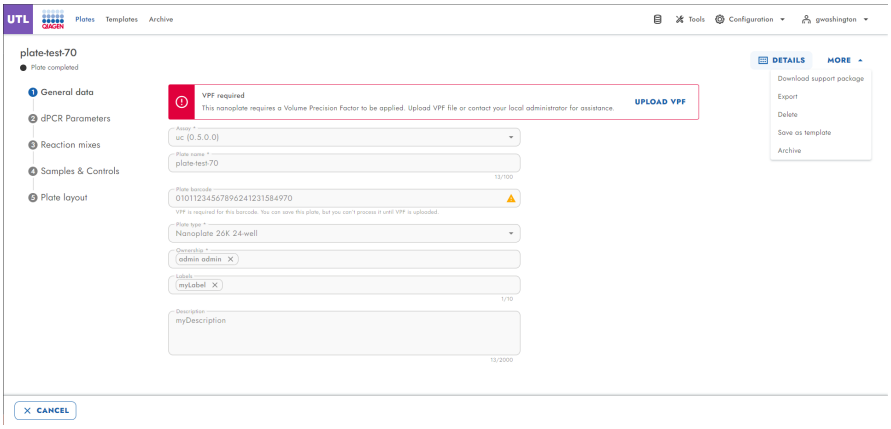


CAUTION **Loss of sensitive information**

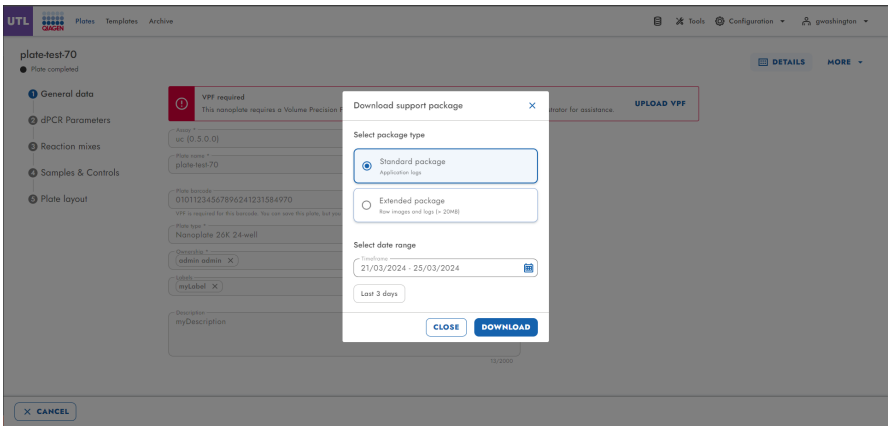
The Software Suite automatically removes log data older than 60 days. These log data encompass system information, audit trail activity, user management records, and records of external communications with LIMS. To ensure compliance with data retention policies and prevent the loss of sensitive information, we advise performing regular backups of the QIAcuityDx Suite Software Support Package and Instrument Support Package, ideally at intervals of 60 days or less.

5.13.2. Plate support packages

Each user with Create Support Package (Plates) permission is able to create a plate support package in the Software Suite.

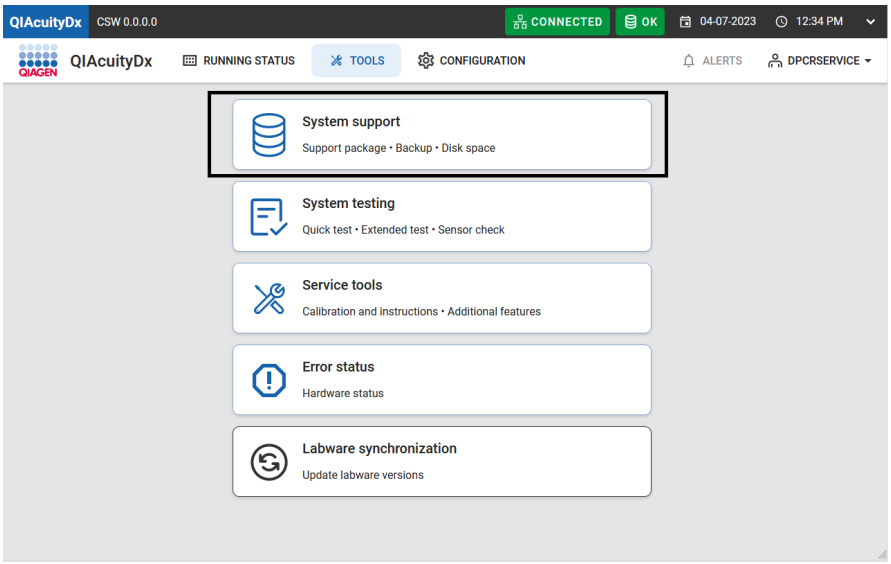


To download the plate support package, it is needed to define the package type (standard or extended) and the date range to be considered.

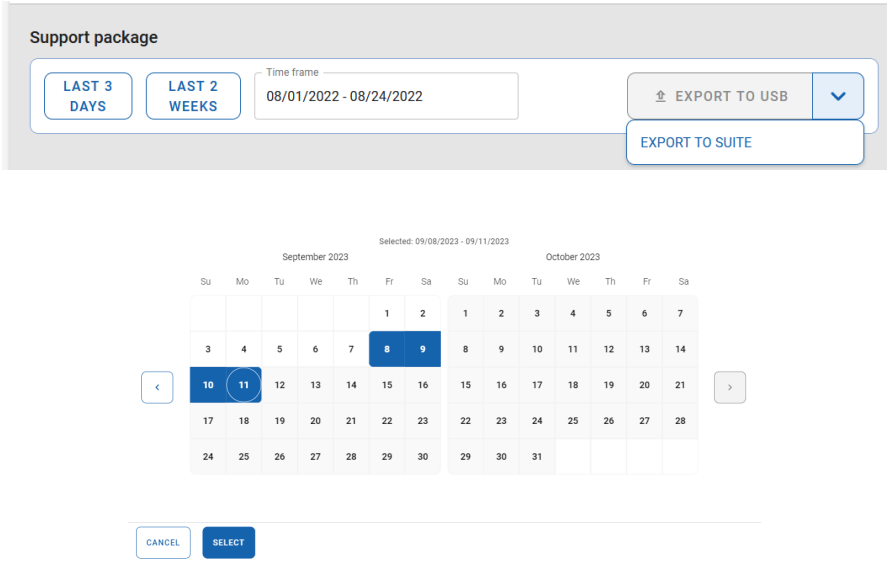


5.13.3. Instrument support packages

The instrument GUI does allow the user to export a support package that can be used from Global Product Support and the SW development team for troubleshooting; the instrument support package can be downloaded to an attached USB drive navigating to the **Tools** > **System Support** > **Support Package**.



The user, after connecting a USB Flash drive, can then choose the date interval of interest.

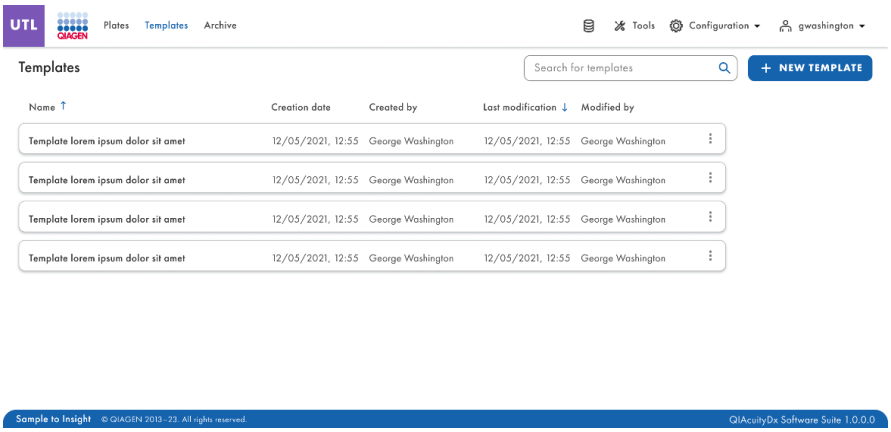


CAUTION **Loss of sensitive information**

The QIAcuityDx Software Suite automatically removes log data older than 60 days. These log data encompass system information, audit trail activity, user management records, and records of external communications with LIMS. To ensure compliance with data retention policies and prevent the loss of sensitive information, we advise performing regular backups of the QIAcuityDx Suite Software Support Package and Instrument Support Package, ideally at intervals of 60 days or less.

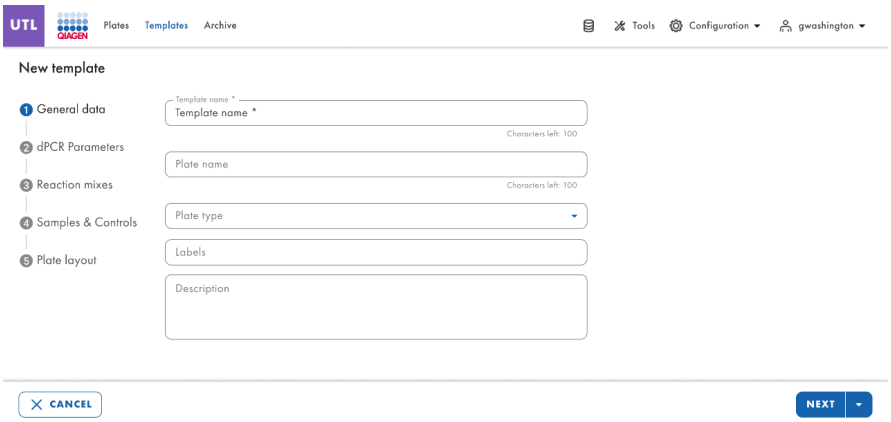
5.14. Using plate templates in Utility mode

Each authorized user with Create Template permission can create a new template in the QIAcuityDx Software Suite by clicking **New template** button.



The following fields are to fill in the General data section:

- Template name (mandatory)
- Plate name
- Plate type
- Labels
- Description



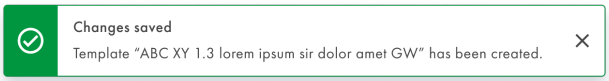
In the dPCR Parameters screen, the user can define the partitioning, cycling, and imaging.

In the Reaction mixes screen, the user can specify the reaction mixes.

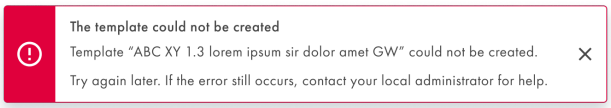
In the Samples & Controls screen, the user can define samples, controls, and NTCs.

In the Plate Layout screen, the user can define the Plate Layout.

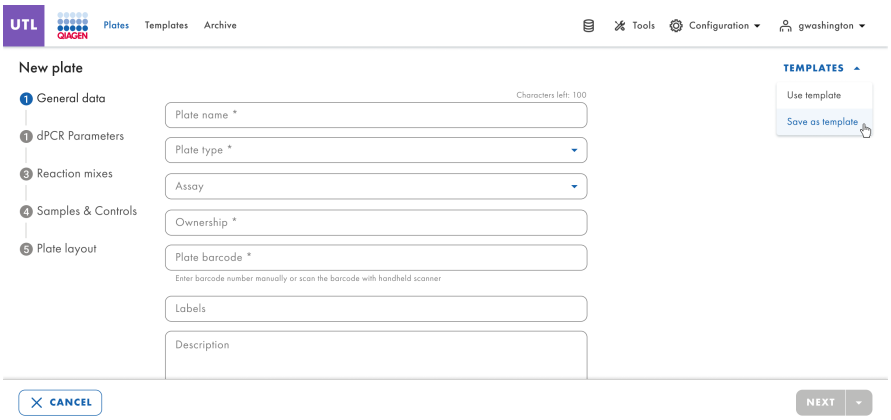
Upon successful creation of the template, a success notification pop/up is displayed.



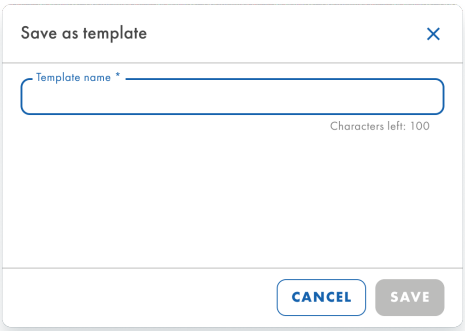
An error notification is displayed whenever a plate template cannot be created.



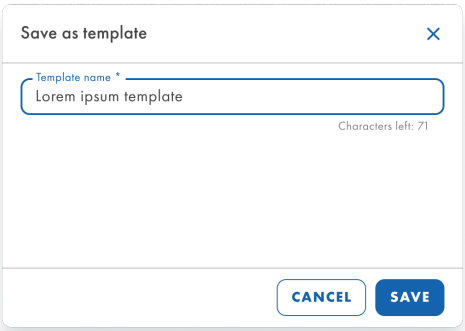
Additionally, a user with Create Template and Edit Plate permissions can create a new template from an existing plate in the Software Suite by clicking **Save as template** in the **Templates** split button menu.



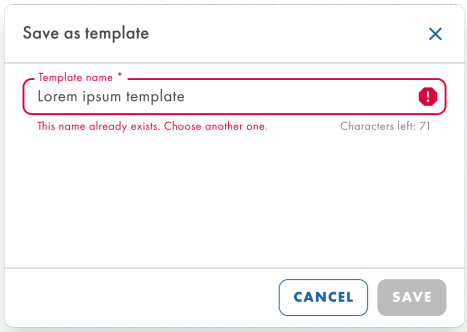
A pop-up window is displayed, allowing the user to enter the plate template name.



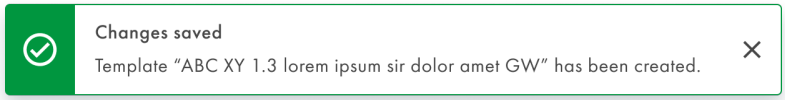
The **Save** button is enabled after some text has been entered.



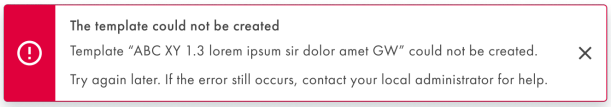
The Software Suite validates whether the entered template name already exists on the system and prevents creating a new plate template with the same name.



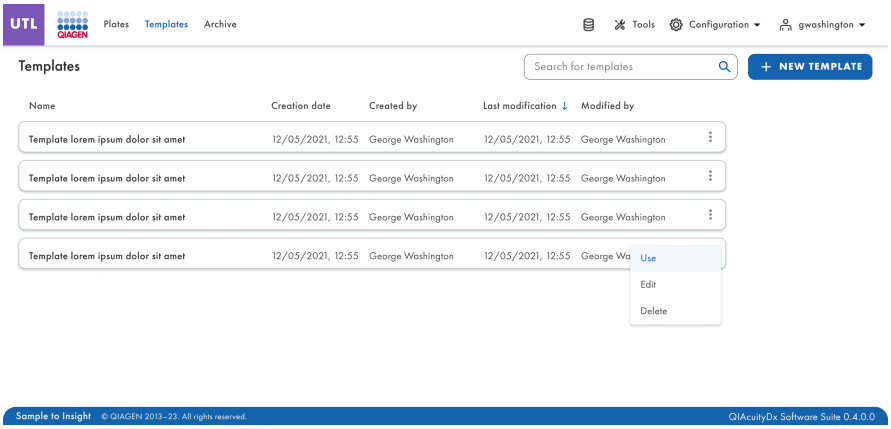
Upon successful creation of the template, a success notification pop-up is displayed.



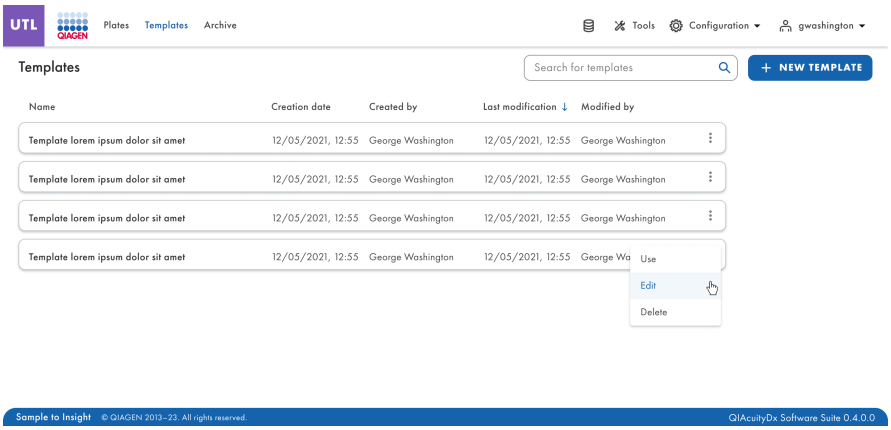
An error notification is displayed whenever a plate template cannot be created.



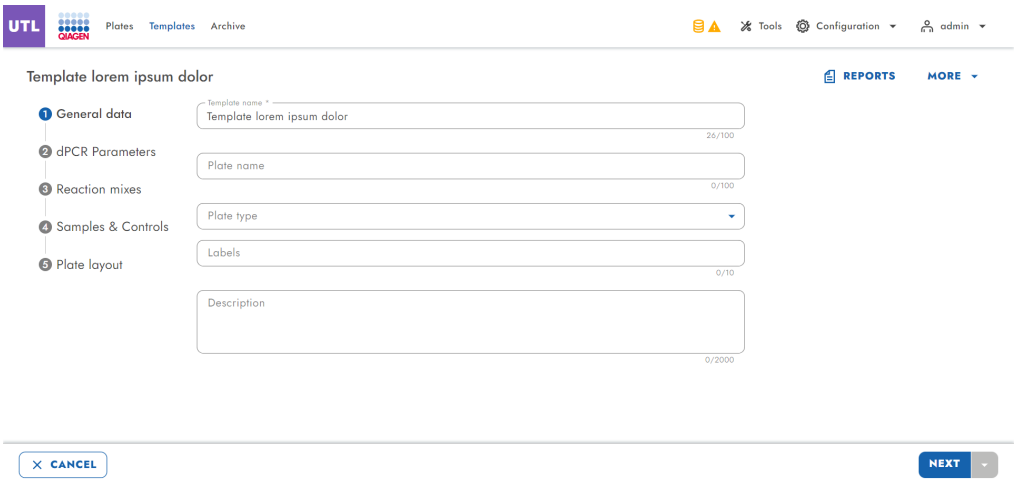
The authorized user with Read Template and Create Plate permissions can use plate templates when creating new plates.



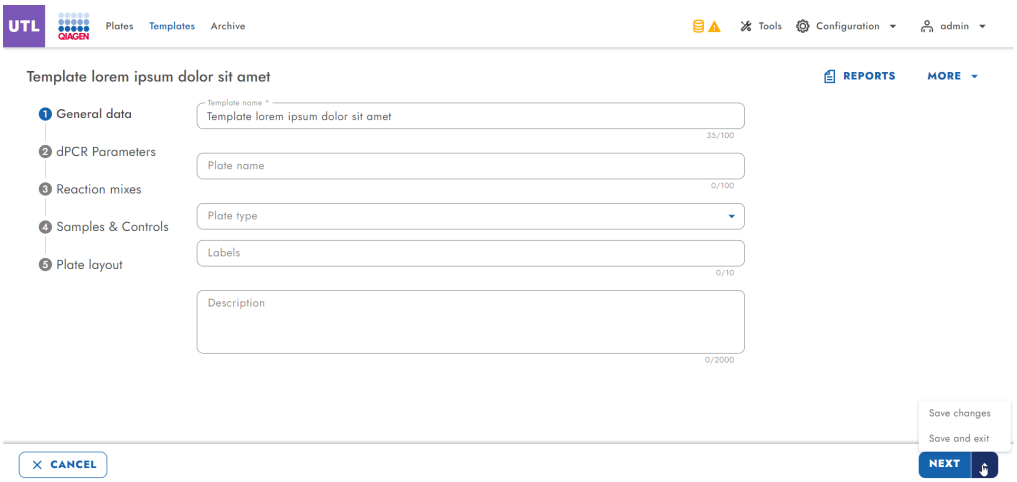
The authorized user with Edit Template permission can edit existing plate templates.



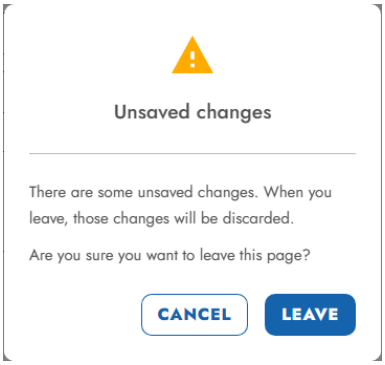
When the user clicks on the template name or selects the **Edit** option from the 3-dot menu, the Template configuration screen appears.



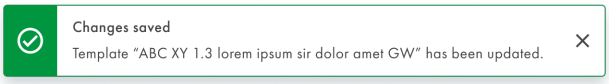
The **Save** button remains disabled until changes are made. When the user makes changes, the save button becomes active. However, if the user later undoes those changes, the **Save** button becomes disabled again.



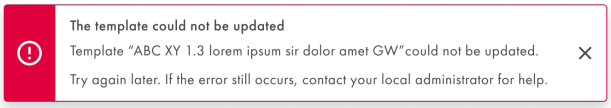
Whenever the user has modified a template and clicks the **Cancel** button without saving first, a warning confirmation pop-up is displayed:



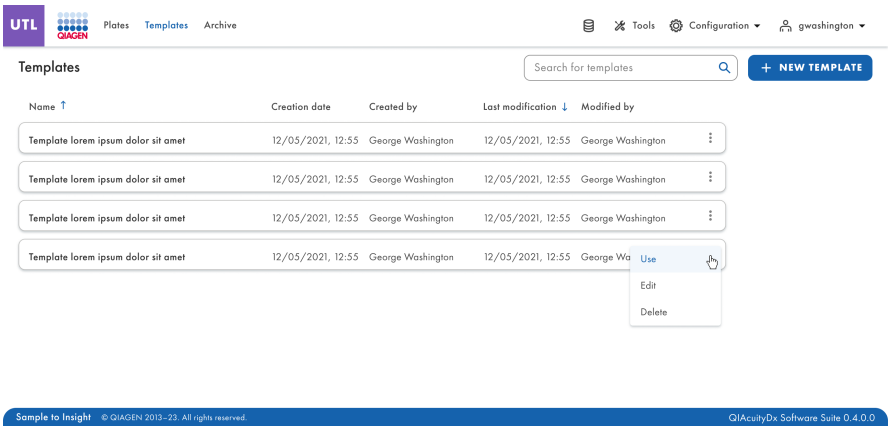
After updating an already created template, a success notification pop-up is displayed:



An error notification is displayed whenever the changes on a template cannot be saved:

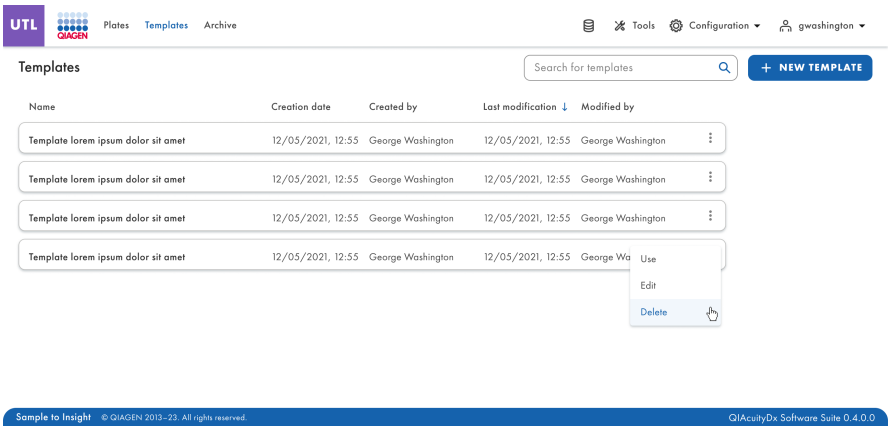


The authorized user with Read Template permission can view the details of the plate template. The template configuration screen appears when the user clicks the template name or selects **Use** or **Edit** from the 3-dot menu.

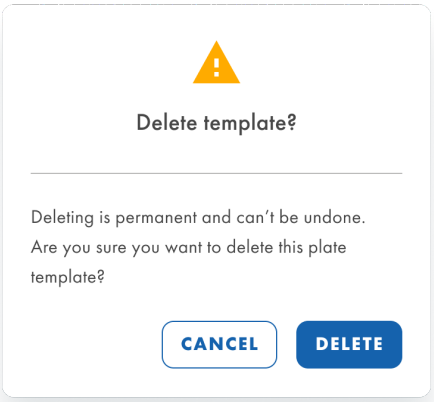


The split button on the bottom of the screen switches to the following template editing step and saving remains disabled until the changes are done.

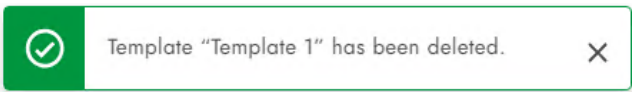
The authorized user with Delete Template permission can delete plate templates.



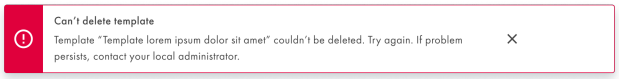
When the user selects **Delete** from a 3-dot menu, a warning confirmation pop-up message is displayed, informing the user that deleting a template is permanent.



After confirming the deletion of the template, a success notification pop-up is displayed once the template has been successfully deleted.

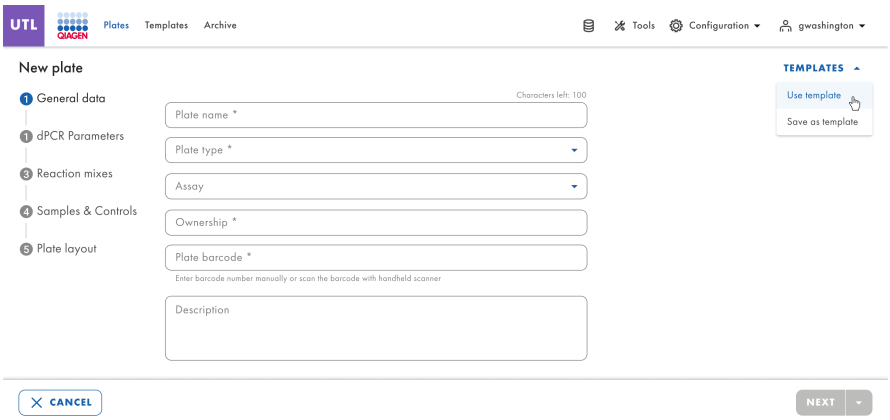


An error notification is displayed whenever a plate template cannot be deleted.

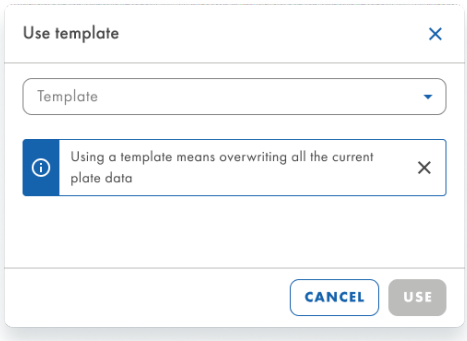


The authorized user with Read Template and Create Plate permissions can use a plate template when creating a new plate. The authorized user with Read Template and Edit Plate permissions can use a plate template when editing an existing plate. Importing plates loads a set of predefined data into the plate.

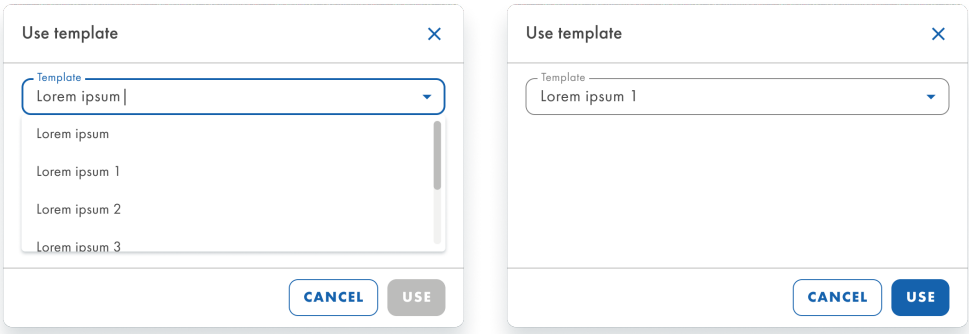
The user can import a template in the plate configuration screen, by clicking the **Templates** button, and selecting **Use template** in the drop-down.



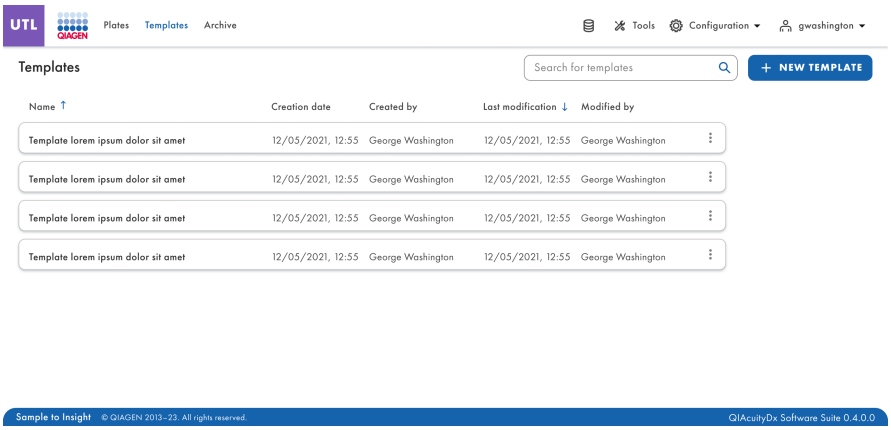
An information notification informs the user that by using a plate template all the current plate data are overwritten, and the data in the plate template are used instead.



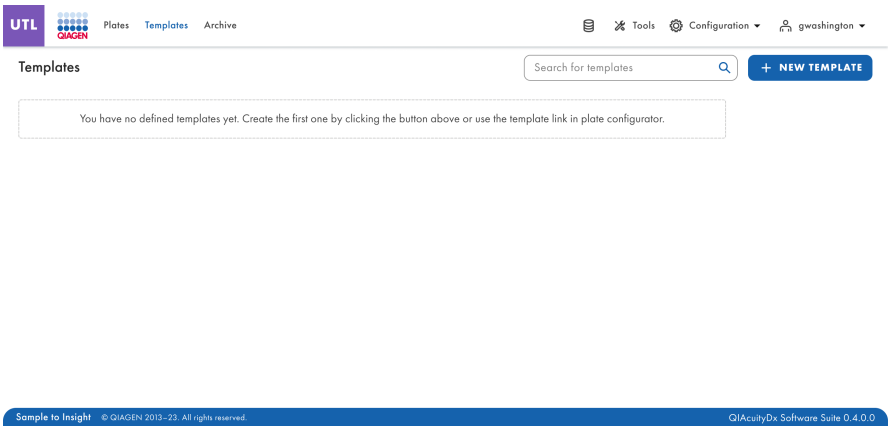
The user can select from the drop-down which plate template to use, and upon clicking **Use**, the plate template data are loaded.



Each authorized user with Read Template permission can see the list of templates in the Templates screen. The user can sort the list using the “Sort by” drop-down menu and sort by “Name”, “Creation date”, or “Last modification”. The sort value is “Last modification” by default. It is also possible to search for templates in the Search bar by name.

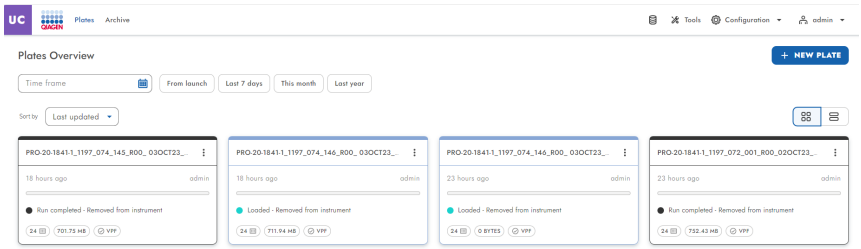


If no templates have been created yet, the following message is displayed:

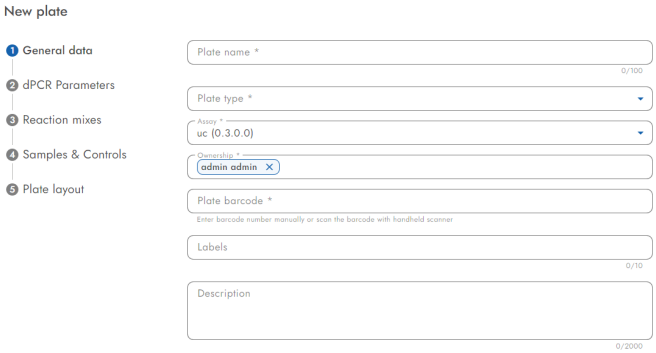


5.15. Create a new plate in Utility Mode

1. Click on the **New Plate** button at the top right of the screen in the plates overview screen to open the New Plate configurator overview page.

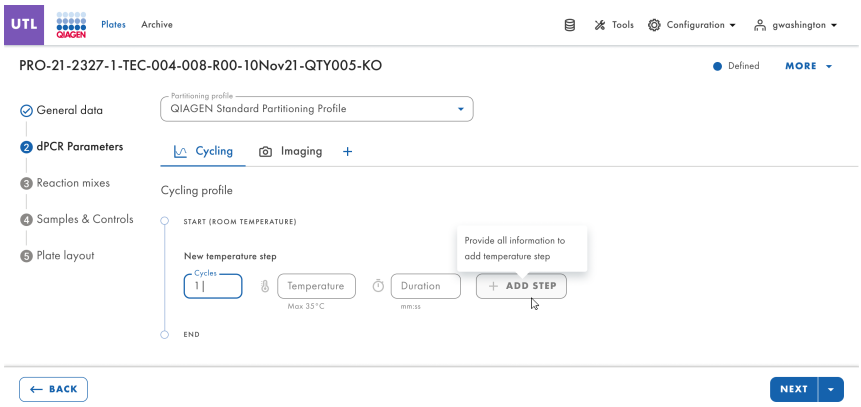


2. To create a new plate, enter a plate name, plate type, and assay plugin (um (1.0.0) will be selected by default) to save the plate information. It is recommended to scan or enter the plate barcode at this point.



Under the **General Data** tab: Mandatory input fields are marked with an asterisk. The plate name and plate type are required to save a plate.

3. Click **Next** thereafter fill out the **dPCR Parameters** as per your run set-up parameters.



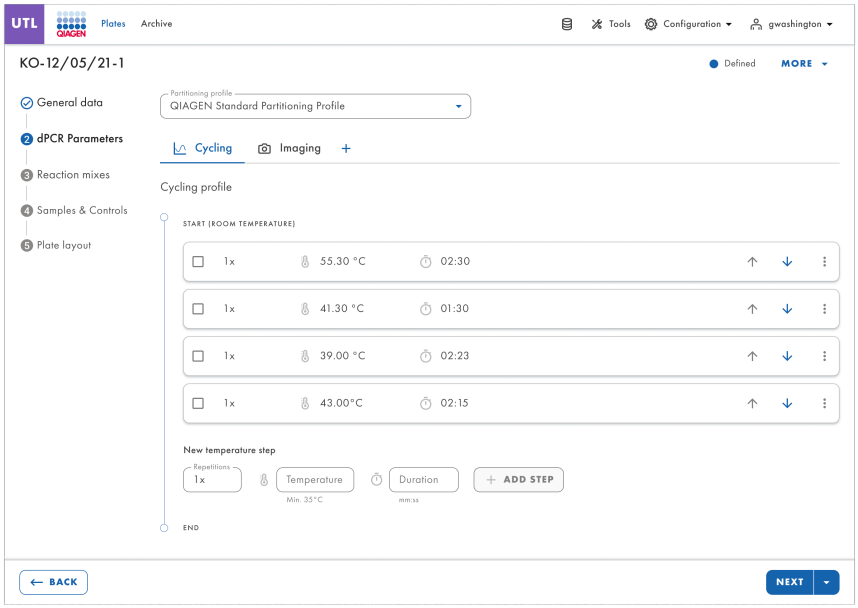
Select the partitioning profile applicable for the plate and your type of experiment.

Next, define the temperature profile of your experiment in the **Cycling** tab. To do this, follow these steps:

a. In the Temperature field, specify the temperature of the step the duration of the temperature step in the Duration field and the number of cycles of this Temperature step.

b. Click **Add Step**. The temperature step is added to your cycling profile.

See an example below on how to define Partitioning and Cycling:



As per the *QIAcuityDx Universal MasterMix Kit Product Sheet*, an initial heat activation step of 95°C for 2 minutes is recommended when using the QIAcuityDx Universal MasterMix Kit (1 mL: cat. no. 260101; 5 mL: cat. no. 260102) for dPCR runs. This initial incubation step activates the QuantiNova® DNA Polymerase in the QIAcuityDx Universal MasterMix Kit.

Repeat steps a and b for all temperature steps.

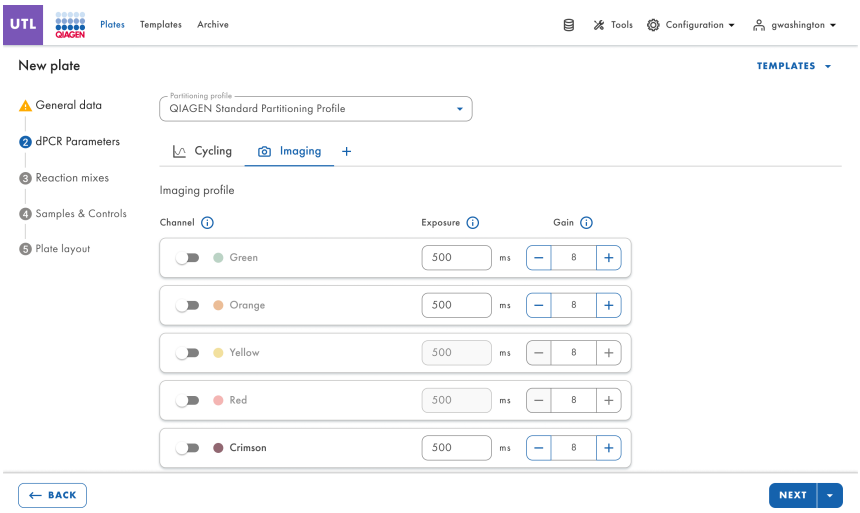
Note: Use the up and down arrows to arrange the order of the temperature steps.

Check the box corresponding to the temperature steps that you want to use for the repeated cycling. Then, click **Group**.

In the first column of the grouped temperature steps, add the number of cycles.

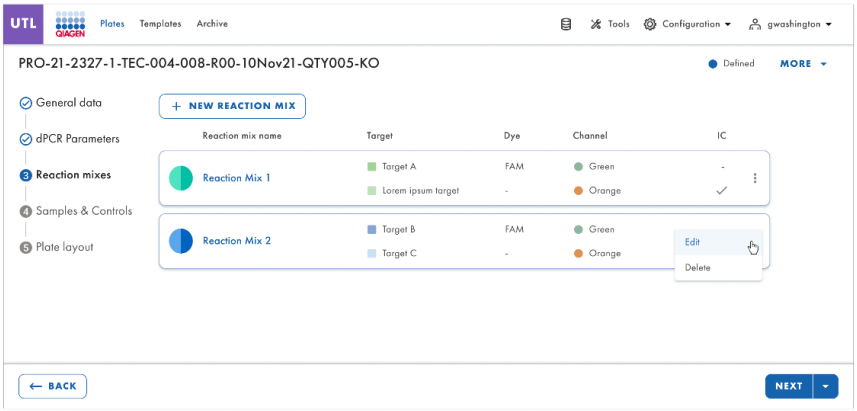
Note: To separate the grouped temperature steps, check the box corresponding to the group, then click **Ungroup**. To delete a temperature step, check the box corresponding to the step, then click **Delete**. The 3-dot menu in each temperature step enables you to edit or delete the step. You can enter values for the temperature between 35°C and 99°C.

The **Imaging** tab enables you to set the respective exposure duration and gain value for each channel. The QIAcuityDx Four instrument offer 5-plex analysis, with the available channels shown in the following table.

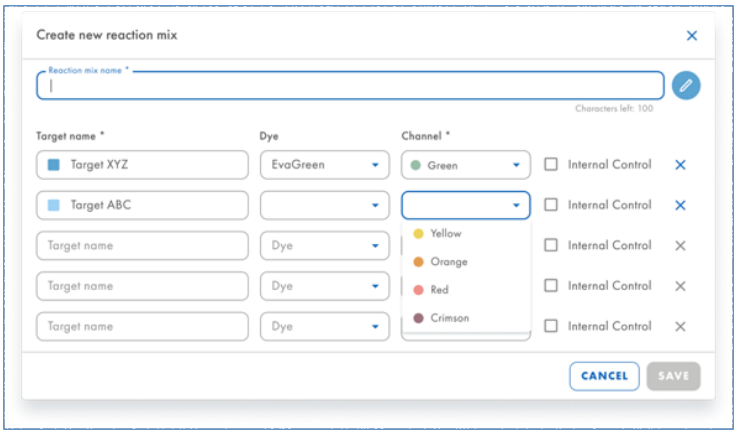


Note: The instruments offer an exposure duration from 1 to 4000 ms and a gain value of 0 to 40 dB.

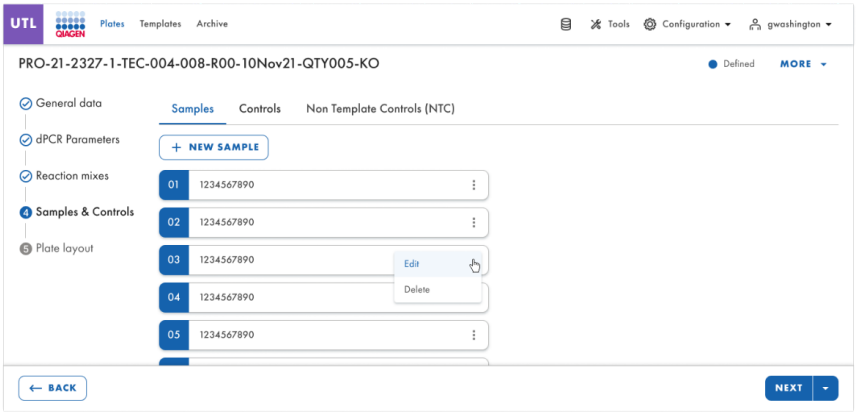
4. The default exposure times and gain settings are applied automatically. Depending on the assay, different settings may be required and so can be altered.
5. Ensure images are not oversaturated to allow crosstalk compensation algorithm for accurate correction. In the event of oversaturation, a warning message will be displayed on the Analysis screen during results analysis.
6. In QIAcuityDx, the dPCR Parameters, Reaction mixes, Samples & controls, and Plate layout screens must be defined before the run. Plates that do not have these sections defined cannot be run in the QIAcuityDx instrument.



7. To create a reaction mix, click on the **Reaction mix** tab. Define the reaction mix name, the target name, and the detection channel. If an Internal Control is present in a reaction mix, this can be defined here by checking the Internal Control box. Thereafter, click **Create** after completion.



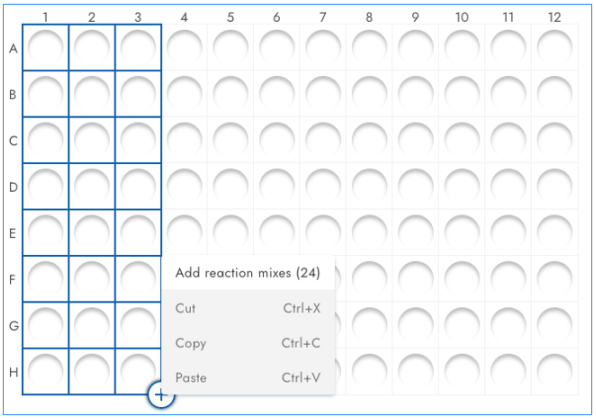
8. To enter sample details, click the **Samples & Controls** tab and add the samples required:



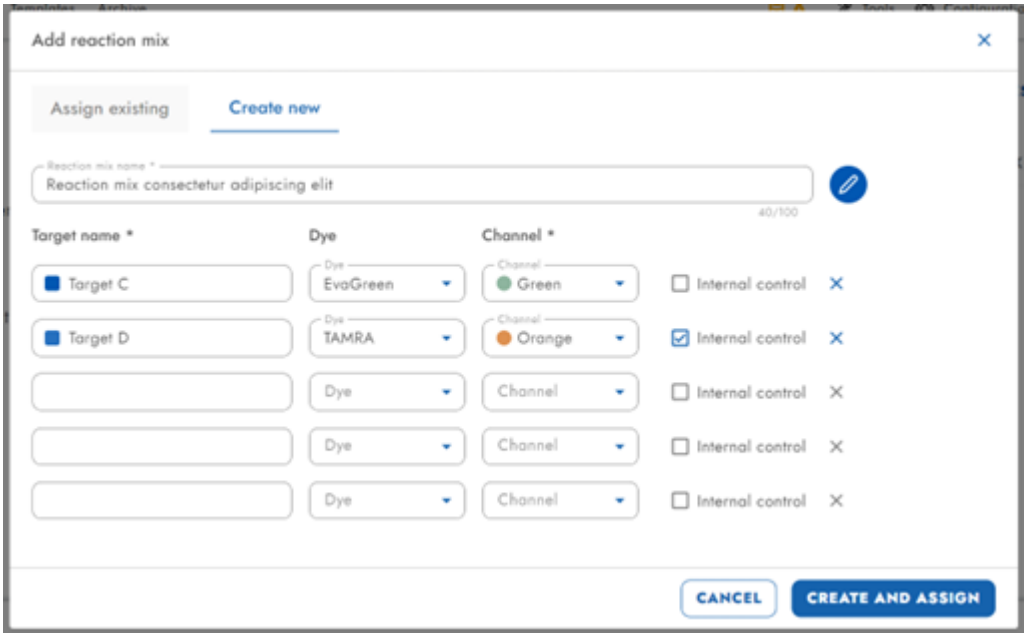
9. Allocate wells in the plate: In the **Plate Layout** tab, for the controls, and the non-template controls, only the name needs to be entered. Once added, click **Add Control**.

10. Creating reaction mix or controls can also be done in the **Plate Layout** tab.

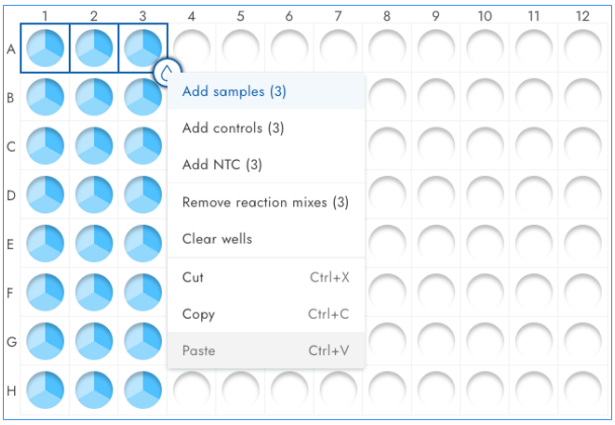
    a. First, click the well required that will contain the PC, NTC, or template.



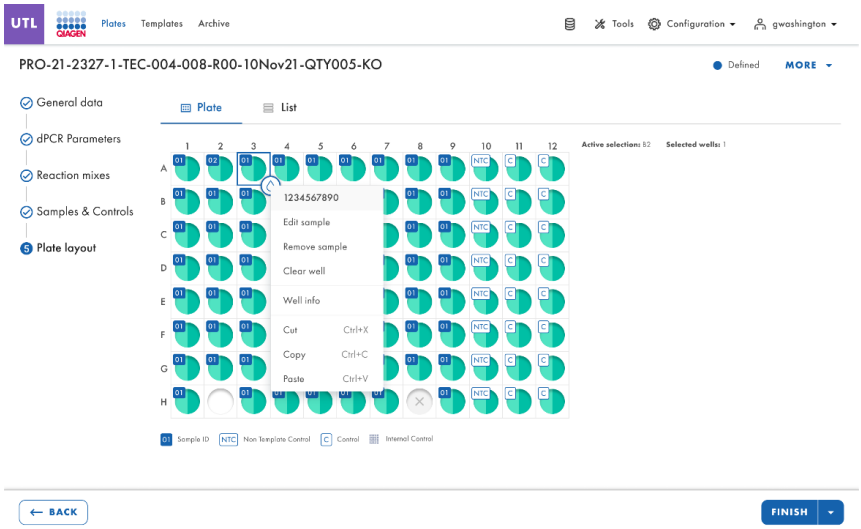
    b. Assign a reaction mix by selecting an existing one in **Assign existing** tab and then clicking **Assign** button, or create and assign a new reaction mix in **Create new** tab and then click the **Create & Assign** button.



One can assign each well with any of the templates or controls by selecting the drop-down menu after selecting the target well/s:



11. Once the plate layout has been entered save the layout by clicking **Finish**. Then click **Done** to return to the plates overview screen. The following message will appear on the screen:



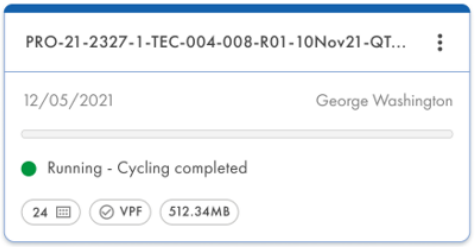
CAUTION **Sample mismatch**

To avoid potential sample mismatches, please be careful when assigning samples in the plate layout during Plate Creation. Ensure that the layout created in the application corresponds to the layout of the samples dispensed in the Nanoplate.

12. If the plate layout was not saved correctly due to error in plate layout the message “Plate saved with status: Drafted” will appear, indicating that one of the dPCR steps was not defined. Return to the run layout and check the data input and re-define. Once done, click the **Save** button again.
13. To return to the Plate overview screen, click **Done**. The run should now have a status of “Defined”.
14. The plate is now ready to run on the instrument.

    Users with Read Plate (All Plates) permission in Utility Mode can see the following details of all the UC plates in the system:

- Plate title
- Plate type
- Plate status
- Last update date
- Plate size
- Plate ownership
- VPF status



Note: Plate must have a status of "Defined". Plates with a status as drafted will not be able to run on the instrument.

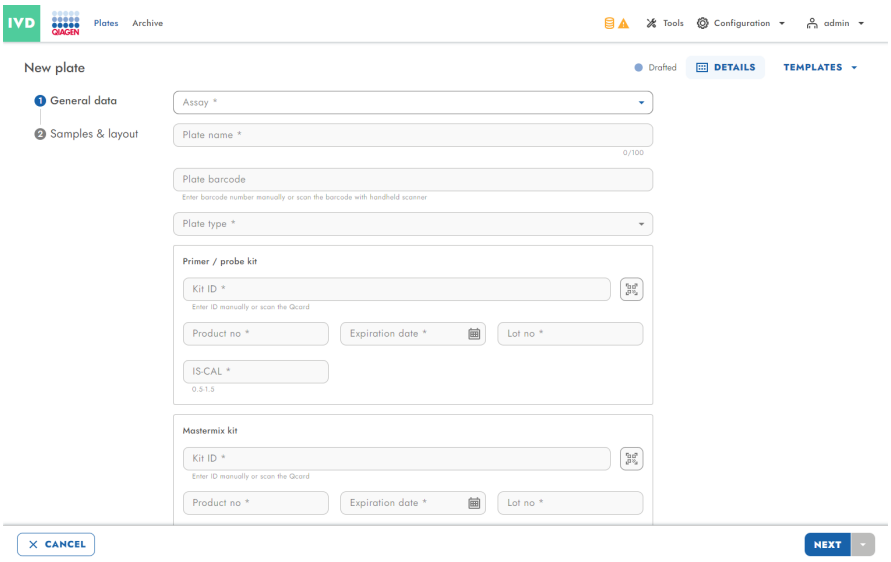
5.16. Create a new plate in IVD mode

Users can create new plates in IVD mode if they have Create Plate permission for the IVD Channel. To create new plates in IVD Mode, the following fields are mandatory to be filled in **General data**:

- Assay
- Plate name
- Plate type
- Kit information
  - Product no.
  - IS-CAL
- Ownership

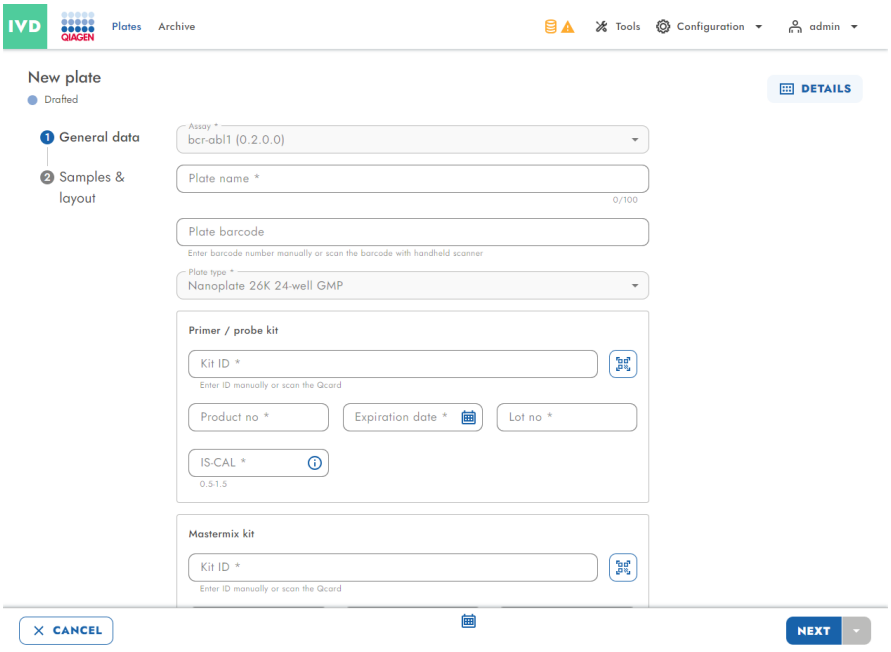
The following fields are also available to be filled in **General data**:

- Labels
- Description

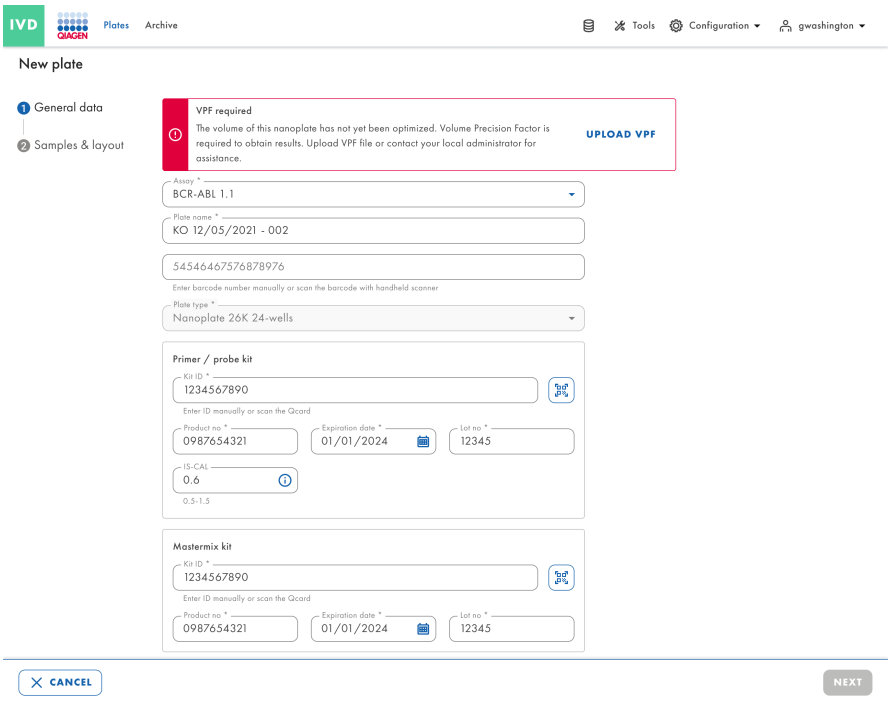


All fields are disabled until the assay is specified by the user.

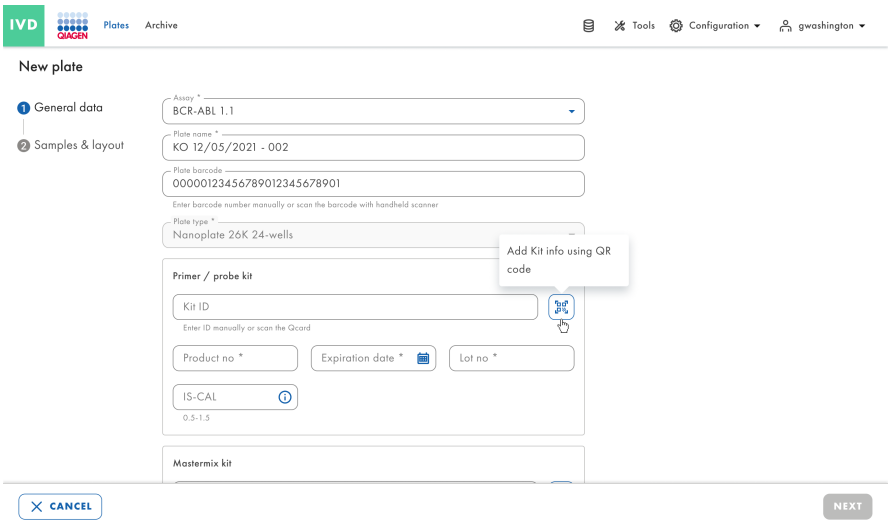
The user can save the first draft of the new plate after filling in the required mandatory fields. By clicking the arrow on the right of the **Next** button, the user can choose between the **Save changes** and **Save and exit** options.

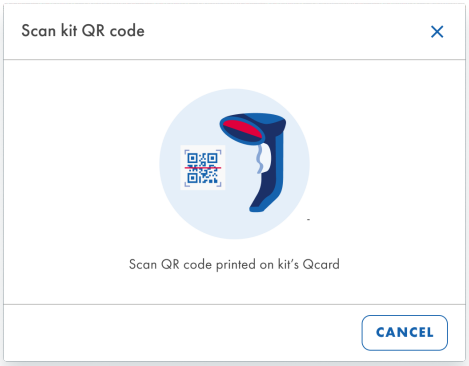


If the plate barcode does not match with a Volume Precision Factor (VPF) present in the system, the VPF warning is displayed.



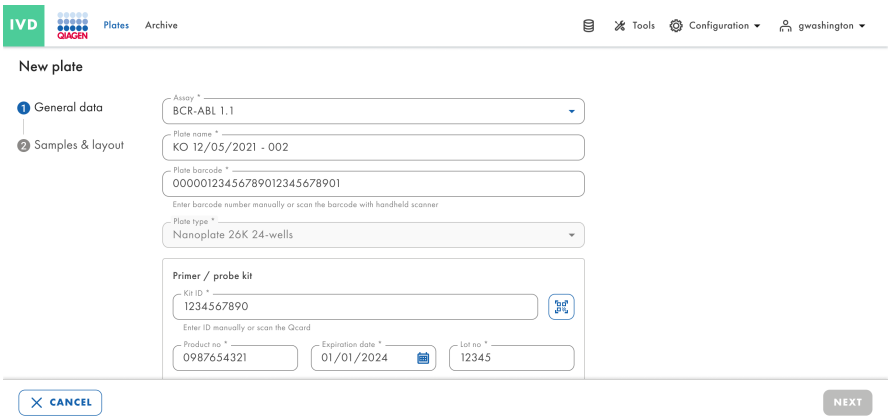
The authorized user with the required permissions can create an IVD Plate in the Software Suite with the appropriate reagent kit and perform regulated experiments.



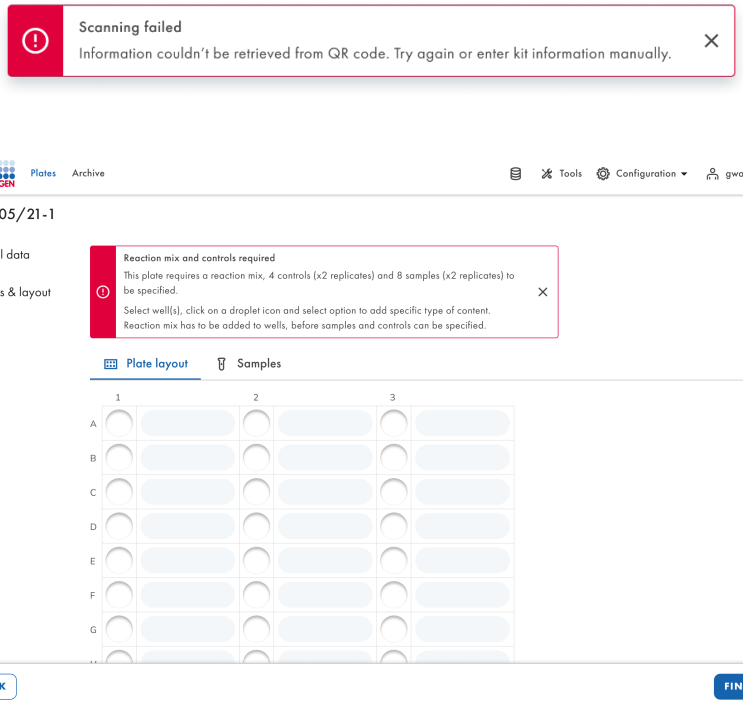


Using the connected scanner, the Subsystem obtains the correct Prime/Probe Kit and/or Master Mix Kit information and fills in the following fields:

- Prime/Probe Kit: Product ID, Lot Num, Expiry Date, Kit ID, IS-CAL Value
- Master Mix Kit: Product ID, Lot Num, Expiry Date, Kit ID.



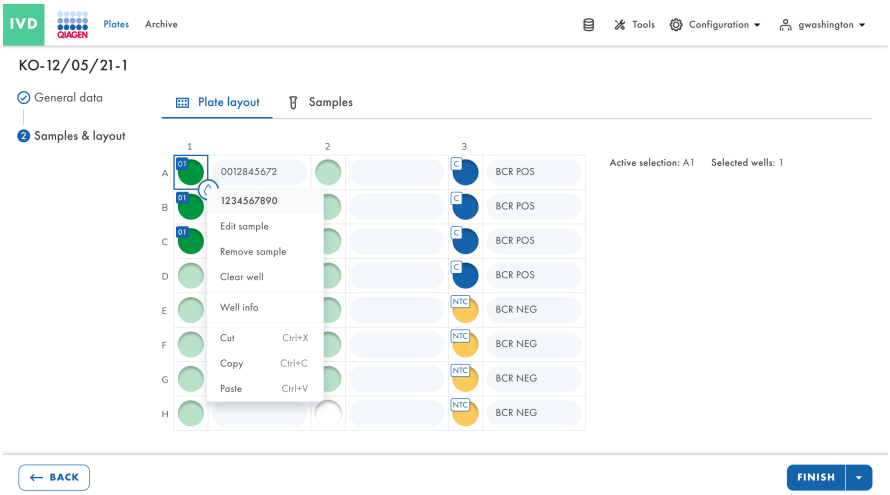
The subsystem will inform the user in the case of a scan error.



After the General information has been set, the user can configure the layout of the IVD plate. The **Samples & layout** tab contains the assignment of reaction mix, the creation and assignment of samples, as well as the assignment of controls and Non Template Controls (NTC). When creating a sample, it is possible to define the sample ID (mandatory), its labels, and its description. For the sample, control, and NTC assignment, a drop-down with the name of all the available options is displayed.

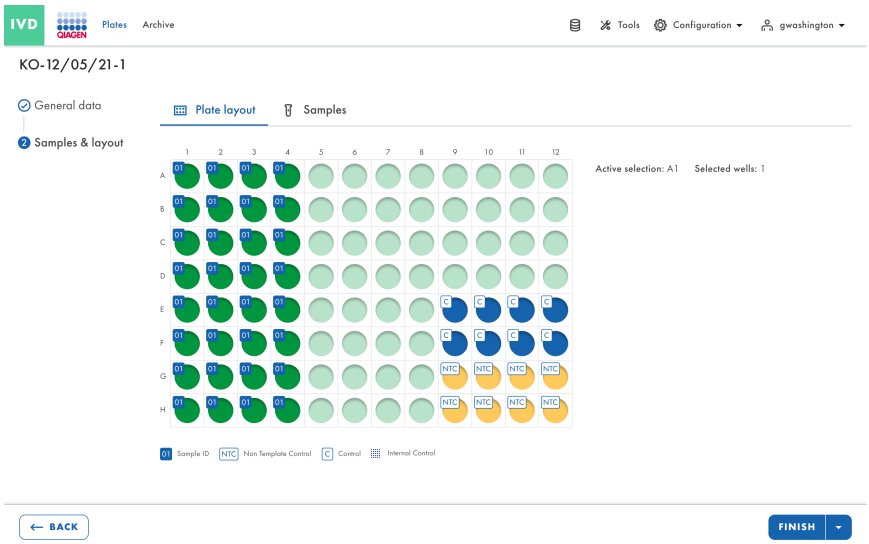
To define a wells contents, click on a well, select the droplet icon and select the option to add specific type of reaction mix'. A reaction mix has to be added to the wells, before samples and controls can be specified.

After the reaction mix is assigned to the well, the user can assign a sample. Controls and NTC are automatically placed in the layout by the assay. In future versions, users will be able to change the positions of controls and NTCs.

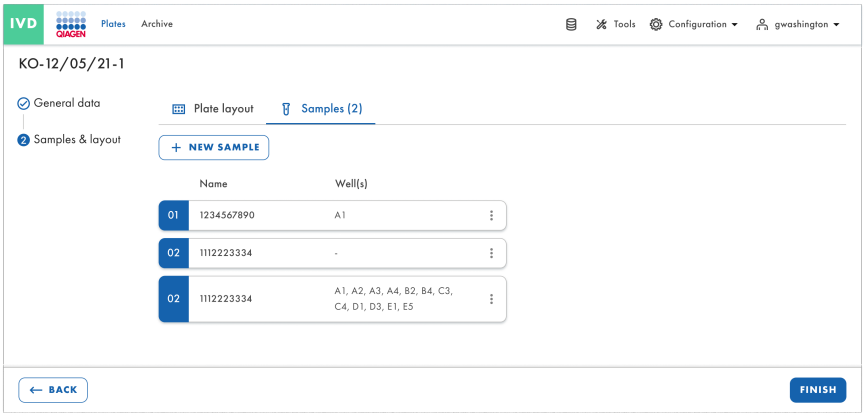


The Samples & layout screen contains 2 views:

- Plate Layout:



- Sample List:



5.17. Features of the Plate overview page in the QIAcuityDx Software Suite

A plate saved in the Software Suite will provide the plate properties of a run performed at a glance: this will include (1) the plate name, (2) the type of plate (24/96 wells), (3) the status of the plate, (4) a timestamp of the last plate update, and (5) the size of the data on the hard disk.

Clicking on the 3-dot menu in the bottom right corner of each tile opens a drop-down menu where users can directly select an action or redirection, depending on the selected mode (IVD or UTL), or the status of the plate.

5.17.1. IVD mode

In the IVD mode the following options can be selected based on the different plate status' described below:

Drafted status:

- Edit
- Export

Defined status:

- Edit
- Reports
- Export
- Archive

Loaded, In queue, Waiting, and Running status:

- Details
- Reports

Pending Review status:

- Details
- Review
- Reports

Plate Completed status:

- Details
- Review
- Reports
- Archive

Failed or Invalidated status:

- Details
- Review
- Reports
- Archive

5.17.2. Utility mode

In the Utility mode the following options can be selected based on the different plate status' described below:

Drafted status:

- Edit
- Export
- Delete

Defined status:

- Edit
- Export
- Delete
- Archive

Loaded, In queue, Waiting, and Running status:

- Details

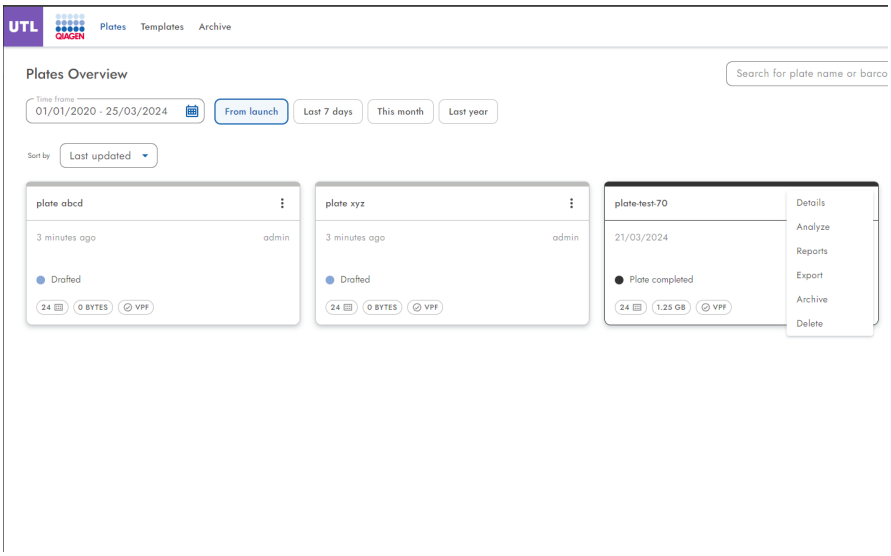
Plate Completed status:

- Details
- Export
- Archive
- Delete
- Analyze

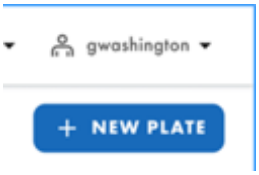
Failed or Invalidated status:

- Details
- Export
- Archive
- Delete
- Analyze

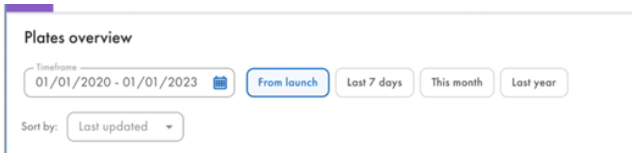
Note: The **Archive** plate option is only available if an archive location has been configured.



Users can switch between “tile view” and “list view” by clicking on the icons in the top right corner.



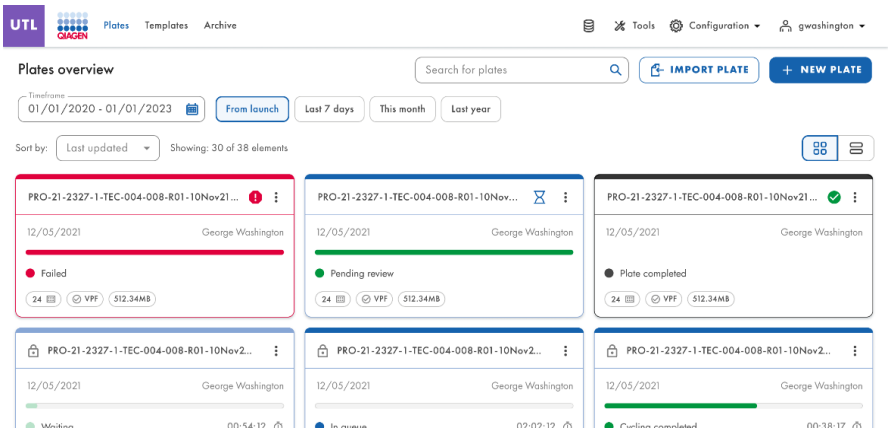
The date or calendar icon above the plate tile allows users to filter out or find runs for a specific date.



Users can also sort plates by various other criterion, by clicking on “sort by” drop-down menu. This enables users to sort plates by last update, plate name, or plate status.

Note: Plates cannot be imported from other versions of the suite into the Software Suite.

Users can search plates by plate name and plate barcode by typing in the **Search for plates** search bar.



5.18. Volume Precision Factor (VPF) upload

The Volume Precision Factor (VPF) offers a unique feature to ensure precision of concentration results obtained from a QIAcuityDx dPCR run. In general, nanoplates provide partitions of fixed sizes that enable a very precise way of sample concentration calculation. Potential variation of partition sizes in nanoplate batches, caused by different stampers (molding form for microstructures), can be addressed by applying the stamper-specific VPF. The VPF specifies the exact cycled volume of a well within a Nanoplate and therefore further increases precision of concentration calculation in each well. The microstructure molding form is defined by the first 2 digits of the plate barcode.

Note: Multiple plate batches can come from one microstructure molding form.

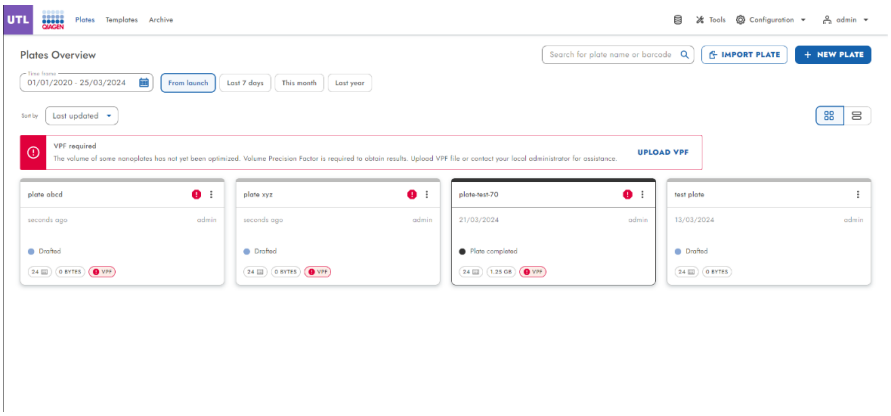
New sets of VPFs will be published during production of the nanoplate batches and can be downloaded from the QIAGEN website.

The new VPF must be uploaded to the Software Suite.

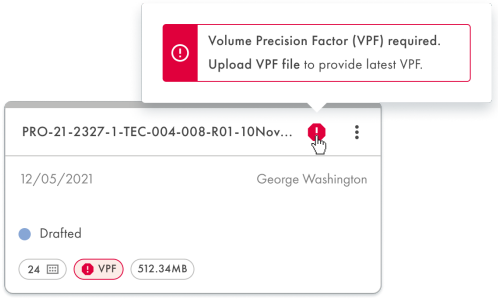
The Software Suite applies the uploaded VPF to the plate for calculating the partition volume variations when determining the concentration. The file is required to optimize the partition volumes of the Nanoplates to obtain results.

When defining a plate, the QIAcuityDx Software Suite verifies the presence of a valid VPF for the intended nanoplate. For nanoplates without a valid VPF encoded by the nanoplate the VPF icon circled in red.

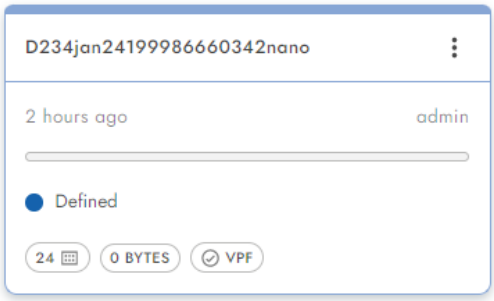
An inline warning message is displayed to all users to upload VPF files if any of the created plates are missing a VPF file.



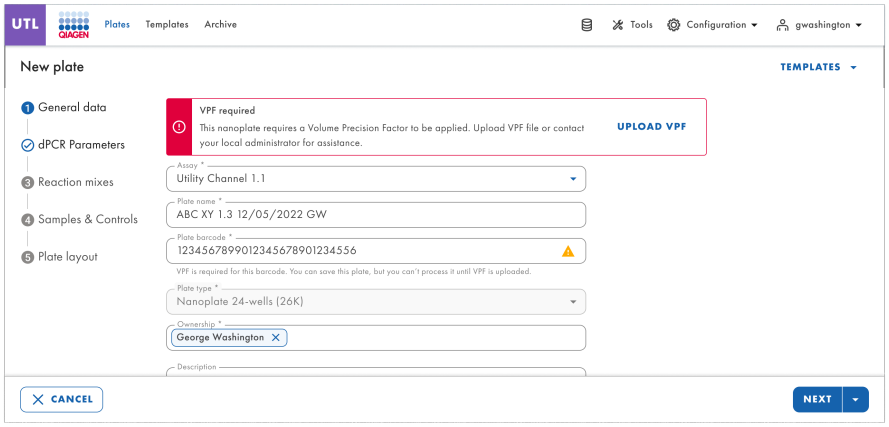
The “Volume Precision Factor (VPF) required. Upload VPF file to provide latest VPF.” pop-up warning message is displayed to each user if any of the created plates are missing a VPF file.



Nanoplates that have a barcode that encodes valid and uploaded VPF file do not display a warning in the VPF icon.

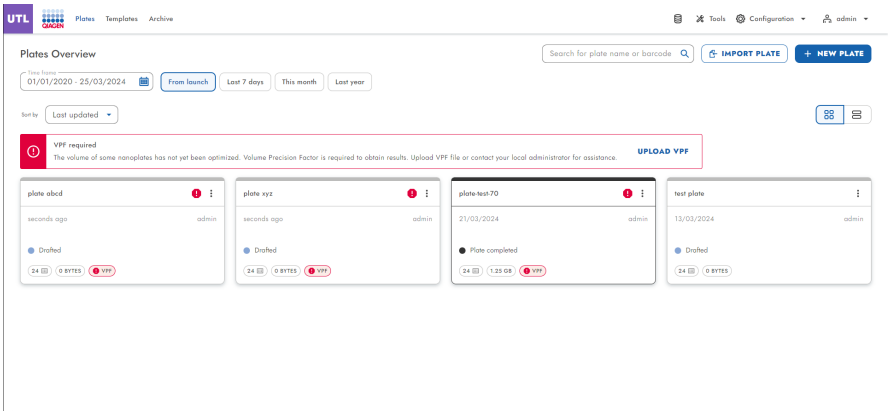


The Software Suite warns the user of the need to add the VPF in real-time when creating or editing a plate, without the need of saving it.

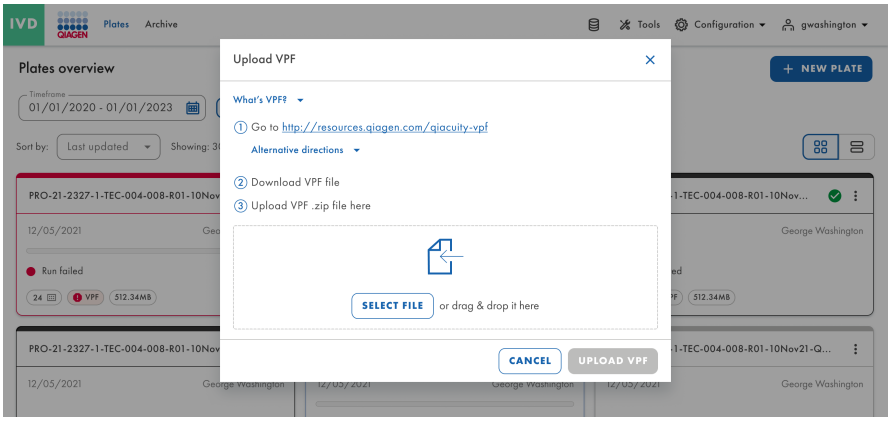


Upload VPF file from Plates Overview

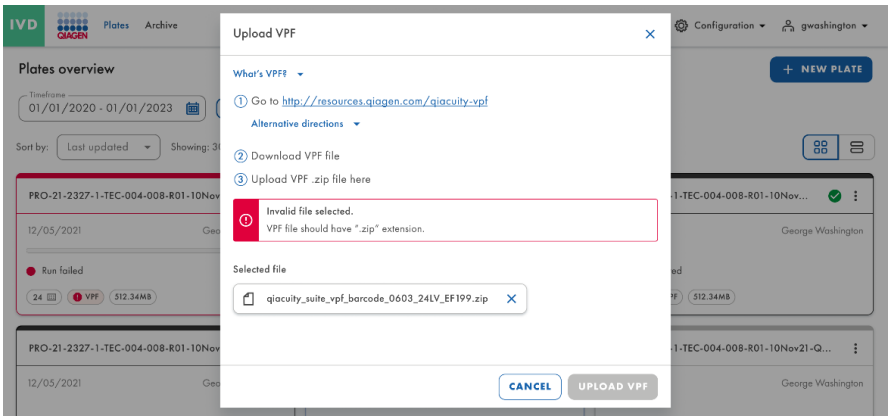
Users with Upload VPF permission can upload VPF files from the **Plates Overview** tab by clicking the **UPLOAD VPF** link in the inline warning message.



The “Upload VPF” pop-up is displayed. The “Upload VPF” pop-up contains the links and instructions for obtaining the VPF files.

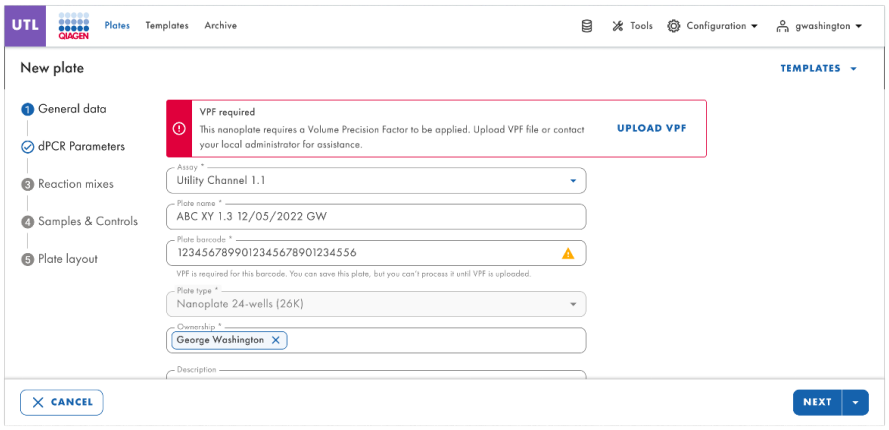


If the file format does not meet the requirements, an error message is displayed.

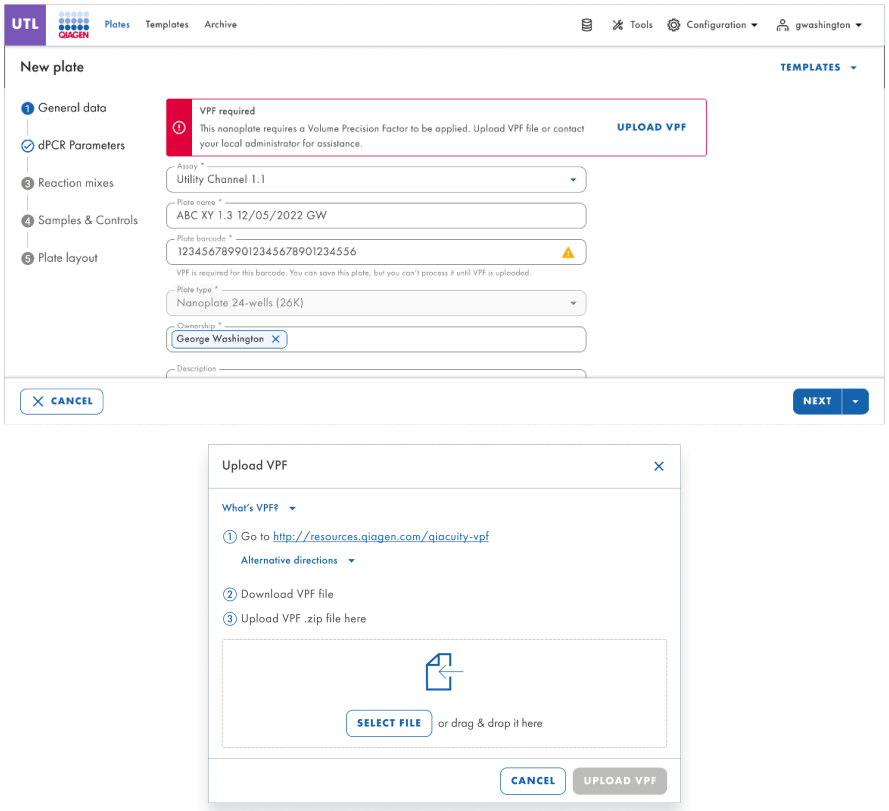


Upload VPF file from Plate Configurator

Users with "Read plate" (in the applicable channel) and "Upload VPF" permissions can upload VPF files from the "Plate Configurator" screen by clicking the **Upload VPF** link in the warning message.



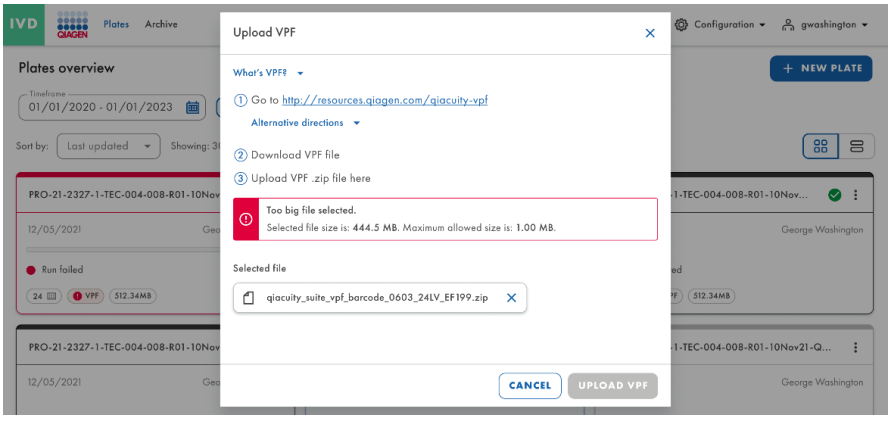
The Upload VPF pop-up is displayed.



The "This nanoplate requires a Volume Precision Factor to be applied. Upload VPF file or contact your local administrator for assistance." pop-up warning message without the **Upload VPF** link is displayed to users not authorized to upload VPF files whenever the plate is missing a VPF file.

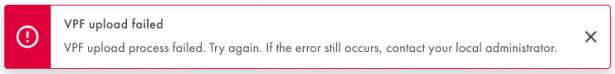
VPF file size and validity check

The Software Suite performs a file size check after a file has been uploaded via the VPF pop-up. Upon upload of a file, the Software Suite displays the file size and the file name. Files exceeding 1 MB cannot be uploaded and an error message is displayed.



If the size of the file uploaded is less than 1MB, a validity check will be performed.

An error message is displayed for invalid files and the VPF file will not be applied. All notifications are displayed in the top center of the screen.



An information pop-up is displayed after correct files have been successfully uploaded.

5.19. Performing a run

5.19.1. Loading the QIAcuityDx Nanoplate onto the instrument

CAUTION **Damage to the instrument**

Loading of a nanoplate without a top seal will trigger an error upon closing the drawer. Attach a top seal and re-load the nanoplate into the drawer.

CAUTION **Risk of material damage**

Users should allow the loaded nanoplate to reach ambient temperature prior to loading the QIAcuityDx instrument if stored under refrigeration.

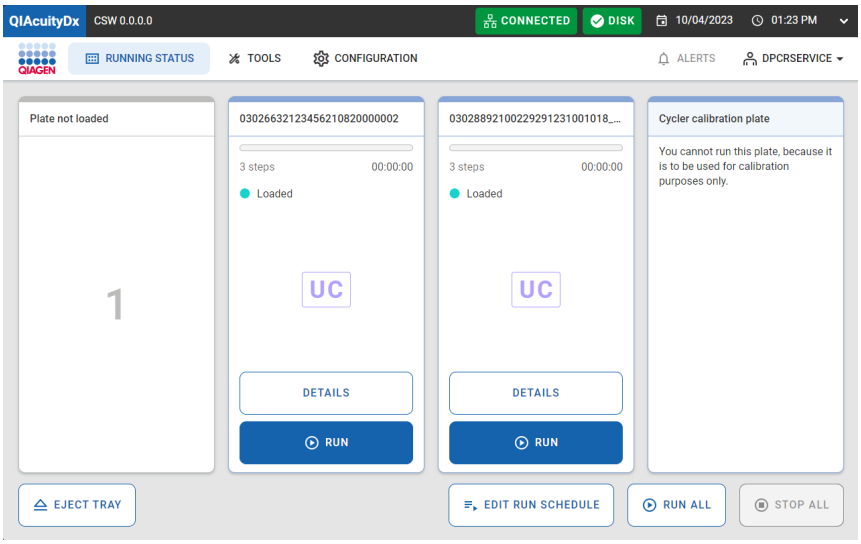
CAUTION **Damage to the instrument**

User should ensure the nanoplate is flat when loaded into the instrument drawer. Failure to do so may cause a collision.

1. If the instrument is not powered on, press the blue switch button at the front of the instrument.

2. Enter the username and password on the Login screen using the Control Software virtual keyboard.

3. The running status and available plate slots will be displayed on the screen.



The upper **Network** button with a green tick  or  shows that the instrument and Software Suite are connected.

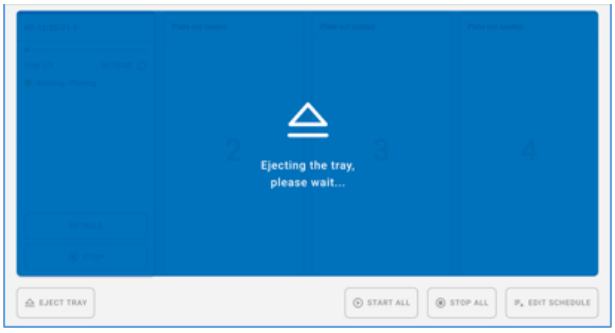
Note: If the instrument is not connected to the Software Suite via laboratory network or a direct cable connection, it will not be possible to run any plates on the instrument.

Note: Before loading a plate into the instrument, the plate run configuration shall be completed ("Defined") in the connected Software Suite. If no plate definition is found matching the barcode of the plate loaded, an error will be shown.

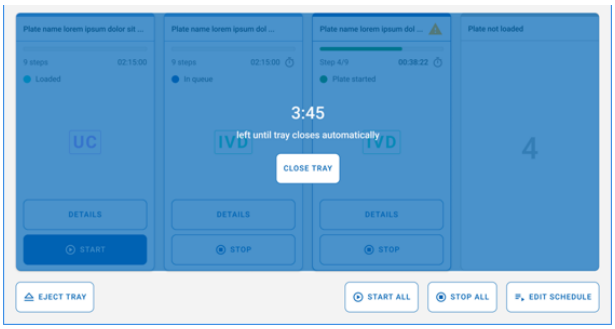
Note: Sample ID is a critical identifier needed to identify each test, which may be used by the manufacturer to investigate reported events, as required by law. For data protection reasons, it is required that sample IDs are de-identified (pseudonymized) by using alphanumerical codes, which do not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual.

4. At the bottom of the screen, the description shows that all modules are "idle." This indicates that all modules are ready for use. Now plates can be loaded.

5. Press the **EJECT TRAY** button on the GUI or press the physical button on the device itself to open the drawer.



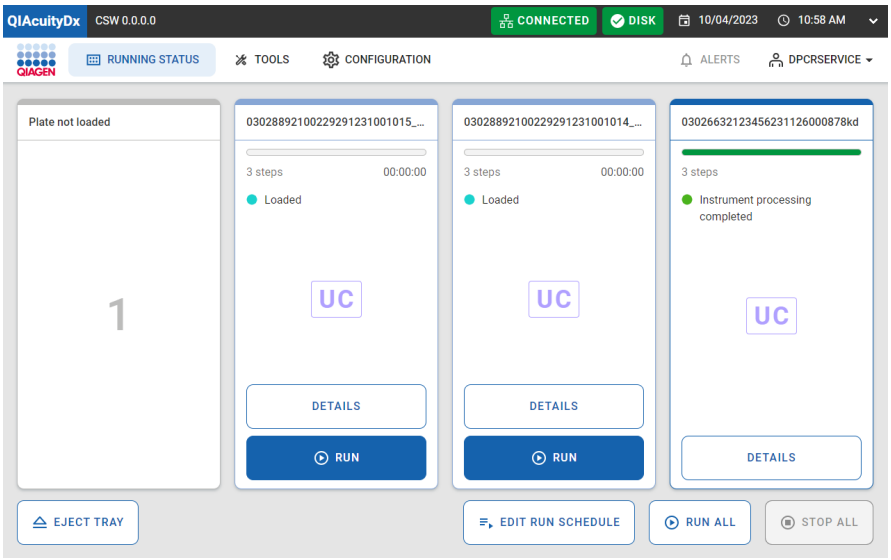
6. Remove the Nanoplate from the tray by using the GUI or physical tray release button. Place the Nanoplate into one of the free slots (not highlighted by an LED light) of the instrument with the barcode facing the device.



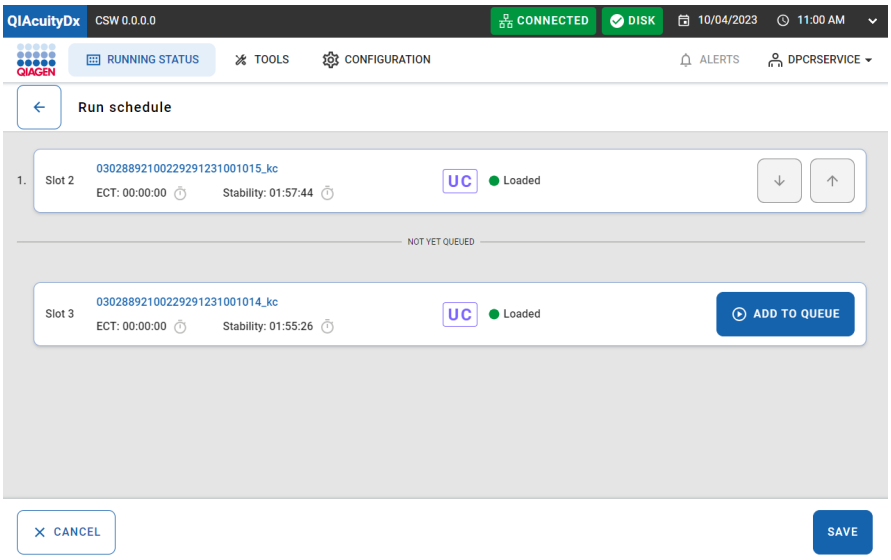
7. Press the **CLOSE TRAY** button to close the drawer once the plate is in place. If the button is not pressed, after the timer ends, it will close automatically automatically.
8. LED lights will show different colors depending on the status of the instrument:
    - **Blue**: for Nanoplates loaded but not started and while running.
    - **Red**: for a run that has error.
    - **Green**: for a run that is complete.

5.19.2. Editing the run schedule

The run schedule is the functionality that provides an overview of the current plates' run order and allows a user to modify it by moving plates up and down in the schedule, stopping currently running plates, and/or adding plate runs that have not yet started.



An overview of the current run schedule with the plate order and some basic information about each plate (such as *estimated completion time*, *stability time*, *name or location*, etc.) is available.



In this screen, a user has the ability to manipulate the order of scheduled plates as long as the plate is not already processed in a module. Clicking on the section delimited by the black border in the picture above, the user can see the full plate details.

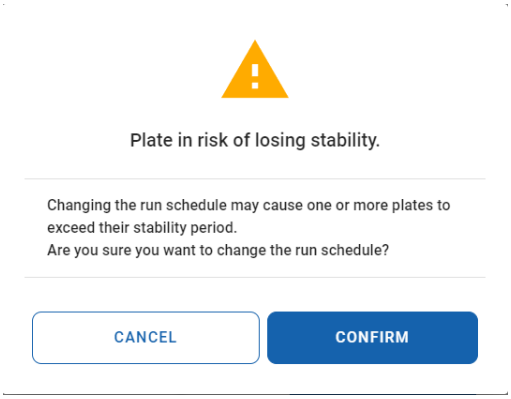
The Run schedule screen has 2 sections: one for scheduled plates and another for unscheduled ones. If there are no plates in one of these two, then that section is not displayed at all.

Moving a plate "up in the schedule" is allowed only if that plate is not on the top or not yet processed. Moving a plate "down the schedule" is possible for any plate not being processed yet that is also not at the bottom of the schedule already.

All the changes are only processed once the user clicks on the **Save** button and gets a successful response. Therefore, reordering operations can be performed without effectively altering the schedule as long as the **Save** button is not pressed. Moreover, any modifications carried out in scheduling are updated as the CSW updates the progress of the currently scheduled plates. Operators should be aware that completed plates are removed from the schedule and not be considered when any further changes are made to the schedule.

Opening the drawer while schedule modifications ongoing will discard all changes and redirect the user to the Running Status page.

In **Utility Channel**, the user will see the following dialog.



Onboard stability

The *Nanoplate Onboard Stability* is the time window within which a nanoplate, once loaded in the instrument, must be processed. Note that the time taken between sealing the nanoplate and loading it on the instrument does not count toward the onboard stability time window. The onboard stability timer is triggered when the nanoplate barcode is successfully scanned (i.e., loaded).

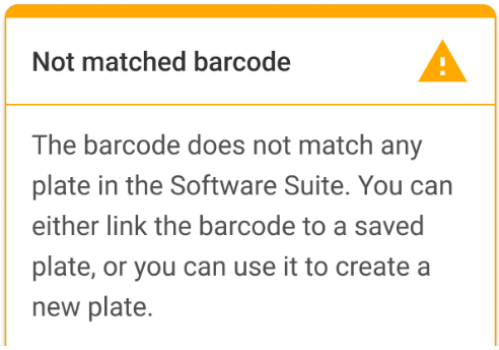
The onboard stability of the nanoplate can be seen as a dynamic metric, as it varies depending on the processing step the plate is at. There are 3 stages over which the onboard stability is timed:

- Post-loading: waiting to be primer rolled (2 hour stability time)
- Post-priming: awaiting for thermocycling (6 hour stability time, counting down)
- Post-thermocycling: waiting to be imaged (24 hour stability time, counting down)
- For each of these stages, the stability timeframes provided are parametrized (see Section 5.2 for more details) and provided by the Assay Plugin; therefore, the stability timeframes can be different depending on the Assay Plugin. For every other stage, the nanoplate onboard stability is not counted down, but instead reset. In those cases (i.e., plate in the primer-roller module, plate in the thermocycler module, or plate in the imaging module).

5.19.3. Running the QIAcuityDx Nanoplate

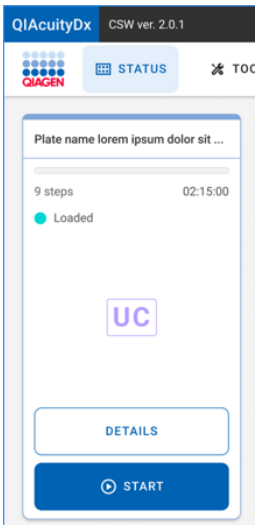
Once the QIAcuityDx Nanoplate is in place, the instrument will scan the barcode on the plate and the instrument tray LED lights will light up with a blue light.

If the barcode does not match up to an existing run then (i.e., the barcode has not been defined in the Software Suite), the following menu screen will be displayed in the Control Software:

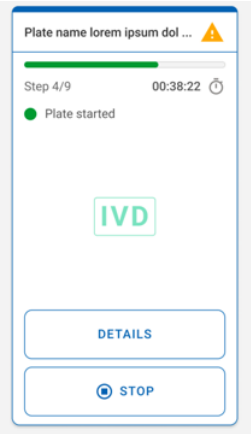


Note: If the barcode has not been predefined in the Software Suite, the plate must be removed from the instrument and the barcode must scanned into plate configurator in the Software Suite (see Sections 5.15 5.15 and Create a new plate in IVD mode Create a new plate in IVD mode).

The run can then be started by pressing the **START** button.



When the plate is running the following screen will appear:



Additional plates can be added while the instrument is running . If the instrument arm is busy, wait a few seconds then retry loading.

5.19.4. Check Plate Status during a run

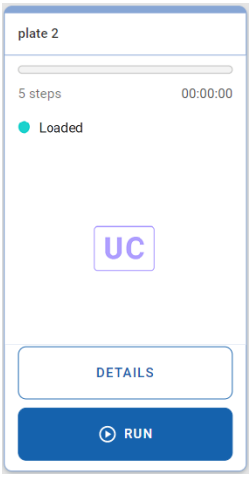
The plate is processed in the primary loading module, and the reaction mix of each well is partitioned into individual reactions. Then, a PCR is performed in the thermocycler. A positive fluorescence signal indicates the presence of suitable template material within a particular partition, which is detected during imaging.

The images are sent to the Software Suite for imaging processing.

The play status of the instrument can be viewed either on the instrument or on the software installed onto a computer.

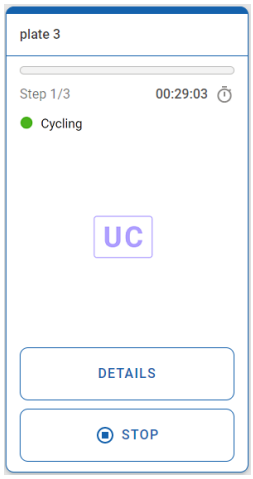
In the instrument's Running Status screen, each slot view can render a plate in any of its different possible states (thus, with different actions available for each case):

- Loaded



Each plate in the “Loaded” state can, as the name suggests, be run. If the user triggers the plate run (by clicking on the respective button), the plate changes its state to “in progress” (in case the run starts right away) or “in queue” (in case the run needs to wait until starting).

- In progress

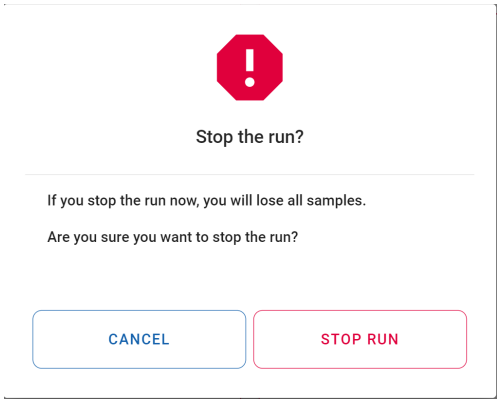


If a plate run is in progress, one of the following states can be displayed:

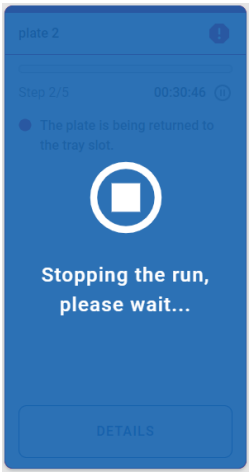
  - Plate started
  - Partitioning
  - Partitioning completed
  - Waiting – partitioning completed
  - Imaging
  - Imaging completed
  - Waiting – imaging completed
  - Cycling
  - Cycling completed
  - Waiting – cycling completed

When at least 1 plate is running all the page tabs are disabled. A plate can be stopped while it is in progress.

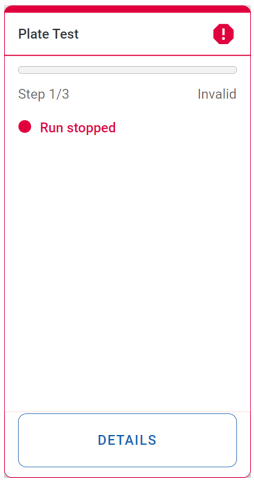
When clicking on the **Stop** button, the user has then to confirm that action via a confirmation dialog.



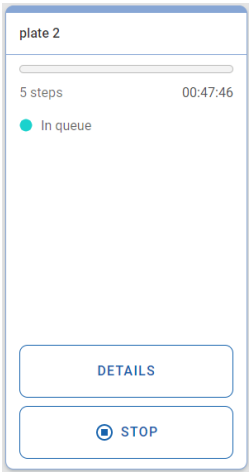
When a plate run is stopped, the plate is transported back to the tray (to its original slot) and, while that is happening, a blue overlay is displayed over its tile.



Once the plate is back to its original slot, the overlay disappears. From that point, the plate is invalidated (it will not be possible to run it again) and an error title is shown instead.

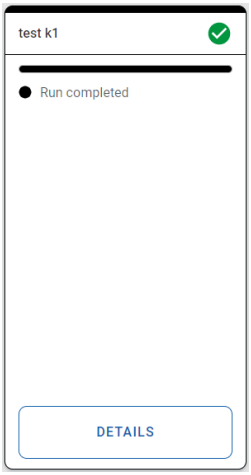


- In queue



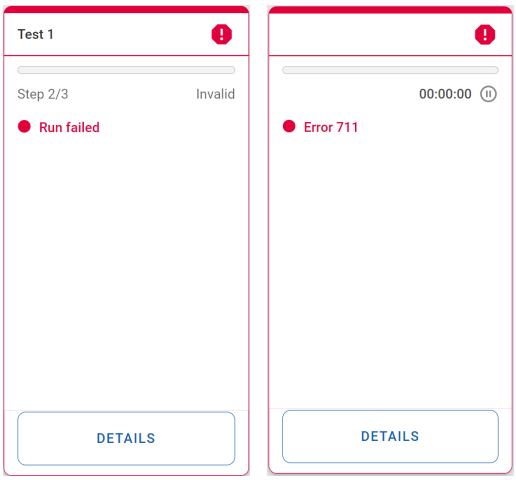
When a plate is “in queue”, it can be stopped. If so, it immediately changes its state back to “loaded”. In such case, as no run has started, the plate can still be run.

- Completed



This tile is visible when a plate run is successfully completed.

- Error

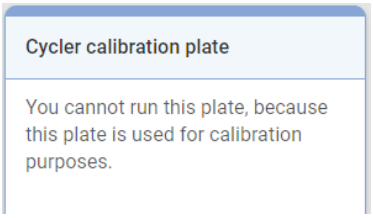


These tiles are visible when a plate run failed or when there is another error affecting the plate tile status (e.g., Error 711 – Software Suite Connectivity Issues).

- Plate not loaded

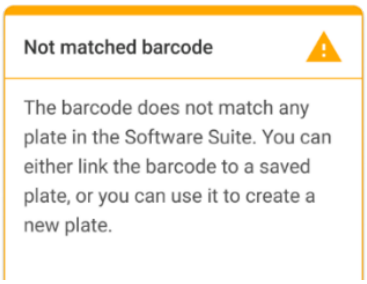
This tile is visible when the tray slot does not have any plate loaded.

- Calibration plate



This tile is visible when the tray slot has a calibration plate loaded.

- Not matched barcode



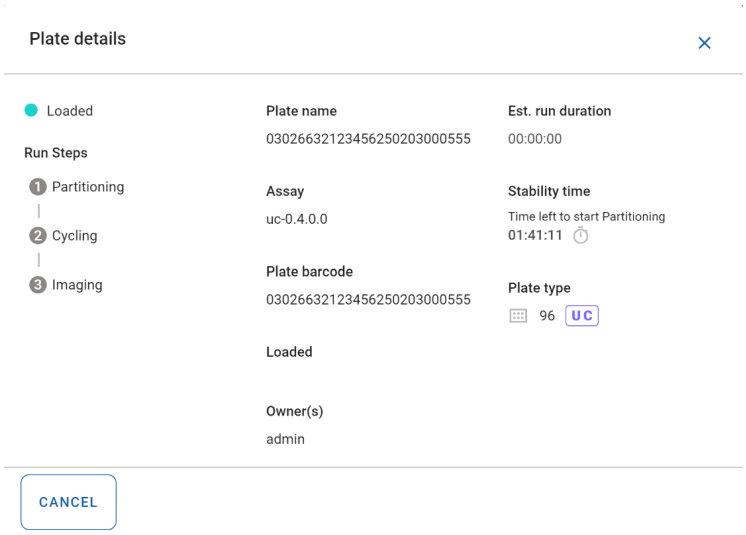
This tile is visible when there is no barcode match (considering the labware data retrieved from Software Suite) for the loaded plate.

Plate details

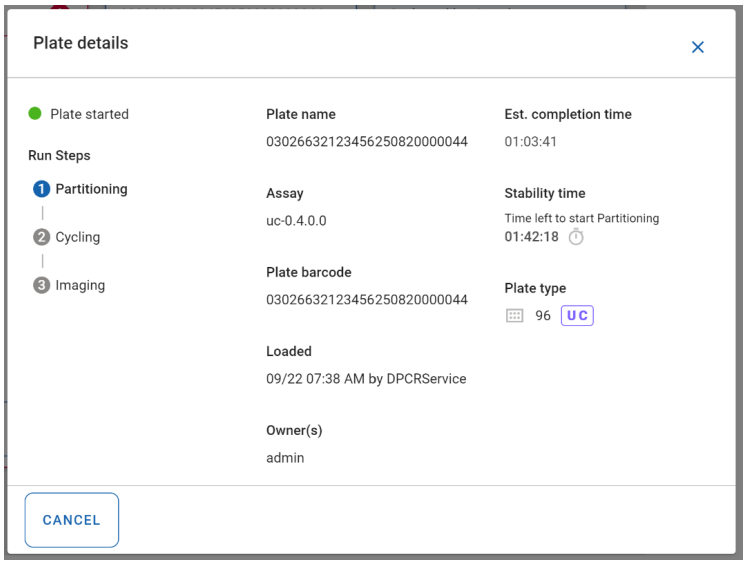
This feature provides additional details for a given plate if the user requires further information than is presented on the "Running status" page.

Plate details can be accessed by clicking the **details** button for a given plate.

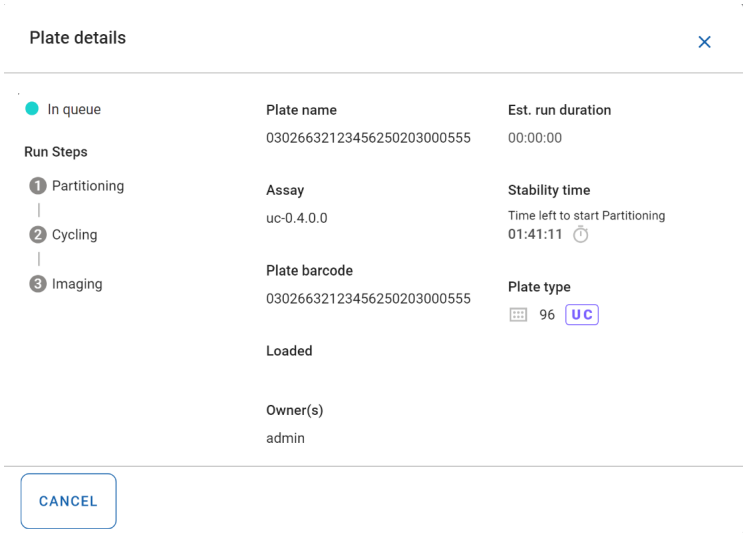
- Plate is pending run



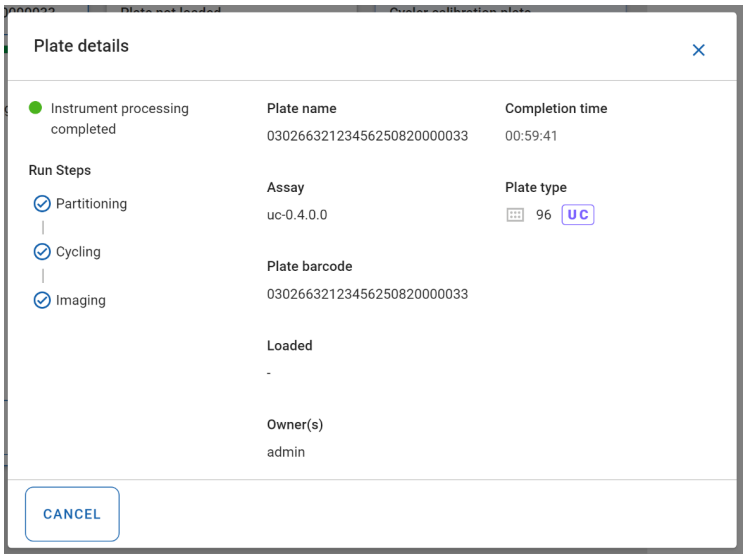
- Plate is in progress



- Plate is in queue



- Plate run is completed



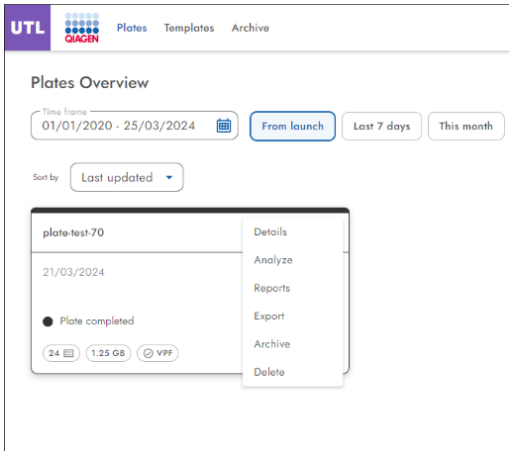
5.19.5. Check if images have a good quality or are over-saturated (only available in Utility mode)

In the Software Suite plates are presented in running order, current runs are displayed at the top of the screen, while completed runs are shown below in date order.

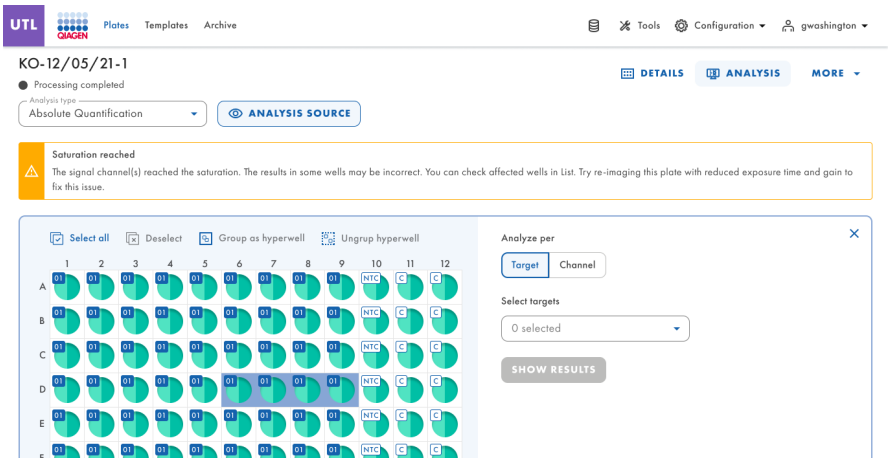
For analysis, click on the plate and select **Analyze** from the drop-down menu bar.

The fluorescence signal in the reference channel is measured to determine the number of valid partitions in a well. Differences in the signal intensities between partitions are normalized and the fluorescence signals in the target channels are corrected accordingly.

If the fluorescence signal is saturated in too many partitions of a well in a target channel, a warning message will be shown to the customer. Saturated signals lower the signal-to-noise ratio and can lead to improper analysis results, for example, the crosstalk correction algorithm might be affected. The recommendation is to re-image the plate with 30% less exposure time in the respective channel.



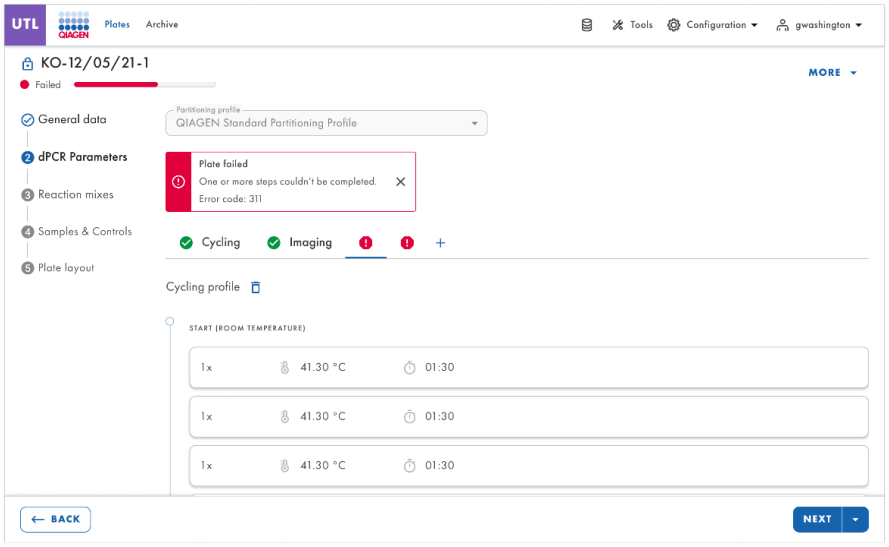
Note: If the signal for channels reached saturation, they will be highlighted in yellow. It is therefore recommended to reimage the plate with 30% lower exposure time.



Adding imaging steps after the completion of the experiment (reimaging)

After the completion of an experiment, once the plate reaches the Plate Complete status, adding additional imaging steps is allowed.

For that, the **+** icon next to the dPCR Parameters step screen will be available. A maximum of 7 steps, including the existing steps, are allowed.



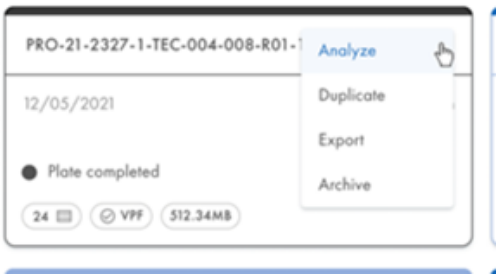
After adding the desired additional imaging steps, click **Save**. The plate status will remain as "Completed".

The plate is now ready to run on the instrument the additional imaging steps.

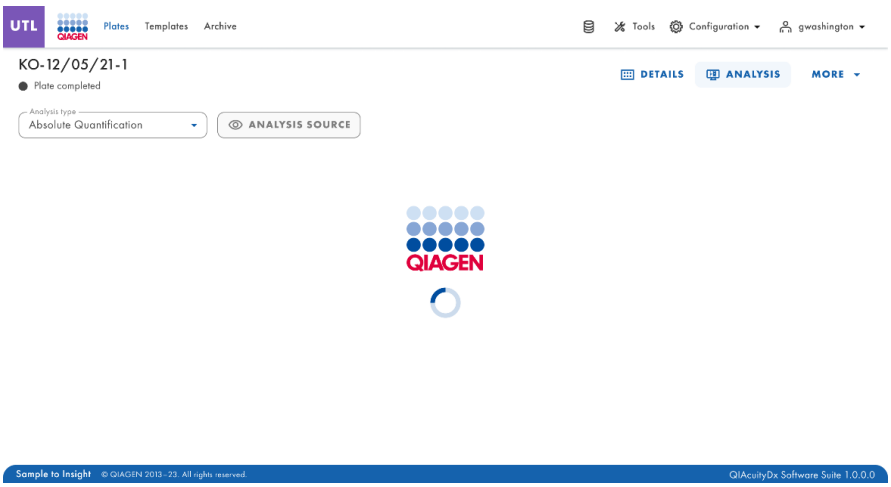
After the instrument has performed the additional imaging steps, no more additional steps are allowed to be added.

5.19.6. Run analysis

When a run has finished, search for the plate you wish to analyze on the Plates Overview page of the Plates environment. Only plates in status “Run Failed”, “Run Stopped”, “Run Loaded”, and “Run Completed” can be analyzed by selecting the Analyze option. Plates listed as “Drafted”, “Defined”, and “Running” do not have this option in the context menu.

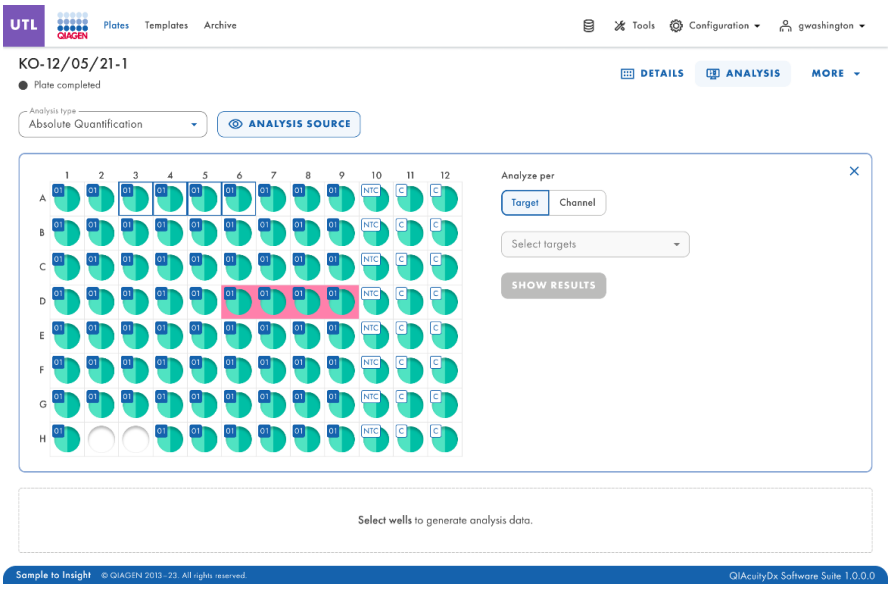


It is also possible to access the Plate Analysis environment from inside the plate, by entering in the plate and clicking the **Analysis** button. A loader page with the QIAGEN logo is displayed.



The Software Assay Plugin enables the user to analyze plates that have been processed by the instrument. The following analysis types are available:

- Absolute Quantification
- Mutation Detection
- Genome Editing
- Copy Number Variation
- Gene Expression



The Plate Layout contains well identifiers in rows and columns (e.g., A1, B2, etc.) that represent the well position on the plate layout depending on the Plate Type (24 or 96 wells).

The Plate Layout differentiates the available wells between full and empty wells.

The color of the wells depends on the color of the reaction mix assigned to them.

The different well labels identify the samples (with their ID) and indicate if they are a Control or an NTC.

It is possible to select multiple wells at once, either by clicking on them individually or clicking on one and dragging the cursor over all the desired wells.

It is possible to select all wells by clicking **Select all**.

Selected wells can be unselected by clicking on them.

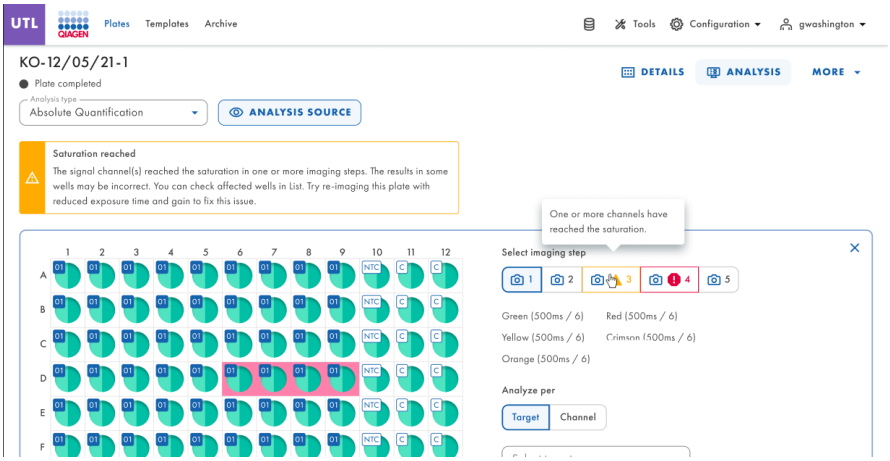
Authorized users can analyze the plate's wells processed by the instrument by selecting the analysis type.

Image quality control

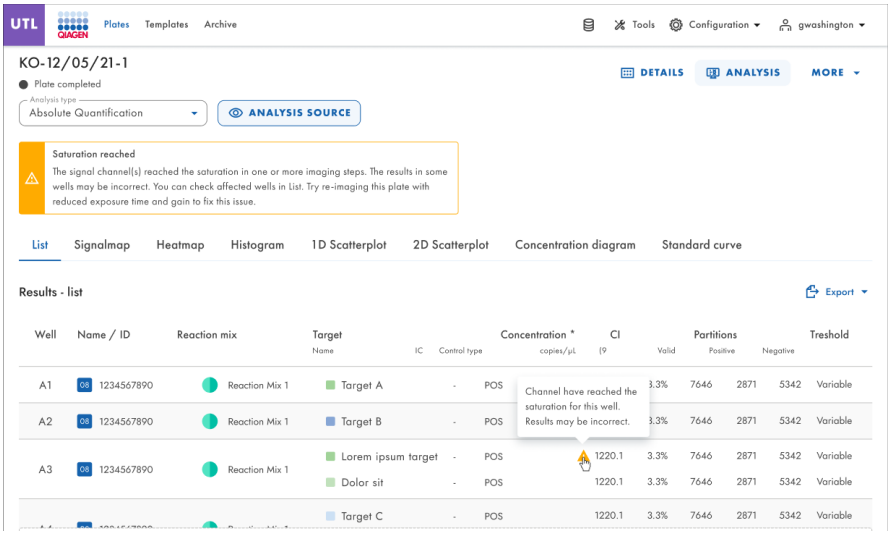
The fluorescence signal in the reference channel is measured to determine the number of valid partitions in a well. Differences in the signal intensities between partitions are normalized and the fluorescence signals in the target channels are corrected accordingly.

Note: The optimal relative fluorescence unit (RFU) range of the positives is 80–120 to avoid saturation and proper functioning of image analysis algorithms.

If more than 1 imaging step has been performed, the imaging step where the saturation occurred is marked in yellow and the warning message is shown when moving the mouse over the camera icon.



Whenever the fluorescence signal is saturated in too many partitions of a well in a target channel (green, yellow, orange, red, and crimson), a warning message is displayed to the user and all saturated signals are marked within the Results overview.



Invalidation of well images (Error)

On rare occasions, the image quality is too poor and the image cannot be used for further analysis. A message is shown to the users that some wells have been invalidated. Invalidated wells are grayed out in the plate layout and cannot be used for analysis. The message is also displayed whenever not all wells were used in the plate run.

If more than 1 imaging step has been performed, the imaging step where the low signal quality occurred is marked in red and the message is shown when moving the mouse over the camera icon.

Reasons for the invalidation of an image are:

- Not enough fluorescence signal, for example, when the Nanoplate is re-imaged after a long storage period.
- Vibration during the imaging process leads to blurry images. If the image of the reference channel is affected, the number of valid partitions cannot be determined and the whole well is invalidated for analysis. If a target channel is affected, only the image of the respective channel is invalidated for analysis.
- Incomplete filling of a well can lead to too few valid partitions in the reference channel needed for analysis. In this case, the whole well is invalidated.

Image corrective measures

To ensure proper analysis based on valid partitions, artifacts that could influence the result analysis are removed from the images. The corrections are done automatically by the Software Suite and do not require any user action. The partitions that are affected by artifacts are blacked out and are invalidated for further analysis. Artifacts can be:

- Dust and other particles
- Low amplification areas
- Areas of bad filling

Dust and other particles

Dust and other particles like hairs or strands are detected by the Software Suite and are removed from the images. This figure shows an example of a well before and after dust/other particles correction.

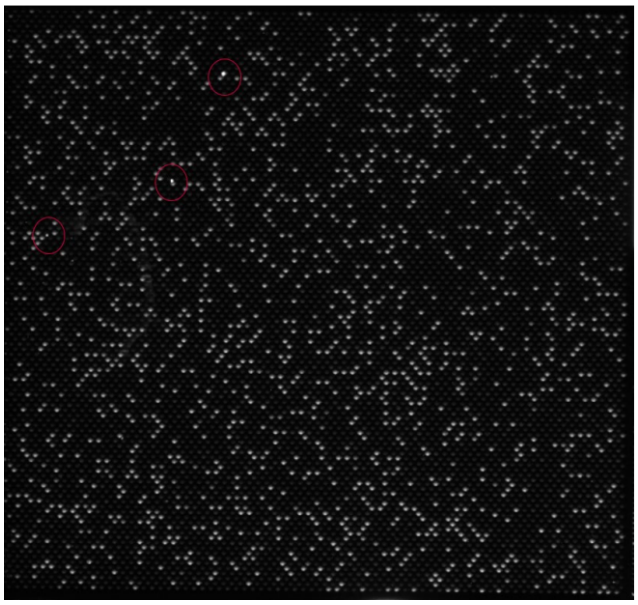


Figure 12. Raw image of a well showing dust particles (marked with red circles).

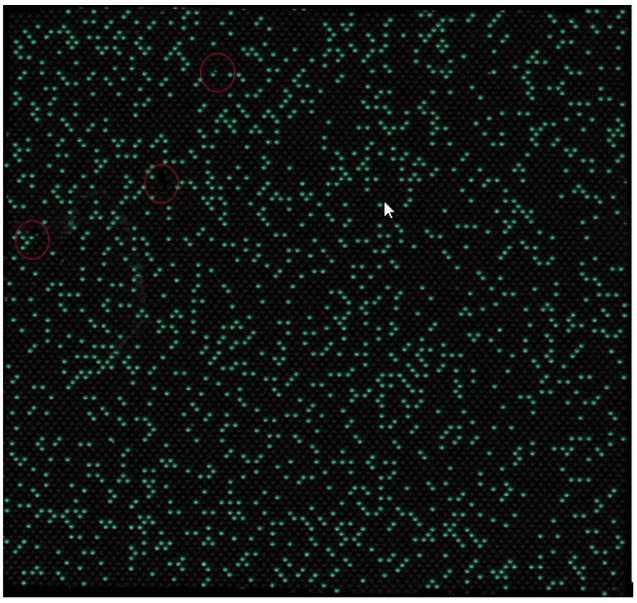


Figure 13. Signal map of the dust-corrected image.

If the images still show dust particles or other particles after correction, the recommendation is to unload the plate, wipe the plate with a lint-free tissue, and re-image the plate.

Note: The Software Suite always images all channels even if they are not used by the assay in order to improve dust detection

Low amplification areas

The fluorescence signal in a target channel can sometimes be less pronounced or undetectable in certain areas of a well, while the signal in the reference channel is not affected. If an equal amplification did not take place in the well, the area of low amplification does not meet the requirements for Poisson distribution. Therefore, the partitions in those areas are blacked out in the image and are not included in the analysis.

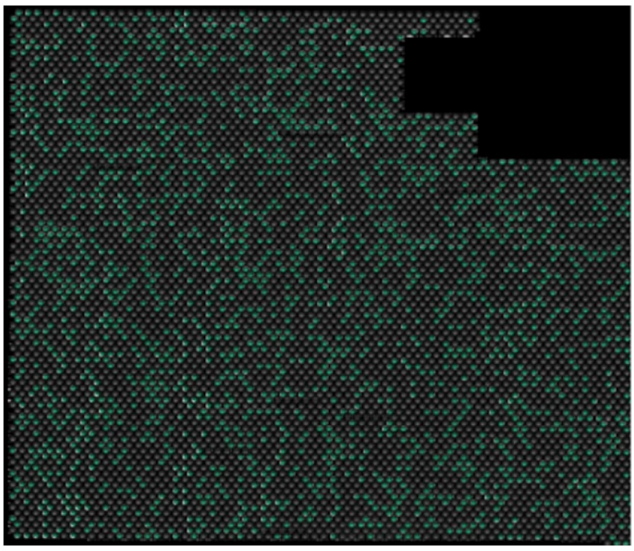


Figure 14. Signal map of an image with blacked-out low amplification areas.

Areas of bad filling

Incorrect pipetting or sealing can lead to areas of the well that are not filled with reaction mix. Those areas affect the reference channel as well as the target channels and reduce the number of valid partitions. See Section 5.7 Reaction setup for instructions on how to pipette and seal the Nanoplates properly.

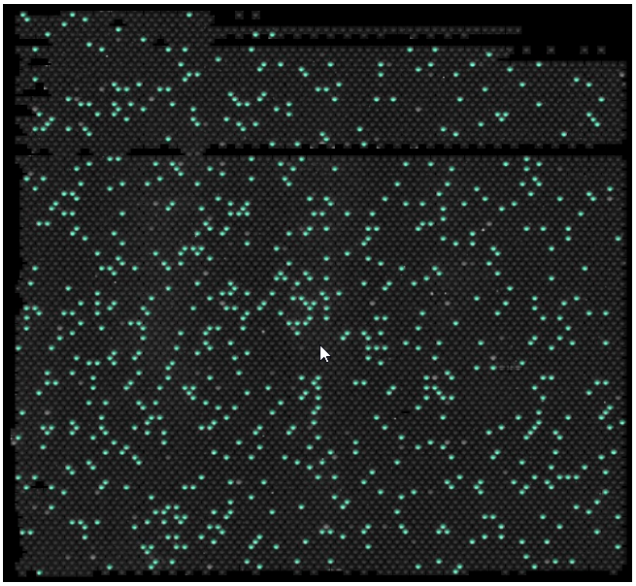


Figure 15. Signal map of an image showing areas of bad filling.

Crosstalk correction algorithm

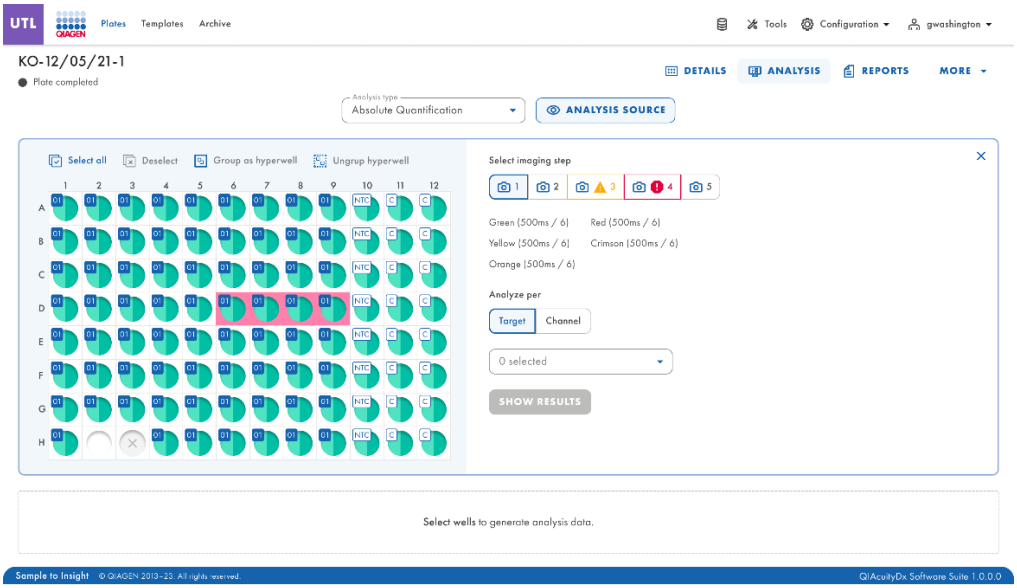
The QIAcuityDx instrument can detect 5 fluorescent channels. To compensate for the spectral overlap between the fluorescent dyes, a crosstalk correction algorithm is implemented in the Software Suite. This correction is done automatically by the software and does not require any user action. The bleed-through signals are removed from the images and are not considered in the result analysis. The crosstalk correction corrects an absolute value based on the RFU level of the neighboring channel.

Note: If insufficient compensation or overcompensation is seen (e.g., as double negative bands), check if the RFU levels of positive signals in neighboring channels are saturated or very bright. Lowering the RFU level of positive signals can reduce the occurrence of under and overcompensation.

General analysis options

Selecting wells for analysis:

- To select multiple wells at the same time, click the individual wells or click 1 well then drag your mouse until all wells are selected.
- To select all wells, click **Select all**.
- To remove a selected well, click the well.
- To remove all selected wells, click **Unselect all**.



Well information

To view more information about an individual well, double-click the well in the plate layout. The Well Information dialog box appears. Click **OK** to close the dialog box.

List of fields in the Well Information modal:

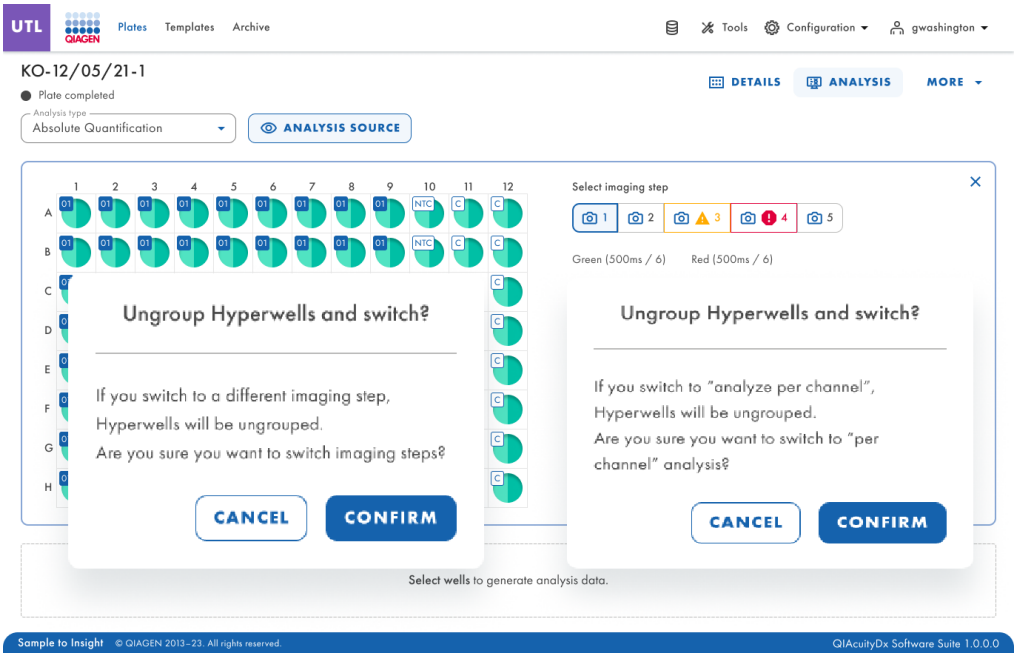
- Header
  - Well information — <Well ID>
- Subheader
  - Reaction mix name
  - Sample ID
  - Sample Name
- Table
  - Column 1 : Target number
  - Column 2: Target name
  - Column 3: IC
  - Column 4: Dye
  - Column 5: Channel

Hyperwells group and ungroup

To increase the volume of sample analyzed, multiple wells can be grouped together and analyzed as a single well. To define a hyperwell, select multiple wells with the same reaction mix and same sample name. Then click neighbor from the menu below or right-click and select **Group as hyperwell** from the context menu.

To ungroup the hyperwell, select the hyperwell and click **Ungroup hyperwell** from the menu below or from the context menu.

For the analysis, hyperwells are treated as a single well but with a larger number of partitions. This may be helpful for rare event detection if the sample volume to be analyzed exceeds the volume that can be loaded into a single well. Results from all wells grouped into a hyperwell will be aggregated and presented as a result from a single well.



Multiple imaging steps

If the plate was configured with multiple imaging steps, the user can select one to be used for analysis.

Important: When switching imaging steps, the application will ask to ungroup existing hyperwells. All wells linked as hyperwells will be ungrouped as individual wells when switching imaging steps.

Note: If an imaging step failed during the run or images are of low quality, a message is shown by moving the mouse over the camera icon to indicate that the results might be incorrect. Furthermore, error messages are indicated with a red box around the image step icon, warnings with a yellow box.

Note: If the images are of good quality, but not all the wells have been filled, the following error appears: For some wells in this step, images are low quality, and we cannot obtain the result for them. Those wells are unavailable for analysis.

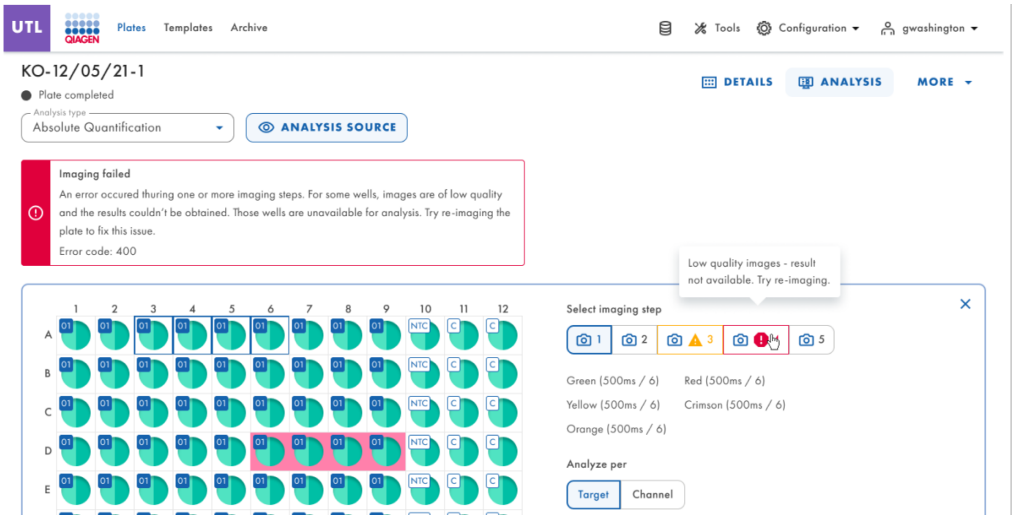


Diagram option

There are tools related to the diagrams and charts that enable the user to adjust the view and download the chart you want to view. To access the tools, point to a diagram.

- **Download plot**: Downloads the plot as an PNG file.
- **Zoom in**: Zooms in the signalmap. To reset the zoom, double-click the signal map.
- **Zoom out**: Zooms out the signal map. To reset the zoom, double-click the signal map.

Range sliders

If more wells are selected for the analysis than fit on a chart, some charts, such as concentration diagrams or point diagrams, offer the additional option of a range slider. This tool lets users view the data that do not fit on the diagram. You can also adjust the range of data that are shown to see more information at the same time.

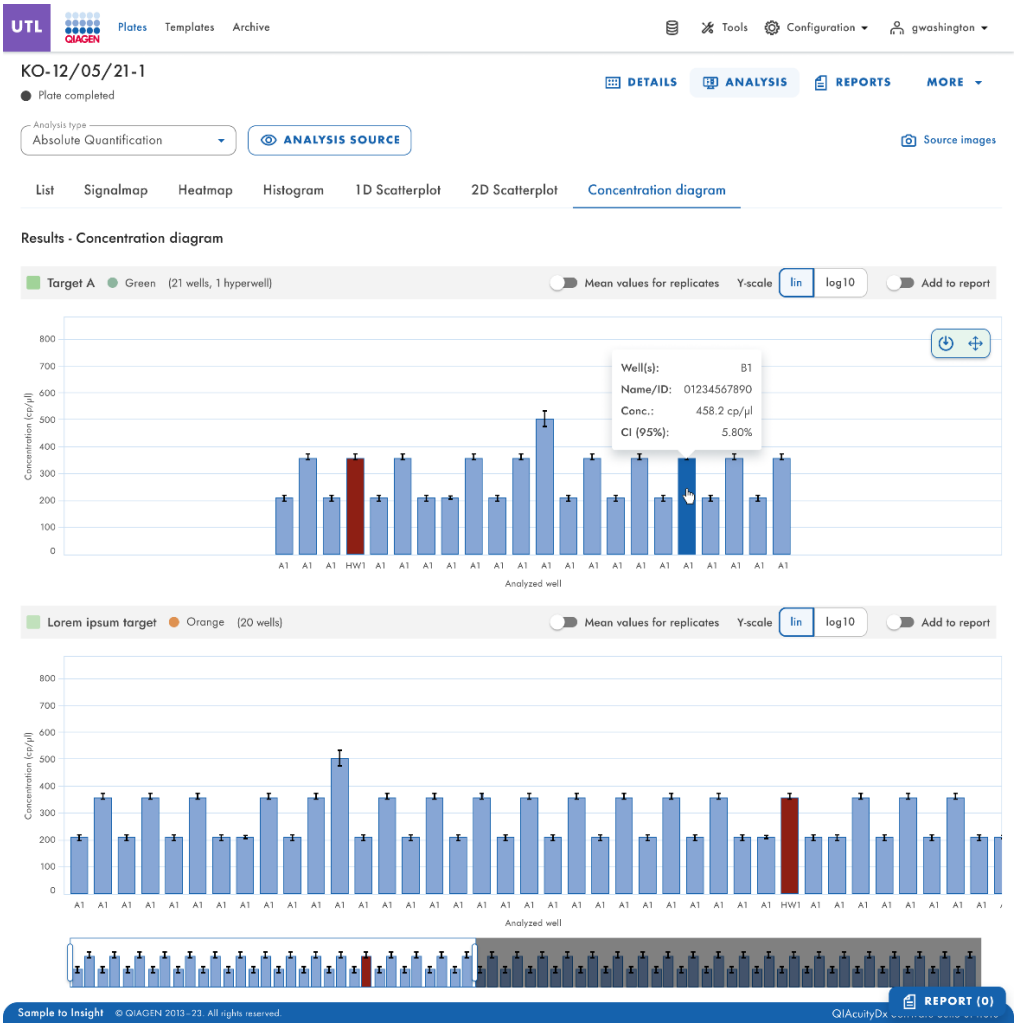


Figure 16. Example of a range slider below a chart.

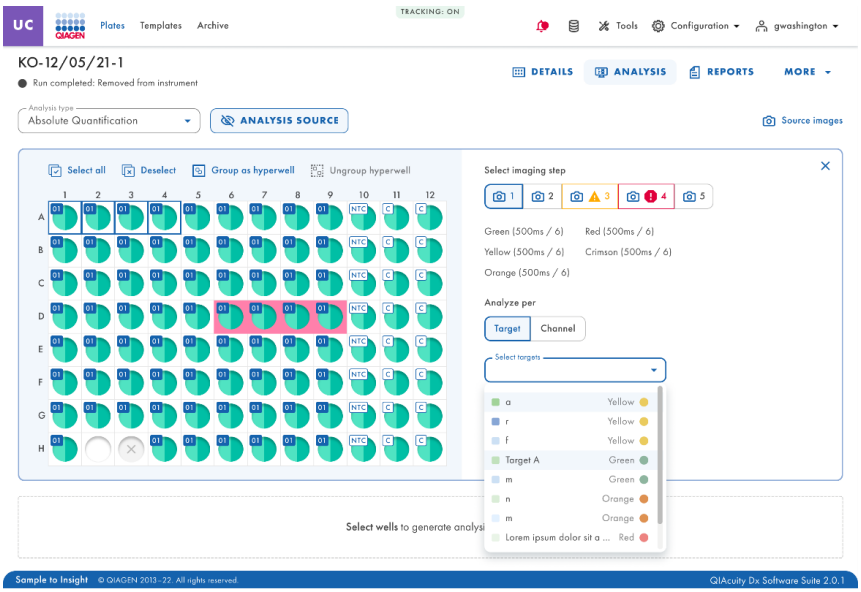
The highlighted area of the slider shows the portion of the chart that is currently displayed. The gray part of the slider is a preview of the rest of the chart. To view another part of a diagram, click the highlighted area of the slider and drag to the part that you want to view. To adjust the range of the displayed data, click one of the handlebars on the left or right side of the highlighted area and drag until you reach your preferred range.

Absolute quantification

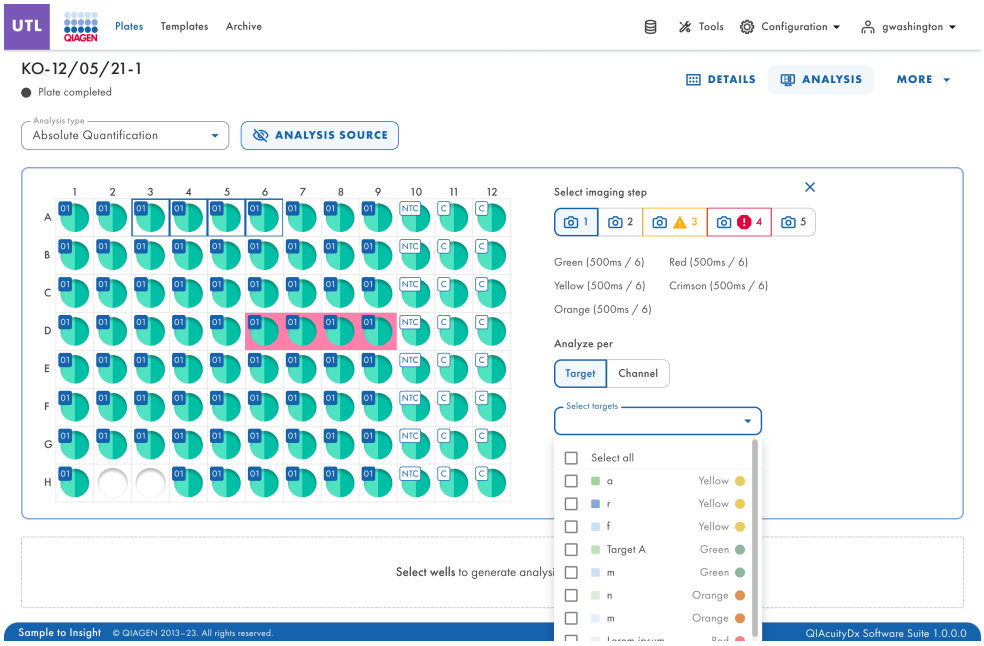
The Absolute Quantification Analysis is the first option in the Analysis drop-down. After selecting the wells to be analyzed, you can view lists, signal maps, heatmaps, histograms, 1D scatterplots, 2D scatterplots, and concentration diagrams in this option.

Analyze per target

1. Click the applicable wells in the plate layout. “Analyze per” is disabled if no wells are selected.
2. Ensure that there are reaction mixes available on the plate; otherwise, the **Target** button is disabled.
3. To analyze the plate by target, click **Target**.
4. Select the targets from the Select targets list. You can select one or more targets from the list. To select all targets, click **Select all**. The targets are sorted by reaction mix, and within a reaction mix, they are sorted by channel (green, yellow, orange, red, and crimson).

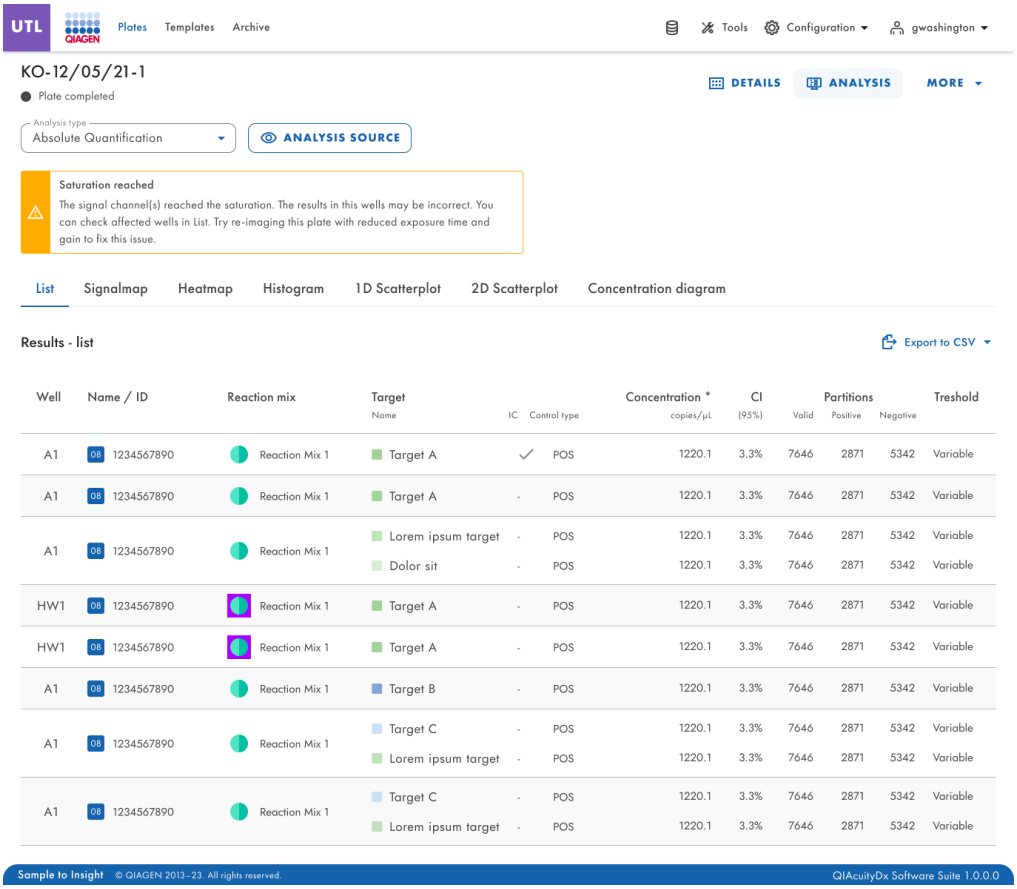


5. Then **Show results** button will be available to be clicked.



Once the **Show results** button is pressed, the **List** tab for Absolute Quantification contains a table with an overview of the analyzed wells. The following columns are available in the table:

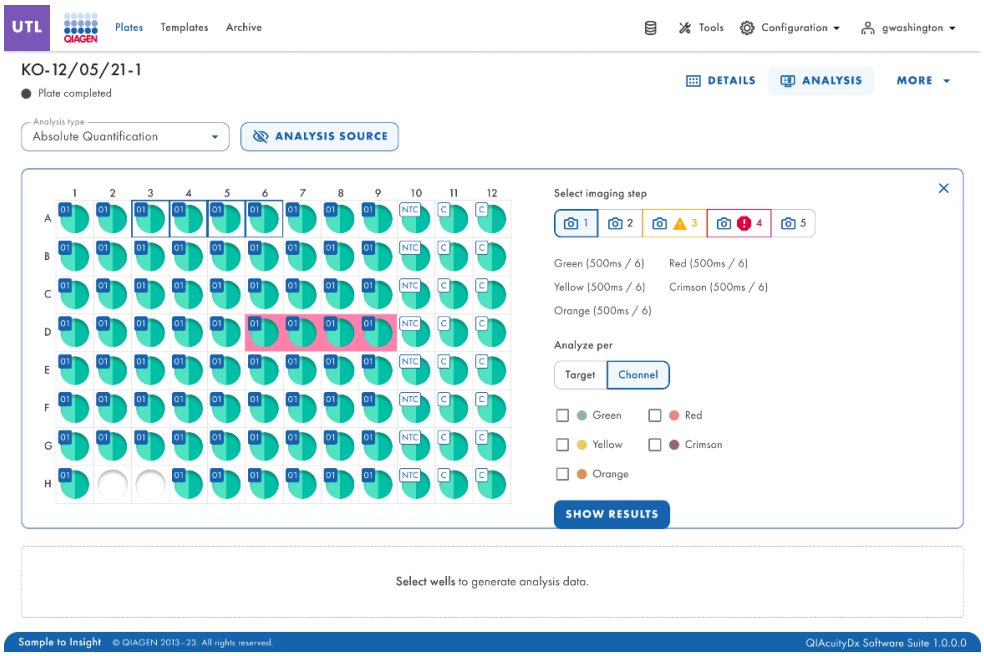
- **Well** – For example, A1, B2, etc.
- **Name / ID** – This column shows the sample, NTC, or control name with its corresponding icon that identifies the sample or indicates whether the entry is an NTC or control.
- **Reaction mix** – This column contains the icon and the name of the reaction mix.
- **Target** – This column shows the target names and their corresponding color.
- **Concentration (copies/µL)** – This column shows the concentration assigned to each channel per well.
- **CI (95%)** – This column shows the value of the confidence interval at a 95% confidence level.
- **Partitions (Valid, Positive, Negative)** – This column shows the number of valid, positive, and negative partitions per well and channel.
- **Threshold** – This column shows the current threshold value applied to the well.



Analyze per channel

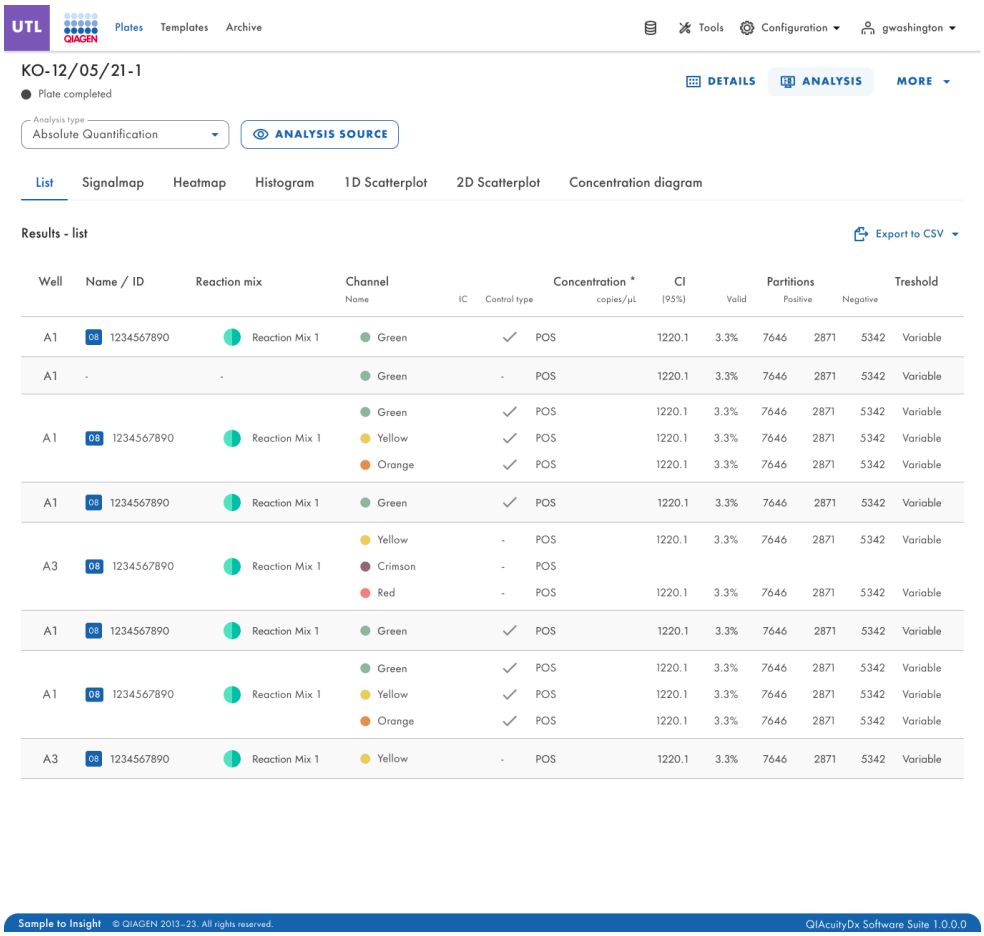
1. Click the applicable wells in the plate layout. “Analyze per” is disabled if no wells are selected.
2. To analyze the plate by channel, click **Channel**.
3. Check the boxes of the corresponding channel color to select the relevant channels. If images are not taken for a channel, the channel becomes disabled.

4. Then the **Show results** button will be available to be clicked.



Once the **Show results** button is pressed, the **List** tab for Absolute Quantification contains a table with an overview of the analyzed wells. The following columns are available in the table:

- **Well** – For example, A1, B2, etc.
- **Name / ID** – This column shows the sample, NTC, or control name with its corresponding icon that identifies the sample or indicates whether the entry is an NTC or control.
- **Reaction mix** – This column contains the icon and the name of the reaction mix.
- **Channel** – Depending on the settings defined when selecting a source, this column shows channel names and their corresponding color.
- **Concentration (copies/µL)** – This column shows the concentration assigned to each channel per well.
- **CI (95%)** – This column shows the value of the confidence interval at a 95% confidence level.
- **Partitions (Valid, Positive, Negative)** – This column shows the number of valid, positive, and negative partitions per well and channel.
- **Threshold** – This column shows the current threshold value applied to the well.


UTL
QIAGEN
Plates
Templates
Archive
Tools
Configuration
gwashington
KO-12/05/21-1
Plate completed
DETAILS
ANALYSIS
MORE
Analysis type
Absolute Quantification
ANALYSIS SOURCE
List
Signalmap
Heatmap
Histogram
1D Scatterplot
2D Scatterplot
Concentration diagram
Results - list
Export to CSV
Well
Name / ID
Reaction mix
Channel
Name
IC
Control type
Concentration *
copies/µL
CI
(95%)
Partitions
Valid
Positive
Negative
Treshold
A1 08 1234567890 Reaction Mix 1 Green POS 1220.1 3.3% 7646 2871 5342 Variable
A1 - - Green - POS 1220.1 3.3% 7646 2871 5342 Variable
A1 08 1234567890 Reaction Mix 1 Green POS 1220.1 3.3% 7646 2871 5342 Variable
Yellow POS 1220.1 3.3% 7646 2871 5342 Variable
Orange POS 1220.1 3.3% 7646 2871 5342 Variable
A1 08 1234567890 Reaction Mix 1 Green POS 1220.1 3.3% 7646 2871 5342 Variable
A3 08 1234567890 Reaction Mix 1 Yellow - POS 1220.1 3.3% 7646 2871 5342 Variable
Crimson - POS
Red - POS 1220.1 3.3% 7646 2871 5342 Variable
A1 08 1234567890 Reaction Mix 1 Green POS 1220.1 3.3% 7646 2871 5342 Variable
A1 08 1234567890 Reaction Mix 1 Green POS 1220.1 3.3% 7646 2871 5342 Variable
Yellow POS 1220.1 3.3% 7646 2871 5342 Variable
Orange POS 1220.1 3.3% 7646 2871 5342 Variable
A3 08 1234567890 Reaction Mix 1 Yellow - POS 1220.1 3.3% 7646 2871 5342 Variable
Sample to Insight
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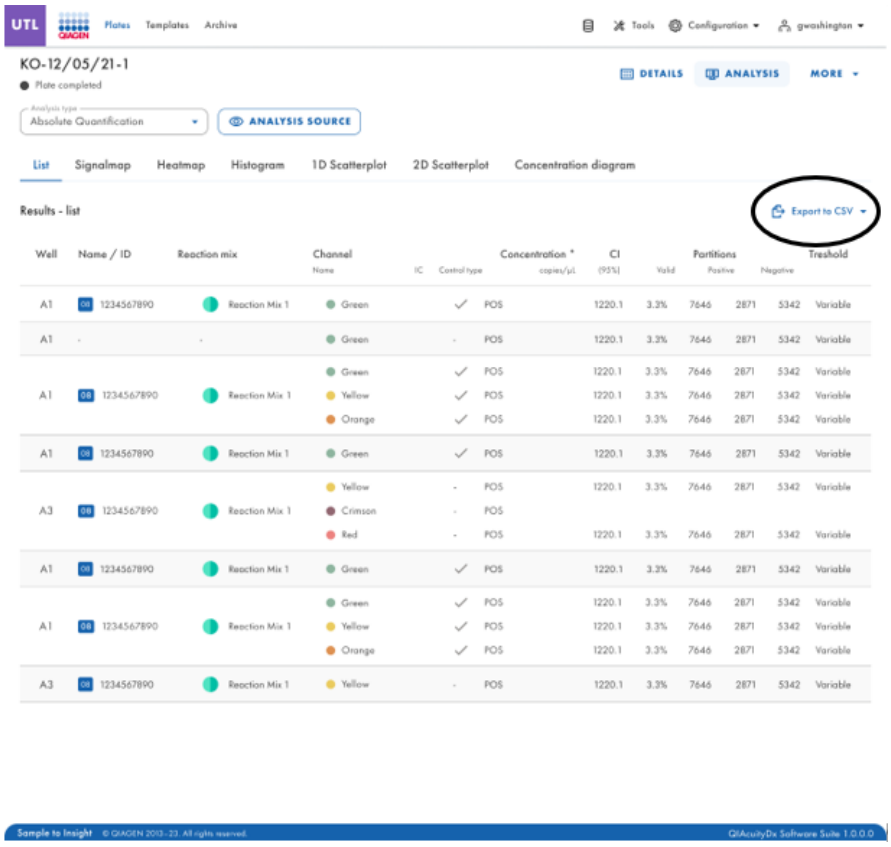
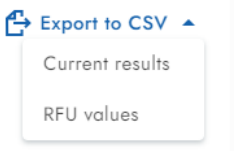
QIAcuityDx Software Suite 1.0.0.0

Export CSV for Analysis in Utility mode

Once you have selected the wells and channels of interest and are ready to export a CSV with the run results, in the **List** tab, click **Export to CSV** on the top right of the table (see below).



There are 2 options: **Current results** and **RFU values**.



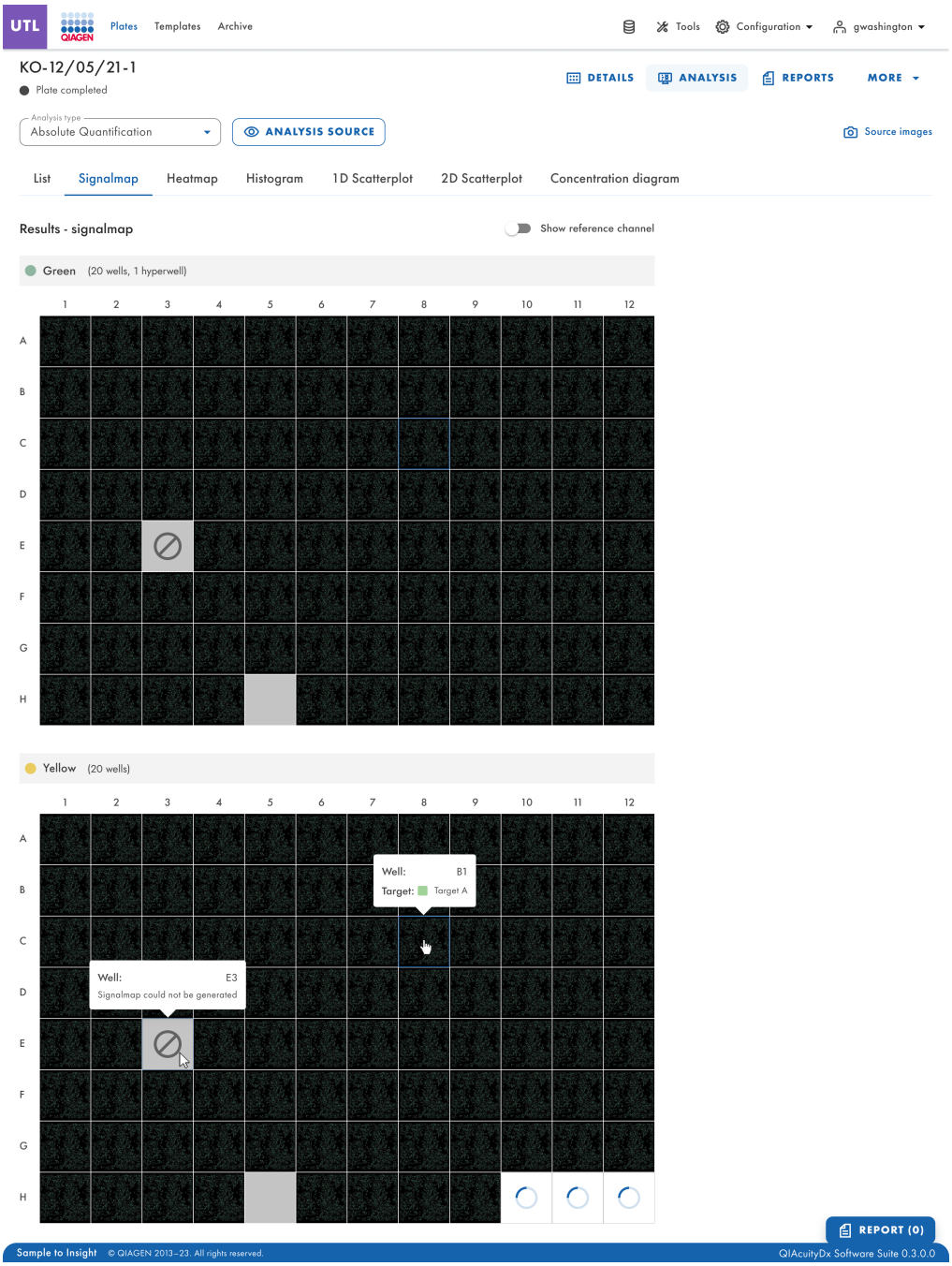
By selecting **Current results**, a list view of the current results per sample for selected wells will be downloaded as a CSV file.

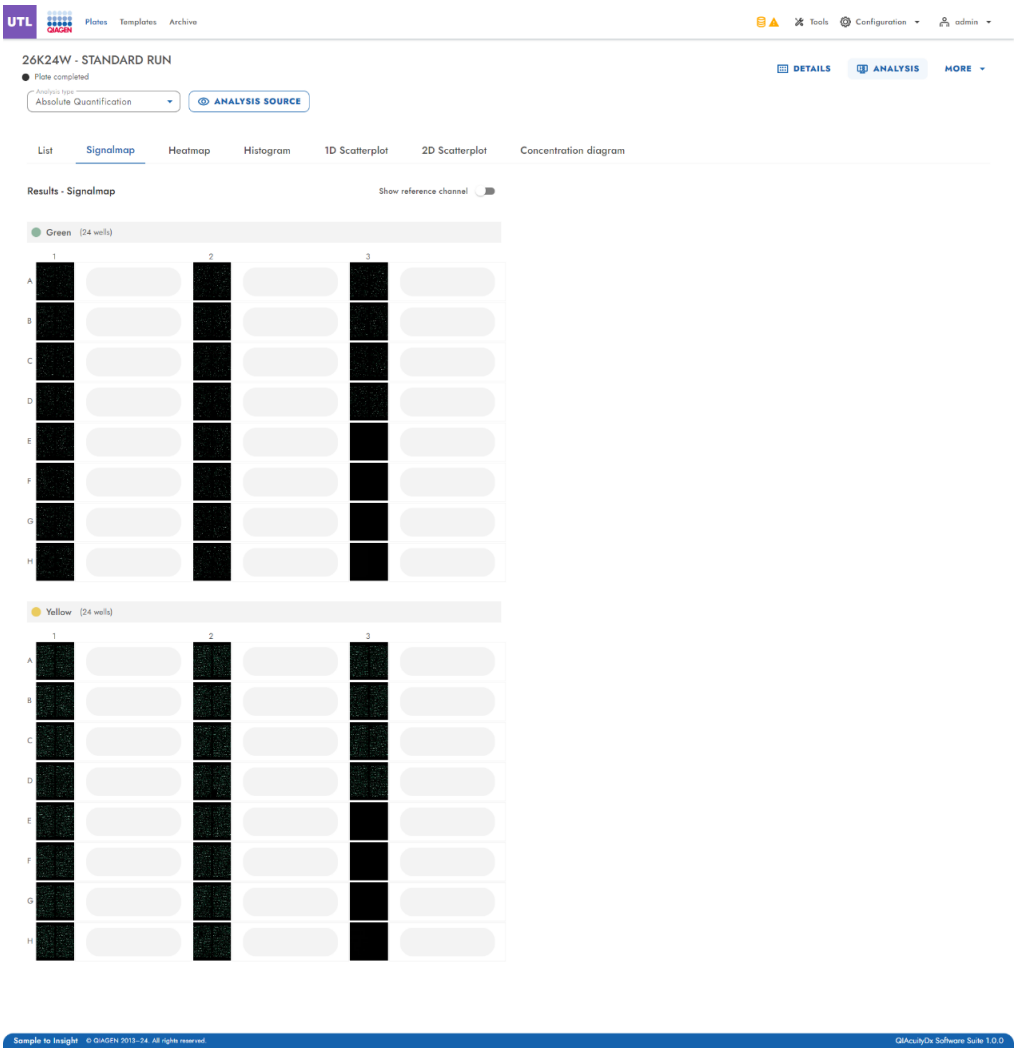
By selecting **RFU values**, a list view of the RFU values (compact version) per partitions for selected wells will be downloaded as a CSV file.

Signal map tab for absolute quantification

The **Signal map** tab provides positive partitions for target channels and valid partitions for the reference channel of selected wells. For each channel included in target or channel selection, 1 signal map view is created. The signal map views are sorted by channel position in imaging (green, yellow, orange, red, and crimson), separated by a horizontal line.

Each signal map represents the plate layout for a selected channel where only the images of the selected wells are loaded. The remaining wells are displayed as gray squares. When the image of a well cannot be calculated by the algorithm, a placeholder image is shown. On hovering the mouse over the well, the user is informed that the signal map for this well could not be created. The title of a signal map shows the channel name and, if more than 1 well is selected, the number of selected wells is also shown. When the user hovers over a well with the mouse, a tooltip appears displaying label information about the well and the associated target (if defined). When hovering over the well image, the image is highlighted and the cursor changes to the zoom icon.





- Signal map for a target channel
- Zoom In
- Zoom Out
- Download signal map of this well as picture
- Close zooming window

The Zoom-In and Zoom-Out feature is also possible using the mouse wheel. The well ID, channel name and the associated target (if defined) is shown at the top left side.

The Software Suite provides a signal map view for the reference channel, which is hidden by default. To view the signal map for the reference channel, click **Show reference channel**. The functionality of the signal map view for the reference channel is analogous to the signal map views of the target channels. Valid partitions in the reference channel are marked and highlighted with blue dots, whereas positive partitions of target channels are marked and highlighted with green dots.

Heatmap tab for absolute quantification

The **Heatmap** tab shows the concentration of the selected targets or channels in each well. The values of all selected wells are also displayed in this tab. The values for disabled wells are not displayed. One heatmap view is created for each selected target or channel. The heatmap views are sorted by channel position in imaging (green, yellow, orange, red, and crimson), separated by a horizontal line.

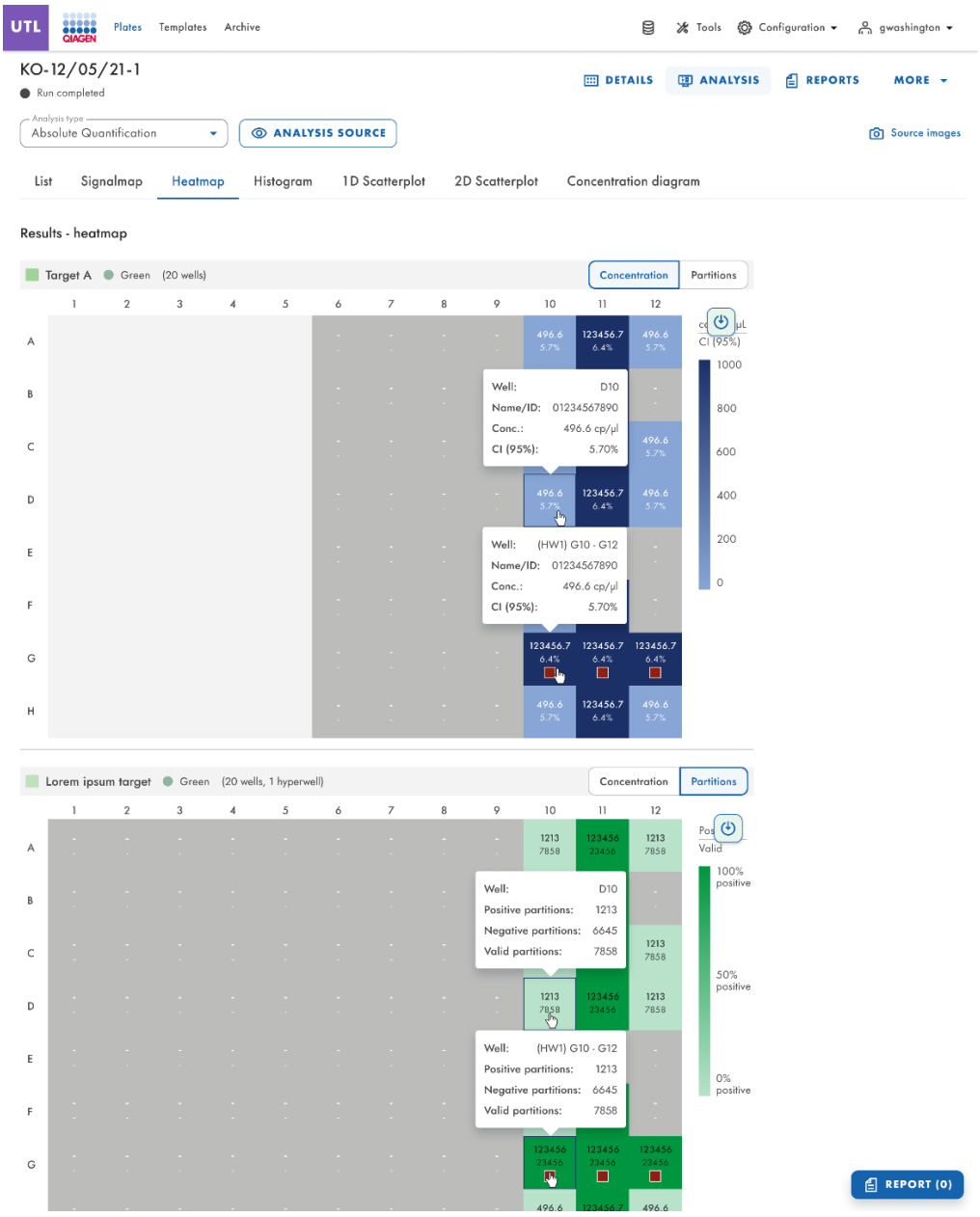
If the target or channel shown in a heatmap is not relevant to 1 or more wells, those wells do not have a value displayed and their background color is gray.

Hovering the mouse over a well will display further detailed information about that well.

To view an additional toolbar that enables actions related to the diagram, such as downloading the plot, hold the cursor over the diagram. For more details about the toolbar, refer to the “Diagram option” section.

There are 2 views of each heatmap – the concentration view and the partitions view (see the following images). To switch between the views, click **Concentration** or **Partitions**.

To show the mean concentration values for replicates in the concentration view, click **Show mean values for replicates**. Mean values are not supported in the partition view. Therefore, the related checkbox is grayed out in the partition view and a message displaying relevant information is shown to the user.


UTL
QIAGEN
Plates
Templates
Archive
Tools
Configuration
gwashington
KO-12/05/21-1
Run completed
DETAILS
ANALYSIS
REPORTS
MORE
Analysis type
Absolute Quantification
ANALYSIS SOURCE
Source images
List
SignalMap
Heatmap
Histogram
1D Scatterplot
2D Scatterplot
Concentration diagram
Results - heatmap
Target A
Green
(20 wells)
Concentration
Partitions
CI (95%)
1000
800
600
400
200
0
Well: D10
Name/ID: 01234567890
Conc.: 496.6 cp/µl
CI (95%): 5.70%
Well: (HW1) G10 - G12
Name/ID: 01234567890
Conc.: 496.6 cp/µl
CI (95%): 5.70%
Lorem ipsum target
Green
(20 wells, 1 hyperwell)
Concentration
Partitions
Valid
100% positive
50% positive
0% positive
Well: D10
Positive partitions: 1213
Negative partitions: 6645
Valid partitions: 7858
Well: (HW1) G10 - G12
Positive partitions: 1213
Negative partitions: 6645
Valid partitions: 7858
REPORT (0)

Histogram tab for absolute quantification

The **Histogram** tab displays graphs that visualize the fluorescence values of selected wells for the selected target or channel. One histogram view is created for each selected target or channel. The histograms are sorted by channel position in imaging (green, yellow, orange, red, and crimson) separated by a horizontal line.

Each histogram has 2 axes. The x-axis represents the relative fluorescence intensity. The y-axis represents the number of partitions with that fluorescence intensity. The values on the y-axis have 2 available scales – linear and logarithmic.

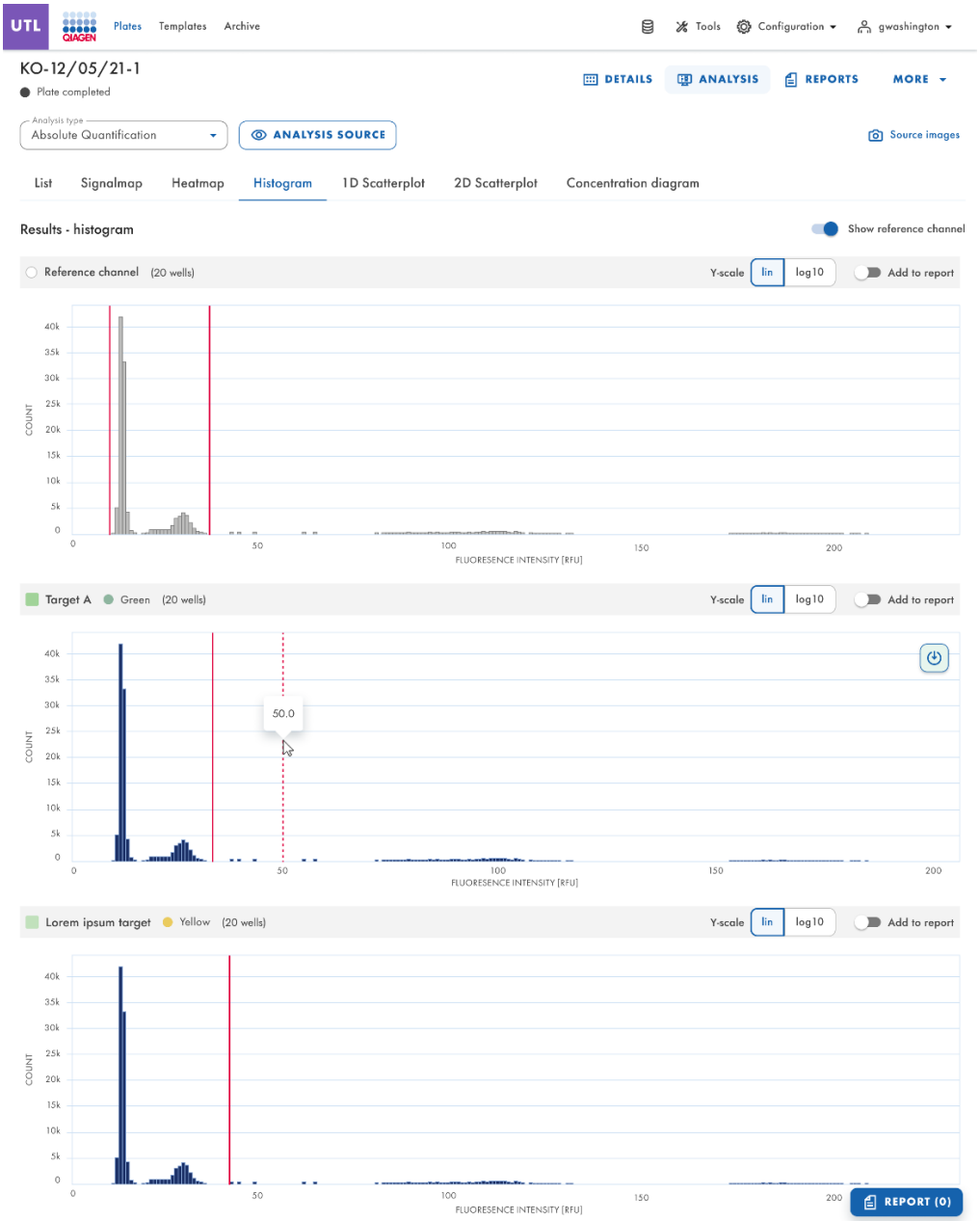
To view an additional toolbar that enables actions related to the diagram, such as downloading the plot, hold the cursor over the diagram. For more details about the toolbar, refer to the "Diagram option" section.

The y-axis scale can be modified using the buttons located above each graph. The buttons are visible when you hold the cursor over a graph. To view the values on a linear scale, click lin. To view the values on a logarithmic scale, click **log10**.

The threshold field shows the threshold value of the fluorescence intensity that is used to distinguish between positive and negative calls. If only one source well is selected, the value of the threshold is shown in the threshold field and on the graph as a red line. If multiple source wells are defined and their automatically calculated threshold values are different, a threshold value is initially not shown in the histogram.

Reference channel

The Software Suite also provides a histogram for the reference channel, which is hidden by default. To view the histogram for the reference channel, click **Show reference channel**. The title of this histogram indicates that the histogram is related to the reference channel. The graph for the reference channel allows the user to see the common lower and upper thresholds that exclude partitions with too low/too high RFU. Setting the upper threshold is not possible in this chart; see the "1D Scatterplot" section.

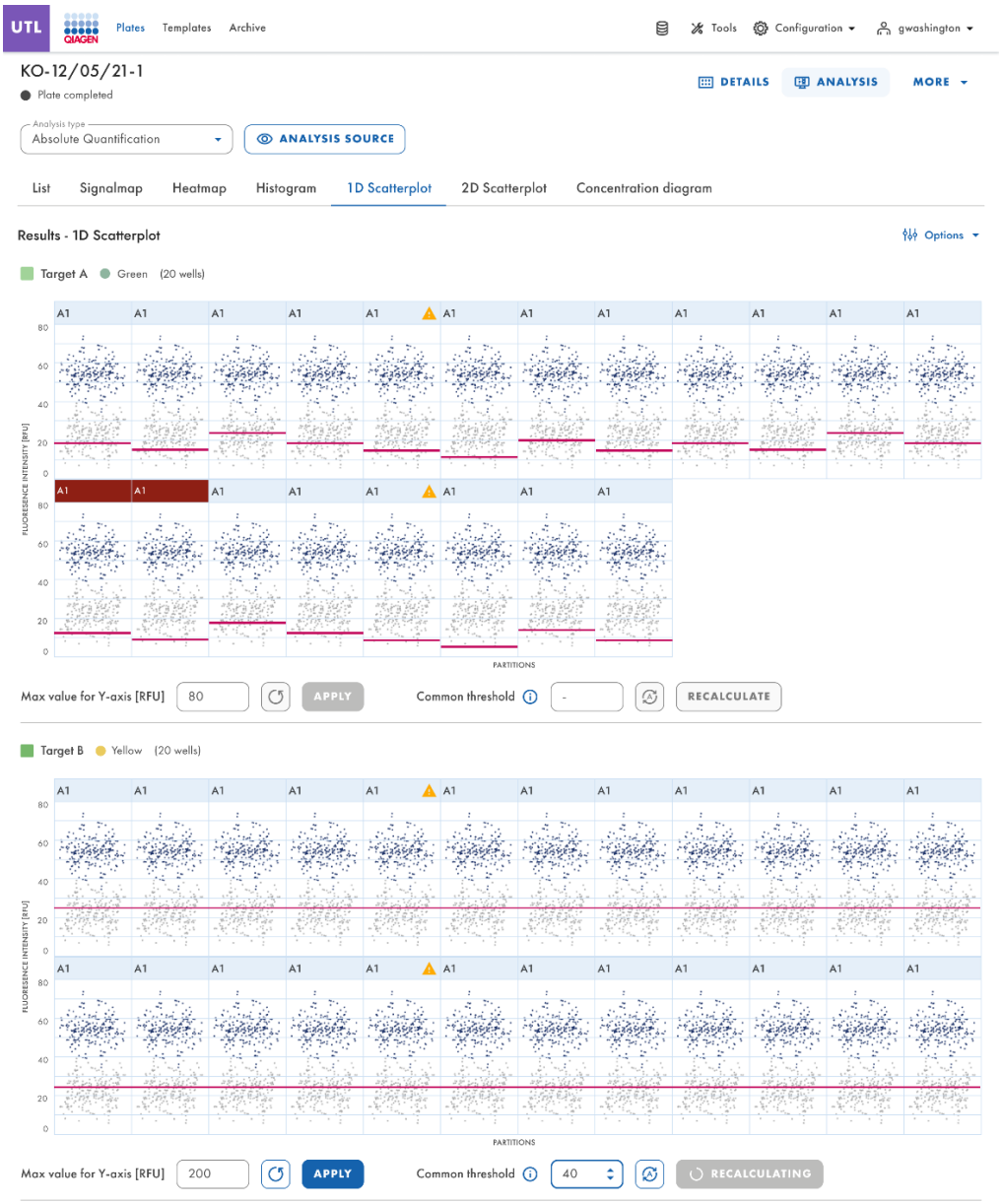


1D Scatterplot

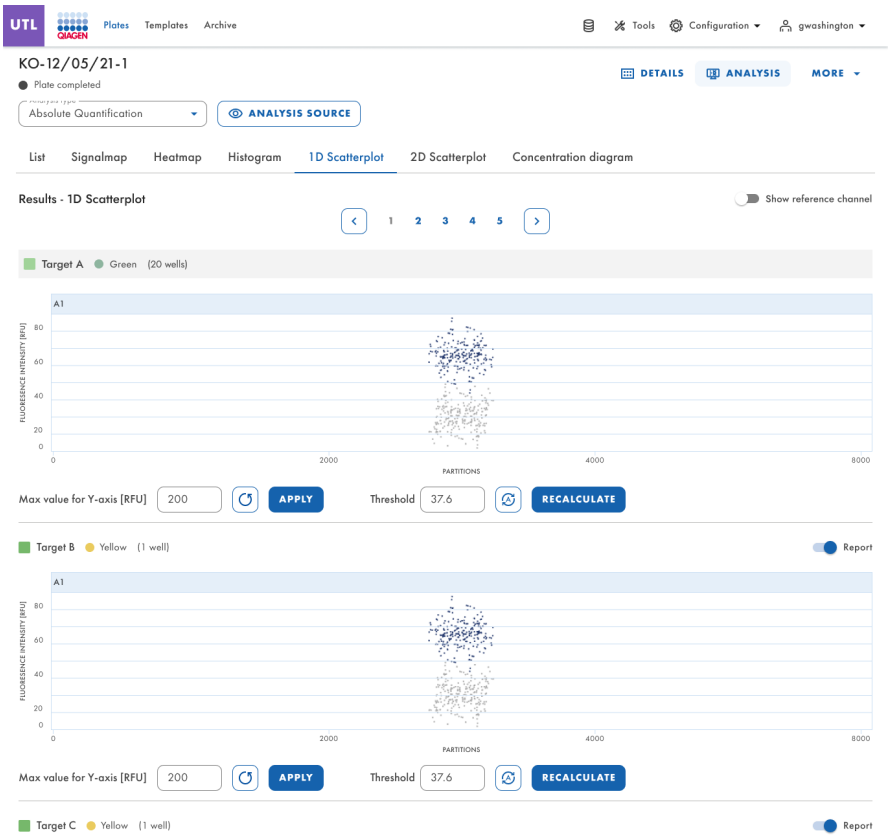
The **Absolute Quantification** tab is the first tab in the Analysis environment. After selecting the wells to be analyzed, the user can view the list and the **1D Scatterplot** tab.

- The **1D Scatterplot** tab shows one 1D Scatterplot view for each analyzed target or channel. If there is more than one 1D Scatterplot view, they are separated with a horizontal line.
- The 1D Scatterplot views are sorted by channel position in imaging (green, yellow, orange, red, and crimson).
- The title of a 1D Scatterplot view displays the related channel name, including the dot channel color indicator and, if defined, it also displays the target name. If more than 1 well is selected the number of wells is also shown.
- A 1D Scatterplot view has 2 axes. The x-axis represents the analyzed partitions, while the y-axis represents the relative fluorescence intensity of each partition.
- A 1D Scatterplot view concatenates the diagrams for each well, with a header indicating the co-ordinate of each well on the plate.
- A red line represents the current threshold fluorescence intensity value (decimal value) that is used to distinguish between positive and negative partitions. Fluorescence values below the threshold are shown in gray, and in blue when above the threshold.

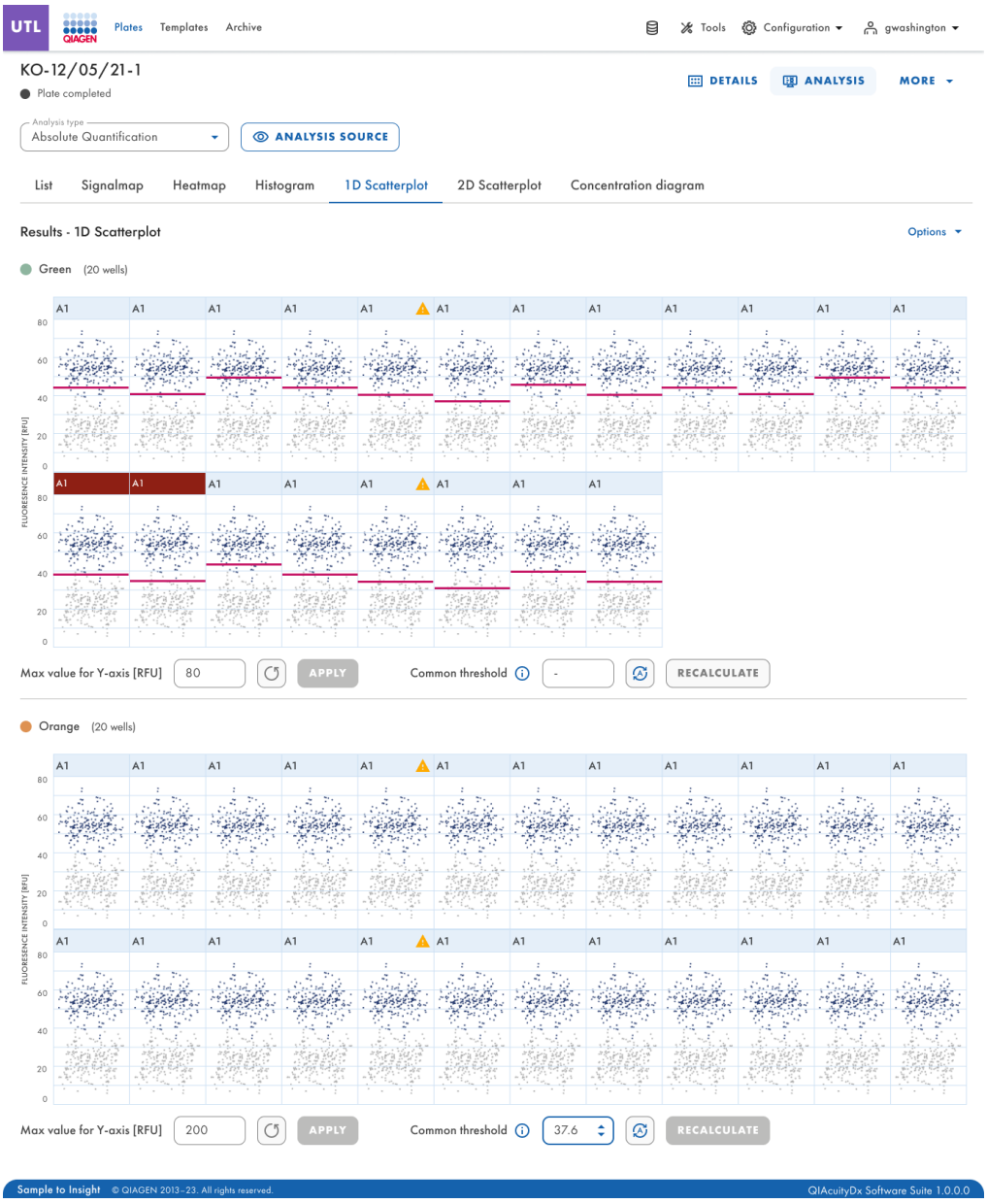
If the 1D Scatterplot is analyzed by target (the DNA/RNA sequence or molecule for which the copy number/µL is detected), the user will see the following structure:



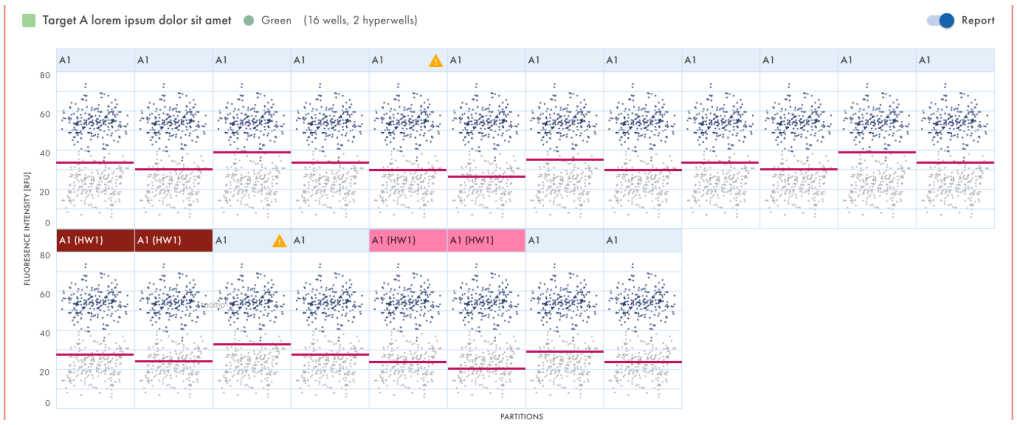
If the analysis is done by channel data is presented based upon the wavelength filters used during image acquisition, the user will see an output such as:



It is important to mention that this analysis can be also done in multiple wells simultaneously.



Users are able to clearly identify the hyperwells defined in the Plate Layout when running a 1D Scatterplot analysis.

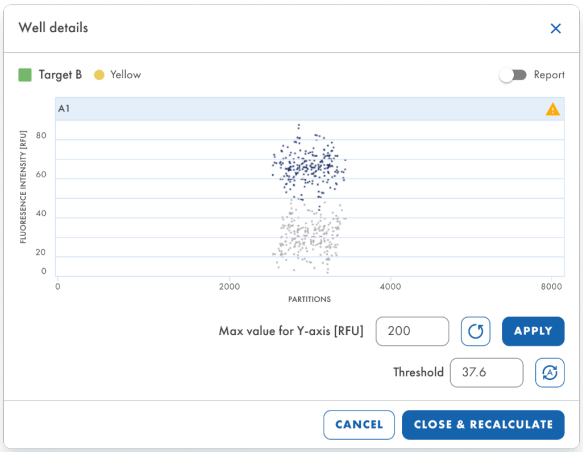


Users with Edit Analysis Data permissions can change the maximum RFU value for the scatterplots when running a 1D Scatterplot analysis. The accepted range for the max. RFU value is 0–300.

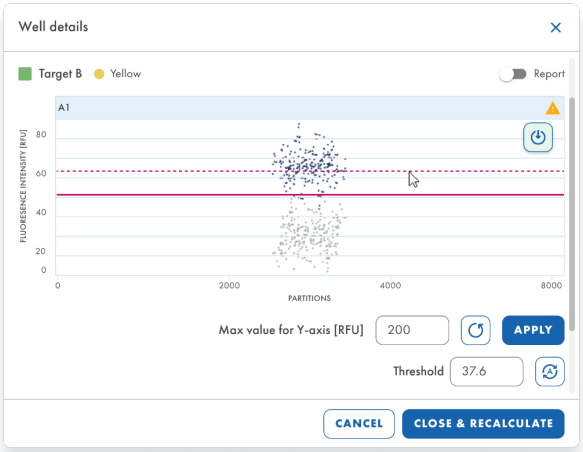
Changing the threshold

1. To change the threshold individually per well, click on the appropriate header of the well in the 1D Scatterplot view. A window opens and the threshold can be changed by pointing over the chart, which triggers the appearance of a dotted line.
2. Once the dotted line is in the appropriate spot, click the chart. The line becomes solid, and the threshold value is updated and shown in the threshold field.
3. To change the value again using this method, click the red line and drag it to the appropriate spot. Alternatively, you can also directly edit the value in the Threshold field. Use the **auto-threshold** button to set the threshold to the value calculated by the analysis algorithm.

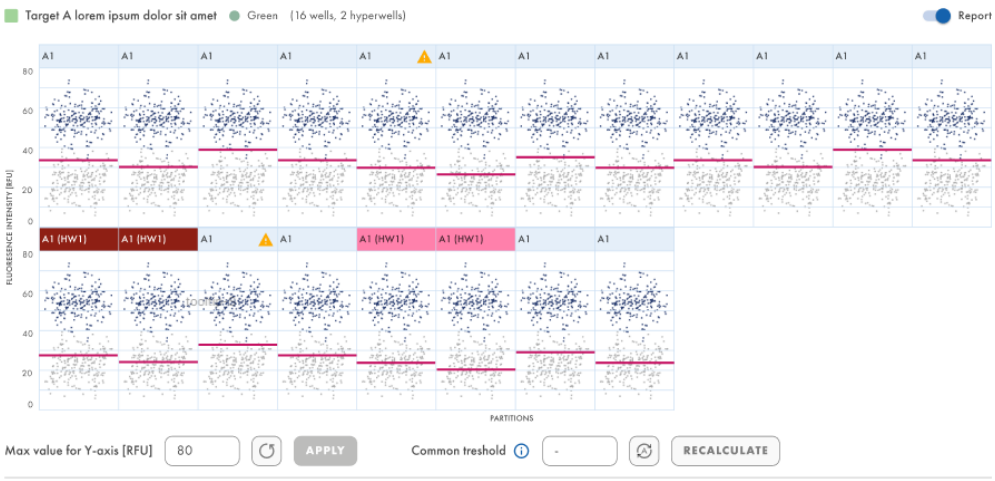
   Note: The threshold field and the **auto-threshold** button only become visible by moving the cursor in the range of the well diagram.
4. Click **CLOSE & RECALCULATE** to trigger the re-analysis of data and to close the window. Click **Cancel** to close the window without any changes.



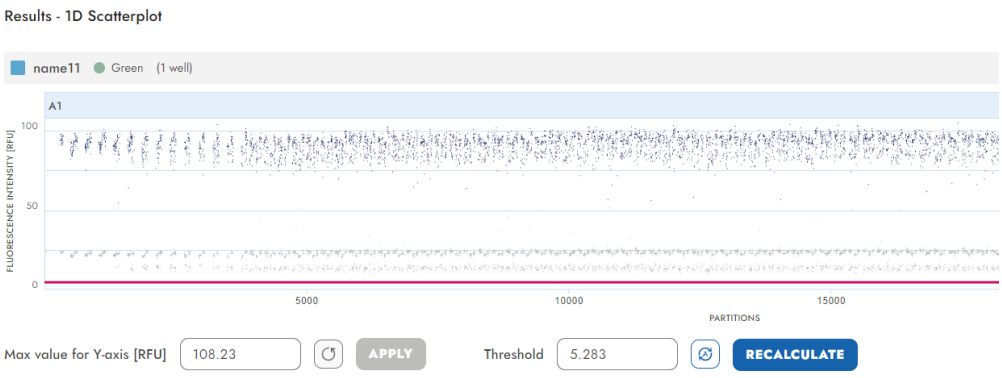
Dotted threshold line when dragging it over the graph:



Users are able to change the threshold of a single well when running a 1D Scatterplot analysis.



Clicking on the title of a plot in a 1D Scatterplot with more than 1 well opens the well detail modal window.



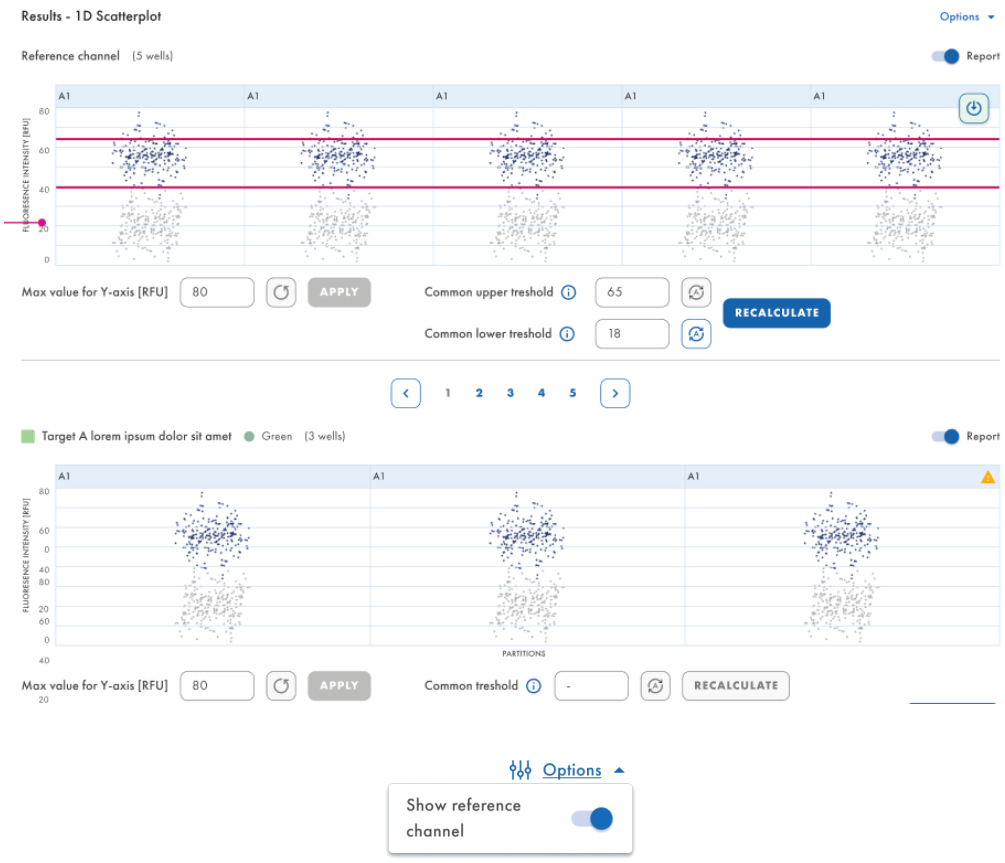
In the modal, the threshold can be changed by either changing the value in the threshold field or by clicking inside the plot and dragging the red line.

If a value higher than 300 is entered, an input validation error is shown.

If the value has been changed, the modal window can be closed via the **CLOSE & RECALCULATE** button. The value can be set back to the default value by clicking on the auto-threshold button below the threshold field, which also closes the window after setting back the value.

Reference channel on 1D Scatterplot

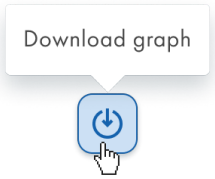
The reference channel 1D Scatterplot is displayed for every selected well whenever running a 1D Scatterplot analysis with "Show reference channel" enabled. When disabled, the 1D Scatterplot of Reference Channel is not visible.



Users with Edit Analysis Data permissions can change the lower and upper thresholds for the reference channels when running a 1D Scatterplot analysis.

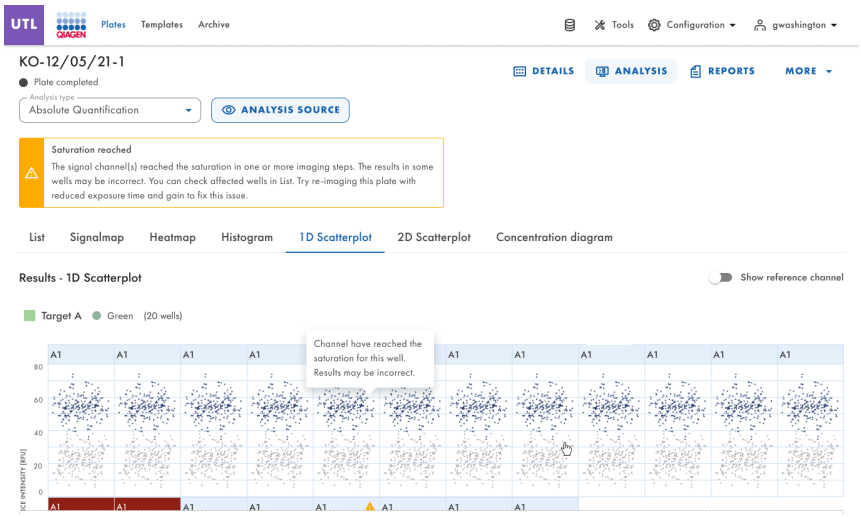
Download 1D Scatterplot Analysis

It is possible to download 1D Scatterplots when running a 1D Scatterplot analysis.

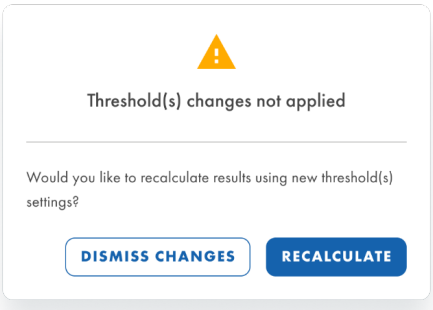


Warnings

- In the **1D Scatterplot** tab, when the results from the analysis have already been loaded in the tab, for each well diagram with a saturation flag, the header shows a warning icon whenever the fluorescence signal of the channel is over 120 RFU. When the user hovers over the warning icon with the mouse, a tooltip is shown: "Channel has reached the saturation for this well. Result may be incorrect."



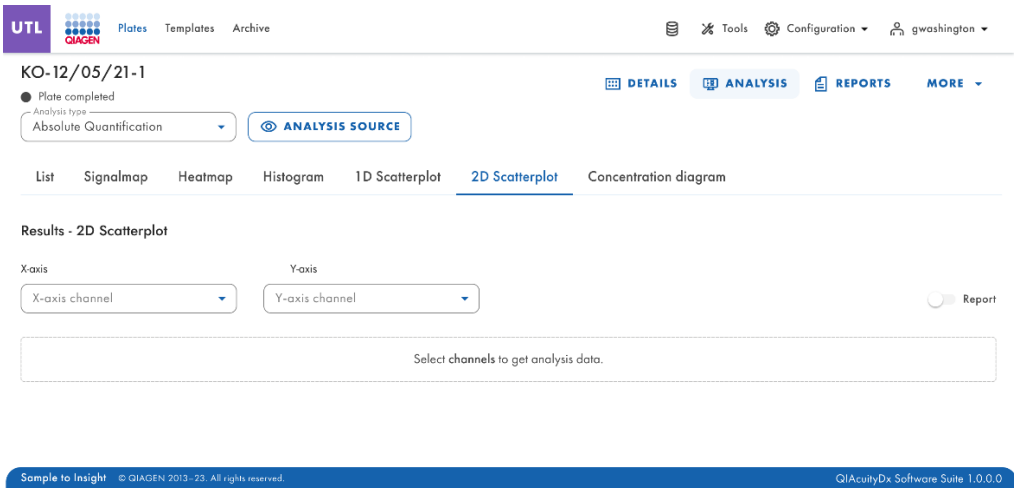
- The QIAcuityDx Software Assay Plugin displays a modal window whenever the threshold input has been changed, and the results are not recalculated before selecting another well in the plate layout, going to the List tab or selecting another scatterplot from the list.

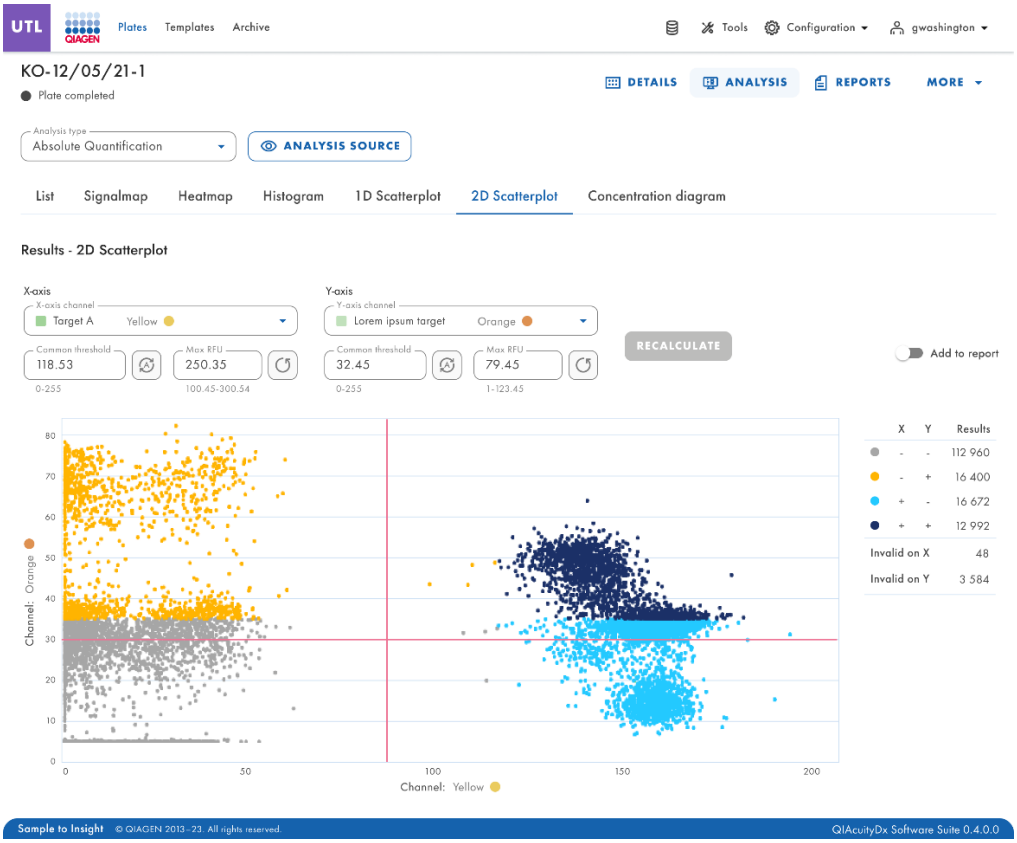


2D Scatterplot

The authorized user with corresponding permissions can download plots when running a 2D Scatterplot analysis. Plates can be analyzed by target or by channel.

After the user selects the targets from the Select Targets list or the channels from the Select Channels list and clicks the **Show results** button, the analysis results must be assigned to x- and y-axes in the **2D Scatterplot** tab.

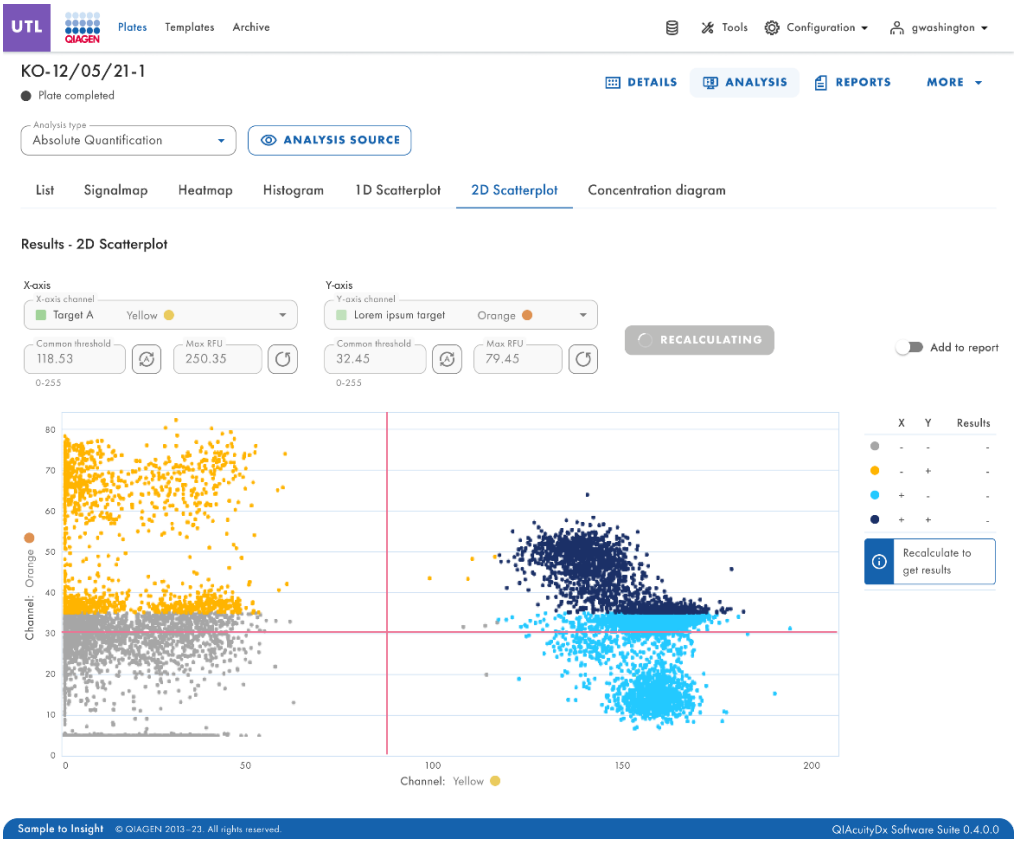




The **Download** button is visible in the upper right corner when the user hovers over the graphs.

Recalculate the thresholds in the 2D Scatterplot

It is possible to recalculate the threshold in the 2D Scatterplot. After the user selects x-axis and y-axes target or channel, the results from the analysis are loaded in the plot, and only valid partitions are shown.



Red lines (Common threshold) generate 4 quadrant areas and the following partitions:

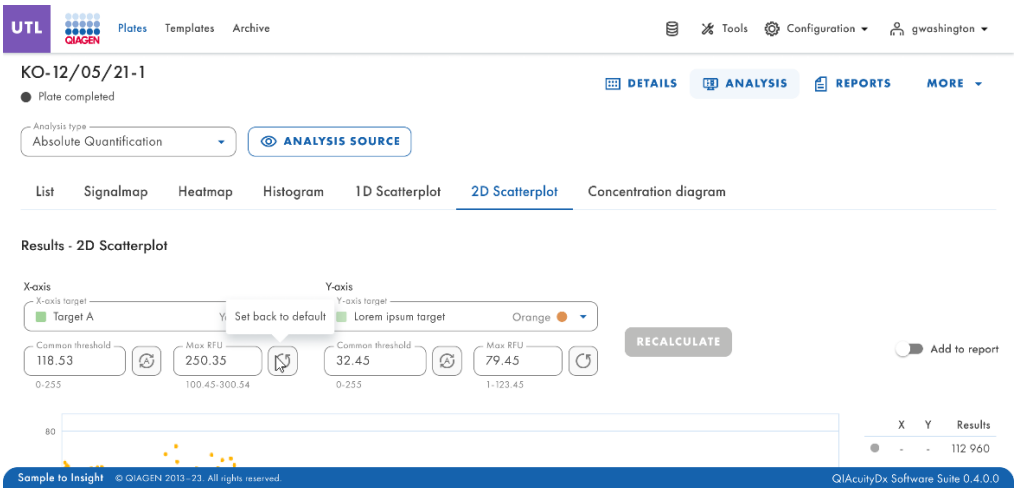
- + + partition n is positive on both X and Y channels (dark blue).
- + – partition n is positive on X but negative on Y channel (light blue).
- – – partition n is negative on both X and Y channels (gray).
- – + partition n is negative on X, but positive on Y channel (yellow).

If only one source well is selected, the thresholds for the targets or channels on each axis are shown in the Common threshold fields and in the graph as red lines.

If multiple source wells are selected, and their automatically calculated threshold values differ, a common threshold value is initially not shown.

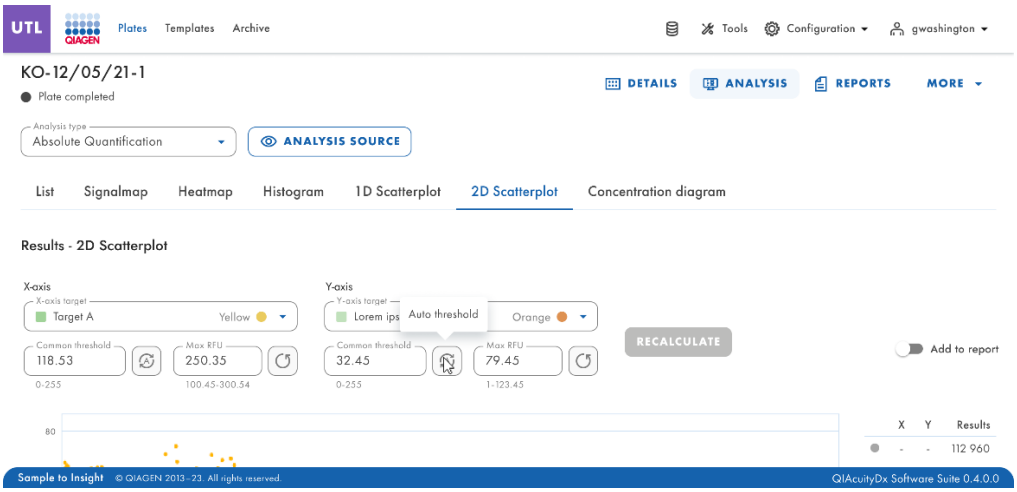
A “Recalculate to get results” notification is shown in the legend.

The user can change the common threshold by dragging and dropping the red lines and typing the values into the input fields. It is also possible to set the default values back or set the auto-threshold.

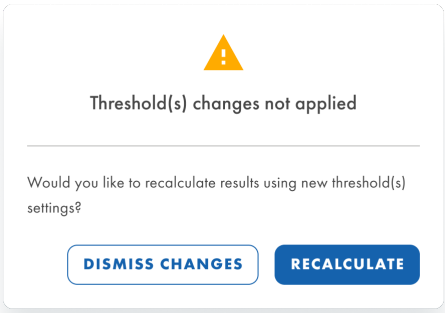


The prompt on leaving without recalculating with the changed thresholds appears when the user:

- leaves the changes and selects another well in plate layout.
- changes the analysis type.
- changes the selected targets.
- changes the selected channels.
- changes the x-axis and y-axis.
- changes the **List** tab without clicking the **Recalculate** button.
- changes the selected wells.
- changes the selected hyperwells.
- groups and ungroups hyperwells –> list refresh.
- selects other imaging step → list refresh.
- makes any changes in the URL (navigating) → list refresh.
- clicks on a well in the plate layout to check its details.

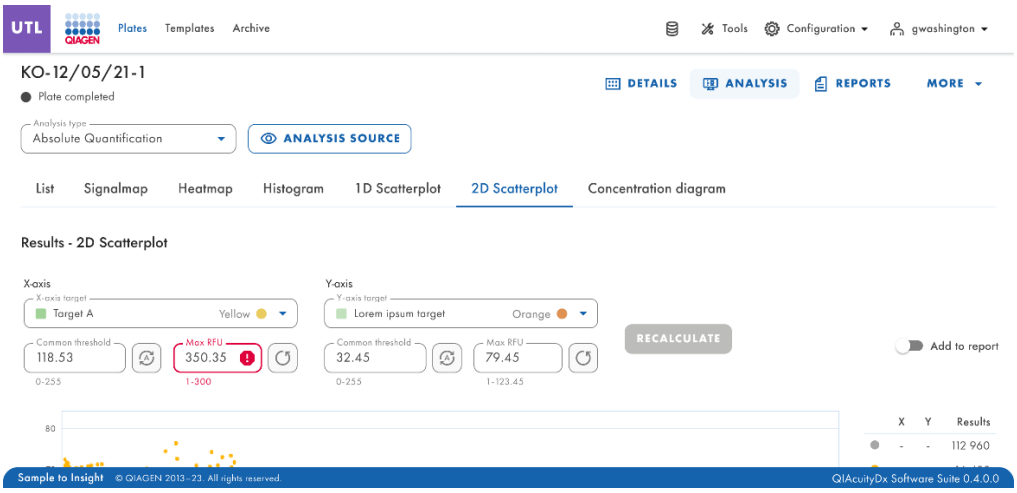


Recalculation is triggered when the user moves to a different tab. The pop-up window appears with a warning.



Max RFU value for y and x axes

Users with Edit Analysis Data permissions can change the maximum RFU values for y- and x-axes for the 2D Scatterplot and review the experiment result. The axis ranges are aligned with the maximal values presented from 0 to the measured maximal fluorescence intensity of the selected channel.



Concentration diagram tab for absolute quantification

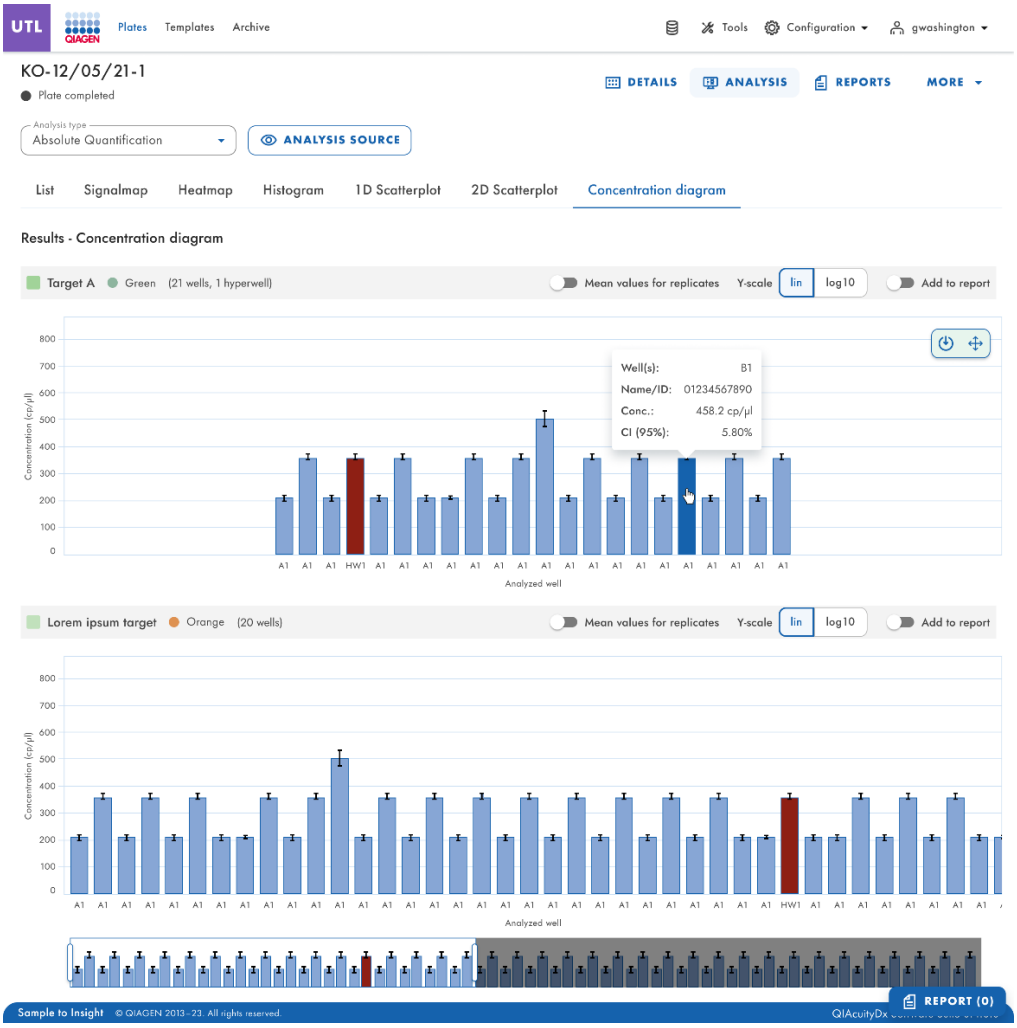
The **Concentration diagram** tab shows the diagrams that display the distribution of concentration values and confidence intervals. One diagram is created for each selected target or channel. A concentration diagram has 2 axes. The x-axis shows the analyzed wells, and the y-axis represents the concentration values for the selected targets or channels of each well. The values on the y-axis have 2 available scales – linear and logarithmic.

To view an additional toolbar that enables you to perform actions related to the diagram, such as downloading the plot, hold the cursor over the diagram. For more details about the toolbar, refer to the "Diagram option" section.

The y-axis scale can be modified using the buttons located below each graph. The buttons are visible when you hold the cursor over a graph. To view the values on a linear scale, click **lin**. To view the values on a logarithmic scale, click **log10**.

Each diagram presents 2 values for each well – the concentration value, displayed as a bar, and the confidence interval, displayed as an error bar. To view the exact values, point to one of the bars. After a concentration diagram loads, the first 32 wells are shown in the diagram. To view other wells, use the slider located below the diagram.

To view the mean values for replicates on the diagram, click **Show mean values for replicates**. In this case, one bar is shown for a replicate group showing the mean concentration value and the mean CI value of the replicate group. To view exact values and a list of wells belonging to the replicate group, point to the associated bar.



Mutation detection

The Plate Analysis environment of the Software Suite includes the **Mutation Detection** tab. Mutation Detection analysis is based on the concentrations (see the "Absolute quantification " section). To use mutation detection, the definition of targets in the reaction mixes and samples is mandatory.

The **Mutation Detection** tab is used to show the results of analyzing plate contents to detect mutations in the samples. The analysis results are put into list views, heatmaps, point diagrams, and concentration diagrams.

Note: Saving mutation detection tests is not available.

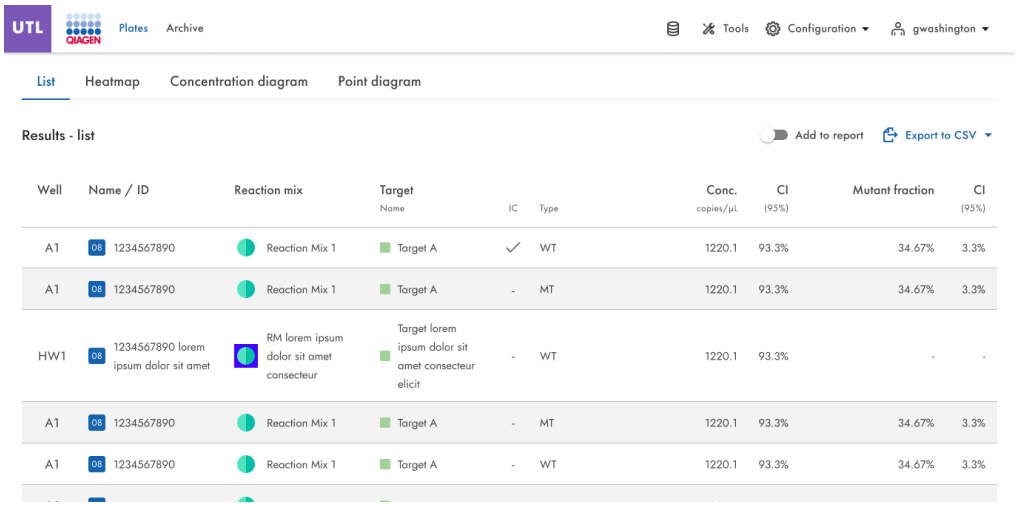
Setting up a mutation detection analysis

1. Click the relevant wells in the Select wells pane. For more information, see the “General analysis options” section.
2. Select the applicable wild-type target from the Wild-type target list.
3. Select the applicable mutant target from the Mutant target list.
4. To view the results of the analysis, click **Show results**. The results are divided into several tabs. To view the contents of the tab, click the tab title.

List tab for mutation detection

The **List** tab contains a table with an overview of the analyzed wells. The following columns are available in the table:

- **Well** – represents the well position on the plate layout.
- **Name / ID** – This column shows the sample, NTC, or control name with its corresponding icon that identifies the sample or indicates whether the entry is an NTC or control.
- **Reaction mix** – This column contains the icon and the name of the reaction mix.
- **Target** – This column shows all target names with its corresponding target type. Targets that were selected as wild type or mutant are marked accordingly.
- **Concentration (copies/µL)** – This column shows the concentration assigned to each target.
- **CI (95%)** – This column shows the value of the confidence interval at a 95% confidence level.
- **Mutation fraction** – This column shows the mutant fraction value in percentage.
- **CI (95%)** – This column shows the value of the confidence interval for mutant fraction at a 95% confidence level.



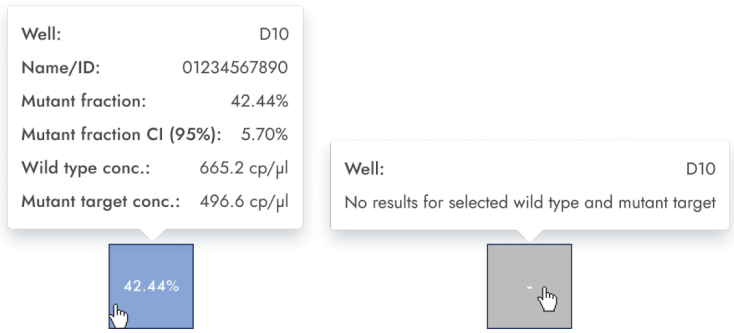
To export the list view information as CSV file, click **Export to CSV**.

Heatmap tab for mutation detection

The **Heatmap** tab contains a heatmap that shows the mutant fraction as percentage in each of the wells. If a well is not selected as a source for the analysis, the value is not displayed on the heatmap and its background color is gray.

To view an additional toolbar that enables actions related to the diagram, such as downloading the plot, hold the cursor over the diagram. For more details about the toolbar, refer to the "Diagram option" section.

To view detailed information about a well, point the cursor over the well. A tooltip with detailed information opens.



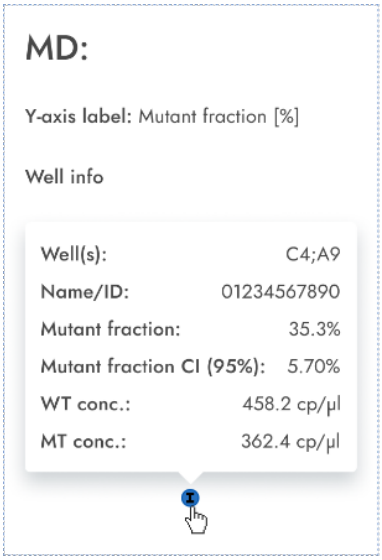
Point diagram tab for mutation detection

The **Point diagram** tab shows a diagram that displays the percentage of mutant fractions in each analyzed well. A point diagram has 2 axes. The x-axis shows the analyzed wells and samples, and the y-axis represents the mutant fraction, shown as a percentage.

To view an additional toolbar that enables actions related to the diagram, such as downloading the plot, hold the cursor over the diagram. For more details about the toolbar, refer to the "Diagram option" section.

The y-axis scale can be modified from linear to logarithmic scale using the buttons located on the left below the diagram. The buttons are visible when you hold the cursor over a graph. To view the values on a linear scale, click **lin**. To view the values on a logarithmic scale, click **log10**.

Each combination of wild-type target and mutant target in 1 sample throughout the selected wells is represented in the diagram with one point showing the concentration value together with the confidence interval. To view detailed information, hold the mouse cursor over its corresponding point. A tooltip with detailed information opens.

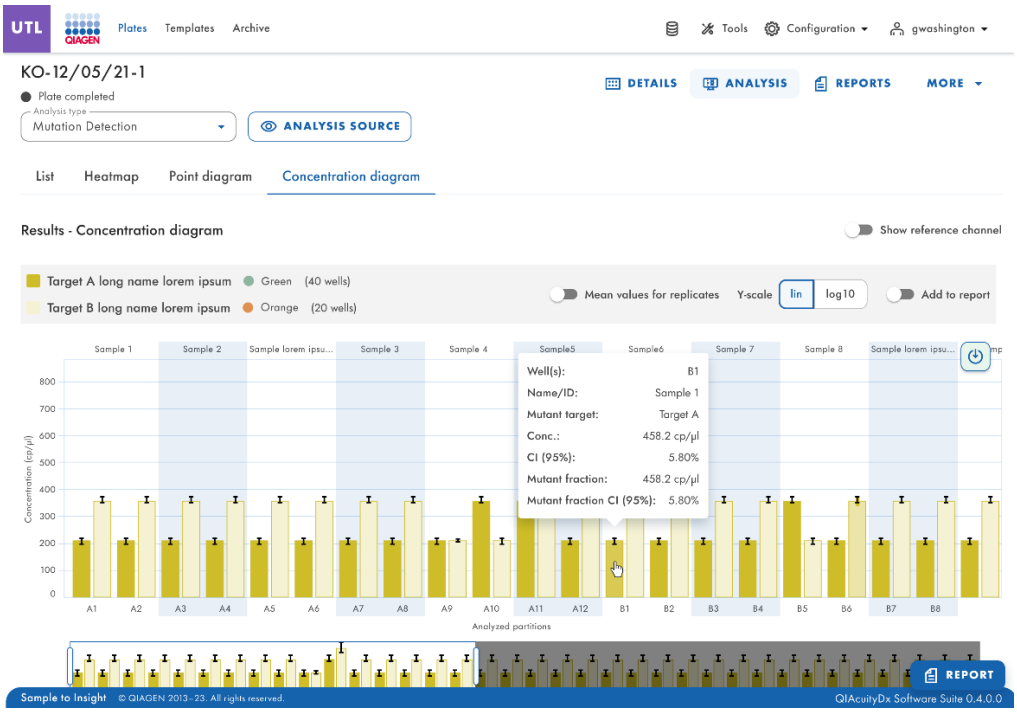


Concentration diagram for mutation detection

The **Concentration diagram** tab shows a diagram that displays the distribution of concentration values in the wells together with their confidence intervals. A concentration diagram has 2 axes. The x-axis shows the analyzed wells and samples, and the y-axis represents the concentration values. The y-axis scale can be modified using the buttons located on the left below each graph. The buttons are visible when you hold the cursor over a graph. To view the values on a linear scale, click **lin**. To view the values on a logarithmic scale, click **log10**.

To view an additional toolbar that enables actions related to the diagram, such as downloading the plot, hold the cursor over the diagram. For more details about the toolbar, refer to the "Diagram option" section.

Each combination of wild-type target and mutant target in 1 sample throughout the selected wells is represented in the diagram with 1 bar showing the concentration value together with the confidence interval. To view detailed information, hold the mouse cursor over its corresponding bar. A tooltip with detailed information opens.

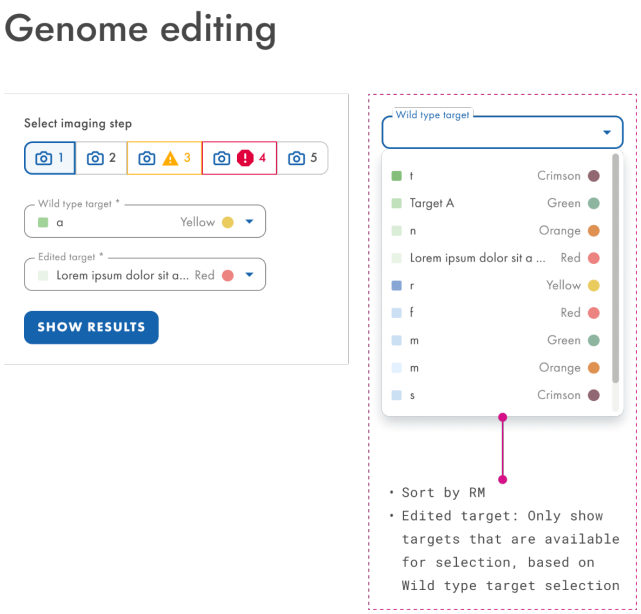


Genome editing

The Genome editing option analysis contains views that provide insight into the number of edited genomes in analyzed wells. The analysis results are put into list views, heatmaps, point diagrams, and concentration diagrams.

Note: Saving genome editing tests is not yet provided.

Setting up a genome editing analysis



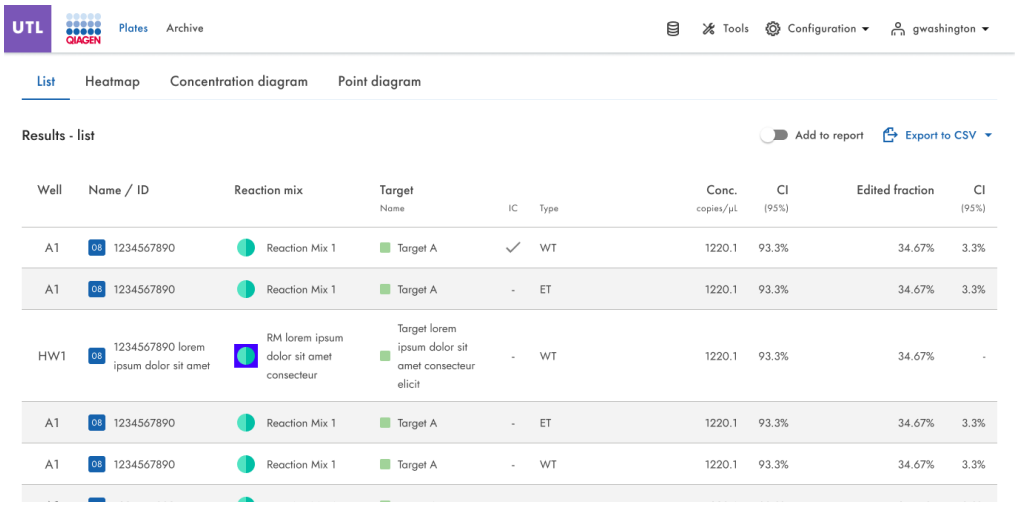
1. Click the applicable wells in the plate layout. For more information, see the "General analysis options" section.
2. Select the applicable wild-type target from the wild-type target list. The targets are sorted by reaction mix, and within each reaction mix are sorted by channel (green, yellow, orange, red, and crimson).
3. Select the applicable edited target from the Edited target list.
4. To view the results of the analysis, click **Show results**.
5. The results are divided into several tabs. To view the contents of the tab, click the tab title.

List tab for genome editing

The **List** tab contains a table with an overview of the analyzed wells. The following columns are available in the table:

- **Well** – This column represents the well position in the plate layout.
- **Name / ID** – This column shows the sample, NTC, or control name with its corresponding icon that identifies the sample or indicates whether the entry is an NTC or control.
- **Reaction mix** – This column contains the icon and the name of the well.
- **Target** – This column shows all target names with its corresponding target type. Targets that were selected as wild type or edit type are marked accordingly.
- **Concentration (copies/µL)** – This column shows the concentration assigned to each target or channel.
- **CI (95%)** – This column shows the value of the confidence interval at a 95% confidence level.
- **Edited fraction** – This column shows the edited fraction for the edited target as percentage.
- **CI (95%)** – This column shows the value of the confidence interval for the edited target at a 95% confidence level.

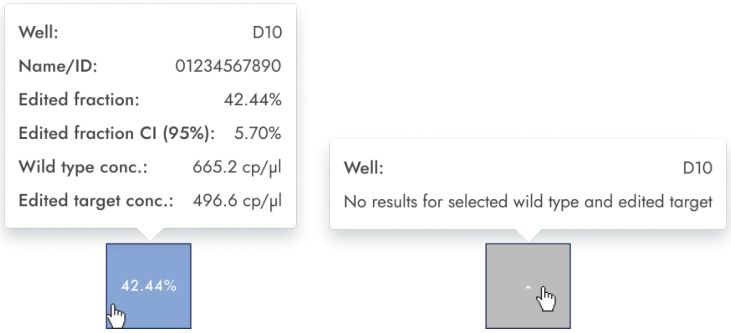
To export the list view information as CSV file, click **Export to CSV**.



Heatmap tab for genome editing

The **Heatmap** tab contains heatmaps that show the edited fraction as percentage in each of the wells. If a well is not selected as a source for the analysis, the value is not displayed on the heatmap and its background color is gray.

To view an additional toolbar that enables actions related to the diagram, such as downloading the plot, hold the cursor over the diagram. For more details about the toolbar, refer to the “Diagram option” section. To view detailed information about a particular well, point the cursor over the well. A tooltip with detailed information opens.

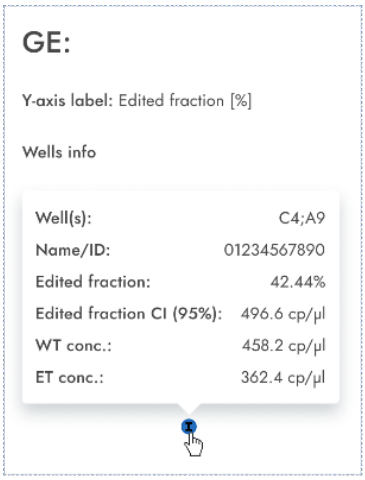


Point diagram tab for genome editing

The **Point diagram** tab shows a diagram that displays the percentage of edited fractions in each analyzed well. A point diagram has 2 axes. The x-axis shows the analyzed wells and samples, and the y-axis represents the edited fraction, shown as a percentage.

To view an additional toolbar that enables actions related to the diagram, such as downloading the plot, hold the cursor over the diagram. For more details about the toolbar, refer to the "Diagram option" section. The y-axis scale can be modified using the buttons located below each graph. The buttons are visible when you hold the cursor over a graph. To view the values on a linear scale, click **lin**. To view the values on a logarithmic scale, click **log10**.

Each combination of wild-type target and edited target in 1 sample throughout the selected wells is represented in the diagram with one point showing the concentration value together with the confidence interval. To view detailed information, hold the mouse cursor over its corresponding point. A tooltip with detailed information opens.

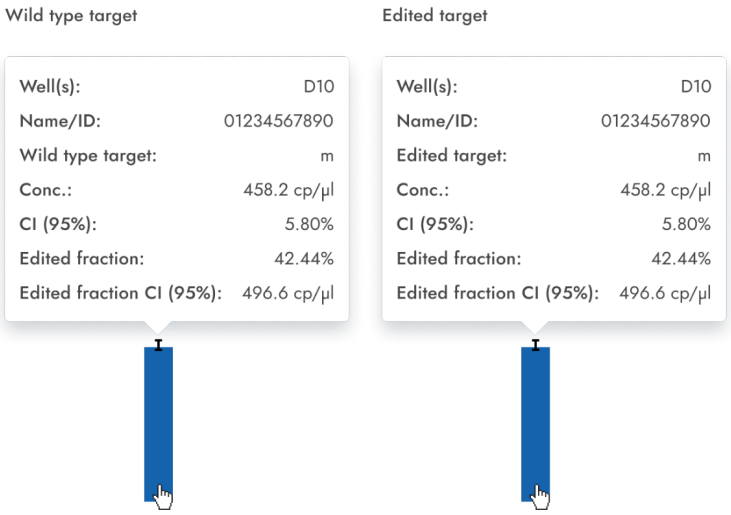


Concentration diagram tab for genome editing

The **Concentration diagram** tab shows a diagram that displays the distribution of concentration values in the wells together with their confidence intervals. A concentration diagram has 2 axes. The x-axis shows the analyzed wells and samples, and the y-axis represents the concentration values. The y-axis scale can be modified using the buttons located below each graph. The buttons are visible when you hold the cursor over a graph. To view the values on a linear scale, click **lin**. To view the values on a logarithmic scale, click **log10**.

To view an additional toolbar that enables actions related to the diagram, such as downloading the plot, hold the cursor over the diagram. For more details about the toolbar, refer to the "Diagram option" section.

Each combination of wild-type target and edited target in 1 sample throughout the selected wells is represented in the diagram with 1 bar showing the concentration value together with the confidence interval. To view detailed information, hold the mouse cursor over its corresponding bar. A tooltip with detailed information opens.



Copy number variation

The Copy number variation analysis option contains diagrams that visualize the data related to copied genes in targets of interest and reference targets. The analysis results are put into list views, heatmaps, point diagrams, and concentration diagrams.

Note: Saving copy number variation tests is not yet provided.

Setting up a copy number variation analysis

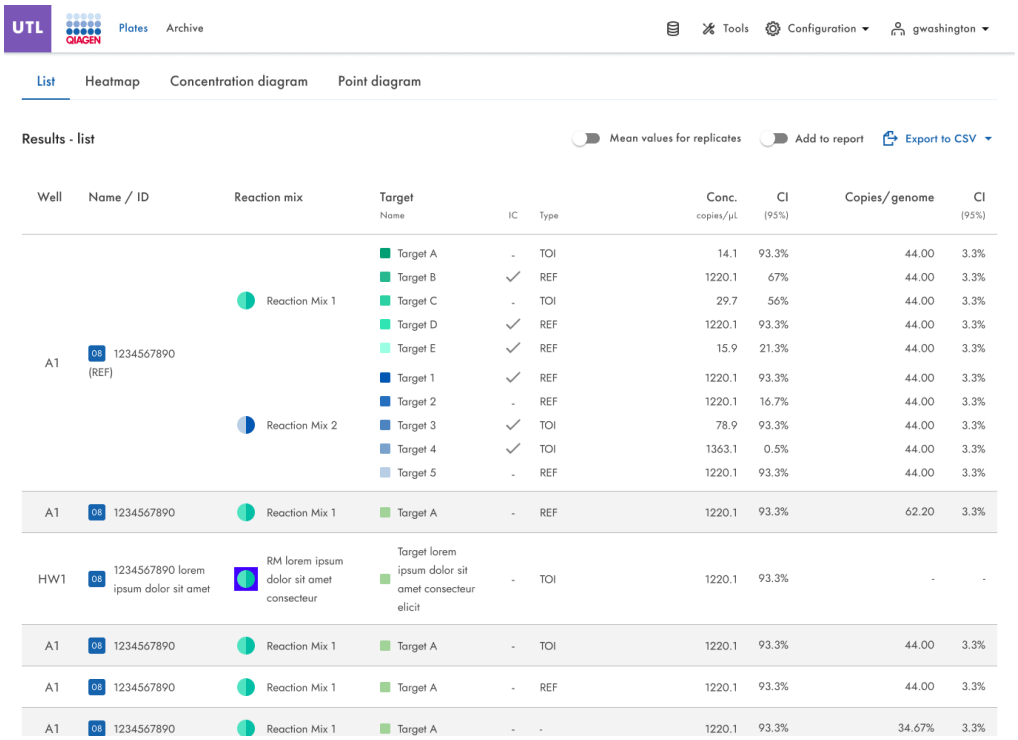
1. Click the applicable wells in the plate layout. For more information, see the "General analysis options" section.
2. Select the applicable reference sample from the Reference sample list.
3. Enter the number of copies per genome in the copies/genome field for the target of interest in reference sample. The value should be between 1 and 99.
4. Select the applicable target that you want to investigate from the Target of interest list. The targets are sorted by reaction mix, and within a reaction mix, they are sorted by channel (green, yellow, orange, red, and crimson).
5. Select 1 or more reference targets from the Reference target(s) list.

   Note: You can select more than 1 reference target.
6. To view the results of the analysis, click **Show results**. The results are divided into several tabs. To view the contents of the tab, click the tab title.

List tab for copy number variation

The **List** tab contains a table with an overview of the analyzed wells. The following columns are available in the table:

- **Well** – This column represents the well position in the plate layout.
- **Name / ID** – This column shows the sample, NTC, or control name with its corresponding icon that identifies the sample or indicates whether the entry is an NTC or control. Reference samples are marked with the word Ref.
- **Reaction mix** – This column contains the icon and the name of the reaction mix.
- **Target** – This column shows all target names with its corresponding target type. Targets that were selected as target of interest (TOI) or reference target (Ref) are marked accordingly.
- **IC** – This column indicates the Internal control (IC).
- **Type** – This column shows the target type as target of interest (TOI) or reference target (Ref).
- **Concentration (copies/µL)** – This column shows the concentration assigned to each target or channel.
- **CI (95%)** – This column shows the value of the confidence interval at a 95% confidence level.
- **Copies/genome** – This column shows the number of copies per genome in each of the targets of interest.
- **CI (95%)** – This column shows the value of the confidence interval for the target of interest at a 95% confidence level.



Replicates are treated different for multiplex and simplex test setup:

- Multiplex test (configured target of interest and reference targets are part of the same reaction mix):
  - On the right side above the table there is a toggle that allows the user to show the mean values for replicates. By default, results are displayed with mean values. Replicates from the same group are grouped together in the list view. (By default, the button is unchecked, and results are displayed without mean values. When the button is checked, the list view still shows independent rows for each selected well but replicates are grouped together. Replicates from the same group are next to each other in the list view.)The list view has columns indicating the following mean values:
    - Mean concentration value
    - CI (95%) — CI of mean concentration as percentage
    - Mean copies/genome
    - CI (95%) — CI of mean mutation fraction as percentage
- Simplex test (configured target of interest and reference targets are part of different reaction mixes):
  - For tests having the configured targets in different wells/reaction mixes, the mean result is calculated and shown for replicates in the selection. The list view is extended by 4 columns indicating the following mean values:
    - Mean concentration value
    - CI (95%) — CI of mean concentration as percentage
    - Mean copies/genome
    - CI (95%) — CI of mean mutation fraction as percentage.

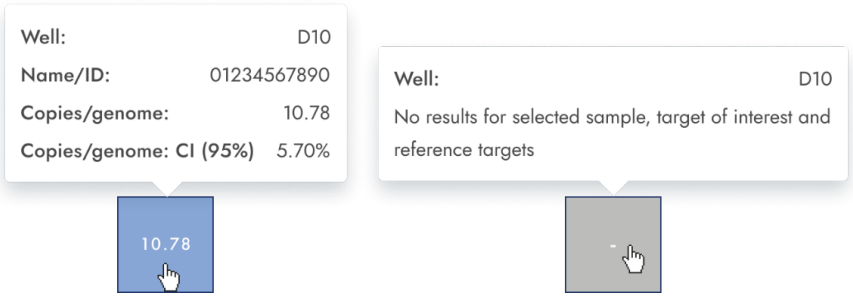
To export the results of the list view to a CSV file, click **Export to CSV**.

Heatmap tab for copy number variation

The **Heatmap** tab contains a heatmap that shows the number of copies per genome in each of the wells. If a well is not selected as a source for the analysis, the value is not displayed on the heatmap, and its background color is gray.

To view an additional toolbar that enables actions related to the diagram, such as downloading the plot, hold the cursor over the diagram. For more details about the toolbar, refer to the "Diagram option" section.

To view detailed information about a particular well, point the cursor over the well. A tooltip with detailed information opens.



Point diagram tab for copy number variation

The **Point diagram** tab shows the diagram that displays the number of copies per genome of the configured copy number variation test and the confidence intervals related to every value. A point diagram has 2 axes. The x-axis shows the analyzed wells and samples, and the y-axis represents the number of copies in each genome. A confidence interval displayed as an error bar is shown for each of the points on the diagram.

To view an additional toolbar that enables actions related to the diagram, such as downloading the plot, hold the cursor over the diagram. For more details about the toolbar, refer to the "Diagram option" section.

The y-axis scale can be modified using the buttons located below each graph. The buttons are visible when you hold the cursor over a graph. To view the values on a linear scale, click **lin**. To view the values on a logarithmic scale, click **log10**.

The diagram shows the values as points with the CI as error bar for the selected samples. When targets are in the same reaction mix, then each sample is represented by 1 point. The point color reflects the color assigned to the corresponding target of interest.

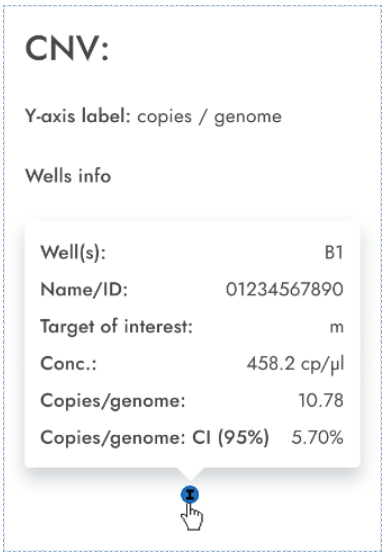
The samples are sorted by sample ID but the reference sample of a test is always shown. The well IDs and sample IDs are labeled on the x-axis.

When targets are in different reaction mixes then each combination of target of interest and reference targets in 1 sample throughout the selected wells are shown in the diagram with a point for the result. To view detailed information, hold the mouse cursor over its corresponding point. A tooltip with detailed information opens.

To view the mean values for replicates, click **Show mean values for replicates**. If the user clicks onto the toggle to select the mean representation for replicates, the points of individual replicates disappear and only 1 point is shown with the sample label that represents the mean copies per genome value of the replicates. When there are no replicates within selected wells the points do not change. The corresponding well IDs of the replicates are shown on the x-axis. This also applies to the targets in different reaction mixes. In this case individual replicate results are not available. Mean values are calculated of all

replicates that are included in the well selection only. If there are further replicates of the same sample that are not included in the well selection, they are not considered in the calculated mean value and their individual values will be shown.

Note: If the selected analysis source contains replicates of the reference sample, your results can be calculated only by using mean results for replicates. In this case, the "Show mean values for replicates" needs to be on.



Concentration diagram tab for copy number variation

The concentration diagram tab shows the diagram that displays the concentration values of the configured copy number variation test and the confidence intervals related to every value. A concentration diagram has 2 axes.

- X-axis represents labels of wells and samples that it belongs to.
- Y-axis represents the concentration values for selected targets or channels for each well. A confidence interval displayed as an error bar is shown for each of the bars on the diagram.

The y-axis scale can be modified using the buttons located below each graph. The buttons are visible when you hold the cursor over a graph. To view the values on a linear scale, click **lin**. To view the values on a logarithmic scale, click **log10**.

To view an additional toolbar that enables actions related to the diagram, such as downloading the plot, hold the cursor over the diagram.

For more details about the toolbar, refer to the "Diagram option" section.

The Concentration diagram is a bar plot which presents 2 values:

- Concentration value as bar
- CI value as error bar

The diagram consists of all possible combinations. Each sample on the diagram is represented by the number of bars according to targets that were selected as a target of interest and reference targets. Samples on the diagram are sorted by the sample ID. Target bars in the sample show 1 concentration bar for the target of interest at the first position and

concentration bars for reference targets sorted by their well ID. The bar color reflects the color assigned to the corresponding targets. The sample ID is shown center-aligned below the bars.

The bar size is fixed if:

- The reference targets and target of interests are situated in 1 well, then these targets will be represented by 1 well label.
- The reference targets and target of interests are situated in 2 or more wells, then each target will have a unique well label.

When hovering over a bar in the diagram, a tooltip appears presenting details about the actual values of concentration and CI and results of tests.

To view the mean values for replicates on the diagram, click **Show mean values for replicates**. When this toggle is ON, the concentration diagram shows bars that represent mean concentration values of replicates within the well selection. The label below the bar shows well positions of these replicates. Hovering on the bar, shows a tooltip with details about wells, sample and target that are part of the replicate group, and the results are shown as mean values with a corresponding mean label. This also applies to targets in different reaction mixes. In this case individual replicate results are not available. When selected wells have no replicates within the selection, then individual result values are shown.

Note: If the selected analysis source contains replicates of the reference sample, your results can be calculated only by using mean results for replicates. In this case, the "Show mean values for replicates" needs to be set on.

Gene expression

The Software Suite analyzes the gene expression of the samples. The analysis results are put into list views, heatmaps, point diagrams, and concentration diagrams.

Note: Saving gene expression tests is not yet provided.

Setting up a gene expression analysis

1. Click the applicable wells in the plate layout.
2. Select the applicable reference sample from the Reference sample list.
3. Select the applicable target from the Target of interest list. The targets are sorted by reaction mix, and within a reaction mix, they are sorted by channel (green, yellow, orange, red, and crimson).
4. Select 1 or more reference targets from the Reference target(s) list.
5. To view the results of the analysis, click **Show results**. The results are divided into several tabs. To view the contents of the tab, click the tab title.

List tab for gene expression

The **List** tab contains a table with an overview of the analyzed wells. The following columns are available in the table:

- **Well** – This column represents the well position in the plate layout.
- **Name / ID** – This column shows the sample, NTC, or control name with its corresponding icon that identifies the sample or indicates whether the entry is an NTC or control. Reference samples are marked with the word Ref.
- **Reaction mix** – This column contains the icon and the name of the Reaction mix.
- **Target** – This column shows all target names with its corresponding target type. Targets that were selected as target of interest (TOI) or reference target (Ref) are marked accordingly.
- **Concentration (copies/µL)** – This column shows the concentration assigned to each target.
- **CI (95%)** – This column shows the value of the confidence interval at a 95% confidence level.
- **Fold change** – This column shows the change in the level of gene expression in the sample.
- **CI (95%)** – This column shows the value of the confidence interval for the fold change at a 95% confidence interval.
- **Fold regulation** – This column shows the change in the level of gene expression compared to the reference sample.

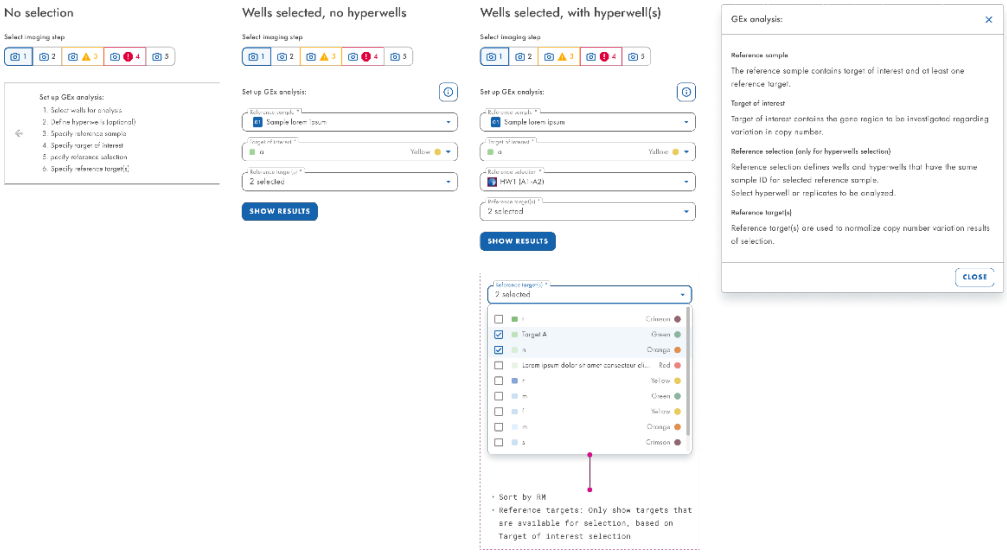
Replicates are treated different for multiplex and simplex test setup:

- Multiplex test (configured target of interest and reference targets are part of the same reaction mix):
  - On the right side above the table there is toggle which allows the user to show mean values for replicates . By default, the button is unchecked and results are displayed without mean values. When the button is checked, the list view still shows independent rows for each selected well, but replicates are grouped together. Replicates from the same group are next to each other in the list view. The list view is extended by 5 columns indicating following mean values:
    - Mean concentration value
    - CI (95%) – CI of mean concentration as percentage
    - Mean fold change
    - CI (95%) – CI of mean fold change as percentage
    - Mean fold regulation
- Simplex test (configured target of interest and reference targets are part of different reaction mixes):
  - For tests having the configured targets in different wells/reaction mixes, the mean result is calculated and shown for replicates in the selection. The list view is extended by 5 columns indicating following mean values:
    - Mean concentration value
    - CI (95%) – CI of mean concentration as percentage
    - Mean fold change
    - CI (95%) – CI of mean fold change as percentage
    - Mean fold regulation

Note: If the selected analysis source contains replicates of the reference sample, your results can be calculated only by using mean results for replicates. In this case, the “Show mean values for replicates” checkbox is marked and cannot be changed. In this case, there is a warning message above the table and when the user hovers over the toggle, a tooltip appears to

inform the user that selected analysis source contains replicates of the reference sample, and result is calculated only by using mean results for replicates.

To export the results to a CSV file, click **Export to CSV**.

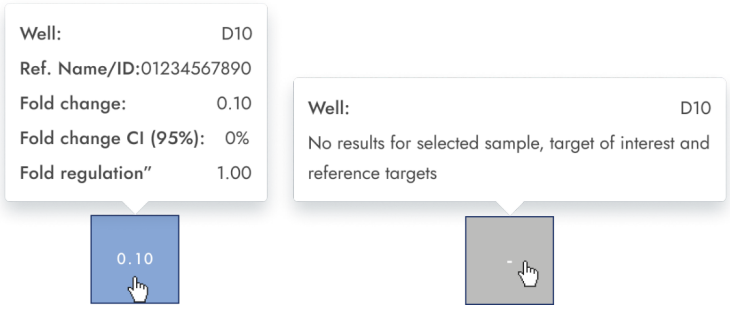


Heatmap for gene expression

The **Heatmap** tab contains a heatmap view that shows the fold change in each of the wells. If a well is not selected as a source for the analysis, the value is not displayed on the heatmap and its background color is gray.

When a fold change is not applicable for a well, then n.a. is shown. To view an additional toolbar that enables actions related to the diagram, such as downloading the plot, hold the cursor over the diagram. For more details about the toolbar, refer to the “Diagram option” section.

To view detailed information about a particular well, point the cursor over the well. A tooltip with detailed information opens.



Point diagram for gene expression

The **Point diagram** tab shows a point diagram view that displays the fold change values of configured gene expression test and the confidence intervals related to every value. A point diagram has 2 axes. The x-axis shows the analyzed wells and samples, and the y-axis represents the fold change. A confidence interval displayed as an error bar is shown for each of the points on the diagram.

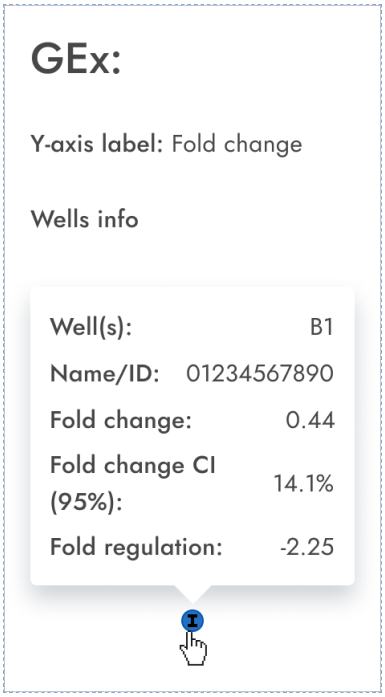
To view an additional toolbar that enables actions related to the diagram, such as downloading the plot, hold the cursor over the diagram. For more details about the toolbar, refer to the "Diagram option" section.

The y-axis scale can be modified using the buttons located below each graph. The buttons are visible when you hold the cursor over a graph. To view the values on a linear scale, click **lin**. To view the values on a logarithmic scale, click **log10**. The diagram shows the values as points with the confidence interval displayed as an error bar, which is shown for each of the points on the diagram for the selected samples. When the targets are in the same reaction mix, then each sample is represented by 1 point. The point color reflects the color assigned to the corresponding target of interest. The samples are sorted by sample ID, but the reference sample of a test is always shown first. The well IDs and sample IDs are labeled on the x-axis.

When the targets are in different reaction mixes, then each combination of target of interest and reference targets in 1 sample throughout the selected wells is shown in the diagram with a point for the result. To view detailed information, hold the mouse cursor over its corresponding point. A tooltip with detailed information opens.

To view the mean values of replicates, click **Show mean values for replicates**. If the user clicks onto the toggle to select the mean representation for replicates, the points of individual replicates disappear and only 1 point is shown with the sample label that represents the mean fold change value of the replicates. When there are no replicates within selected wells, the points do not change. The corresponding well IDs of the replicates are shown on the x-axis. This also applies to targets in different reaction mixes. In this case, individual replicate results are not available. Mean values are calculated and shown for all replicates that are included in the well selection only. If there are further replicates of the same sample which are not included in well selection, they are not considered in the calculated mean value and their individual values are shown.

Note: If the selected analysis source contains replicates of the reference sample, user results can be calculated only by using mean results for replicates. In this case, the "Show mean values for replicates" needs to be set on.



Concentration diagram for gene expression

The concentration diagram tab shows the diagram that displays the concentration values of the configured gene expression test and the confidence intervals related to every value. A concentration diagram has 2 axes.

- X-axis represents labels of wells and samples that it belongs to.
- Y-axis represents the concentration values for selected targets or channels for each well. A confidence interval displayed as an error bar is shown for each of the bars on the diagram.

The y-axis scale can be modified using the buttons located below each graph. The buttons are visible when you hold the cursor over a graph. To view the values on a linear scale, click **lin**. To view the values on a logarithmic scale, click **log10**.

To view an additional toolbar that enables actions related to the diagram, such as downloading the plot, hold the cursor over the diagram. For more details about the toolbar, refer to the "Diagram option" section.

The Concentration diagram is a bar plot which presents 2 values:

- Concentration value as bar
- CI value as bar

The diagram consists of all possible combinations. Each sample on the diagram is represented by the number of bars according to targets that were selected as a target of interest and reference targets. Samples on the diagram are sorted by the sample ID. Target bars in the sample show 1 concentration bar for the target of interest at the first position and concentration bars for reference targets sorted by their well ID. The bar color reflects the color assigned to the corresponding targets. The sample ID is shown center aligned below the bars. The bar size is fixed if:

The reference targets and target of interests are situated on 1 well, then these targets will be represented by 1 well label. The reference targets and target of interests are situated on 2 wells or more wells, then each target will have a unique well label. When hovering over a bar in the diagram, a tooltip appears presenting details about the actual values of concentration and CI and results of tests.

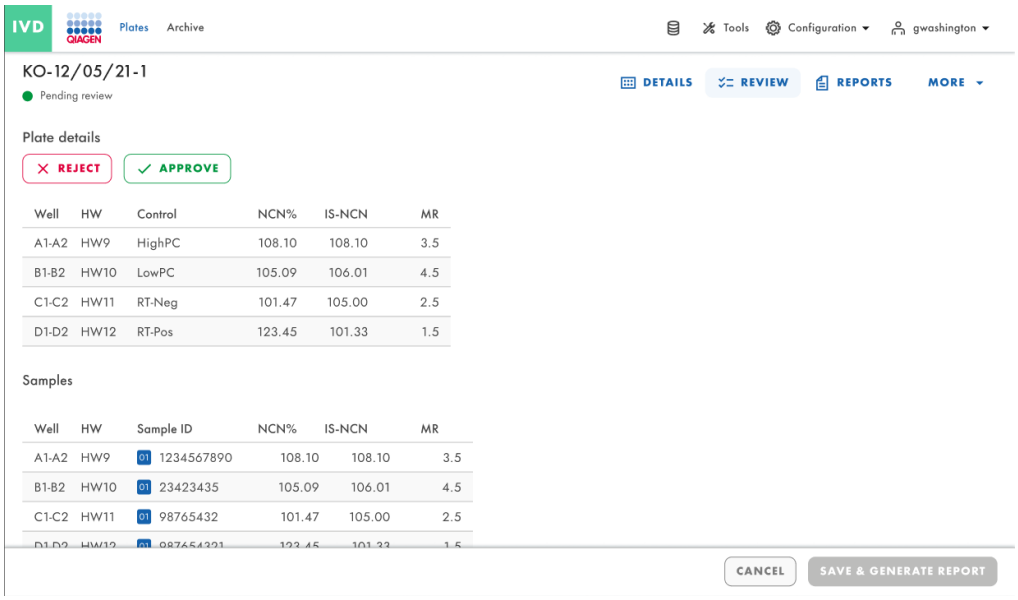
To view the mean values for replicates on the diagram, click **Show mean values for replicates**. When this toggle is ON, the concentration diagram shows bars that represent mean concentration value for replicates within the well selection. The label below the bar shows well positions that are included in the replicates value of mean concentration.

Hover on the bar, there is a tooltip with details about wells, sample, and target that are part of the replicate group, and the results are shown as mean result values with a corresponding mean-label. This also applies to targets in different reaction mixes. In this case individual replicate results are not available. When selected wells have no replicates within the selection, individual values are shown.

Note: If the selected analysis source contains replicates of the reference sample, your results can be calculated only by using mean results for replicates. In this case, the "Show mean values for replicates" needs to be set on.

5.19.7. Review results in IVD mode

Manual validation

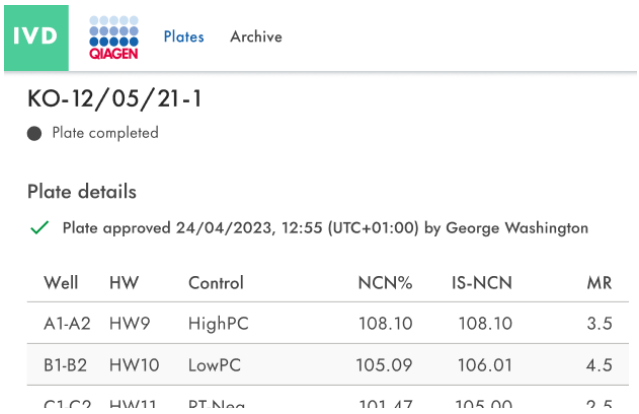


For the plates that have been processed by the instrument configured with Automatic Validation as Off (see Section 5.10.3 Assay plugin management), the results need to be manually approved or rejected.

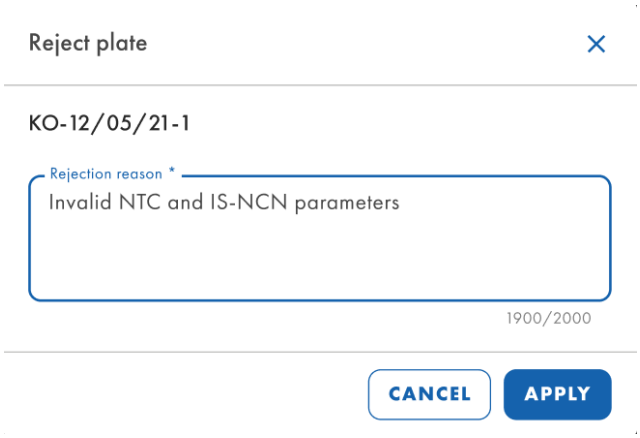
The authorized user with “Review Plate Result” permission can approve or reject a set of results of plate in Pending Review status.

After reviewing the results, the user can approve the plate by clicking **APPROVE**. To make the approval persistent, the user should finally click on **SAVE & GENERATE REPORT**.

After performing this action, the status of the plate will change as "Plate completed" and the details of the approval and the reviewer user will be shown in the Review screen.

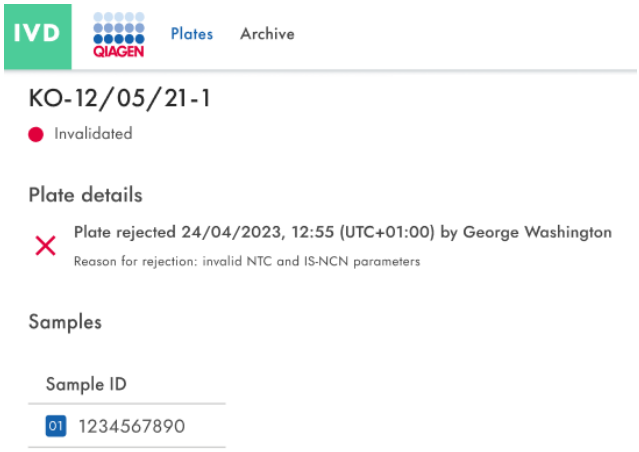


If the user wants to reject the plate, after clicking **REJECT**, a rationale for the rejection will be asked for by the Software Suite.



After clicking **APPLY**, to make the rejection persistent, the user should finally click on **SAVE & GENERATE REPORT** and confirm the dialog by clicking **REJECT PLATE**.

After performing this action, the status of the plate will change as "Plate completed" and the details of the rejection and the reviewer user will be shown in the Review screen.



On the other hand, either when approving or rejecting a plate, the report generation will be triggered automatically after clicking **SAVE & GENERATE REPORT** and confirm action.

Automatic validation

The plates with "Automatic Validation" set as "On" (see Section 5.10.3 Assay plugin management) will be automatically validated.

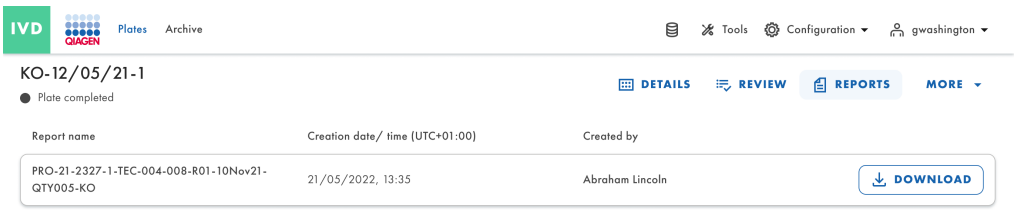
If the quality controls are passed successfully, the Software Suite will approve the plate and subsequently generate the report. The plate will change its status to "Plate Completed".

If the quality controls are not passed successfully, the Software Suite will reject the plate and subsequently generate the report. The plate will change its status to "Invalid".

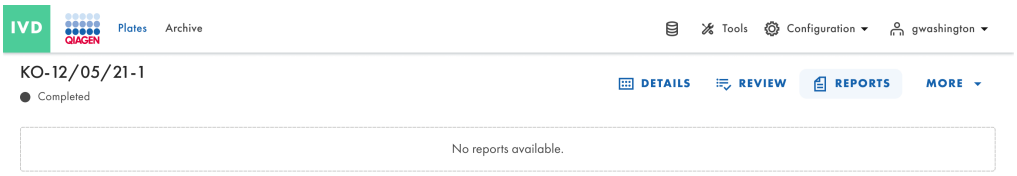
5.19.8. Create a report in IVD mode

In the Software Suite, you can create reports of your plate analysis results. All created reports remain accessible in the Software Suite and can be downloaded.

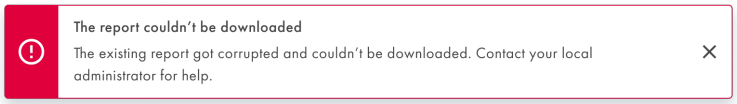
Users with Read plate permission can view and check all the reports created for a plate. All existing reports are downloadable on IVD channel. This is valid for the plates with status on IVD "Plate Completed".



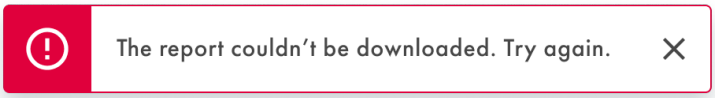
If no reports are available, the "No reports available." message is displayed to the user.



If the download fails due to a corruption of the report, a specific error notification is displayed.



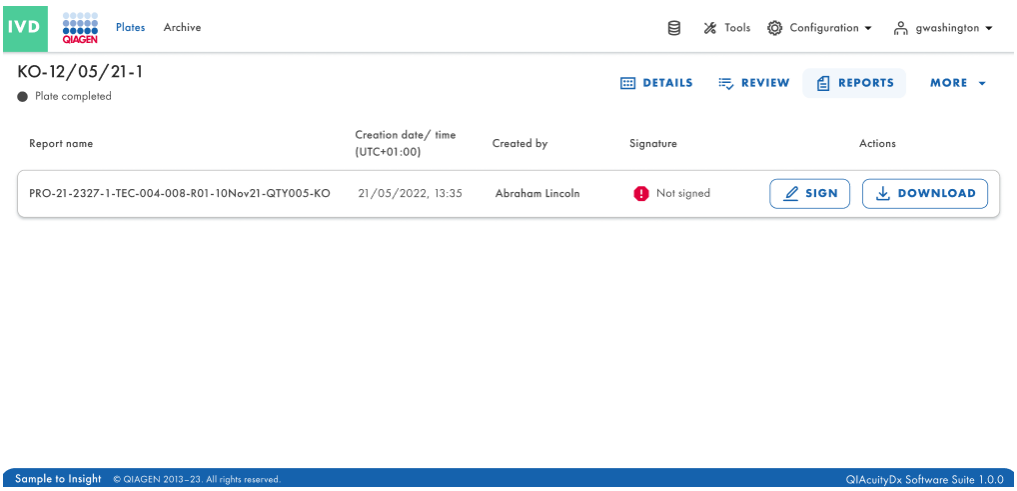
If the download of the report fails due to a different cause, the generic error notification is displayed.



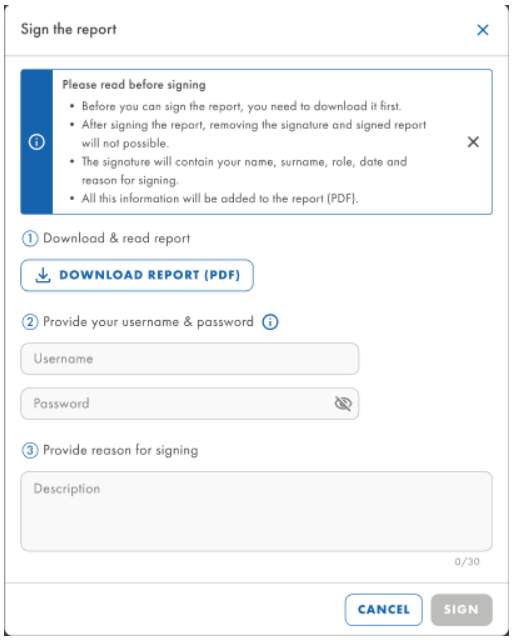
5.19.9. Sign a report in IVD mode

To sign a report in IVD mode, the authorized user must have specific sign permission for the assay which the plate originated the report.

To see the pending to sign report of plate, go to its Reports screen from Plate Overview screen or from inside the plate's **Reports** button.



If the plate has a report pending to be signed, a "Not Signed" text will be shown in the "Signature" column.



To perform the signing of the report, click the **SIGN** button. A prompt will appear, requesting user credentials and rationale for signing. To perform this action, the report must have been downloaded first; for that, a **DOWNLOAD REPORT (PDF)** button will be available in the prompt. This version of the report is not signed, as can be checked in its content.

Once reviewed the report, the user can enter the credentials and the reason for signing.

To finish the signing process, click the **SIGN** button. A notification will be shown.

5.19.10. Run details in report

On the first page of the report, there is information about the plate and the report:

PRO-21-2327-1-TEC-004-008-R01-10Nov21-QTY005-KO

BCR::ABL1 Mbcr

Generated	2023/05/17, 15:33 (UTC+01:00) by George Washington
Plate ID	f1ec62fd-c4c2-49f1-9eee-387e28331c68
Report ID	ab48c0c6-f0a4-4774-9817-50d4c49a65a7
Signed	2023/05/21, 09:03 (UTC+01:00) by George Washington
Reason for signing	CFR 21p11
Comments	Lorem ipsum dolor sit amet, consectetur adipiscing elit. Donec sed risus turpis.

On the next page, there are the processing details and the plate details, as well as the reagents used:

Processing details

Validation	Validated 12/05/2023, 10:07,21 (UTC+01:00) by QIAcuityDx Software Suite
Software	QIAcuityDx Software Suite 1.0
Instrument software	CSW ver. 2.0.1
Instrument	QTY-005, SN: ETI-09017685-G
Processing started	12/05/2023, 09:05:33 (UTC+01:00)
Processing ended	12/05/2023, 10:04:01 (UTC+01:00)
dPCR steps	Priming, Cycling, Imaging, Cycling, Imaging

Plate details

Assay	*BCR::ABL1* Mbcr
Plate name	PRO-21-2327-1-TEC-004-008-R01-10Nov21-QTY005-KO
Barcode	03026692100233000000000809
Plate type	Nanoplate 26K 24Well
Owners	George Washington, George Clooney
Description	-
Created by	George Washington

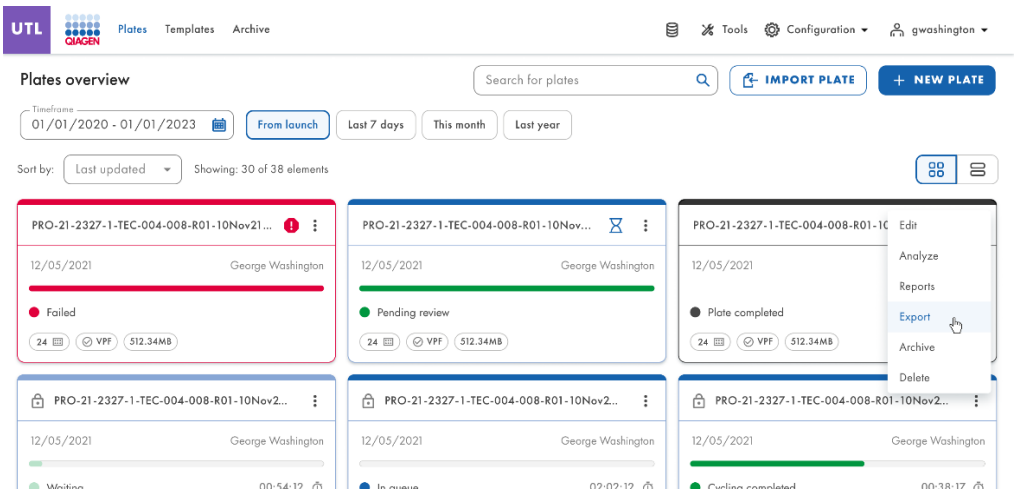
Kits

Kit type	Kit ID	Product no.	Expiration date	Lot no.	IS-CAL
Primer / probe kit	1234567890	1234567890	2023/05/12	134567	0.7
Mastermix	1234567890	1234567890	2023/05/12	134567	n/a
Mastermix	1234567890	1234567890	2023/05/12	134567	n/a
Mastermix	1234567890	1234567890	2023/05/12	134567	n/a

5.19.11. Export plate

Plates can be exported as password-protected zip files, which can be used in another Software Suite instance. Click the respective plate in the plates overview. On the left side of the screen, click **Export plate**.

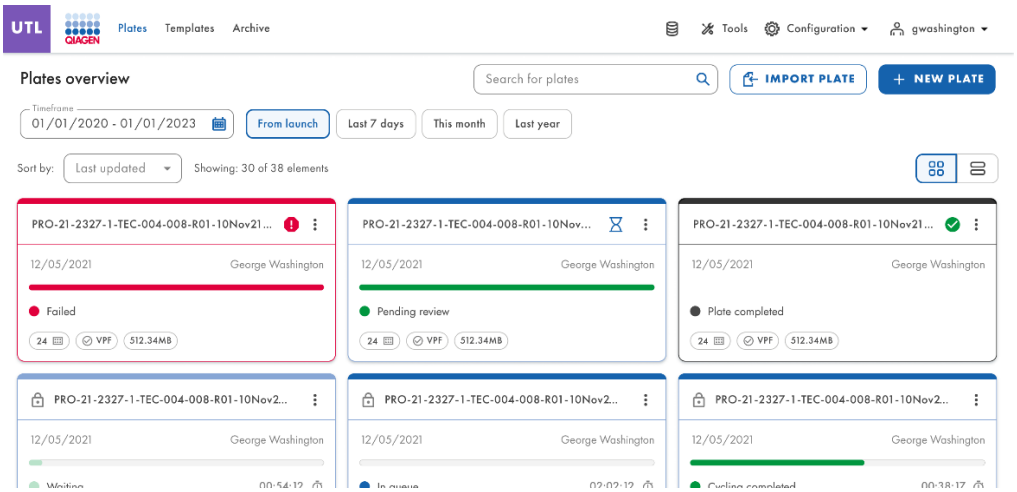
Note: Audit Trail events related to the exported plate will always remain in the original Software Suite instance. The exported plate does not contain Audit Trail information.



5.19.12. Import plate

To import a plate into the Software Suite, click **Import plate** in the Plates overview.

A new window with the system file explorer is opened where you can import plate data by uploading the password protected zip file. Click **Import**, and the plate is added to the Plates overview.



Note: An already existing plate cannot be imported again.

Note: Audit Trail events related to the imported plate remain exclusively in the original Software Suite instance. Exported plates do not contain Audit Trail information.

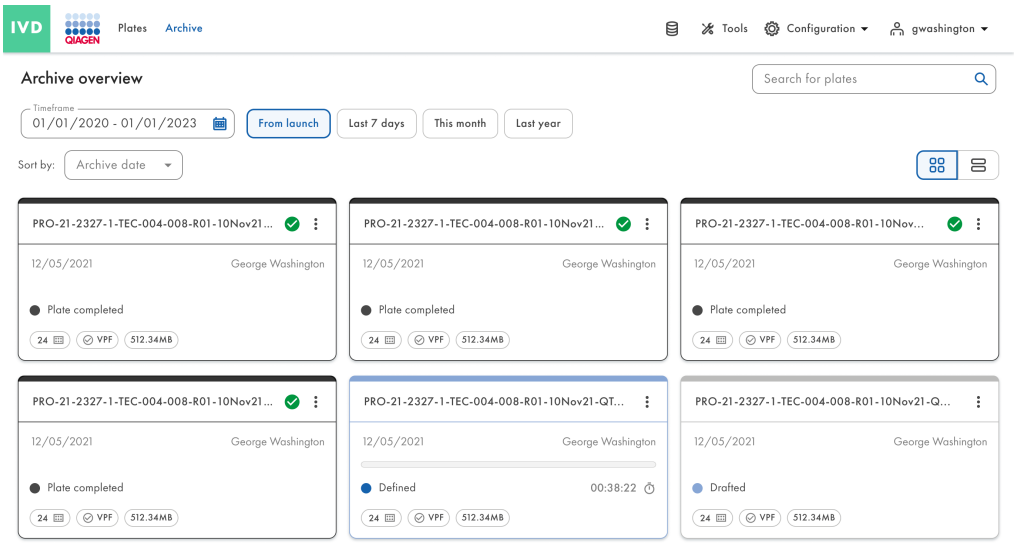
An Audit Trail event for the plate import is generated in the current Software Suite instance, and any actions or events related to the plate in the new Software Suite are also traced.

5.20. Plate archiving

In the Software Suite, users can set up an archive on an external drive. This will allow them to store their old plates and save disk space on the laptop.

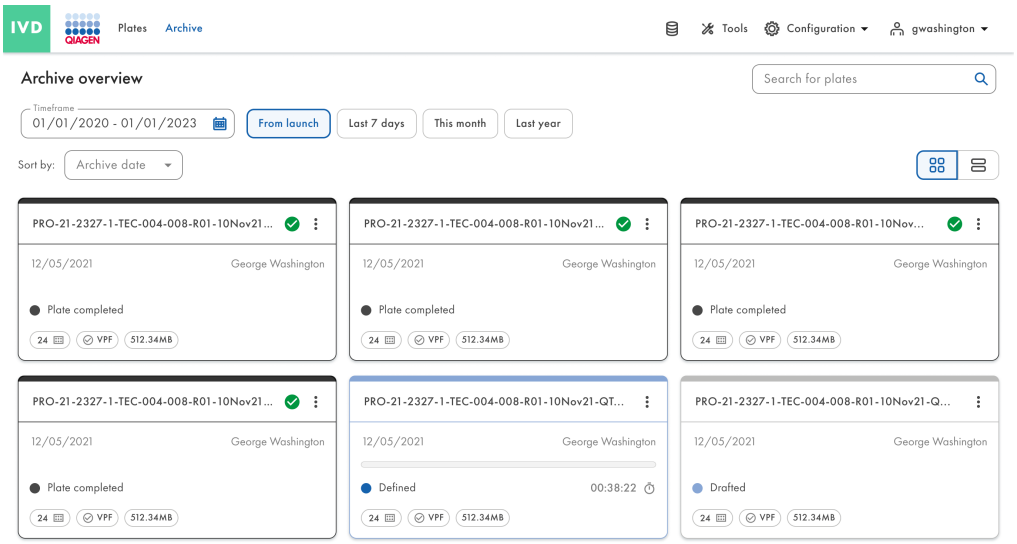
Each authorized user (with Archive Overview and Plate Archiving permissions) can archive plates with a status other than Drafted/Plate started, Loaded, In queue, Partitioning, Partitioning completed, Cycling, Cycling completed, Imaging, Imaging completed, Waiting, and Instrument processing completed/Loaded status, and that are not locked. A valid archive location must be defined to archive plates.

Users with Archive Overview permission can see the Archive Overview screen, containing all the archived plates in either list view or grid view. Archived plates can be filtered by time frame, and sorted by Archive date, Plate name, and Plate status.

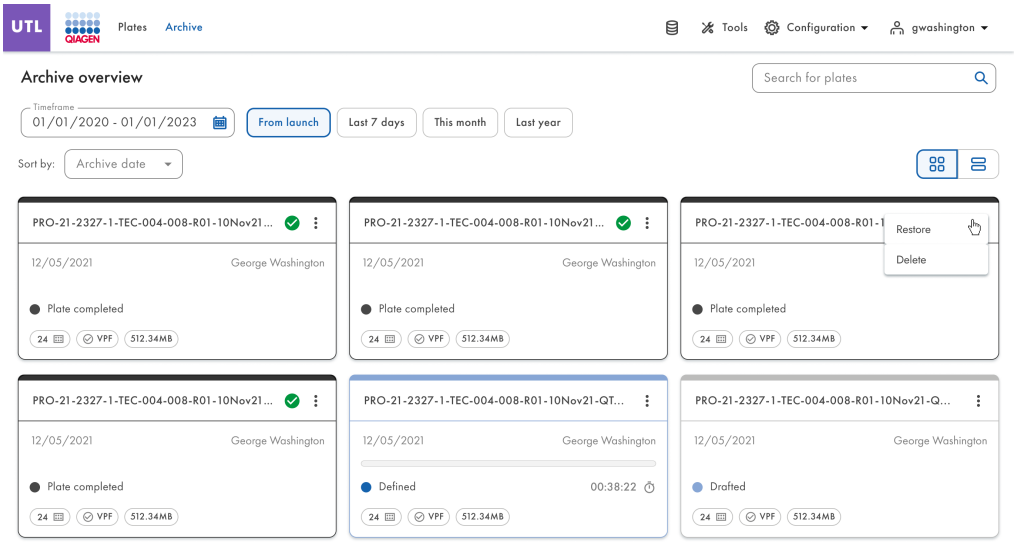


Users with Archive Overview permission can search the archived plates by plate name using the search bar in the Archive Overview screen. After deleting the text from the search bar or pressing **Esc** key, the full list of archived plates is displayed.

Text entered in the search bar is not cleared when switching to other Software Suite menus. The newly archived plates, which comply with the applied filter in Archive Overview, are displayed in the Archive Overview screen. It is possible to filter the search by a certain period of time, from launch, the past 7 days, or the past year.

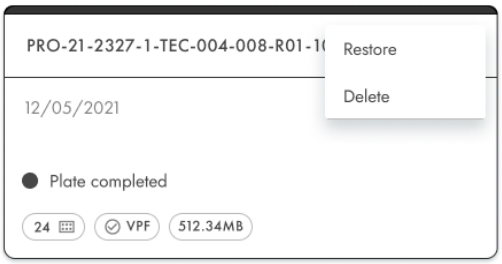


Each authorized user with Delete the Plate from Archive permission can delete archived plates from the Archive Overview list in the Utility mode. The user can trigger the plate deletion from the context menu on the desired plate tile. It is not possible to delete plates from the IVD mode.

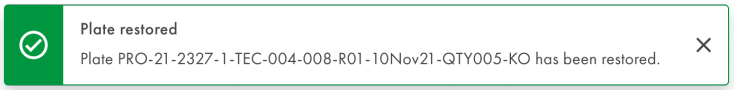


Each authorized user with Recover the Plate from Archive permission can restore archived plates from the Archive Overview list. It is possible to restore plates from IVD mode and Utility mode.

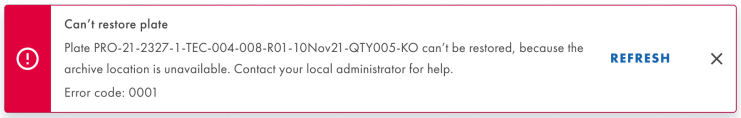
The user looks for the plate to be restored in Archive Overview, clicks the 3-dots menu and selects **Restore**.



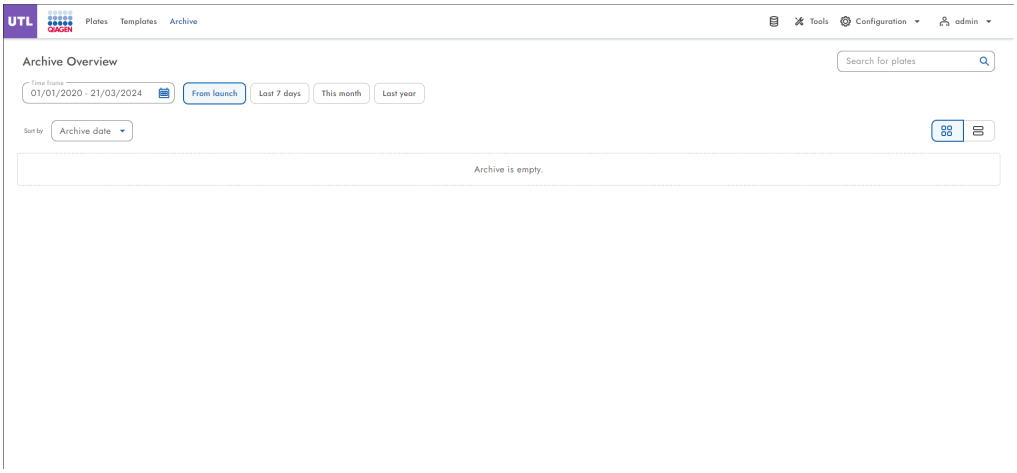
The successful restore is confirmed with the following message.



The warning message appears if the restore fails.



After the refresh, the Archive Overview screen is displayed.



Each authorized user can re-analyze plates which have been previously restored from an archive. It is possible to perform the same actions as for plates that were never archived.

5.21. Cybersecurity disclosure information

Refer to the Security & Privacy Whitepaper for further details. The Software Bill of Materials (SBOM) is also available and can be provided upon request.

5.21.1. Prevent physical access to the instrument

Malicious actors having direct physical access to the instrument may compromise the instrument functionalities and performances, as well as compromise data availability, integrity, and confidentiality: the healthcare provider shall ensure only authorized persons to have access to the instrument.

5.21.2. Network reliability and security

A reliable and secure network infrastructure (in case of connection of the instrument to a local area network (LAN)) is required to guarantee proper and responsive functioning of the QIAcuityDx System as well to guarantee integrity and confidentiality of the processed data.

5.21.3. Number of authentication attempts

Users have up to 10 authentication attempts (by default) for logging into the Software Suite. After the predefined consecutive unsuccessful authentication attempts, the user will be locked for 15 minutes (by default).

Both the number of authentication attempts and the locked time in minutes are configurable per the Software Suite instance.

5.21.4. Use of HTTPS connectivity

The Software Suite uses exclusively the HTTPS protocol both for connectivity with the Control Software and the users.

5.21.5. Data encryption

The Software Suite encrypts all at-transfer communication according to the Cryptographic Standard GLO-POL-22-02-006 Rev.01.

5.21.6. REST communication

The Software Suite authenticates and authorizes all REST communication. The Software Suite logs all REST API calls.

5.21.7. Data manipulation at rest

The Software Suite protects from unauthorized manipulation of data at rest.

5.21.8. Data access at rest

The Software Suite protects from unauthorized access to data at rest.

6. Maintenance

This section describes preventive maintenance of QIAcuityDx instrument.

Note: Only use parts supplied by QIAGEN.

6.1. Daily maintenance

Important: To ensure correct functioning of the QIAcuityDx System, power-cycling of the QIAcuityDx instrument is recommended on a daily basis. Failure to follow this procedure may lead to instrument errors during nanoplate processing.

The basic steps to perform a power-cycle are as follows:

1. Remove any Nanoplates present in the drawer module.
2. Press the power button on the front of the instrument to power down the device.
3. Turn off the power to the instrument from the mains.
4. Wait for a minimum of 2 minutes.
5. Turn on the power to the instrument from the mains.
6. Press the power button on the front of the instrument to power up the device.

6.2. Preventative maintenance

All preventative maintenance activities requiring access to inside the instrument are to be carried out annually and shall be carried out by QIAGEN authorized personnel only.

Replacement of the air-filter that is accessible from the outside of the instrument is described in Section 6.5 below.

One month before the due date, the system will pop up the following message “Due date for the periodic Preventive Maintenance is about to expire in X days. Preventive Maintenance is essential to ensure that the instrument is able to provide accurate results on a continuous basis. Please contact your local technical service to proceed”.

After the due date, the system will pop-up the following message every time the IVD mode is used: “The due date for the Preventive Maintenance has been exceeded. Preventive Maintenance is essential to ensure that the instrument is able to provide accurate results on a continuous basis. QIAGEN does not advise using the instrument for diagnostic purposes with patients if Preventive Maintenances are not passed on a regular basis”.

In both cases, please contact the QIAGEN Technical Services to proceed with the Preventive Maintenance.

WARNING/ CAUTION

Risk of personal injury and material damage

Only perform maintenance that is specifically described in this user manual.

WARNING/ CAUTION

Risk of incorrect results

Preventive Maintenance is essential to ensure that the instrument is able to provide accurate results on a continuous basis. QIAGEN discourages using the instrument for diagnostic purposes with patients if Preventive Maintenance are not passed on a regular basis.

6.3. Cleaning the QIAcuityDx surface

WARNING

Risk of fire or explosion

When using ethanol or ethanol-based liquids on the QIAcuityDx, handle such liquids carefully and in accordance with the required safety regulations. If liquid has been spilled, wipe it off and allow flammable vapors to disperse.

The following disinfectants and detergents are recommended for cleaning the QIAcuityDx Four.

Note: If you want to use disinfectants different from those recommended, ensure that their compositions are similar to those described below.

General cleaning of the QIAcuityDx

- Mild detergents (e.g., Mikrozid® AF sensitive)
- 25% ethanol

6.3.1. Disinfecting the QIAcuityDx surface

Ethanol-based disinfectants can be used for disinfection of surfaces: for example, 25 g ethanol and 35 g 1-propanol per 100 g liquid or Mikrozid Liquid (Schülke & Mayr GmbH, cat. no. 109160).

Disinfectants based on glyoxal and quaternary ammonium salt can be used, e.g., 10 g glyoxal, 12 g lauryldimethylbenzylammonium chloride, 12 g myristyldimethylbenzylammonium chloride, and 5–15% nonionic detergent per 100 g liquid, Lysetol® AF (Gigasept Instru AF in Europe, cat. no. 107410, or DECON-QUAT® 100, Veltek Associates, Inc., in the USA, cat. no. DQ100-06-167-01).

Removal of RNase contamination

RnaseZap® RNase Decontamination Solution (Ambion, Inc., cat. no AM9780) can be used for cleaning surfaces. RnaseZap can also be used to perform decontamination by spraying the respective items.

Removal of nucleic acid contamination

DNA-ExitusPlus™ (AppliChem, cat. no. A7089,0100) can be used for cleaning surfaces. DNA-ExitusPlus can also be used to perform decontamination by spraying the respective items. DNA-ExitusPlus is very sticky and foamy. For this reason, after cleaning the items with DNA-ExitusPlus, you must clean the items with a wet cloth several times, or rinse them with running water, until the DNA-ExitusPlus is completely removed.

General instructions

- Do not use spray bottles to spray cleaning or disinfectant liquids onto surfaces of the QIAcuityDx.
- If solvents or saline, acidic, or alkaline solutions are spilt on the QIAcuityDx, wipe the spilt liquid away immediately.
- Follow manufacturer's safety instruction for handling cleaning agents.
- Follow manufacturer's instruction for soaking time and concentration of the cleaning agents.
- Important: Immersing for longer than the recommended soak time can harm the instrument.
- **Note**: Disinfection reagents shall be distributed equally on the instrument surface and drops shall be avoided
- Ensure that no liquid runs down the touchscreen. Liquid may be drawn through the dust protection sealing by capillary forces and cause malfunction of the display. To clean the touchscreen, moisten a soft lint-free cloth with water, ethanol, or a mild detergent and carefully wipe the display. Wipe dry with a paper towel.

CAUTION **Damage to the instrument**

Do not use bleach, solvents, or reagents containing acids, alkalis, or abrasives to clean the QIAcuityDx.

CAUTION **Damage to the instrument**

Do not use spray bottles containing alcohol or disinfectant to clean surfaces of the QIAcuityDx. Take special care while cleaning the extended drawer that no liquid is spilled into the inside of the instrument.

WARNING **Damage to the instrument**

Do not allow cleaning fluid or decontamination agents to come into contact with the electrical parts of the QIAcuityDx. Take special care while cleaning the extended drawer that no liquid is spilled into the inside of the instrument.

WARNING **Risk of electric shock**

Do not open any panels on theQIAcuityDx.

Risk of personal injury and material damage

Only perform maintenance that is specifically described in this user manual. Any other maintenance or repair may only be carried out by an authorized Field Service Specialist.

WARNING **Hazardous chemicals and infectious agents**

The plates may contain hazardous material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures.

WARNING/ CAUTION **Risk of personal injury and material damage**

Improper use of the QIAcuityDx may cause personal injuries or damage to the instrument. The QIAcuityDx must only be operated by qualified personnel who have been appropriately trained. Servicing of the QIAcuityDx must only be performed by a QIAGEN Field Service Specialist.

WARNING/ CAUTION **Risk of personal injury and material damage**

Only perform maintenance that is specifically described in this user manual.

WARNING **Toxic fumes**

Do not use bleach to clean or disinfect the QIAcuityDx.

WARNING **Toxic fumes**

Do not use bleach to disinfect the labware.

6.4. Decontaminating the QIAcuityDx

If the QIAcuityDx is contaminated with infectious material, it should be decontaminated. If hazardous material is spilled on the outer surfaces or the plate trays of the QIAcuityDx, the user is responsible for carrying out appropriate decontamination. If damaged plates were used and the inside of the instrument is contaminated, please contact QIAGEN Technical Services.

The QIAcuityDx should also be decontaminated before shipping (e.g., back to QIAGEN). In this case, a decontamination certificate must be completed to confirm that the decontamination procedure has been carried out.

To decontaminate the QIAcuityDx, follow the procedure in Section Disinfection, using the recommended disinfection agents.

6.5. Replacing the air filter

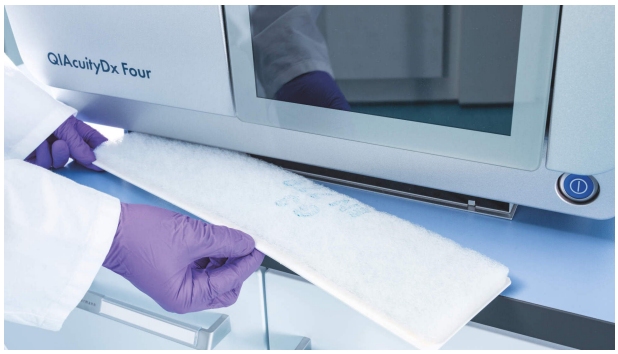
We recommend that the air inlet filter of the instrument is changed once per year. This will be part of an annual scheduled service visit. When operating the instrument in unusual dusty environments, a more frequent filter change might be necessary.

Note: Air filters can be ordered separately. See the "Ordering information" section for more information.

Follow these steps for changing the air filter:

1. Turn off instrument and remove power cord.
2. Reach under the front of the instrument and push both buttons simultaneously upwards, the filter panel will swing open from the edge closest to you exposing the filter pad.

3. Remove the filter pad from the swing-out filter compartment by pinching the pad and lifting it over the metal retention clasp.



4. Replace with a new filter and push the swing compartment upwards to the top and click to close.

6.6. Calibration of the thermocycler

The thermocycler is designed to operate with the same specifications over the lifetime of the instrument. To ensure and verify the quality of the cycler, the calibration of the thermocycler is part of an annual scheduled service visit.

6.7. QIAcuityDx repair

Perform the maintenance as described in Section 6. QIAGEN charges for repairs that are required due to incorrect maintenance.

7. Troubleshooting

This section provides information about what to do if an error occurs when using the QIAcuityDx System.

If further assistance is required, contact QIAGEN Technical Services using the contact information below:

Website: **support.qiagen.com**

When contacting QIAGEN Technical Services about an error with the QIAcuityDx, note the steps leading up to the error and any information appearing in any dialog boxes. This information will help the QIAGEN Technical Services solve the problem.

When contacting QIAGEN Technical Services about errors, please have the following information ready:

- QIAcuityDx serial number, type, and version
- Software version (if applicable)
- Timepoint when the error occurred for the first time
- Frequency of error occurrence (i.e., intermittent or persistent error)
- Detailed description of the error situation
- Photo of the error, if possible
- Copy of Instrument log files and Extended Support Package

This information will help you and your QIAGEN Technical Service Specialist deal with your issue efficiently.

Note: Information about the latest software and protocol versions can be found at **www.qiagen.com**. In some cases, updates may be available for addressing specific problems. Failure to implement software updates may result in compromised performance.

7.1. Hardware and software errors

7.1.1. Instrument Control Software errors

Code	Error message	Required action
2	The firmware performed an unexpected reboot. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
3	CSW unexpected shutdown	Power off the instrument and restart again. If the problem still exists, please contact QIAGEN Technical Services.
21	Low disk space. You do not have enough disk space to proceed with this task. Delete temporary data to free up some disk space. Contact your local administrator for assistance. If the problem still exists, please contact QIAGEN Technical Services.	Delete temporary data to free up some disk space. Contact your local administrator for assistance. If the problem still exists, please contact QIAGEN Technical Services.
22	There are no logs found for selected date range.	N/A

Code	Error message	Required action
23	USB drive is not connected. Connect the USB drive to download the file.	Connect the USB drive to download the file.
24	The upload cannot be completed because this backup is created in a version that is not compatible with the current version of the software.	N/A
25	Backup file could not be found.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
26	The data could not be copied to/from USB drive. Try again.	Retry the action. If the problem still exists, please contact QIAGEN Technical Services.
27	Upload support package not supported. You are using simulated suite.	Please contact QIAGEN Technical Services.
30	Change priority state unsatisfied	N/A.
31	Change priority cannot find substitute	N/A
32	There is no QIAGEN Nanoplate labware file found for the loaded plate. Contact your local administrator to synchronize the labware files or restart the instrument to download the latest labware files from the Software Suite.	Contact your local administrator to synchronize the labware files or restart the instrument to download the latest labware files from the Software Suite.
33	The required plate recovery task during startup of instrument cannot be performed because there is no free plate slot available in the tray. Remove at least 1 plate from the drawer and close it.	Remove at least 1 plate from the drawer and close it.
34	Expired nanoplate	N/A
35	The drawer is currently in use. Try opening/closing the drawer later.	Try opening/closing the drawer later.
36	Retract rejected, wrong plate position	N/A
37	The drawer is currently in use. Try opening/closing the drawer later.	Try opening/closing the drawer later.
38	Only 1 tray can be ejected at a time. Close the previous tray before opening the next tray.	Close the previous tray before opening the next tray.
39	The tray cannot be ejected at this time because all slots in this tray contains a plate that is currently running.	N/A
40	There is a generic issue with sensors. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
41	The communication to sensor is failed. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
45	**Sensor**: read-out value too small/large, sensor may be damaged	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
94	An error prevented the instrument from completing a movement sequence. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
100	A critical error has been detected in the gripper module. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, contact QIAGEN Technical Services.
120	The barcode reader cannot read the plate barcode or the barcode is wrong. Check if the barcode is damaged and retry scanning the plate. If the problem still exists, please contact QIAGEN Technical Services.	Check if the barcode is damaged and retry scanning the plate. If the problem still exists, please contact QIAGEN Technical Services.

Code	Error message	Required action
121	The plate barcode cannot be read. Check if the plate barcode is damaged or if the plate is incorrectly placed on the tray slot. If the problem still exists, please contact QIAGEN Technical Services.	Check if the plate barcode is damaged or if the plate is incorrectly placed on the tray slot. If the problem still exists, please contact QIAGEN Technical Services.
122	The system cannot detect the top seal of the plate. Ensure that the top seal is placed properly on the plate. If the problem still exists, please contact QIAGEN Technical Services.	Ensure that the top seal is placed properly on the plate. If the problem still exists, please contact QIAGEN Technical Services.
129	Failed to initialize Barcode Scanner module	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
143	The plate is not gripped properly. Contact your local administrator to resolve the gripper module error. If required, restart the instrument to start recovery. Then, start a plate run to check. If the problem still exists, please contact QIAGEN Technical Services.	Contact your local administrator to resolve the gripper module error. If required, restart the instrument to start recovery. Then, start a plate run to check. If the problem still exists, please contact QIAGEN Technical Services.
144	The plate is not unloaded properly. Contact your local administrator to resolve the gripper module error. If required, restart the instrument to start recovery. Then, start a plate run to check. If the problem still exists, please contact QIAGEN Technical Services.	Contact your local administrator to resolve the gripper module error. If required, restart the instrument to start recovery. Then, start a plate run to check. If the problem still exists, please contact QIAGEN Technical Services.
160	The gripper module was not able to home properly. Contact your local administrator to resolve the gripper module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
170	The gripper module cannot move properly. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
175	The gripper module detected an error while gripping. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
176	There is no target position specified for the planned movement. Please contact QIAGEN Technical Services.	Please contact QIAGEN Technical Services.
177	Insufficient teaching detected. Please contact QIAGEN Technical Services.	Please contact QIAGEN Technical Services.
194	A motor movement cannot be performed at this time. Contact your local administrator to resolve the gripper module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
199	Failed to initialize Hand module	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
200	A critical error has been detected in the partitioning module. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
201	The plate type is not supported. Remove the plate from the instrument.	Remove the plate from the instrument.
202	A movement position is out of range. Contact your local administrator to resolve the partitioning module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Contact your local administrator to resolve the partitioning module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.

Code	Error message	Required action
203	A movement velocity is out of range. Contact your local administrator to resolve the partitioning module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Contact your local administrator to resolve the partitioning module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
204	A movement acceleration is out of range. Contact your local administrator to resolve the partitioning module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
205	A movement waypoint cannot be found. Contact your local administrator to resolve the partitioning module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
206	The remaining steps cannot be performed because the priming task is aborted. You can no longer use this plate.	N/A
243	The plate is not loaded into the partitioning module properly. Contact your local administrator to resolve the module error. Restart the instrument to start the recovery task. If the problem still exists, please contact QIAGEN Technical Services.	Contact your local administrator to resolve the module error. Restart the instrument to start the recovery task. If the problem still exists, please contact QIAGEN Technical Services.
244	The used plate is not unloaded properly. Contact your local administrator to resolve the partitioning module error. Restart the instrument to start the recovery task. If the problem still exists, please contact QIAGEN Technical Services.	Contact your local administrator to resolve the partitioning module error. Restart the instrument to start the recovery task. If the problem still exists, please contact QIAGEN Technical Services.
250	You can no longer use this plate because the priming step has been aborted for this plate during a previous run.	N/A
260	The partitioning module was not able to home properly. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
272	The partitioning module was not able to partition the plate properly. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
273	The partitioning module was not able to fill the plate partitions properly. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
274	The partitioning module was not able to clamp the plate properly. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
275	During priming or rolling pressure was lost. Restart the instrument and perform a run . If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument and perform a run. If the problem still exists, please contact QIAGEN Technical Services.
299	Failed to initialize PrimerRoller module	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
300	A critical error is detected in the thermocycler module. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.

Code	Error message	Required action
302	The set temperature is out of range. Please contact QIAGEN Technical Services.	Please contact QIAGEN Technical Services.
303	The set ramping speed is out of range. Please contact QIAGEN Technical Services.	Please contact QIAGEN Technical Services.
304	The set cycling profile contains empty steps. Please contact QIAGEN Technical Services.	Please contact QIAGEN Technical Services.
310	This step failed to execute because the previous step is aborted. You can no longer use this plate.	N/A
311	The remaining steps cannot be performed because the cycling task is aborted. Define a new thermocycling profile and imaging steps in the Software Suite or instrument to rerun this plate. Please contact QIAGEN Technical Services if you require assistance regarding the aborted cycling process.	Define a new thermocycling profile and imaging steps in the Software Suite or instrument to rerun this plate. Please contact QIAGEN Technical Services if you require assistance regarding the aborted cycling process.
320	A critical error is detected in the thermocycler module. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
324	The specified temperature is incorrect. If the problem still exists, please contact QIAGEN Technical Services.	If the problem still exists, please contact QIAGEN Technical Services.
326	This task cannot be performed due to a maintenance error.	N/A
330	A critical error has been detected in the thermocycler module. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
343	The plate is not loaded into the thermocycling module properly. Contact your local administrator to resolve the module error. Restart the instrument to start the recovery task. If the problem still exists, please contact QIAGEN Technical Services.	Contact your local administrator to resolve the module error. Restart the instrument to start the recovery task. If the problem still exists, please contact QIAGEN Technical Services.
344	The used plate is not unloaded properly. Contact your local administrator to resolve the thermocycling module error. Restart the instrument to start the recovery task. If the problem still exists, please contact QIAGEN Technical Services.	Contact your local administrator to resolve the thermocycling module error. Restart the instrument to start the recovery task. If the problem still exists, please contact QIAGEN Technical Services.
350	The thermocycling step for this plate is aborted during a previous run. Remove the plate from the instrument. Define a new thermocycling profile and imaging steps in the Software Suite or instrument to rerun this plate. Please contact QIAGEN Technical Services if you require assistance regarding the aborted cycling process.	Remove the plate from the instrument. Define a new thermocycling profile and imaging steps in the QIAcuityDx Software Suite or instrument to rerun this plate. Please contact QIAGEN Technical Services if you require assistance regarding the aborted cycling process.
360	The thermocycling module was not able to home properly. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
373	An issue is detected with the clamping unit. Contact your local administrator to resolve the thermocycling module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Contact your local administrator to resolve the thermocycling module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
399	Failed to initialize Cycler module	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.

Code	Error message	Required action
400	A critical error is detected in the imaging module. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
401	The imaging module does not support this plate type. Please contact QIAGEN Technical Services.	Please contact QIAGEN Technical Services.
402	The selected imaging channels are not available. Remove the plate and change the imaging channels in the Software Suite or Instrument Software. Please contact QIAGEN Technical Services for assistance if you want to upgrade your instrument.	Remove the plate and change the imaging channels in the Software Suite or Instrument Software. Please contact QIAGEN Technical Services for assistance if you want to upgrade your instrument.
403	The set gain is out of range. Please contact QIAGEN Technical Services.	Please contact QIAGEN Technical Services.
404	The set exposure is out of range. Please contact QIAGEN Technical Services.	Please contact QIAGEN Technical Services.
405	The imaging process contains empty steps. Please contact QIAGEN Technical Services.	Please contact QIAGEN Technical Services.
410	This imaging task failed to execute because the cycling step for this plate was aborted during a previous run. You can no longer use this plate.	N/A
411	The remaining steps cannot be performed because the imaging step is aborted. Define a new imaging step in the Software Suite or instrument to rerun this plate.	Define a new imaging step in the QIAcuityDx Software Suite or instrument to rerun this plate.
424	A defect was detected in the Imaging Module (LED power error). Please contact QIAGEN Technical Services.	Please contact QIAGEN Technical Services.
450	This task failed to execute because the imaging process for this plate was aborted during a previous run. Define a new imaging step in the Software Suite or instrument to rerun this plate.	Define a new imaging step in the QIAcuityDx Software Suite or instrument to rerun this plate.
460	The imaging module was not able to home properly. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
471	A channel error occurred in the imaging module. Please contact QIAGEN Technical Services.	Please contact QIAGEN Technical Services.
490	Due to a technical issue, images could not be transferred to the Suite. Please set up an additional imaging step and re-image the plate to get the images.	Please set up an additional imaging step and re-image the plate to get the images.
491	Notify image transfer started failed	N/A
492	Due to missing communication images could not be transferred to the Suite. Please check your Suite connection. Images will be transferred automatically once connection is successfully re-established. If the images were not transferred to your Suite please re-image the plate.	Please check your QIAcuityDx Software Suite connection. Images will be transferred automatically once connection is successfully re-established. If the images were not transferred to your QIAcuityDx Software Suite please re-image the plate.
499	Failed to initialize Imager module	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
600	A critical error is detected in the drawer. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
643	There is no plate loaded in the drawer.	N/A

Code	Error message	Required action
644	The gripper was not able to grip the plate from the drawer. If applicable, allow other plates to finish the run. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	If applicable, allow other plates to finish the run. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
660	The drawer cannot perform the homing sequence. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
675	The drawer cannot eject or retract at this time. Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
676	The sensor detected drawer movement failure. Clear the error, restart the instrument and perform a run. If the problem still exists, please contact QIAGEN Technical Services.	Clear the error, restart the instrument, and perform a run test run using non-critical samples. If the problem still exists, please contact QIAGEN Technical Services.
699	Failed to initialize Drawer module	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
700	Run steps failed to complete because you removed the plate during a run. Add a new run step in the Software Suite or instrument to rerun the plate.	Add a new run step in the QIAcuityDx Software Suite or instrument to rerun the plate.
701	Plate barcode does not exist.	N/A
702	The plate name is not defined.	N/A
704	There are no dPCR parameters defined.	N/A
706	Opening/closing of drawer was requested at a time where no opening/closing is possible. Retry once again.	Retry once again.
710	Plate with matching barcode could not be found in Software Suite. Remove the nanoplate from the instrument, configure the plate properly in Software Suite and load nanoplate again. Be aware that stability countdown for this plate has started.	Remove the nanoplate from instrument, configure the plate properly in QIAcuityDx Software Suite and load nanoplate again. Be aware that stability countdown for this plate has started.
711	A connectivity issue is detected between the instrument and the Software Suite. Check your network connection settings. If the problem still exists, please contact QIAGEN Technical Services.	Check your network connection settings. If the problem still exists, please contact QIAGEN Technical Services.
712	This plate cannot be assigned to an existing experiment because some parameters are not defined. Remove the plate and complete its plate definition in the Software Suite.	Remove the plate and complete its plate definition in the Software Suite.
713	The plate cannot be saved because some parameter settings are not applicable to the Suite parameter range. Check your settings and/or contact your local administrator for assistance. If the problem still exists, please contact QIAGEN Technical Services.	Check your settings and/or contact your local administrator for assistance. If the problem still exists, please contact QIAGEN Technical Services.
714	The configuration failed to save. Please try again. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
715	The new configuration settings failed to apply. Please try again. If the problem still exists, please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.

Code	Error message	Required action
716	The configuration integrity check failed. Files have been modified outside of the Control Software. Please contact QIAGEN Technical Services.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
719	Unable to set instrument hostname.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
721	Plate barcode has multiple plate definition	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
722	The plate is currently locked bySoftware Suite as imaging data from previous plate/imaging run are being processed.	N/A
750	The restart of instrument failed. Power off the instrument and restart again. If the problem still exists, please contact QIAGEN Technical Services.	Power off the instrument and restart again. If the problem still exists, please contact QIAGEN Technical Services.
800	The teaching plate cannot be found.	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
801	The teaching contains an invalid configuration.	N/A
802	Rejected another hand calibration in progress	N/A
803	Rejected save hand calibration not complete	N/A
808	Rejected calibration request, wrong state	N/A
809	Rejected another imager calibration in progress	N/A
810	Plate not found in drawer	N/A
811	Cycler calibration timeout	N/A
812	Rejected another cycler calibration in progress	N/A
814	Rejected servicing request, wrong state	N/A
850	Rejected request, required module busy	N/A
902	The FW version failed to update. Please contact QIAGEN Technical Services.	Please contact QIAGEN Technical Services.
904	The compatible FW Version for the device is not found.	Please contact QIAGEN Technical Services.
905	The integrity check for FW file is failed.	Please contact QIAGEN Technical Services.
951	A connectivity issue is detected between the instrument and the Software Suite. Check your network connection settings or your Suite configuration. If the problem still exists, please contact QIAGEN Technical Services.	Check your network connection settings or your Suite configuration. If the problem still exists, please contact QIAGEN Technical Services.
955	The version of Software Suite you're going to connect is not compatible with the version of software installed on the instrument. Update appropriate software and connect again. If the problem still exists, please contact QIAGEN Technical Services.	Update appropriate software and connect again. If the problem still exists, please contact QIAGEN Technical Services.
956	Service responsible for authentication cannot be reached right now. Wait 1 minute before the next login attempt. If the problem still exists, restart the instrument when there is no ongoing run. If the problem still exists, please contact QIAGEN Technical Services.	Wait 1 minute before the next login attempt. If the problem still exists, restart the instrument when there is no ongoing run. If the problem still exists, please contact QIAGEN Technical Services.
995	The Software Suite cannot be reached at this address. Change your Suite address. If the problem still exists, please contact QIAGEN Technical Services.	Change your Suite address. If the problem still exists, please contact QIAGEN Technical Services.
1100	Suite API not implemented	Please contact QIAGEN Technical Services.

Code	Error message	Required action
1102	The plate is already registered in another instrument	N/A
1103	Plate lock rejected. The plate is currently synchronizing a pending task to suite.	N/A
1804	Rejected another fill calibration in progress	N/A
1805	Rejected save fill calibration not complete	N/A
1806	Rejected fill calibration not yet running	N/A
1807	Rejected fill servicing not yet running	N/A
8000	Generic API error	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
8003	Unable to switch to service state, there is a plate running. Please wait until the running process is complete or abort the current running process.	Please wait until the running process is complete or abort the current running process.
8004	Suite API request parameter not satisfied.	Please contact QIAGEN Technical Services.
10001	Reset module counter error	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
11001	Clear module fault error	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
12001	Unable to connect authorization server	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.
12003	Login or/and password are incorrect	N/A
12004	Your account is locked	N/A
12005	Invalid or non-existent token. Please login	Please login
12006	User's session is still active	Please contact QIAGEN Technical Services.
12008	Please login to eject	Please login to eject drawer
12400	Generic task error	Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.

7.1.2. QIAcuityDx Software Suite errors

Section	Description	Action
In application	Failed to fetch software version	Contact your local administrator to check the Software Suite installation.
In application	Failed to fetch public configuration data	Contact your local administrator to check the Software Suite installation.
Archive	Plate {plate-Name} can't be archived because the archive configuration can't be found. If problem persist, contact your local administrator for help.	Re-try to archive the plate. If it doesn't work, please contact your local administrator for help.
Archive	Plate {plate-Name} can't be archived because the archive location is unavailable. Contact your local administrator for help.	Contact your local administrator for help.
Archive	The configured archive location [{path}] is not accessible right now. Check the connection with the Archive location or contact your administrator	Check connection with the archive location. If still unable to access the location, please contact your administrator.

Section	Description	Action
Archive	There are plates currently being processed. Changes to archive settings cannot be saved until processing is complete.	Wait until the active process completes.
Archive	Invalid path	Type a valid Path
Archive	The Archive location is incorrect	Check the archive path
Archive	The Archive location is not available	Check the archive path
Archive	An error has occurred while deleting the Archived Plate. Contact your administrator to solve this issue	Contact your administrator.
Archive	An archiving error has occurred. Contact your administrator to solve this issue.	Contact your administrator.
Archive	Can not read location: [{path}]. Please check if destination is accessible.	Contact your administrator.
Archive	The Plate was not found. Refresh the page to see updated data.	Refresh the web page.
Archive	The device is not available or the path is incorrect. Check the spelling and the Archive device access.	Check the spelling and the Archive device access.
Archive	The configured archive location [{path}] is not accessible right now. Check the connection with the Archive location or contact your administrator	Check the connection with the Archive location or contact your administrator
Archive	Plate {plate-Name} can't be archived, because there is not enough archive disk available. Contact your local administrator for help.	Contact your local administrator for help.
Archive	Can not read location: [{path}]. Please check if destination is accessible.	Please check if its destination is accessible, if not, contact your administrator for help.
Archive	An invalid parameter was used in the location: [{path}]	Check the archive parameters configuration. If the problem persists, please contact your administrator
Archive	Plate {plate-Name} can't be archived, because it is in locked status. Contact your local administrator for help.	Wait for the plate to change to a valid state to be archived. If the problem persists, please contact your local administrator for help
Archive	Plate {plate-Name} can't be archived, because it is in Drafted status. Contact your local administrator for help.	Contact your local administrator for help.
Archive	The Plate is in Running status and cannot be archived.	Wait for the plate to change to a valid state to be archived.
Archive	The Plate is in Loaded status and cannot be archived.	Wait for the plate to change to a valid state to be archived.
Archive	Can not archive plate because this plate already exists in the archive. To be able to archive this plate, duplicated plate needs to be removed from the archive.	Remove duplicated plate from the archive
Archive	The configured archive location [{path}] is not accessible right now. Check the connection with the Archive location or contact your administrator.	Check the connection with the Archive location or contact your administrator.
Archive	Restore is not possible because the Plate already exists. Remove the existing Plate form Plates Overview and try to restore it from Archive Overview again.	Remove the existing Plate form Plates Overview and try to restore it from Archive Overview again.
Archive	Plate archiving is ongoing. Please wait until the archiving process will be done.	Wait until the current archiving process is finished.

Section	Description	Action
Archive	Plate {plate-Name} can't be archived, because an error occurred. Contact your local administrator for help.	Contact your local administrator for help
Archive	Plate {plate-Name} can't be archived, because there is not enough archive disk space available. Contact your local administrator for help.	Contact your local administrator for help.
Archive	Plate {plate-Name} can't be archived, because its plugin is unavailable. Contact your local administrator for help.	Contact your local administrator for help.
Archive	There are plates currently being processed. Changes to archive settings cannot be saved until processing is complete.	Wait until the active process completes.
Archive	The Plate was not found. Refresh the page to see updated data.	Refresh the page to see updated data.
Archive	Plate {plate-Name} can't be exported because an error occurred. Contact your local administrator for help.	Contact your local administrator for help.
Archive	Plate {plate-Name} can't be exported because it is in locked status. Contact your local administrator for help.	Wait for the plate to change to a valid state to be exported.
Archive	Plate {plate-Name} can't be restored, because the restore location is unavailable. Contact your local administrator for help.	Choose a valid restore location.
Archive	Plate {plate-Name} can't be restored because an error occurred. Contact your local administrator for help.	Contact your local administrator for help.
Archive	Plate {plate-Name} can't be restored because there is not enough restore disk space available. Contact your local administrator for help.	Contact your local administrator for help.
Archive	Plate analysis data couldn't be restored	Contact your local administrator for help.
Archive	Plate audit events couldn't be restored	Contact your local administrator for help.
Archive	Basic plate data couldn't be restored	Contact your local administrator for help.
Archive	Plate metadata couldn't be restored	Contact your local administrator for help.
Archive	Unknown error, it must be treated as 'Internal error' because won't be useful for the user perspective	Contact your local administrator for help.
Archive	Plate {plate-Name} can't be restored because the barcode {barcode-Number} already exists in the system. Contact your local administrator for help.	Contact your local administrator for help.
Archive	Plate {plate-Name} can't be restored because its name already exists in the system. Contact your local administrator for help.	Contact your local administrator for help.
Archive	Plate {plate-Name} can't be restored because the plate is being restored. Contact your local administrator for help.	Contact your local administrator for help.
Archive	Archive service is not available. Please contact your administrator.	Contact your local administrator for help.
Authentication	An authentication service can't be reached right now. Wait 1 minute before the next login attempt. If the problem still exists, please contact your local administrator for help.	Wait 1 minute before the next login attempt. If the problem still exists, please contact your local administrator for help.
Authentication	Provide correct username and password and try again.	Provide correct username and password and try again.

Section	Description	Action
Authentication	Provide correct username and password and try again. If problem persists, contact your local administrator for help. If your username is correct, but you provide incorrect password {attempts} times, your account will be locked for 15 minutes.	Provide correct username and password and try again
Authentication	Insufficient permissions. Please contact administrator	Contact your administrator.
Authentication	You have provided incorrect password {attempts} times. Due to security reasons, your account will be locked and you will not be able to log in for the next 15 minutes.	Wait fifteen minutes and try again.
Authentication	An authentication service can't be reached right now. Wait 1 minute before the next login attempt. If the problem still exists, please contact your local administrator for help.	Wait for a minute and try again. If the problem persists please contact your administrator.
Authentication	Account has been deactivated. Contact your local administrator for assistance.	Contact your local administrator.
Password change	Something went wrong when generating new password. Try again or contact your local administrator for help.	Try again or contact your local administrator
Password change	The new password should not be the same as the old password.	Enter a valid password
Password change	Current password is incorrect.	Make sure you are entering the correct password.
Password change	Password doesn't meet security requirements.	Make sure that your new password meets the security requirements.
Password change	The password is incorrect. It should contain min. 8 characters, at least 1 lower case letter, 1 upper case letter, 1 number and 1 symbol (e.g. {example-Symbols}).	Make sure that your new password meets the security requirements.
User profile	Can’t save changes.	Contact your administrator.
User profile	Surname can’t contain special characters ({ symbols }).	Please enter a valid surname
User profile	Surname can’t start or finish with a dot ('.').	Please enter a valid surname.
User profile	Surname can’t start or finish with a blank space (' ').	Please enter a valid surname
User profile	Provided password is incorrect.	Please enter your current valid password
User profile	The new password should not be the old password	Please enter a valid password
User profile	Specified passwords don't match.	Enter in the confirmation password the same password that you have entered in the new password field.
Audit trail	Something went wrong when generating audit trail. Try again or contact your local administrator for help.	Try again or contact your local administrator.
Audit trail	Failed to get audit trail list filters	Contact your administrator to resolve the issue.
Audit trail	Audit trail list couldn’t be displayed due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue.
Audit trail	Audit trail is not responding. Try again later or contact your local administrator for help.	Try again later or contact your local administrator for help.
User management	The user list couldn’t be displayed due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue.
User management	User "{user-Name}" could not be activated. Refresh the page and try again.	Refresh the page and try again.

Section	Description	Action
User management	User "{user-Name}" could not be deactivated. Refresh the page and try again.	Refresh the page and try again.
User management	User login is already taken. To provide a unique login consider a combination of letters and numbers.	Enter a non-existent login user
User management	This user's details have already been updated by another user, and your changes cannot be saved. Please refresh the page to continue.	Please refresh the page to continue.
User management	Could not create user: User cannot be duplicated.	Enter a non-existent login user
User management	Could not create user: User must have a username.	Enter a valid username.
User management	Could not create user: User must have a name.	Enter a valid name.
User management	Could not create user: User must have a surname.	Enter a valid surname.
User management	Could not create user: User does not have permissions.	Contact your administrator
User management	Could not create user: Unreachable mode(s).	Contact your administrator
User management	Could not create user: Permission(s) not found.	Contact your administrator
User management	Could not create user: Role not found.	Contact your administrator
User management	Could not create user: Password does not meet password requirements.	Enter a valid password
User management	Could not create user: Password does not meet password requirements or is invalid.	Enter a valid password
User management	Could not load user data due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to solve this issue.
User management	Could not load grouped roles due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to solve this issue.
User management	Could not load global permissions due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue.
User management	Could not load mode permissions due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue.
User management	Could not create user: User already exists.	Enter a non-existent user
User management	Could not create user: Internal Server Error.	Contact your administrator.
User management	Could not create user: Unknown Error.	Contact your administrator.
Plugin management	Plugin list couldn't be displayed due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator.
Plugin management	Incorrect Plugin parameters.	Contact your administrator.
Plugin management	Mandatory information missing.	Contact your administrator.
Plugin management	Plugin version obsolete (version not allowed).	Contact your administrator.
Plugin management	Error validating plugin fields.	Contact your administrator.

Section	Description	Action
Instrument	This instrument can't be disabled, because there are plates loaded/runs in progress. Remove plates from instruments and try again.	Remove plates from instruments and try again.
Instrument	There has been a problem with the server connection. Contact your administrator to solve this issue.	Contact your administrator.
Instrument	Check your network connection. Refresh the page and try again. If problem persists, contact your local administrator for assistance.	Refresh the page and try again. If problem persists, contact your local administrator for assistance.
Instrument	Clearing error	Try again. If the problem persists, contact your local administrator for assistance.
User management	The user's name is required. Please enter the name.	Enter a valid name
User management	The user's surname is required. Please enter the surname.	Enter a valid surname
User management	Login is required	Enter a valid login
User management	User with this login already exists. Choose another login.	Choose another login.
User management	Minimum number of characters: {number}	Enter a valid login
User management	Maximum number of characters: {number}	Enter a valid login
User management	Enter a value without ~ ‘ “ ! ? @ ^ * ( ) = [ ] { } : ; , < > | / \\	Enter a valid login
User management	This login is restricted. Choose another login.	Enter a valid login
User management	Current password is required.	Enter a valid current password.
User management	The password is incorrect.	Enter a valid password.
User management	The passwords you entered do not match.	Enter a valid password.
User management	At least 1 role is required	Enter at least 1 role
User management	Users couldn’t be displayed due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue.
User management	User couldn’t be updated due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue.
User management	Roles couldn’t be displayed due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue.
User management	The user couldn’t be deleted due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue.
User management	The user couldn’t be edited due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue.
User management	The profile couldn’t be edited due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue.
User management	The user couldn’t be created due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue.

Section	Description	Action
User management	The user password couldn't be changed due to the authentication problem.	Login again in the application and try again.
User management	The user password couldn't be changed due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue.
Disk monitoring	One or more disk spaces are full. It may not be possible to configure new plates or archive data. Contact your local administrator to free up or extend disk space.	Contact your local administrator to free up or extend disk space.
Disk monitoring	Disk monitoring couldn't be displayed due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue.
Archive	Go to the Plate Overview, select a Plate you want to archive, and choose Archive Plate option.	Go to the Plate Overview, select a Plate you want to archive, and choose Archive Plate option.
Archive	Contact your administrator to set up the Archive.	Contact your administrator
Archive	Go to the Configuration panel in the menu, click on the "Archive" tab, and set up the Archive options. Then, go to Plate Overview, select a Plate you want to add to Archive, and choose Archive Plate option.	Go to the Configuration panel in the menu, click on the "Archive" tab, and set up the Archive options. Then, go to Plate Overview, select a Plate you want to add to Archive, and choose Archive Plate option.
Archive	The Archive is configured but not visible to the system. Check if the device is accessible and contact administrator.	Check if the device is accessible and contact administrator.
Archive	The Archive is configured but not visible to the system. Check if the device is accessible.	Check if the device is accessible and contact administrator.
Archive	Contact your administrator to set up the Archive.	Contact your administrator
Archive	Go to the Configuration panel in the menu, click on the "Archive" tab and set up the Archive options.	Go to the Configuration panel in the menu, click on the "Archive" tab and set up the Archive options.
Plates overview	Import not possible. Content in exported plate file has been modified after export outside the application.	Contact your administrator
Plates overview	Import not possible. File with plate is corrupted. Please re-export plate and try again with new plate file.	Please re-export plate and try again with new plate file.
Plates overview	Import not possible. Incompatible suite version.	Contact your administrator
Plates overview	Import not possible. Incompatible plate type.	Contact your administrator
Plates overview	Import not possible. Plate file is not a correct file type.	Contact your administrator
Plates overview	Import not possible. Barcode already exists.	Delete or update the barcode of the plate currently registered within the system and try again.
Plates overview	The plate couldn't be imported due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to solve this issue.
Plates overview	Import not possible. Imported file is not a correct plate file.	Choose a correct file
Plates overview	Unable to import plate data due to damaged import file.	Re-Try importing the plate. If the problem persists, please contact your administrator.
Plates overview	Import not possible. Access denied.	Contact your administrator
Plates overview	Import not possible. Plate already exists. Please remove existing plate before importing it.	Please remove existing plate before importing it.
Plates overview	There was a server time-out error while importing plate. Please check your computer's network connection and try again. If the issue still occurs, contact Administrator.	Please check your computer's network connection and try again. If the issue still occurs, contact Administrator.

Section	Description	Action
Plates overview	The plate couldn't be imported due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue
Plates overview	Err: {error-Code}	Contact your administrator.
Plates overview	The plate couldn't be marked as primed due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to solve this issue.
Plates overview	The plate couldn't be unlocked due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to solve this issue.
Plates overview	Instrument Error: {error-Code}.	Contact your administrator to resolve the issue
Plates overview	Run of {plate-Name} has failed during Partitioning step on {date} at {time}	Contact your administrator to resolve the issue
Plates overview	Run of {plate-Name} has failed during Cycling step at Cycle {last-Cycle} on {date} at {time}	Contact your administrator to resolve the issue
Plates overview	Run of {plate-Name} has failed during Imaging step on {date} at {time}	Contact your administrator to resolve the issue
Plates overview	Run of {plate-Name} has failed on {date} at {time}	Contact your administrator to resolve the issue
Plates overview	Your plates couldn't be displayed due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue
Plates overview	The plate couldn't be deleted due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue
Plates overview	The plate couldn't be upgraded due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue
Plates overview	The plate couldn't be exported due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue
Export plate	Something went wrong - try again. If problem persists, contact your local administrator for support.	Try again. If problem persists, contact your local administrator for support.
Export plate	This plate has been archived or deleted. Refresh the page.	Refresh the page.
Import plate	Plate file should have '.zip' extension	Choose a valid file.
Import plate	Selected file size is: {size}. Maximum allowed size is {max-Size}.	Choose a valid file.
Import plate	Cannot import plate because this plate already exists in the system. To be able to import this plate, duplicated plate needs to be removed from the system.	Delete duplicated plates.
Import plate	A plate with the same barcode already exists.	Update the barcode for the already existing plate, or remove this plate.
Import plate	Something went wrong - try again. If problem persists, contact your local administrator for support.	Try again. If problem persists, contact your local administrator for support.
Import plate	Plate named "{name}" already exists	Update the name for the already existing plate, or remove this plate

Section	Description	Action
Import plate	The system doesn't have any available plate owner, and the importing user doesn't have ownership permission.	Contact your administrator to solve this issue.
Import plate	The source and target versions of the plugins must be equal for importing plates.	Contact your administrator.
Import plate	An error has occurred during the import. Please try again or contact the administrator.	Try again or contact the administrator.
Labware	An error has occurred while uploading labware file. Please try again or contact your local administrator.	Try again or contact your administrator.
Labware	Some files in the labware file are not valid and will be ignored. Please try again or contact your local administrator.	Try again or contact your administrator.
Labware	Something went wrong, try again. If problem persists, contact QIAGEN Technical Services	Try again. If problem persists, contact your administrator.
Labware	Labware file should have '.zip' extension.	Choose a valid labware file
Labware	The labware file is not compliant. Please, upload a valid labware file.	Choose a valid labware file
Reports	A report could not be created	Contact your administrator.
Reports	Additional data for report could not be retrieved. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue
Reports	The report could not be saved due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue
Reports	Failed to get report signers	Contact your administrator to resolve the issue
Reports	Could not add signature to report	Contact your administrator to resolve the issue
Reports	Due to the problem with server connection the report couldn't be downloaded. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue
Reports	Due to the problem with server connection the report couldn't be deleted. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue
Plate analysis	Sorry, error analyzing plate.	Contact your administrator
Plate analysis	Failed to fetch multiple occupancy data	Try again. If it doesn't work, please contact your administrator.
Plate analysis	Failed to fetch RFU data.	Try again. If it doesn't work, please contact your administrator.
Plate analysis	A report with this name already exists. Choose another name.	Choose another name.
Plate analysis	Enter a name without ~ ' " ! ? @ ^ * ( ) = [ ] { } : ; , < > | / \\	Enter a valid name
Plate analysis	Report name is required	Enter a valid name
Plate analysis	Maximum number of characters: {number}	Enter a valid name
Plate analysis	Due to the problem with server connection some of the data couldn't be displayed properly. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue
Plate analysis	For some wells in this step, images are of low quality, and we cannot obtain the results for them. Those wells are unavailable for analysis. Try re-imaging the plate to fix this issue.	Try re-imaging the plate to fix this issue.

Section	Description	Action
Plate analysis	The same target cannot be used as wildtype and edited target.	Choose a different target.
Plate analysis	Failed to get genome editing list	Contact your administrator.
Plate analysis	Failed to get genome editing concentration diagrams	Contact your administrator
Plate analysis	Failed to get genome editing point diagrams	Contact your administrator
Plate analysis	Failed to get genome editing heatmap data	Contact your administrator
Plate analysis	Image for this channel is unavailable. Check your connection and try again by refreshing this page. In case it doesn't work, contact our customer support.	In case it doesn't work, contact our customer support.
Plate analysis	Images are not available due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue
Plate analysis	Source images were not found.	Contact your administrator
Plate analysis	Due to the problem with server connection some of the data couldn't be displayed properly. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue
Plate analysis	Failed to change thresholds.	Try again. If it doesn't work, please contact your administrator to resolve the issue.
Plate analysis	Image is not available.	Contact your administrator
Plate analysis	Images are not available due to the problem with server connection. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue
Plate analysis	Failed to retrieve partitions data for analysis.	Try again. If it doesn't work, please contact your administrator.
Plate analysis	Failed to retrieve concentrations data for analysis.	Try again. If it doesn't work, please contact your administrator.
Plate analysis	Failed to retrieve Mutation Detection data for analysis.	Try again. If it doesn't work, please contact your administrator.
Plate analysis	Failed to retrieve Genome Editing data for analysis.	Try again. If it doesn't work, please contact your administrator.
Plate analysis	Failed to retrieve Copy Number Variation data for analysis.	Try again. If it doesn't work, please contact your administrator.
Plate analysis	Failed to retrieve Gen Expression data for analysis.	Try again. If it doesn't work, please contact your administrator.
Plate analysis	Reference target cannot be a target of interest at the same time.	Choose a different reference target.
Plate analysis	Failed to get gene expression data	Try again. If it doesn't work, please contact your administrator.
Plate analysis	Reference target cannot be a target of interest at the same time.	Choose a different reference target.
Plate analysis	Failed to get copy number variation data	Try again. If it doesn't work, please contact your administrator.
Plate analysis	The same target cannot be used as wildtype and mutant target.	Choose a different target.

Section	Description	Action
Plate analysis	Failed to get mutation detection list	Try again. If it doesn't work, please contact your administrator.
Plate analysis	Failed to get mutation detection concentration diagrams	Try again. If it doesn't work, please contact your administrator.
Plate analysis	Failed to get mutation detection point diagrams	Try again. If it doesn't work, please contact your administrator.
Plate analysis	Failed to get mutation detection heatmap data	Try again. If it doesn't work, please contact your administrator.
Plate analysis	An error occurred during 1 or more imaging steps. For some wells, images are of low quality and the results couldn't be obtained. Those wells are unavailable for analysis. Try re-imaging the plate to fix this issue.	Try re-imaging the plate to fix this issue.
Plate analysis	This imaging step has failed during the run. Results might be incorrect.	Try again. If the error still occurs, please contact your local administrator.
Plate analysis	Min value is {min-Value}, max value is {max-Value}.	Enter a valid min value and max value
Plate analysis	Min value is {min-Value}.	Enter a valid min value
Plate analysis	Max value is {max-Value}.	Enter a valid max value
Plate analysis	Upper threshold value needs to be higher than the lower threshold.	Enter a valid upper threshold
Plate analysis	Lower threshold value needs to be smaller than the upper threshold.	Enter a valid lower threshold
Plate analysis	Min value is 1.	Enter valid min value
Plate analysis	Max value is 300.	Enter a valid max value
Plate analysis	Required	Enter all the required values
Plate layout	All reactions mixes should have control types assigned to their targets	Assign control types to all the reactions mixes
1D Scatterplot	Error loading scatterplot for a specific well in {channel}.	Try again. If the error still occurs, please contact your administrator.
1D Scatterplot	Unable to retrieve the scatterplot data. Please, contact your local administrator.	Contact your administrator.
1D Scatterplot	The scatterplot for Reference Channel has failed. Please try again. If problem persists, contact your local administrator.	Try again. If problem persists, please contact your administrator.
1D Scatterplot	Changes to Max value for y-axis [RFU] for this target can't be applied now. Please, try again. If problem persists, contact your local administrator.	Try again. If problem persists, please contact your local administrator.
1D Scatterplot	Data for: Target: {target-Name} (Channel: {channel}) can't be retrieved now. Refresh the page. If problem persists, contact your local administrator.	Refresh the page. If problem persists, please contact your local administrator.
1D Scatterplot	Unable to change the threshold for the {channel} scatterplot. Please, contact your local administrator.	Contact your local administrator.
1D Scatterplot	Max value is 300.	Type a valid value.
1D Scatterplot	Min value is 1.	Type a valid value.
1D Scatterplot	Required	Type the required value.
1D Scatterplot	Lower threshold value needs to be smaller than the upper threshold.	Type a valid value.

Section	Description	Action
1D Scatterplot	Min value is {min-Value}, max value is {max-Value}.	Type a valid value.
1D Scatterplot	Max value is {maxValue}.	Type a valid value.
1D Scatterplot	Min value is {minValue}.	Type a valid value.
1D Scatterplot	Upper threshold value needs to be higher than the lower threshold.	Type a valid value.
Plate general data	Plate name in General Data	Enter a valid name.
Plate general data	Plate description in General Data	Enter a valid plate description.
Support package	Something went wrong when generating support package. Try again or contact your local administrator for help.	Try again or contact your local administrator for help.
Support package	Something went wrong when downloading Support package. Try again or contact your local administrator for help.	Try again or contact your local administrator for help.
Support package	Due to a problem with server connection, the support package couldn't be downloaded. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue.
Server connection	Due to the problem with server connection some of the data couldn't be displayed properly. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue.
Certificates	Due to the problem with server connection information about certificate couldn't be displayed properly. Contact your administrator to solve this issue.	Contact your administrator to resolve the issue.
VPF upload	VPF file should have ".zip" extension.	Choose a file with ".zip" extension
VPF notification	This nanoplate requires a Volume Precision Factor to be applied. Upload VPF file or contact your local administrator for assistance.	Upload VPF file or contact your local administrator for assistance.
VPF notification	The volume of some nanoplates has not yet been optimized. Volume Precision Factor is required to obtain results. Upload VPF file or contact your local administrator for assistance.	Upload VPF file or contact your local administrator for assistance.
VPF upload	VPF upload process failed. Try again. If the error still occurs, contact your local administrator.	Try again. If the error still occurs, please contact your local administrator.
VPF upload	Selected file size is {size}. Maximum allowed size is: {max-Size}.	Be sure that you are uploading the right VPF file. If the problem persists, please contact with your administrator for help
Plate configurator	The plate could not be created	Check that all the plate information is valid and try again.
Plate configurator	Plate "{plate-Name}" could not be created. Try again later. If the error still occurs, contact your local administrator for help.	Try again later. If the error still occurs, please contact your local administrator for help.
Plate configurator	The plate could not be updated	Try again later. If the error still occurs, contact your local administrator for help.
Plate configurator	Plate "{plate-Name}" could not be updated. Try again later. If the error still occurs, contact your local administrator for help.	Try again later. If the error still occurs, please contact your local administrator for help.
Plate configurator	Changes cannot be saved	Check the plate data and try again, if it doesn't work, contact your administrator
Plate configurator	This plate was edited in the meantime. Refresh the page to get the newest version.	Refresh the page to get the newest version.

Section	Description	Action
Plate configurator	Refresh	Refresh the page
Plate configurator	Plate name is required	Enter a valid name
Plate configurator	You have already 1 plate with the same name	Enter a different plate name
Plate configurator	Enter a name without {symbols}	Enter a valid name
Plate configurator	Plate type is required	Enter the plate type
Plate configurator	Assay is required	Enter the assay
Plate configurator	There must be at least 1 owner assigned to the plate	Assign to the plate at least 1 owner
Plate configurator	Plate barcode is required	Enter a valid barcode
Plate configurator	Only digits are allowed	Enter a valid barcode
Plate configurator	You have already 1 plate with the same barcode	Enter a valid barcode
Plate configurator	The minimum required wells defined is not reached. Please, add it to proceed with saving.	Add it to proceed with saving.
Plate configurator	The selected plugin has been disabled. Please, select another plugin or refresh the page.	Select another plugin or refresh the page.
Plate configurator	Please provide only Unicode visible characters.	Type only Unicode visible characters.
Plate configurator	Please provide a Sample name without reserved characters: |^~\\&	Type the control name without reserved characters.
Plate configurator	Plate "{name}" could not be updated. Try again later. If the error still occurs, contact your local administrator for help.	Contact your administrator.
Plate configurator	Template "{name}" could not be updated. Try again later. If the error still occurs, contact your local administrator for help.	Try again later. If the error still occurs, contact your administrator
Plate configurator	Plate "{name}" could not be created. Try again later. If the error still occurs, contact your local administrator for help.	Try again later. If the error still occurs, contact your administrator
Plate configurator	Template "{name}" could not be created. Try again later. If the error still occurs, contact your local administrator for help.	Try again later. If the error still occurs, contact your administrator
Plate configurator	Information couldn't be retrieved from QR code. Try again or enter kit information manually.	Try again or enter kit information manually.

7.2. Malfunctions that can be corrected by the user

In the event of a malfunction, the QIAcuityDx will display an error code and an error message, which will prompt a corrective action to be performed by the user(s). Please refer to Section 7 for more details about errors and corresponding corrective actions. If the problem persists, please contact QIAGEN Technical Services.

7.3. Malfunctions that require a service visit

In the event of a malfunction, the QIAcuityDx will display an error code and an error message, which will prompt a corrective action to be performed by the user(s). Please refer to Section 7 for more details about errors and corresponding corrective actions.

If the corrective action prompts the user(s) to contact the QIAGEN Technical Services, please contact QIAGEN Technical Services providing the following details: error code, error message and comprehensive information about the actions that triggered the error.

8. Technical Specifications

8.1. Environmental conditions

8.1.1. Operating conditions

Description	Requirement
Input voltage	100–240 V, 50/60 Hz Mains supply voltage fluctuations do not exceed 10% of nominal supply voltages.
Input power	900 VA
Fuse	2x T12A L 250 V 5 x 20 mm
Overvoltage category	II
Air temperature	15–32°C (59–90°F)
Relative humidity	10–75% (non-condensing)
Place of operation	For indoor use only
Environmental class	3K21 (IEC 60721-3-3)
Audible noise level	55 dB
Operational altitude	2000 m
Pollution degree	2

8.1.2. Transport conditions

Description	Requirement
Air temperature	–25°C to 60°C (–13°F to 140°F) in manufacturer's packaging
Relative humidity	5% to 85% (non-condensing)
Environmental class	2K11 & 2M4 (IEC 60721-3-2)
Ambient pressure	700–1060 hPa

8.1.3. Recommended storage conditions

Description	Requirement
Air temperature	5°C to 40°C (41°F to 104°F) in manufacturer's packaging
Relative humidity	5% to 85% (non-condensing)
Environmental class	1K21 (IEC 60721-3-1)
Ambient pressure	700–1060 hPa

8.2. Mechanical data and hardware features

Description	Requirement
Dimensions QIAcuityDx Four instrument packed and on a pallet	**Width**: 788 mm **Height**: 764 mm **Depth**: 1360 mm
Shipping weight	68 kg (46 instrument + 22 packing materials)
Dimensions QIAcuityDx Four instrument only	**Width**: 600 mm (23.6 in.) **Height**: 580 mm (22.8 in.) **Depth**: 650 mm (25.6 in.) Allow 100 mm (5.9 in.) clearance at the sides and read for airflow
Mass	QIAcuityDx Four: 46.0 kg (94.8 lb.) Accessories: 3.0 kg (6.6 lb.)
Thermal specifications	**Process temperature**: 35°C to 99°C (Control temperature can reach 110°C in overshoot) **Ramp rate**: approx. 3.0°C/s **Accuracy**: ±1°C **Homogeneity (over plate surface)**: ±1°C
Optical specifications	The QIAcuityDx features optics for the following optical channels:

Channel	Green	Yellow	Orange	Red	Crimson
Excitation (nm)	463–503	514–535	543–565	570–596	590–640
Emission (nm)	518–548	550–564	580–606	611–653	654–692

Excitation by high power white LED with average 4750 lumens

Image acquisition by CMOS camera with 6.3 MP

Capacity	Up to 96 samples per plate. Maximum plate capacity is Four plates with continuous loading capability
Touchscreen (QIAcuityDx Four)	10.1" LCD Touch, active area 218.0 x 136.6 mm, resolution 1280*800 HD
Acoustic emission	**QIAcuityDx Four**: Max. 54.6 dB (A)
USB drive	USB 2.0, 8 GB **Compatible OS**: Windows 11, Windows 7, Windows Vista, Windows XP (SP3 or later); Mac OS X 10.1 or later **Operating temperature range**: 0°C to 35°C **Operating humidity range**: 10–90% (with no condensation) **Storage / Transport temperature range**: –20°C to 60°C (–4 to 140°F) **Storage / Transport humidity range**: 10–90% (with no condensation) **Formatting**: FAT32
Handheld scanner	**Scan pattern**: Area Image (1280 x 800-pixel array) **Motion tolerance**: Up to 890 mm/s (35 in/s) **Print contrast ratio**: 15% (minimum) **Decode capability**: Reads standard 1D, 2D, Postal, and stacked codes **Resolution**: 1D Linear: 0.102 mm/4 mils; PDF417: 0.127 mm/5 mils; Data Matrix: 0.195 mm/7.5 mils

8.3. Electromagnetic Compatibility, Emission, and Immunity

QIAcuityDx Four complies with the emission and immunity requirements from EN IEC 61326-2-6:2021 and IEC 60601-1-2: Ed. 4.1 2020-09.

This equipment is designed for use in a Professional Healthcare Facility Environment. Locations include hospitals, clinics, diagnostic laboratories, or scientific environments. Most environments and locations in the Professional Healthcare Facility Environment are considered to have a controlled electromagnetic environment with regard to fixed electromagnetic sources. However, mobile communication devices are widely used by healthcare professionals in providing efficient patient care. For this reason, it is more difficult to control the environment for proximity electromagnetic disturbances. Examples of electromagnetic sources that might be used adjacent to IVD medical equipment are:

- high frequency surgical equipment;
- radio frequency identification (RFID) systems;
- wireless local area networks (WLAN);
- handheld mobile radios (e.g., TETRA, 2-way radio);
- paging systems;
- other wireless devices (including consumer devices).

This equipment is likely to perform incorrectly if used in a Home Healthcare Environment. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Electromagnetic environment should be evaluated prior to operation of the equipment. Do not use this equipment in proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with proper operation.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 300 mm (12 in.) to any part of the equipment, including cables specified by the manufacturer. Otherwise, could result in degradation of the performance of this equipment could result.

WARNING: Do not use any other power cable than the one supplied with the equipment. In case of damage or loss contact QIAGENs service for a replacement. Other cables might negatively affect the EMC performance of the equipment.

WARNING: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

EMC requirements	Compliant with class B Group 1 emission levels and Professional Healthcare Facility Environment immunity levels from IEC 61326 and IEC 60601-1-2.
EMC tests outcome	Basic Safety and Essential Performance was guaranteed for all immunity tests. There were no deviations from the basic or collateral standards listed in the next tables.
Essential performance	Essential performance was defined as ensuring that there were no extraneous alarms or errors and no interruption in sample processing resulting in incorrect results, during immunity EMC testing.
Basic safety	Freedom from unacceptable risk directly caused by physical hazards when the equipment is used under normal condition and single fault condition, during immunity EMC testing.

EMC emissions test levels

Emission test	Test level / compliance level	Electromagnetic environment
Radiated emissions CISPR 11	Class B, Group 1 emissions level	Suitable for use in Professional Healthcare Facility Environment* Also suitable for use in residential environments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes†.
Conducted emissions CISPR 11	Class B, Group 1 emissions level	
Harmonic distortion IEC 61000-3-2	As per IEC 61000-3-2	
Voltage fluctuation and flicker IEC 61000-3-3	As per IEC 61000-3-3	

* Locations include hospitals, clinics, diagnostic laboratories, or scientific environments.

† Locations include diagnostic laboratories or clinics located in residential areas.

EMC immunity test levels

Immunity test	Test level / compliance level		Electromagnetic environment
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air		Professional Healthcare Facility Environment
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz – 6 GHz (@ 80 % AM at 1 kHz)		
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See next table		
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m (50 Hz or 60 Hz)		
Proximity magnetic fields IEC 61000-4-39	Test frequency 134.2 kHz, Pulse modulation 2.1 kHz: 65 A/m Test frequency 13.56 MHz, Pulse modulation 50 kHz: 7.5 A/m		
Electric fast transients / bursts IEC 61000-4-4	AC Power	± 2 kV (5/50 ns, 100 kHz)	
Electric fast transients / bursts IEC 61000-4-4	I/O Lines	± 1 kV (5/50 ns, 100 kHz)	
Surges Line-to-line Surges Line-to-ground IEC 61000-4-5	AC Power	± 0,5 kV, ± 1 KV ± 0,5 kV, ± 1 kV, ± 2 kV	
Surges IEC 61000-4-5	I/O Lines	± 2 kV	
Conducted disturbances induced by RF fields IEC 61000-4-6	AC Power	3 V (150 kHz – 80 MHz) 6 V in ISM bands between 150 kHz – 80 MHz (@ 80 % AM at 1 kHz)	
Conducted disturbances induced by RF fields IEC 61000-4-6	I/O Lines	3 V (150 kHz – 80 MHz) 6 V in ISM bands between 150 kHz – 80 MHz (@ 80 % AM at 1 kHz)	
Voltage dips	AC Power	0 % UT; 0.5 cycle (@ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) 0 % UT; 1 cycle 70 % UT; 25/30 cycles (@ 0°)	
Voltage interruptions IEC 61000-4-11	AC Power	0 % UT; 250/300 cycle	
Electric fast transients / bursts IEC 61000-4-4	AC Power	± 2 kV (5/50 ns, 100 kHz)	

Compliance and test levels, Proximity Fields from RF wireless communications equipment IEC 61000-4-3

Test frequency (MHz)	Band* (MHz)	Service*	Modulation	Immunity test level (V/m)
385	380 to 390	TETRA 400	Pulse modulation† 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM‡ ±5 kHz deviation 1 kHz sine	28
710 745 780	704 to 787	LTE Band 13, 17	Pulse modulation† 217 Hz	9
810 870 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation† 18 Hz	28
1720 1845 1970	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation† 217 Hz	28
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation† 217 Hz	28
5240 5500 5785	5100 to 5800	WLAN 802.11 a/n	Pulse modulation† 217 Hz	9

If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the equipment may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

* For some services, only the uplink frequencies are included.

† The carrier shall be modulated using a 50% duty cycle square wave signal.

‡ As an alternative to FM modulation, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.

Acronyms

Acronym	Definition
cDNA	Complementary DNA
cfDNA	Circulating cell-free DNA
CN	Copy number
CAN	Copy number alteration
CNV	Copy number variation
cp	Copy
ctDNA	Circulating tumor DNA
Cy5	Cyanine5
DEPC	Diethyl pyrocarbonate
dPCR	Digital PCR
EMC	Electromagnetic Compatibility
FAM	Carboxyfluorescein
FFPE	Formalin-fixed, paraffin-embedded
gDNA	Genomic DNA
GMO	Genetically modified organism
GOI	Gene of interest
HEX	Hexachlorofluorescein
IHA	In-House Assay
LDT	Lab Developed Test
LNA	Locked nucleic acid
NEB	New England Biolabs
NTC	No template control sample
QN IC	QuantiNova Internal Control
ROX	Carboxyrhodamine
RT	Reverse transcription
RT-qPCR	qPCR using cDNA template after reverse transcription
TAMRA	Carboxytetramethylrhodamine
TFS	Thermo Fisher Scientific
Tm	Melting temperature
TOI	Target of interest
UV	Ultraviolet
UM	Utility Mode
WT	Wild type

References

1. Sykes, P., Neoh, S., Brisco, M., Hughes, E., Condon, J., & Morley, A. (1992). Quantitation of targets for PCR by use of limiting dilution. Biotechniques, 13(3), 444-9. Retrieved from **https://pubmed.ncbi.nlm.nih.gov/1389177/**

Appendix A – Legal

License terms

The license terms for all software used with QIAcuityDx, including QIAGEN software components, commercial software components and open source software components, are provided in the files **licenses.rtf** and **Prerequisite.LicenseAgreements.rtf** located on the QIAcuityDx workstation under the following paths:

`C:\ProgramData\QIAGEN\QIAcuityDx\licenses.rtf`

`C:\ProgramData\QIAGEN\QIAcuityDx\Prerequisite.LicenseAgreements.rtf`

Waste Electrical and Electronic Equipment (WEEE)

This section provides information about disposal of waste electrical and electronic equipment by users.

The crossed-out wheeled bin symbol (see below) indicates that this product must not be disposed of with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local laws and regulations.

The separate collection and recycling of waste electronic equipment, at the time of disposal, helps to conserve natural resources and ensures that the product is recycled in a manner that protects human health and the environment.

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To recycle electronic equipment, contact your local QIAGEN sales office for the required return form. Once the form is submitted, you will be contacted by QIAGEN either to request follow-up information for scheduling collection of the electronic waste or to provide you with an individual quote.

Batteries and battery disposal

WARNING **Risk of explosion**

Batteries can be a fire risk when over-charged, short-circuited, submerged in water, or damaged. They should also never be disposed of in a household/office or laboratory bin, as this can also cause fires.

The QIAcuityDx Four has a non-user-serviceable battery inside the instrument for the retention of BISO data in memory. The battery should last the serviceable lifetime of the instrument. In the unlikely event of a malfunction that might be attributed to the premature failure of the battery, please contact QIAGEN service. In any event QIAGEN will arrange the replacement and disposal of any batteries following an investigation and root cause analysis.

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12. HIPAA / GDPR

a. **HIPAA.** To the extent that a Party shall send or receive PHI within the United States, such Party shall comply with the requirements of the Health Insurance Portability and Accountability Act of 1996, P. L. 104-191 (the "Act"), the privacy standards set forth in 45 C.F.R. parts 160 and 164 (the "Privacy Rule"), the security standards set forth in 45 C.F.R. parts 160, 162, and 164 (the "Security Rule"), and the Health Information Technology for Economic Clinical Health Act, Title XIII of Division A and Title IV of Division D of Pub. L. 111-5 ("HITECH") and all of the rules and regulations implemented thereunder. The Act, the Privacy Rule, the Security Rule, and HITECH are collectively referred to as "HIPAA".

b. To the extent Personal Data (as defined in the applicable data protection laws) from the European Economic Area (EEA), the United Kingdom and Switzerland are processed by QIAGEN, the EU-US and/or Swiss-US Privacy Shield and/or the Standard Contractual Clauses shall apply. For the purposes of the Standard Contractual Clauses, Customer and its applicable Affiliates are each the data exporter, and Customer's acceptance of this Agreement shall be treated as its execution of the Standard Contractual Clauses and Appendices. To the extent that the California Consumer Privacy Act ("CCPA") is applicable to either Party, such Party agrees to comply with all of its obligations under the CCPA, including but not limited to:

   i. Not to sell the Personal Data;

   ii. Retain, use or disclose the Personal Data for any purpose other than for the specific purpose of performing the services;

   iii. Retain, use or disclose the Personal Data for a commercial purpose other than providing the services; and

   iv. Retain, use or disclose the information outside of the direct business relationship between the Parties

13. General

a. **Language.** This Agreement, any disputes hereunder, and all services to be provided hereunder by QIAGEN to User (if any) shall be conducted and provided in the English language. Any translated version of this Agreement shall be only for convenience and filing with the appropriate government agency, if required, and not for interpretation of this Agreement.

b. **QIAGEN Contact Address.**

QIAGEN GmbH
Qiagen Straße 1
40724 Hilden
Germany
www.qiagen.com

c. **Consent to Use Anonymous Data.** QIAGEN may utilize data capture and analysis tools, and other similar tools, to create non-personally identifiable and aggregate data or information resulting from the User's use of the QIAGEN Software, which may include non-personally identifiable and aggregate usage data, and usage patterns including but not limited to technical information about your device, system and application software, and peripherals ("Anonymous Data"). QIAGEN may (i) use and analyze the Anonymous Data to develop and improve QIAGEN's products and services, such as improving the user experience or QIAGEN's algorithms and (ii) use the Anonymous Data as part of QIAGEN's products and services or (iii) to facilitate the provision of software updates, product support, and other services to you (if any) related to the QIAGEN Software. QIAGEN will ensure that no personally identifiable information is disclosed through the QIAGEN products and services to any third party without Customer's consent. QIAGEN uses and protects that information in accordance with the Software Privacy Policy, which can be found within About page of Software. For the use of instrument data please refer to QIAcuityDx terms of use.

d. **Use of Instrument Data.** You agree that QIAGEN may use the QIAcuityDx Instrument Data transferred to QIAcuityDx in order to use the Software.

QIAGEN collects and processes Instrument Data including but not limited to instrument performance data, assay performance data, run performance data, configuration and protocol data. QIAGEN may also aggregate the Instrument Data with data from other QIAcuityDx customers. QIAGEN may use the Instrument data for a variety of purposes, including without limitation, to monitor the performance of QIAGEN instruments and QIAGEN assays, to improve our products and to provide you with enhanced service and remote system diagnostic.

By using QIAcuityDx, you accept that Instrument Data you provide may be transmitted and processed out of your state or country. BY AGREEING TO THESE TERMS YOU GRANT QIAGEN A PERPETUAL, ROYALTY-FREE, IRREVOCABLE AND WORLDWIDE LICENSE TO USE INSTRUMENT DATA TRANSFERRED BY CONNECTED INSTRUMENTS TO QIASPHERE.

e. **Government End Users.** If you are a U.S. Government end user, we are licensing the QIAGEN Software to you as a "Commercial Item" as that term is defined in the U.S. Code of Federal Regulations (see 48 C.F.R. § 2.101), and the rights we grant you to the QIAGEN Software are the same as the rights we grant to all others under these Terms of Use.

f. **Entire Agreement; Modifications.** This agreement includes the terms herein and the attached exhibits, and any terms incorporated herein by reference, including terms identified herein which are to be identified in and incorporated from an Ordering Document and the Software Privacy Policy , which are hereby incorporated by reference, (collectively "**Agreement**") and constitutes the entire agreement between the parties with respect to the Licensed Materials and other services or products delivered by QIAGEN hereunder as identified in the relevant Ordering Document. Except as expressly provided herein, this Agreement supersedes and cancels all previous written and previous or contemporaneous oral communications, proposals, representations, and agreements relating the subject

matter contained herein. Notwithstanding any language to the contrary therein, no terms or conditions stated in User's purchase order, acknowledgement or conformation or other document issued by User, even if signed and returned by QIAGEN, shall take precedence over the terms of this Agreement.

g. **Waiver.** The failure of either party to enforce any rights granted hereunder or to take action against the other party in the event of any breach hereunder shall not be deemed a waiver by that party as to subsequent enforcement of rights or subsequent actions in the event of future breaches.

h. **Export.** User agrees to comply with all export and re-export restrictions and regulations, and not to transfer, or authorize the transfer of, the Licensed Materials, to a prohibited country or otherwise in violation of any such restrictions or regulations. User shall obtain any and all import licenses necessary or proper for the import and use of the Licensed Materials, as relevant.

i. **Choice of Law; Venue.** This Agreement is governed and interpreted in accordance with the laws of Germany, without reference to its conflict of law principles. Subject to the arbitration clause (where relevant), the parties hereby consent to the exclusive jurisdiction of, and venue in, the state and federal courts within Düsseldorf. The United Nations Convention on Contracts for the Sale of Goods shall not apply to this Agreement.

j. **Notice.** Any and all notices or other information to be given by one of the parties to the other shall be deemed sufficiently given when sent by certified mail (receipt requested), or by courier, or by hand delivery to the other party. Such notices shall be deemed to have been effective on the first business day following the day of such delivery.

k. **Equitable Relief.** The parties agree that a material breach of this Agreement adversely affecting QIAGEN's intellectual property rights in Software or Licensed Materials may cause irreparable injury to QIAGEN for which monetary damages would not be an adequate remedy and QIAGEN shall be entitled to equitable relief (without a requirement to post a bond) in addition to any remedies it may have hereunder or at law

l. **Assignment.** Except as expressly permitted herein, User shall not transfer, assign or delegate this Agreement or any rights or obligations hereunder, in whole or in part, whether voluntarily, by operation of law or otherwise, without the prior written consent of QIAGEN. Any such purported transfer, assignment or delegation shall be null and void. QIAGEN may transfer, assign or delegate this Agreement. Subject to the foregoing, the terms and conditions of this Agreement shall be binding upon and inure to the benefit of the parties to it and their respective heirs, successors, assigns and legal representatives.

m. **Illegality.** If any term or provision of this Agreement is held by a court of competent jurisdiction to be invalid, void or unenforceable under any applicable statute or rule of law, such term or provision shall be modified, limited or eliminated to the minimum extent necessary to effectuate the original intent and such declaration shall have no effect on the remaining terms hereof, which shall continue in full force and effect.

n. **Headings.** Headings are solely for reference and shall not affect the meaning of any term.

o. **Addendum for Customers Located in the People's Republic of China.** Notwithstanding anything to the contrary herein and only to the extent the laws of the People's Republic of China are deemed to apply to this Agreement in some capacity with respect to a Customer because the Customer is located or domiciled in the People's Republic of China, then the following shall also apply with respect to such Customers only:

    i. **Limited Warranty.** QIAGEN owns or has the rights to license the Licensed Materials.

    ii. **Export/Import.** Customer shall take all actions necessary or proper to comply with China's Regulations on Administration of Technology Import and Export Laws and related laws, statutes, regulations, ordinances or government directives.

iii. **Waiver of Sovereign Immunity.** Customer and QIAGEN hereby unconditionally and irrevocably agree that the execution, delivery and performance by it of this Agreement constitute private and commercial acts rather than public or governmental acts. To the extent that any party to this Agreement shall be entitled in connection with any suit, action, judicial or arbitral proceeding arising out of or relating to this Agreement at any time brought against such party, or with respect to any suit, action or judicial proceeding at any time brought for the purpose of enforcing or executing any judgment or arbitral award in any jurisdiction, to any immunity, on the grounds of sovereignty or otherwise, from suit or arbitral proceeding, from the jurisdiction of any court, from attachment prior to judgment or arbitral award, from attachment in aid of execution of judgment or arbitral award, from execution of a judgment or arbitral award or from any other legal or judicial or arbitral process or remedy, and to the extent that in any such jurisdiction there shall be attributed such an immunity, each party hereby unconditionally and irrevocably agrees not to claim and unconditionally and irrevocably waives such immunity to the fullest extent permitted by the laws of such jurisdiction.

p. **Additional International Provisions.** The following provisions shall apply only if you are located in the countries listed below.

- **United Kingdom.** A third party who is not a party to this Agreement has no right under the Contracts (Rights of Third Parties) Act 1999 to enforce any provision of this Agreement, but this does not affect any right or remedy of such third party which exists or is available apart from that Act.

Basis of the Bargain. User acknowledges and agrees that QIAGEN has set its prices and entered into this Agreement in reliance upon the disclaimers of warranty and the limitations of liability set forth herein, that the same reflect an allocation of risk between the parties (including the risk that a contract remedy may fail of its essential purpose and cause consequential loss), and that the same form an essential basis of the bargain between the parties.

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at **www.qiagen.com** or can be requested from QIAGEN Technical Services or your local distributor.

Appendix B – QIAcuityDx Accessories

Ordering Information

Product	Contents	Cat. no.
QIAcuityDx Four instrument	Fully integrated, IVD, dPCR System	911060
IVD consumables		
QIAcuityDx Nanoplate 26k 24-well(10)	24-well dPCR Nanoplate with 26k partitions and 40 µL reaction volume per well, 10 Nanoplates w/ 11 seals	260001
QIAcuityDx Universal MasterMix Kit (1 mL)	1 mL 4X concentrated Probe MasterMix, 1 mL 200 mM MgCl2, 2 x 1.9 mL Water	260101
QIAcuityDx Universal MasterMix Kit (5 mL)	5 x 1 mL 4x concentrated Probe MasterMix, 2 x 1 mL 200mM MgCl2, 5 x 1.9 mL Water	260102
Other consumables		
QIAcuity Nanoplate 26k 24-well	24-well dPCR Nanoplate with 26k partitions and 40 µL reaction volume per well, including Nanoplate seals	250001
QIAcuity Nanoplate 8.5k 96-well	96-well dPCR Nanoplate with 8.5k partitions and 12 µL reaction volume per well, including Nanoplate seals	250021
Nanoplate Seals (11)	Nanoplate seal for sealing QIAcuityDx Nanoplates	250099
QIAcuity Probe PCR Kit (1 mL)	1 mL 4x concentrated QIAcuity Probe MasterMix, 2 x 1.9 mL Water	250101
QIAcuity Probe PCR Kit (5 mL)	5 x 1 mL 4x concentrated QIAcuity Probe MasterMix, 8 x 1.9 mLL Water	250102
Related products		
Nanoplate Tray (2)	Nanoplate Tray improving plate-handling during pipetting or carrying	250098
Barcode Scanner	Barcode Hand Scanner, QIAcuityDx	911106
Plate Roller	Hand roller for preparing the dPCR plates for processing	911105
Air Filter, QIAcuityDx Four	Replacement air inlet filter	9026700

For up-to-date licensing and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at **www.qiagen.com** or can be requested from QIAGEN Technical Services or your local distributor.

Document Revision History

Date	Changes
07/2024	Initial release of the User Manual

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