

QIAcuityDx[®] System User Manual



IVD

For in vitro diagnostic use

CE

REF

911060



QIAGEN, GmbH, QIAGEN Strasse 1, 40724 Hilden, GERMANY

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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
- Control Software version number, Software Suite version number, plus a list of installed software plugins with their version
- Configured language and formats
- 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 (IVD) and Utility mode (UTL). The IVD mode includes clinically validated and globally approved assays, with locked plate configurations, analytics, and defined reporting; whereas the Utility mode offers flexibility to users customizing their own laboratory-developed test (LDT) workflows or simply using the device for non-clinical laboratory applications, including translational research.

Note: Products intended for non-clinical laboratory applications 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 within the wider Utility mode environment. 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.

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 digital PCR System (QIAcuityDx System) is intended for in vitro diagnostic use for the examination of specimens derived from the human body, using automated multiplex quantification digital PCR (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 — a semi-automated digital PCR (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 (SAP) — a dedicated software installed on the same PC as the Software Assay Independent (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 MasterMix reagent set for use within the QIAcuityDx System in conjunction with associated target specific reagents

The QIAcuityDx System is intended to be used by trained personnel in a professional laboratory environment.

1.4.1. Utility mode

The QIAcuityDx System incorporates a Utility (open) mode to allow non-clinical laboratory 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.

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 applications cannot be used with approved IVD assays.

It is possible to open Software Suite in several tabs and for users with appropriate permissions to access both modes simultaneously. Software Suite warns the user in all the opened tabs about a change in operating mode. To minimize the likelihood of error, it is recommended to use operating modes independently.

Instrument malfunction

In the event that the instrument malfunctions, turn off the power, remove the power cable 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, are specified.

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 QIAcuityDx Four
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:

- QIAcuityDx 26k 24-well Nanoplate Kit (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.

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 the QIAcuityDx.

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 OSHA^{*}, 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 and 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

QIAcuityDx 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 QIAcuityDx may 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 waste must be collected and disposed of properly according to local safety regulations. It is recommended to discard processed nanoplates after a period of 14 days.

For more information about how to dispose of the QIAcuityDx Four instrument, see “Waste Electrical and Electronic Equipment (WEEE)”, page 316.

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
	This product fulfills the requirements of the European Regulation (EU) 2017/746 for in vitro diagnostic medical devices (IVDR).
	In vitro diagnostic medical device
	Catalog number
	Material number
	Lot number
	Global Trade Item Number
	Unique Device Identifier
	Contains
	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
	Contains reagents sufficient for <N> reactions
	Protect from light

3. General Description

The QIAcuityDx Four instrument 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 processed. For diagnostic applications, the QIAcuityDx Nanoplate 26K 24-well is available. A total of 4 nanoplates can be simultaneously processed, with continuous loading possible. The QIAcuityDx Control Software (CSW) 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 is installed on a QIAcuityDx Notebook provided with the QIAcuityDx Platform. 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 Four instrument is designed as a walk-away device that integrates and automates all plate processing steps. Only the samples combined with reaction mixes, and nanoplate seal, must be added to a nanoplate manually before starting a 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. Subsequently, the connecting channels between the partitions are sealed by activation of a pressure sensitive adhesive through a pressure-controlled rolling process (see Figure 1).

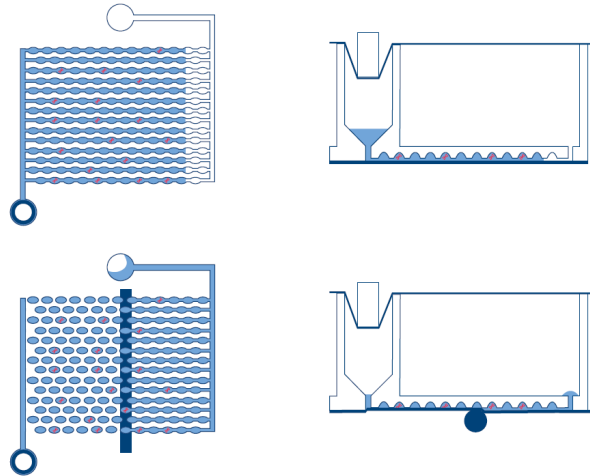


Figure 1. Scheme of filling and partitioning of a well.

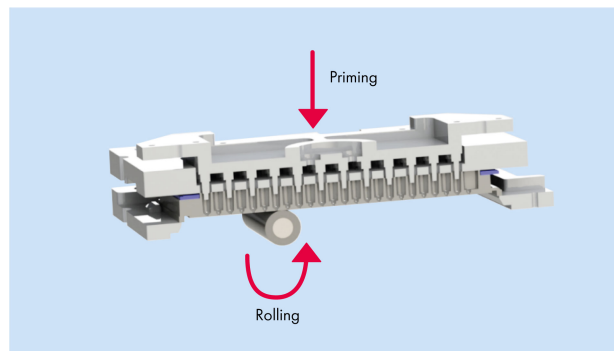


Figure 2. Principle of priming and rolling to allow partitioning of the wells.

- **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.

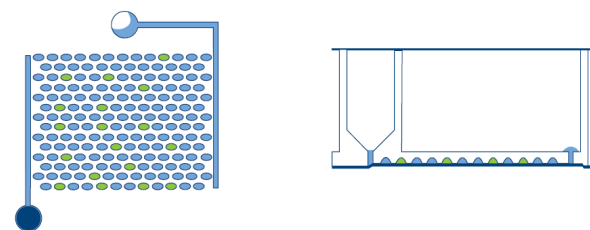


Figure 3. Scheme of positive (green) and negative (blue) partitions after imaging.

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.

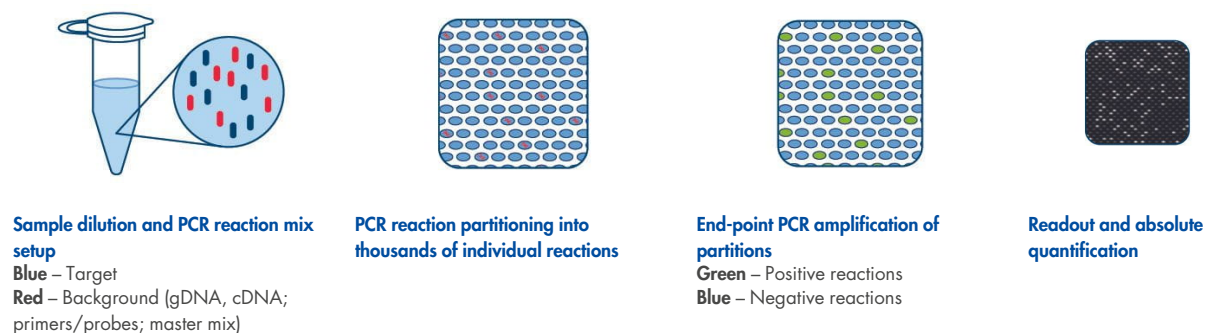


Figure 4. Absolute quantification in 4 steps.

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:

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

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

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.

	8.5K partitions		26K partitions		8.5K partitions Half 1:2 ratio		26K partitions Sub-well 1:4 ratio	
	A	B	C	D	1	2	1	4
PCR product 500 bp	A	F			K	P		
					0.96	1.00		
FFPE gDNA 3000 bp	B	G			L	Q		
					0.95	1.01		
cDNA 1–10 kb	C	H			M	R		
					0.93	1.10		
QIAamp gDNA 20–50 kb	D	I			N	S		
					1.13	1.87		
FlexiGene gDNA >150 kb	E	J			O	T		
					1.30	2.74		

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 QIAcuityDx Control 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 the QIAcuityDx.

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.

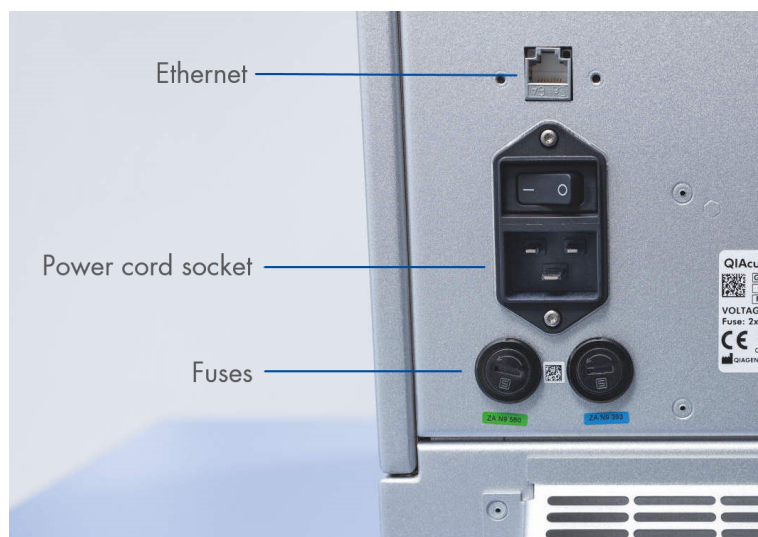


Figure 6. Back view of the QIAcuityDx.

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

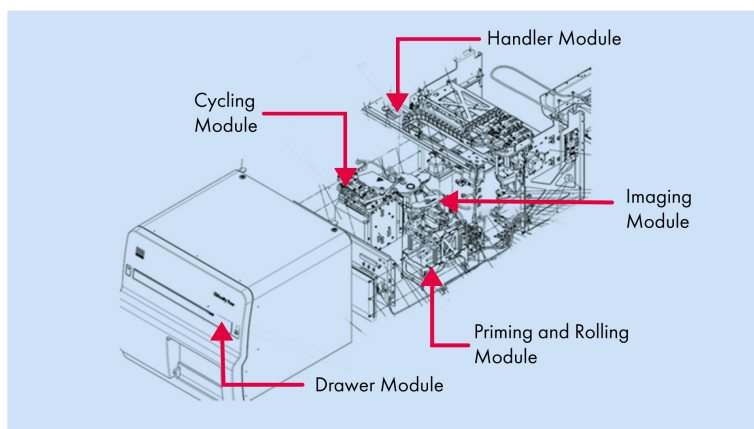
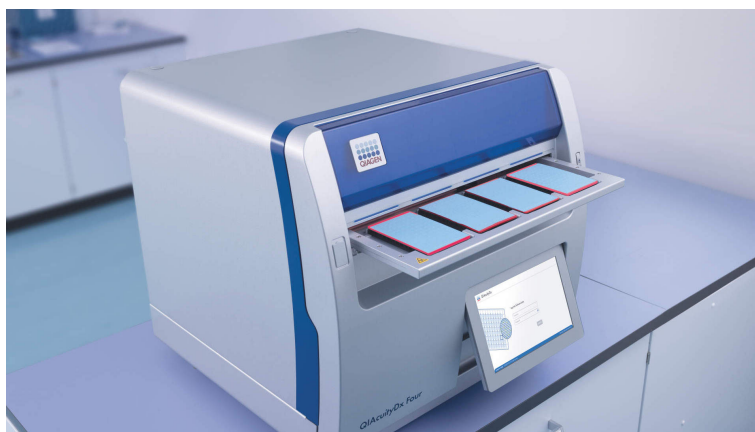


Figure 7. Internal view of the fluidic drawer.

- | | | | |
|---|----------------------------|---|--------------------------|
| 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 handling 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.

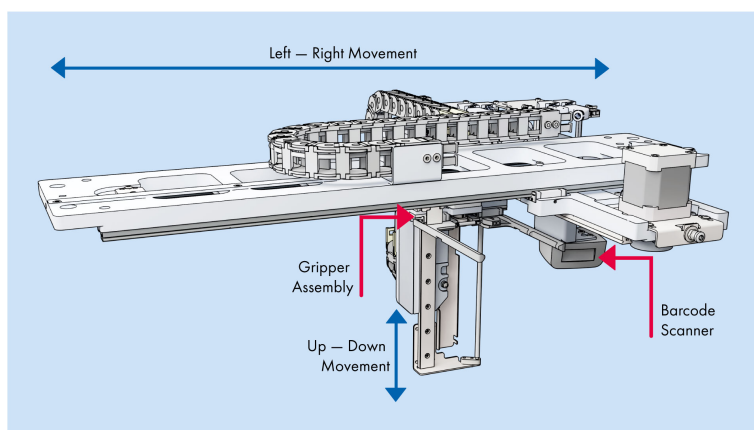


Figure 8. Handling module.

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 (priming)
- Partition closing (rolling)

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.

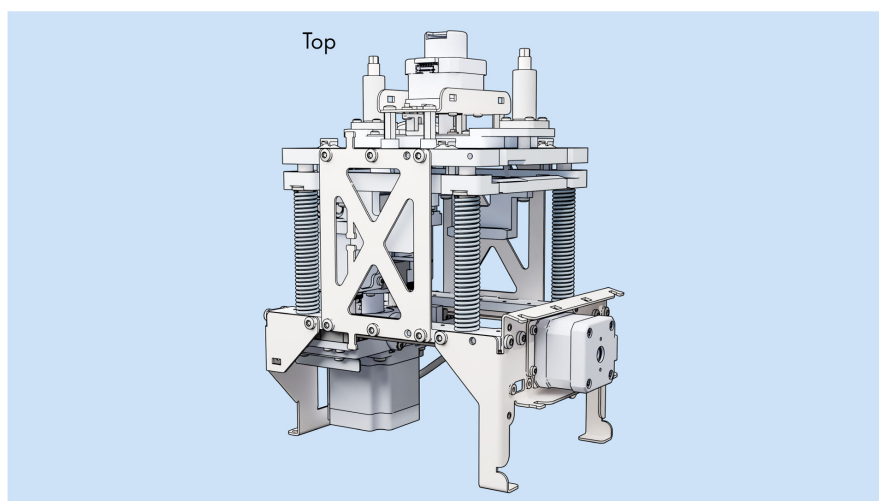


Figure 9. Priming and Rolling Module – Front view.

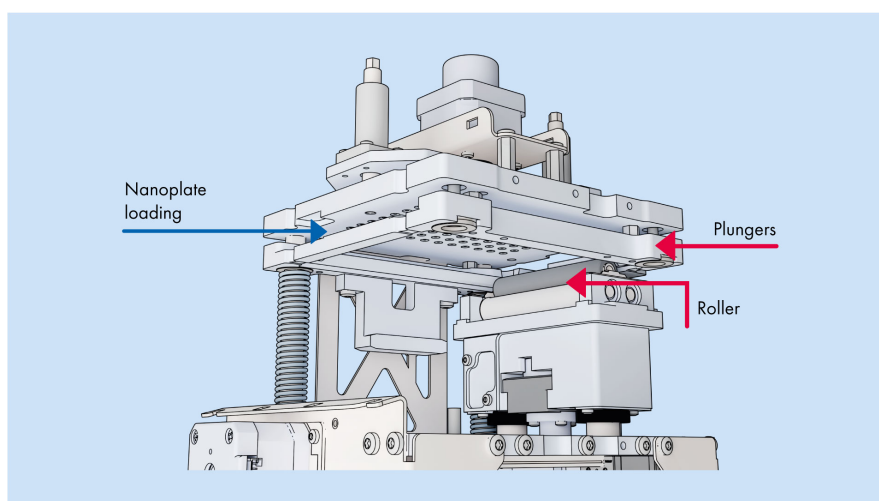


Figure 10. Priming and Rolling Module – Cross section.

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.

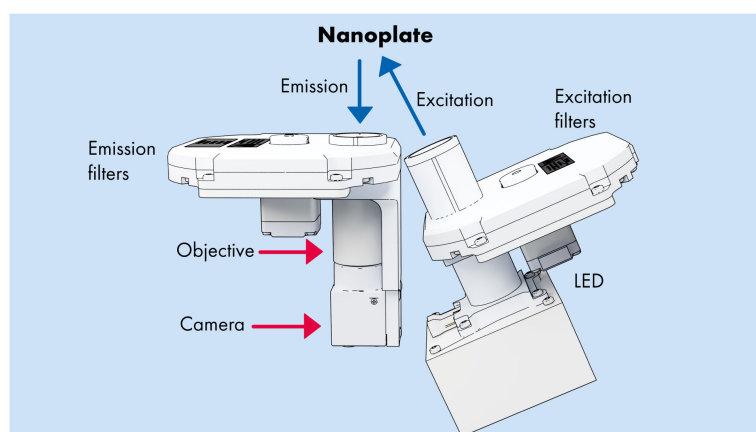


Figure 11. Schematic of Imaging module.

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 non-supported dyes may result in sub-optimal crosstalk correction leading to image artifacts.

4. Installation Procedures

The information provided here is needed to ensure 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 Four instrument
- *QIAcuityDx System User Manual* (this document)
- 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 Four 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, and 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 alongside 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 Platform (cat. no. 911061) 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: <ul style="list-style-type: none">• 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

Note: It is mandatory to change the operating system's default password upon first login to a more cybersecure password. It is recommended to define a password that is between 8 and 100 characters long, has at least one upper case letter, one lower case letter, a number and a symbol.

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.

Warning: Unpacking of the QIAcuityDx Four instrument should be carried out by QIAGEN-trained service engineers only.

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

The QIAcuityDx Four instrument comes preinstalled with the QIAcuityDx Control Software(CSW), which allows the user to operate the instrument via a simple user interface (GUI) located on the swivel mounted touchscreen on the instrument.

The QIAcuityDx System is only fully functional when the QIAcuityDx Control Software is connected to the QIAcuityDx Software Suite. This initial configuration is carried out by a certified QIAGEN Field Service Specialist.

4.9. Installing the QIAcuityDx Software Suite

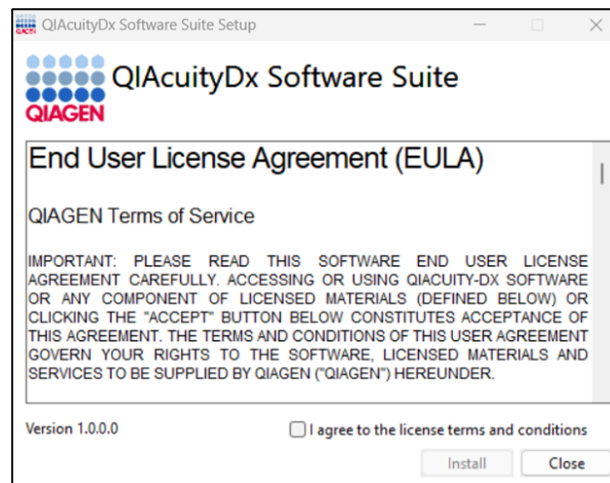
This section is optional; most customers will be supplied with a notebook preinstalled with the golden image.

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. If it is a direct-connection installation with the QIAGEN notebook, skip to step 4.
2. If it is a domain-connection installation, ensure the following ports have been properly configured:

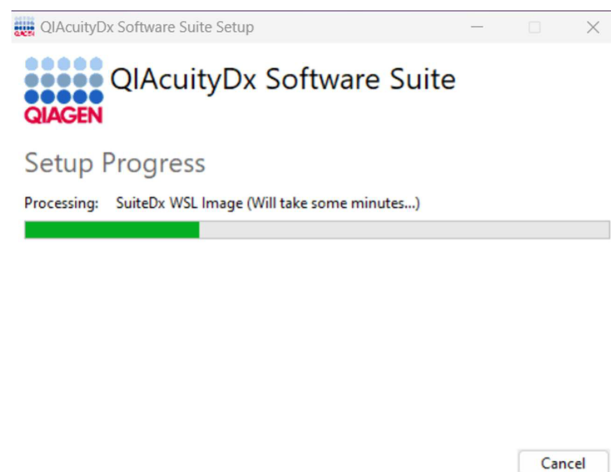
Port	Protocol	Direction
8687	https	IN / OUT
8080	https / http	IN / OUT
44321	https	IN / OUT
9087	https / http	IN / OUT

3. A domain user with local administrator privileges to install, start, and troubleshoot. The account must have permissions to read and write on the remote folder(s) planned to be used for archive and backup. This user will not be used in routine and may not be shared with users.
4. The Software Suite installer will be provided by a field service engineer.
5. Double-click the **SuiteDxInstaller.exe** file to start the installation process.
6. The installer will check whether the required software described in steps 4–6 are installed and enabled. In case the installation process fails, an error message will be displayed.
7. The Software Suite License Agreement will be displayed. Tick the checkbox and click the **Install** button.

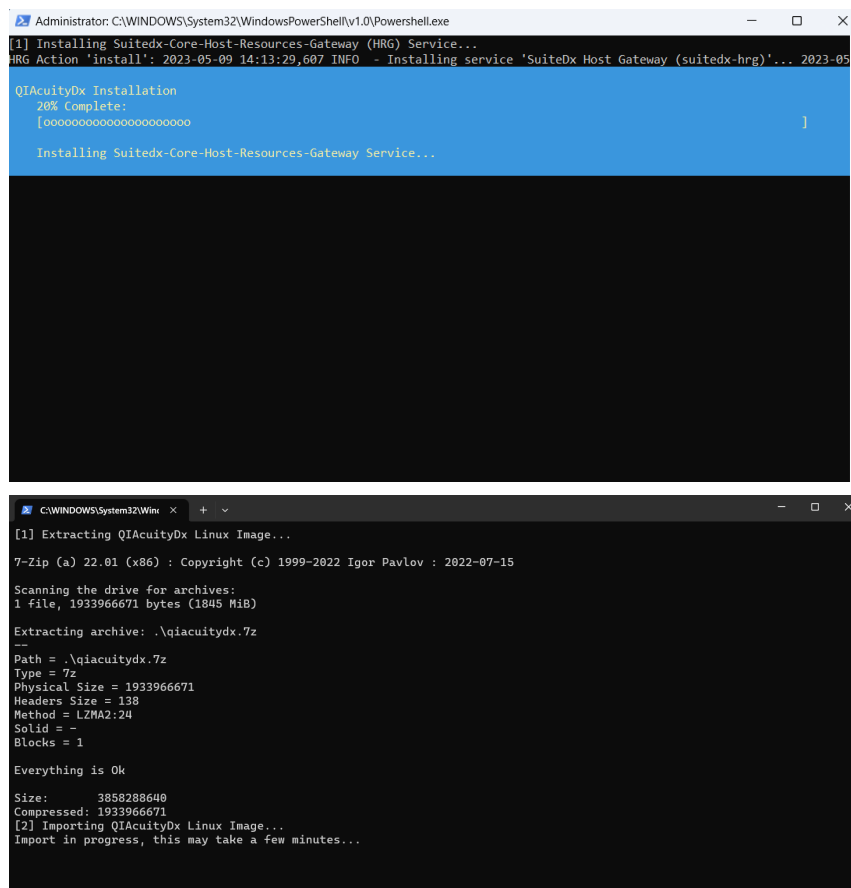


8. In case a prompt requesting Administrator rights is displayed, grant Administrator permission to continue.

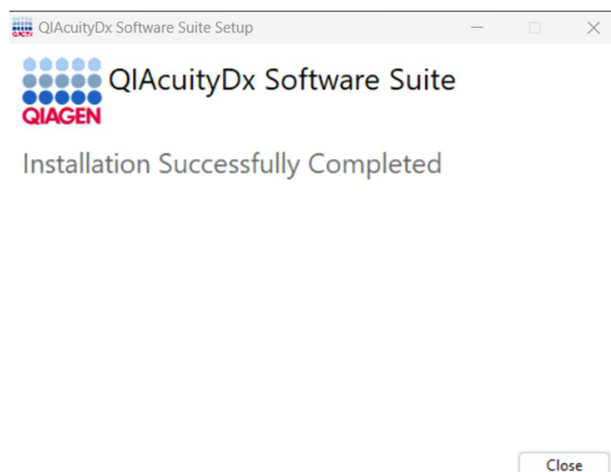
9. The Software Suite installation will start.



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

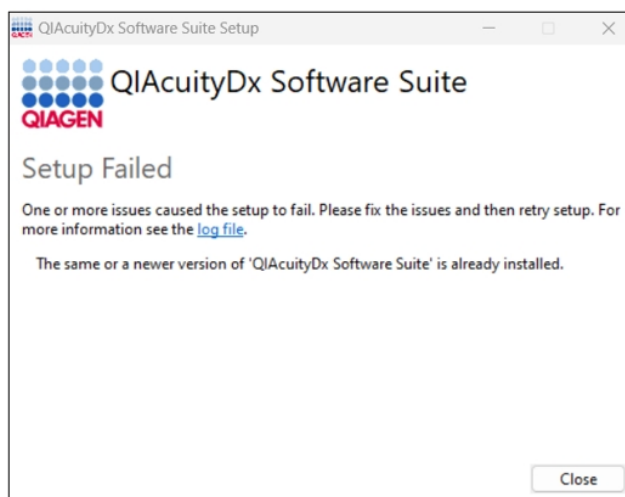


11. Once the services' configuration has finished, then the installation is complete. Click **Close**.



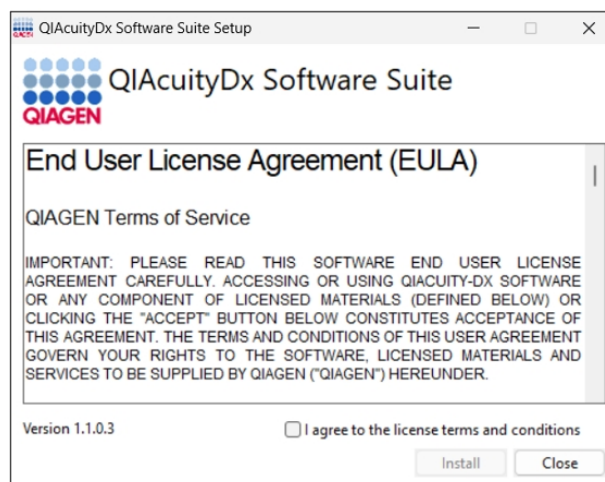
4.9.1. Upgrading the QIAcuityDx Software Suite

A new Software Suite installer is provided by the Field Service Engineer to upgrade the current installation. Downgrades are not allowed. If a version mismatch is detected, the following error is displayed:



Follow these steps to start the upgrade:

1. Ensure Software Suite is not running. Use the Stop QIAcuityDx Software Suite script.
2. Double-click the **Software Suite Installer** to start the process.
3. Check the checkbox to agree to the license terms, and click the **Install** button.



Note: The upgrading process may take several minutes.

4. Once finished, click **Close**. Use the Start QIAcuityDx Software Suite script to have the Software Suite running again.

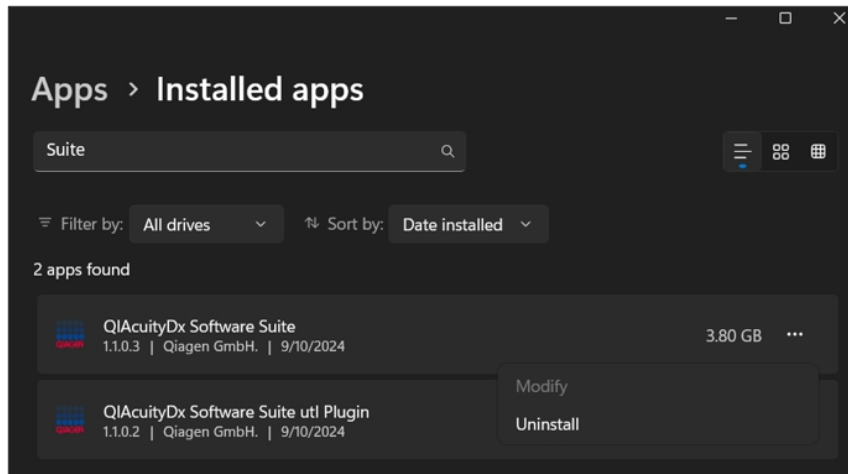
Note: The Software Suite's data are not affected by the process.

4.9.2. 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.

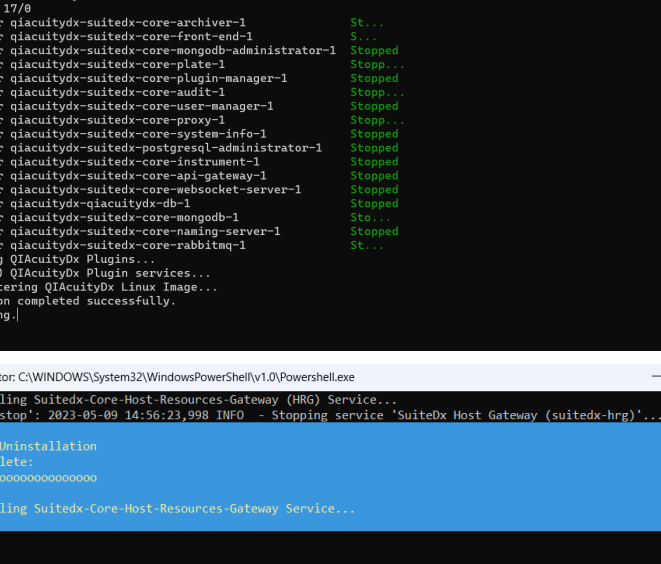
To uninstall the Software Suite, follow these steps:

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



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

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



```

C:\WINDOWS\System32\WindowsPowerShell\v1.0\Powershell.exe

[1] Stopping QIAcuityDx Core...
The operation completed successfully.
Starting docker (via systemctl): docker.service.
[+] Running 17/0
  ✓ Container qiacuitydx-suitedx-core-archiver-1          Stopped 0.0s
  ✓ Container qiacuitydx-suitedx-core-front-end-1        Stopped 0.0s
  ✓ Container qiacuitydx-suitedx-core-mongodb-administrator-1 Stopped 0.0s
  ✓ Container qiacuitydx-suitedx-core-plate-1           Stopped 0.0s
  ✓ Container qiacuitydx-suitedx-core-plugin-manager-1   Stopped 0.0s
  ✓ Container qiacuitydx-suitedx-core-audit-1           Stopped 0.0s
  ✓ Container qiacuitydx-suitedx-core-user-manager-1     Stopped 0.0s
  ✓ Container qiacuitydx-suitedx-core-proxy-1           Stopped 0.0s
  ✓ Container qiacuitydx-suitedx-core-system-info-1      Stopped 0.0s
  ✓ Container qiacuitydx-suitedx-postgresql-administrator-1 Stopped 0.0s
  ✓ Container qiacuitydx-suitedx-core-instrument-1      Stopped 0.0s
  ✓ Container qiacuitydx-suitedx-core-api-gateway-1     Stopped 0.0s
  ✓ Container qiacuitydx-suitedx-core-websocket-server-1 Stopped 0.0s
  ✓ Container qiacuitydx-qiacuitydx-db-1               Stopped 0.0s
  ✓ Container qiacuitydx-suitedx-core-mongodb-1        Stopped 0.0s
  ✓ Container qiacuitydx-suitedx-core-naming-server-1   Stopped 0.0s
  ✓ Container qiacuitydx-suitedx-core-rabbitmq-1        Stopped 0.0s
[2] Stopping QIAcuityDx Plugins...
Stopping (0) QIAcuityDx Plugin services...
[3] Unregistering QIAcuityDx Linux Image...
The operation completed successfully.
Unregistering.

Administrator: C:\WINDOWS\System32\WindowsPowerShell\v1.0\Powershell.exe

[1] Uninstalling Suitedx-Core-Host-Resources-Gateway (HRG) Service...
HRG Action 'stop': 2023-05-09 14:56:23,998 INFO - Stopping service 'SuiteDx Host Gateway (suitedx-hrg)'... 2023-05-09 14:56:23,998 INFO -

QIAcuityDx Uninstallation
20% Complete:
[oooooooooooooooooooooo]

Uninstalling Suitedx-Core-Host-Resources-Gateway Service...

```

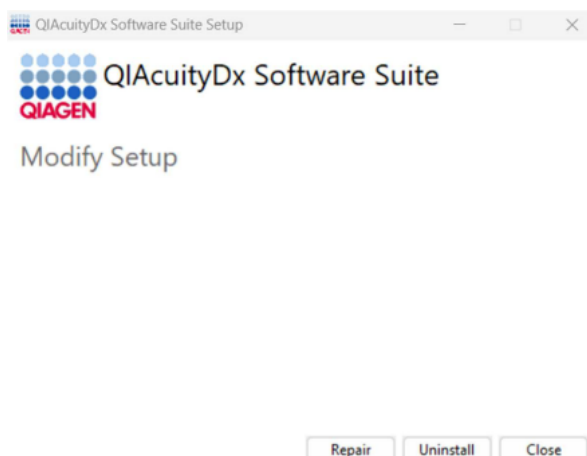
No confirmation will be needed to finish the process.

4.9.3. Repairing QIAcuityDx Software Suite installation

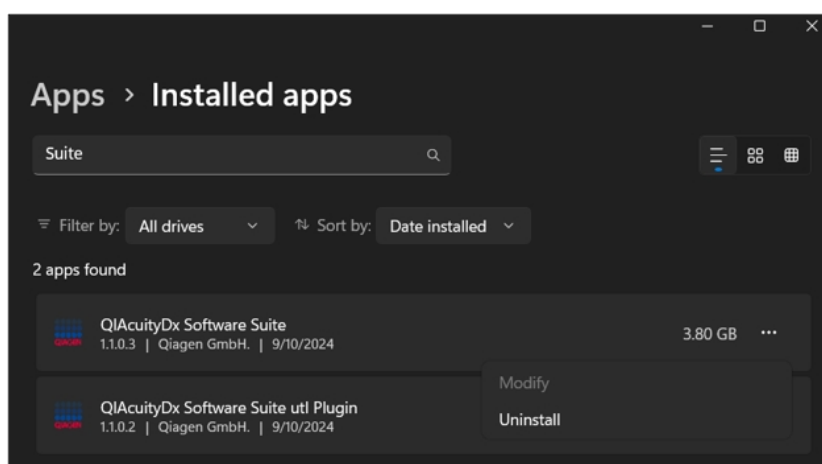
The installer's Repair feature will restore the Software Suite to a stable state with no data loss. All the installation files will be restored, and the scripts will be executed again to have the Software Suite running properly.

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.



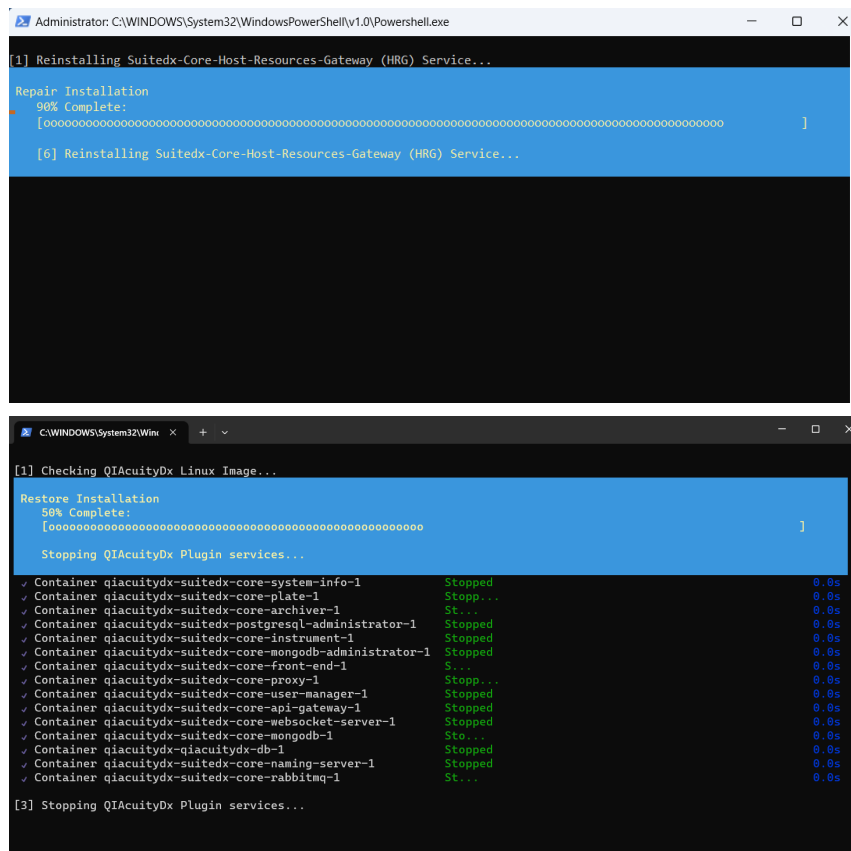
- b. Search "Suite" in the Installed apps, click the 3-dot menu on the QIAcuityDx Software Suite, and click **Uninstall** to open the installation wizard.



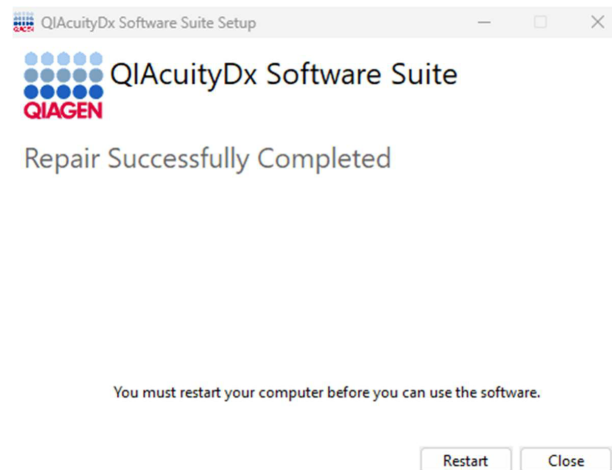
The installation wizard will be displayed.

- 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 **Close** to close the installer and finish the process.



4.9.4. Establish direct connection between QIAcuityDx instrument and QIAcuityDx Software Suite

To properly function each QIAcuityDx Four instrument shall be configured to connect to the QIAcuityDx Software Suite, two connection types are supported: a direct connection via cable and connection through an existing LAN.

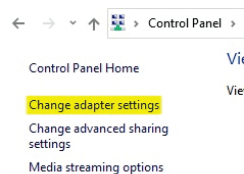
Direct cable connection

Plug in the provided Ethernet cable to the notebook Ethernet port followed by the QIAcuityDx instrument Ethernet port. This should trigger a new Ethernet adapter network to open and appear when command “ipconfig” is executed using the Command Prompt (.cmd). The QIAcuityDx Notebook should be configured to allow incoming connection on ports 8687 TCP, 8080 TCP, 44321 TCP, and 9595 UDP.

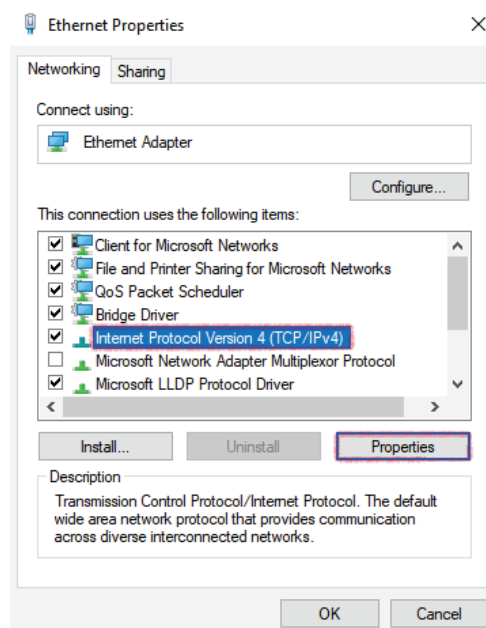
Modify IP address

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

Note: It is highly recommended to set a static IP address to avoid micro-disconnections with the QIAcuityDx instrument, even when Software Suite is not directly connected to the QIAcuityDx instrument.

7. Click **OK**, then click **Close**.

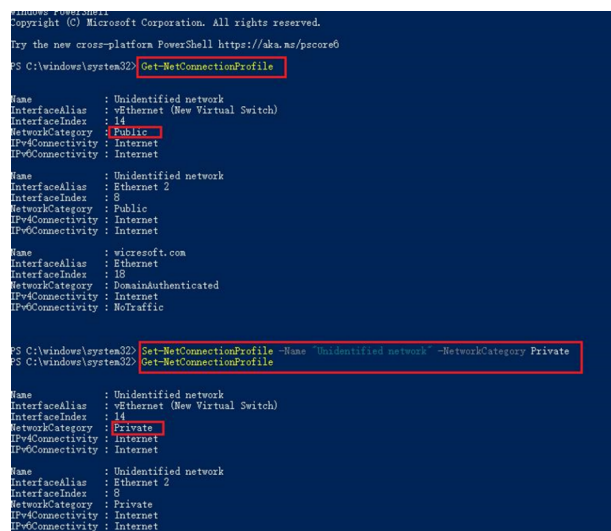
Check NetworkCategory

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.

Note: It might be “Unidentified network”.

5. To double-check that the network location was updated, run the **Get-NetConnectionProfile** command again and check the results.



```
Windows PowerShell
Copyright (C) Microsoft Corporation. All rights reserved.

Try the new cross-platform PowerShell https://aka.ms/powershell

PS C:\windows\system32> Get-NetConnectionProfile

Name                : Unidentified network
InterfaceAlias       : vEthernet (New Virtual Switch)
InterfaceIndex       : 14
NetworkCategory      : Public
IPv4Connectivity     : Internet
IPv6Connectivity     : Internet

Name                : Unidentified network
InterfaceAlias       : Ethernet 2
InterfaceIndex       : 8
NetworkCategory      : Public
IPv4Connectivity     : Internet
IPv6Connectivity     : Internet

Name                : wicresoft.com
InterfaceAlias       : Ethernet
InterfaceIndex       : 18
NetworkCategory      : DomainAuthenticated
IPv4Connectivity     : Internet
IPv6Connectivity     : NoTraffic

PS C:\windows\system32> Set-NetConnectionProfile -Name "Unidentified network" -NetworkCategory Private
PS C:\windows\system32> Get-NetConnectionProfile

Name                : Unidentified network
InterfaceAlias       : vEthernet (New Virtual Switch)
InterfaceIndex       : 14
NetworkCategory      : Private
IPv4Connectivity     : Internet
IPv6Connectivity     : Internet

Name                : Unidentified network
InterfaceAlias       : Ethernet 2
InterfaceIndex       : 8
NetworkCategory      : Private
IPv4Connectivity     : Internet
IPv6Connectivity     : Internet
```

The “NetworkCategory” field should have a different value.

Instrument configuration

The QIAcuityDx Four instrument configuration is carried out by a certified QIAGEN Field Service Specialist during the initial install, the following instructions can be used as a reference to verify or update the connectivity properties:

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, the network connection icon indicates in green (with text "CONNECTED") that the QIAcuityDx Software Suite is connected, and in red (with text "DISCONNECTED") that it is not connected.
4. Log in using a user with the "Instrument Maintenance" permission assigned.
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:

The screenshot shows the QIAcuityDx Configuration screen with the 'CONFIGURATION' tab selected. Under the 'NETWORK CONNECTION' sub-tab, the 'Automatic configuration (DHCP enabled)' toggle is turned off. Below this, there are three input fields: 'Device IP address *' with the value '192.168.1.2', 'Subnet mask *' with the value '255.255.255.0', and 'Gateway IP address *' with the value '192.168.1.1'. At the bottom of the form are 'CANCEL' and 'SAVE' buttons.

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

The screenshot shows the QIAcuityDx Configuration screen with the 'CONFIGURATION' tab selected. Under the 'SOFTWARE SUITE CONNECTION' sub-tab, there are two input fields: 'Software Suite address *' with the value '192.168.1.2' and 'Port number *' with the value '8687'. Below these fields is a 'TEST CONNECTION' button. At the bottom of the form are 'CANCEL' and 'SAVE' buttons.

- Click the **Test Connection** button. A message stating that the connection has been established successfully is displayed onscreen.
- Click the **Save** button. A pop-up window is displayed on screen requesting user to restart the QIAcuityDx instrument; after restart, the instrument will be properly connected to the specified QIAcuityDx Software Suite.

LAN connection

To establish a connection between the Software Suite and the instrument using an existing LAN infrastructure, local IT department should ensure proper configuration of the LAN to which both the QIAcuityDx Notebook and the QIAcuityDx Four instrument are connected.

Software Suite

Plug in the provided Ethernet cable to the notebook Ethernet adapter and into the Intranet Ethernet adapter. Then, ensure the following ports have been properly configured:

Port	Protocol	Direction
8687	https	IN / OUT
8080	https / http	IN / OUT
44321	https	IN / OUT
9087	https / http	IN / OUT

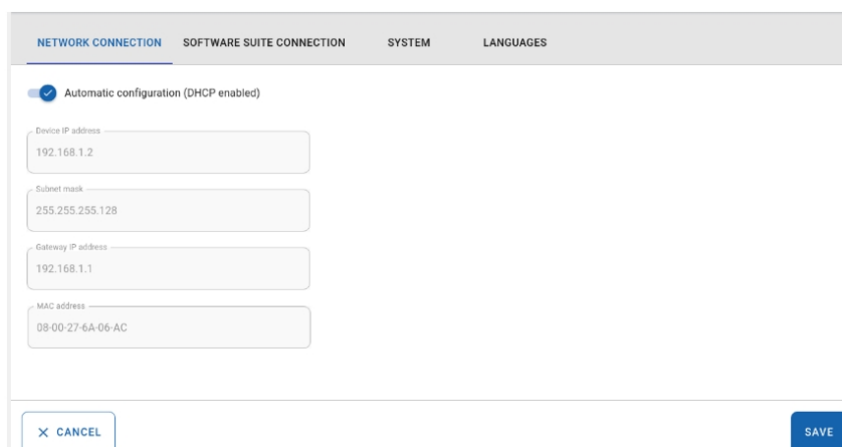
Ensure that there is a domain user with local administrator privileges to install, start, and troubleshoot, which also has permissions to read and write on the remote folder(s) planned to be used for archive and backup. This user account should not be used for routine use and should not be share credentials with other users.

Instrument configuration

The connection of the QIAcuityDx Four instrument and the provided LAN can be configured both using DHCP (automatic IP assignment) or manually by providing a static IP address; the QIAcuityDx Four instrument connectivity configuration is carried out by a certified QIAGEN Field Service Specialist during the initial setup, the following instructions can be used as a reference to verify or update the connectivity properties:

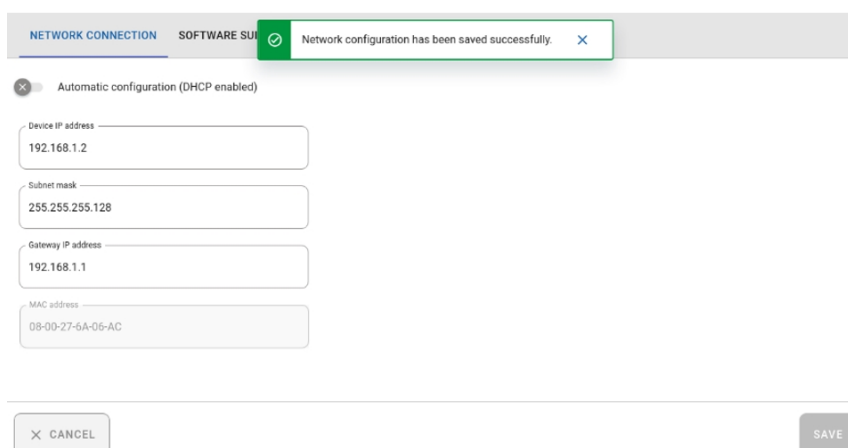
- If it is not already running, power on the instrument by pressing the power button.
- After an initial self-test, the Login screen appears.
- On the status bar, at the top, the network connection icon indicates in green (with text "CONNECTED") that the QIAcuityDx Software Suite is connected, and in red (with text "DISCONNECTED") that it is not connected.
- Log in using a user with the "Instrument Maintenance" permission assigned.
- On the QIAcuityDx instrument toolbar, tap **Configuration**.
- Select the **Ethernet** tab.

7. To use automatic network configuration on the instrument, ensure that the Automatic Configuration (DHCP Enabled) box is checked; in the GUI, the instrument physical network address (MAC address) that can be used by the local IT to troubleshoot connectivity is also visible:



The screenshot shows the 'NETWORK CONNECTION' tab in the GUI. The 'Automatic configuration (DHCP enabled)' toggle is checked. Below it, the following network parameters are displayed in input fields: Device IP address (192.168.1.2), Subnet mask (255.255.255.128), Gateway IP address (192.168.1.1), and MAC address (08-00-27-6A-06-AC). At the bottom, there are 'CANCEL' and 'SAVE' buttons.

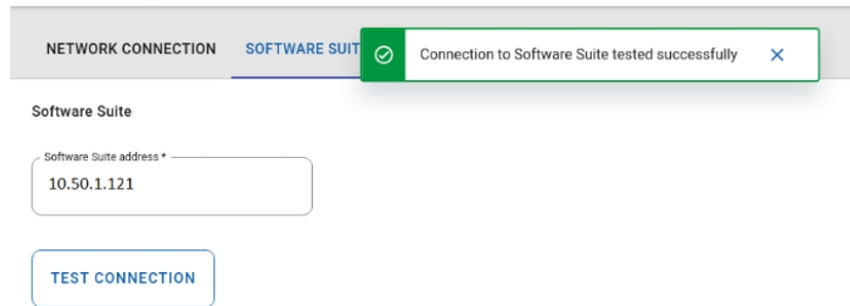
8. It is also possible to define a static IP address for the QIAcuityDx Four instrument; in case such configuration is needed, just unselect the **Automatic configuration** toggle and manually input the network parameters as the local network administrator indicates. Once the configuration is applied, click the **Save** button. See the example for manually configured network parameters below:



The screenshot shows the 'NETWORK CONNECTION' tab. The 'Automatic configuration (DHCP enabled)' toggle is now unchecked. A green success message banner at the top reads 'Network configuration has been saved successfully.' The network parameters (Device IP address: 192.168.1.2, Subnet mask: 255.255.255.128, Gateway IP address: 192.168.1.1, MAC address: 08-00-27-6A-06-AC) remain the same. The 'CANCEL' and 'SAVE' buttons are at the bottom.

9. Click the **Software Suite Connection** tab, and enter the IP address of the machine where the QIAcuityDx Software Suite is installed (in the example below, the Suite IP address is 10.50.1.121).

- Click the **Test Connection** button. A message stating that the connection has been established successfully is displayed onscreen.



- Click the **Save** button. A pop-up window is displayed on screen requesting user to restart the QIAcuityDx instrument; after restart, the instrument will be properly connected to the specified QIAcuityDx Software Suite.

4.9.5. Manually running the QIAcuityDx Software Suite

Manually starting or stopping can only be executed by a user with administrator privileges, normally a Field Service Engineer, using the Start and Stop scripts described in the following sections, available at the installation folder **C:\Program Files\Qiagen\QIAcuityDx**.

Start QIAcuityDx Software Suite

To manually initiate the Software Suite, execute the "Start-SuiteDx.ps1" script, using administrator privileges.

The script will check whether all services are installed properly and start them, including the installed plugins. In case of errors while trying to execute the script, please contact QIAGEN Technical Services.

Please note that this process can take up to several minutes, especially the first time that the Software Suite is started.

```
Administrator: Windows PowerShell
[3] Checking 'QIAIdentity service'...
Service 'QIAIdentity' has status Running

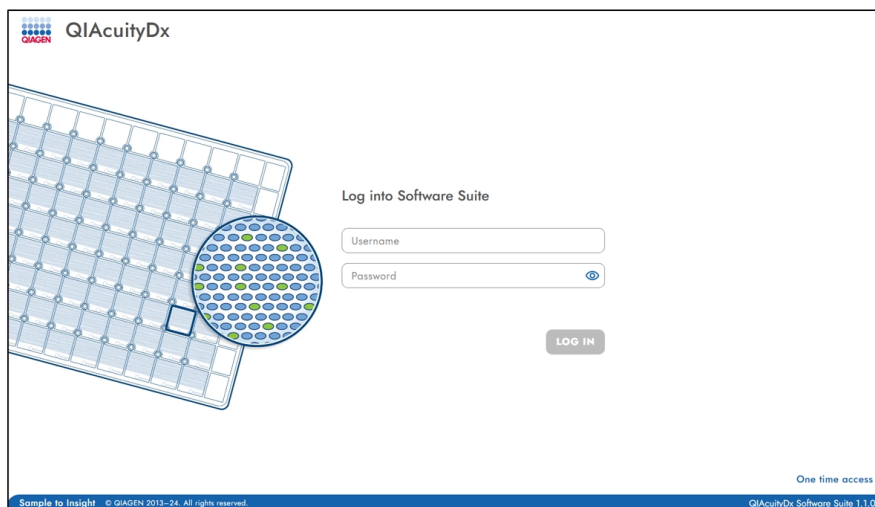
[4] Checking 'LIMS-Connector service'...
Service 'LimsConnector' has status Running

[5] Cleaning 8687 port forwarding...

[6] Setting up QIAcuityDx Environment...
The operation completed successfully.
Starting Docker: docker - WSL DNS resolution method: WSL Ethernet Adapter (IPv4 172.21.64.1)

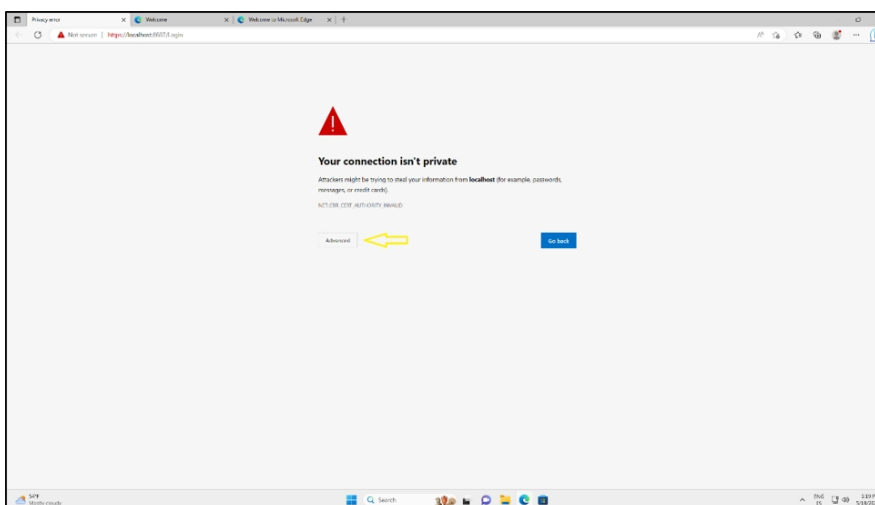
[7] Initializing QIAcuityDx Docker Containers...
- Starting Core Service: 'suitedx-postgresql-administrator'
[+] Running 2/2
✓Container qiacuitydx-db Running 0.0s
✓Container suitedx-postgresql-administrator Started 0.0s
- Starting Core Service: 'suitedx-core-mongodb-administrator'
[+] Running 2/2
✓Container suitedx-core-mongodb Running 0.0s
✓Container suitedx-core-mongodb-administrator Started 0.0s
- Starting Core Service: 'suitedx-core-proxy'
[+] Running 5/8
✓Container suitedx-core-websocket-server Running 0.0s
✓Container suitedx-core-rabbitmq Running 0.0s
✓Container suitedx-core-naming-server Running 0.0s
✓Container suitedx-core-api-gateway Running 0.0s
✓Container suitedx-core-proxy Running 0.0s
- Starting Core Service: 'suitedx-core-naming-server'
```

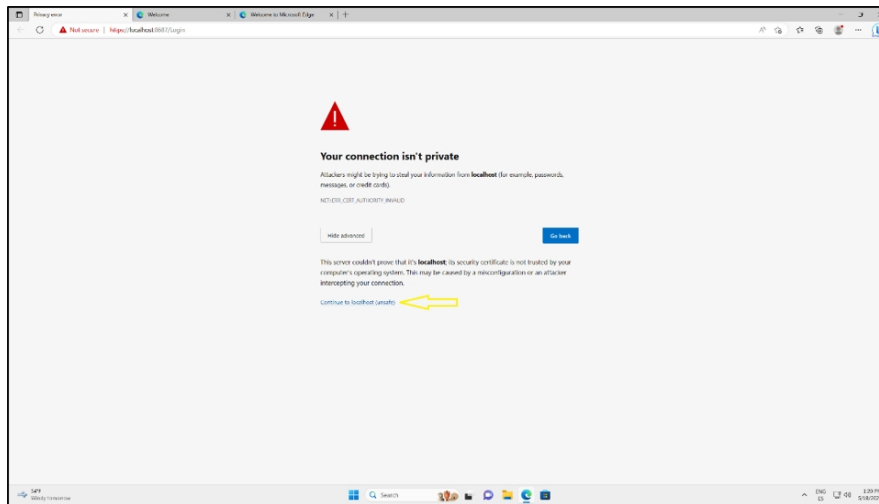
Once all Software Suite services are running, the script window will be closed, and a new tab will be opened in the default browser with the QIAcuityDx Software Suite's URL (<https://localhost:8687/>):



Note: Ensure that the chosen browser is supported.

Depending on the browser configuration, users may be asked to authorize the connection to the QIAcuityDx Software Suite:





Stop QIAcuityDx Software Suite

Run the “Stop-SuiteDx.ps1” script, using a user with administrator privileges, for manually stopping all Software Suite’s running services as well as the plugins. The shutdown implies the stop of some shared services, so installed plugins will also need to be stopped. By executing the script, all the actions will be automatically performed:

```
Administrator: Windows PowerShell
[1] Checking QIAcuityDx Linux Image...
QIAcuityDx Linux Image OK

[2] Stopping QIAcuityDx Docker Containers...
The operation completed successfully.
[+] Stopping 4/15 Docker
  ✓ Container suitedx-postgresql-administrator Stopped 0.0s
  ✓ Container qiaacuitydx-suitedx-core-front-end-1 Stopped 0.6s
  ! Container suitedx-core-instrument Stopping 1.4s
  ! Container suitedx-core-user-manager Stopping 1.4s
  ✓ Container suitedx-core-mongodb-administrator Stopped 0.0s
  ! Container suitedx-core-archiver Stopping 1.4s
  ! Container suitedx-core-audit Stopping 1.4s
  ! Container suitedx-core-plate Stopping 1.4s
  ! Container suitedx-core-plugin-manager Stopping 1.4s
  ! Container suitedx-core-reports Stopping 1.4s
  ! Container suitedx-core-system-info Stopping 1.4s
  ✓ Container suitedx-core-proxy Stopped 0.7s
  ! Container suitedx-core-lims-proxy Stopping 1.4s
  ! Container suitedx-core-websocket-server Stopping 0.7s
  ! Container suitedx-core-api-gateway Stopping 0.7s
```

In case of errors while trying to execute the script, please contact QIAGEN Technical Services.

4.9.6. Configure the QIAcuityDx Software Suite automatic startup

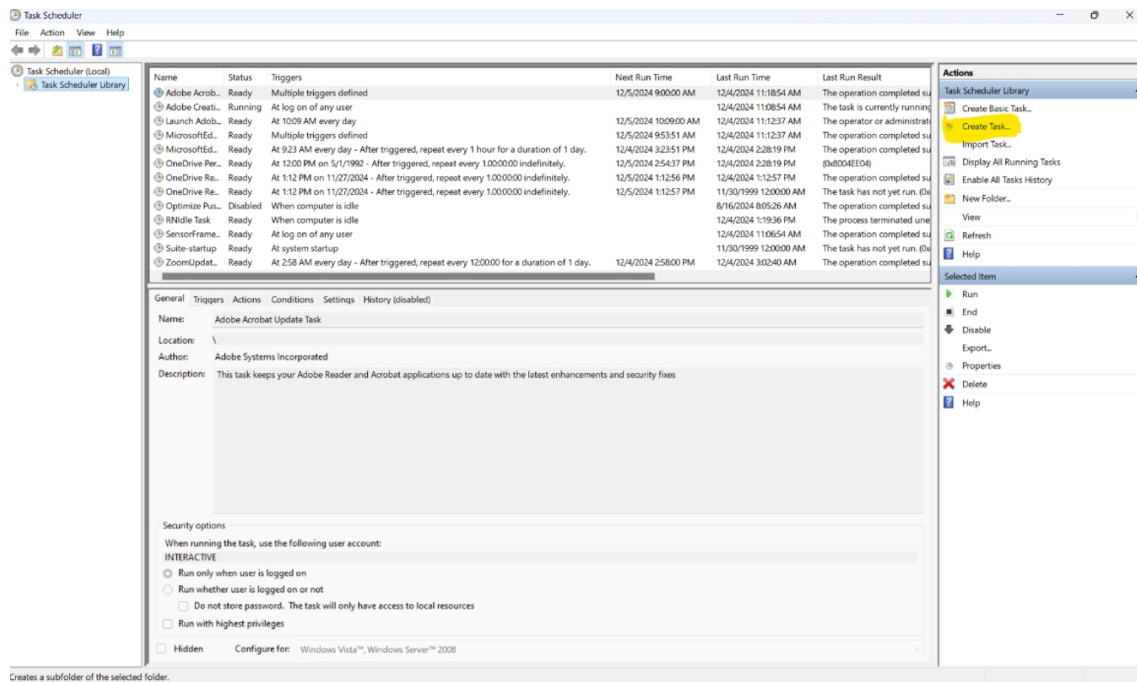
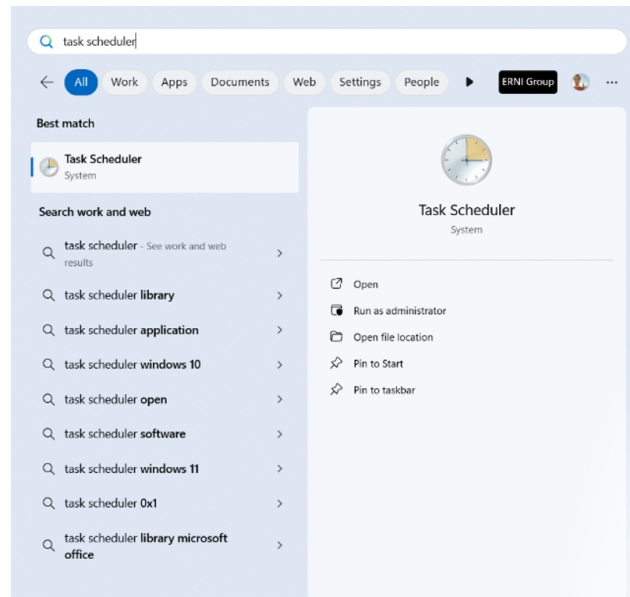
Automatic start configuration must be performed by a user with administrator privileges. This feature must be configured after initial installation of QIAcuityDx Software Suite. After configuration, it is important to make sure the Software Suite is starting properly by following the steps in section “Configure the QIAcuityDx Software Suite automatic startup” section.

This action will force the QIAcuityDx Software Suite to start whenever Windows is started without any user interaction.

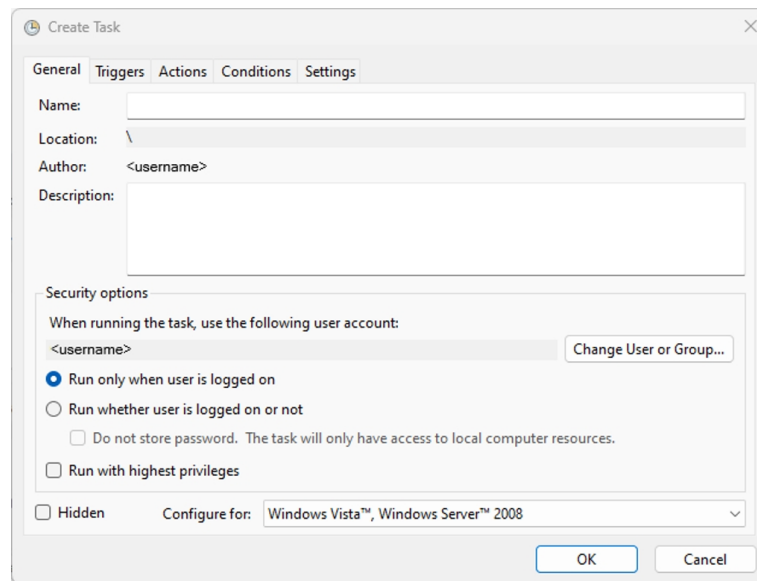
After Windows start has been triggered, QIAcuityDx Software Suite can take between 7 and 15 minutes to start. Once the start process has finished. The Software Suite can be accessed on a browser with URL (https://<<SERVER_IP>>:8687/).

Configure the Task Scheduler manually

Open the Task Scheduler by pressing the Windows key and searching for Task Scheduler.

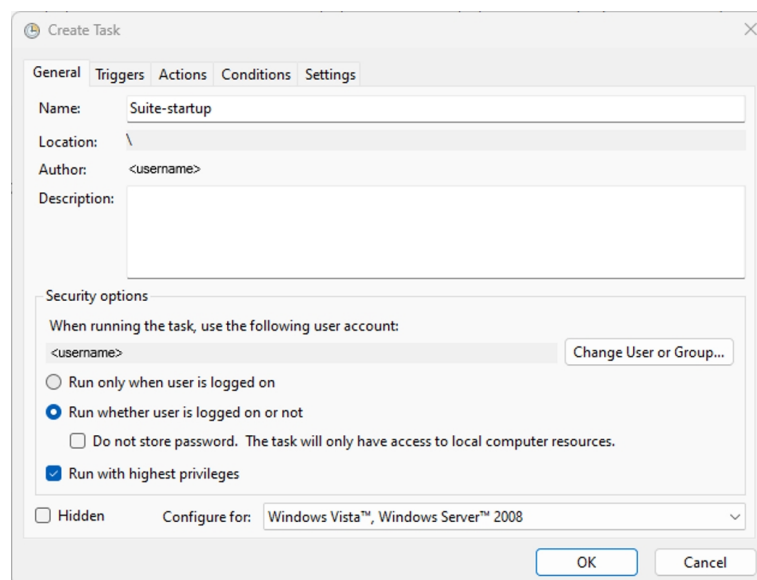


In the **Actions/Task Scheduler Library** menu , click **Create Task**.



In the **General** tab, set the Name to "Suite-startup". Under **General** tab's Security options, set the following:

- When running the task, use the following user account: <Select the user that installed Software Suite>.
- Run whether user is logged or not: true
- Run with highest privileges: true



In the **Triggers** tab, click the **New** button then choose to begin the task **At Startup**.

New Trigger [X]

Begin the task: At startup

Settings

No additional settings required.

Advanced settings

☐ Delay task for: 15 minutes

☐ Repeat task every: 1 hour for a duration of: 1 day

☐ Stop all running tasks at end of repetition duration

☐ Stop task if it runs longer than: 1 hour

☐ Activate: 12/ 4/2024 2:52:02 PM ☐ Synchronize across time zones

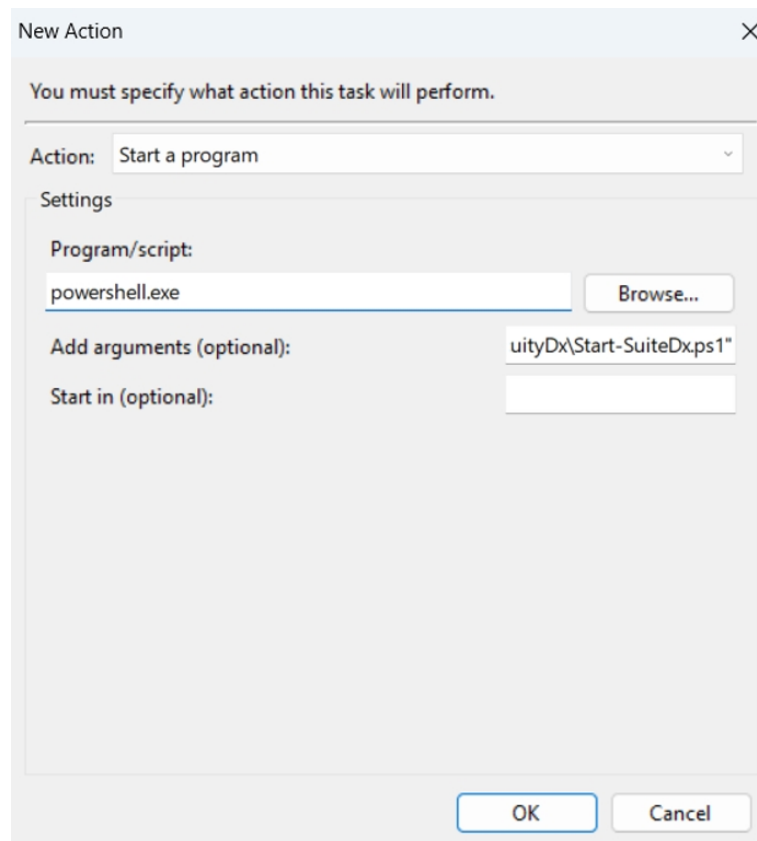
☐ Expire: 12/ 4/2025 2:52:02 PM ☐ Synchronize across time zones

☒ Enabled

OK Cancel

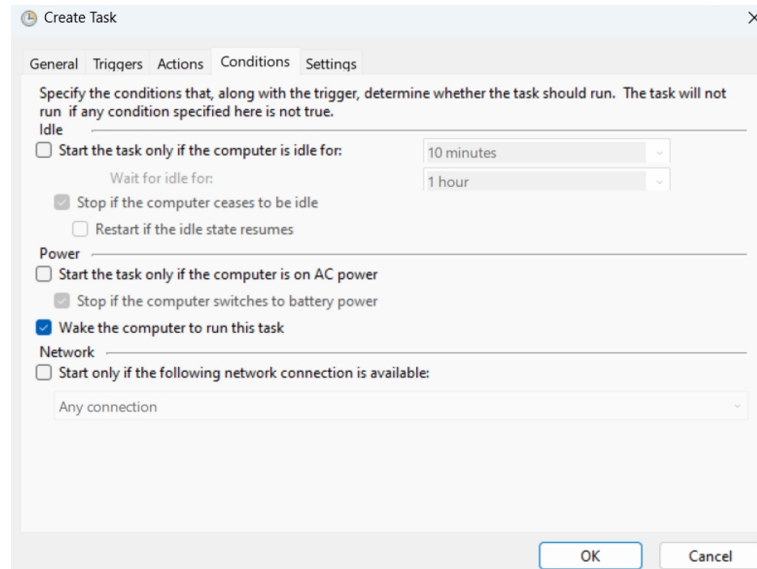
In the **Actions** tab, click the **New** button then set the following:

- Action: **Start a program**
- Program/script: **powershell.exe**
- Add arguments: **-NoExit -File c:\Program Files\Qiagen\QIAcuityDx\Start-SuiteDx.ps1**



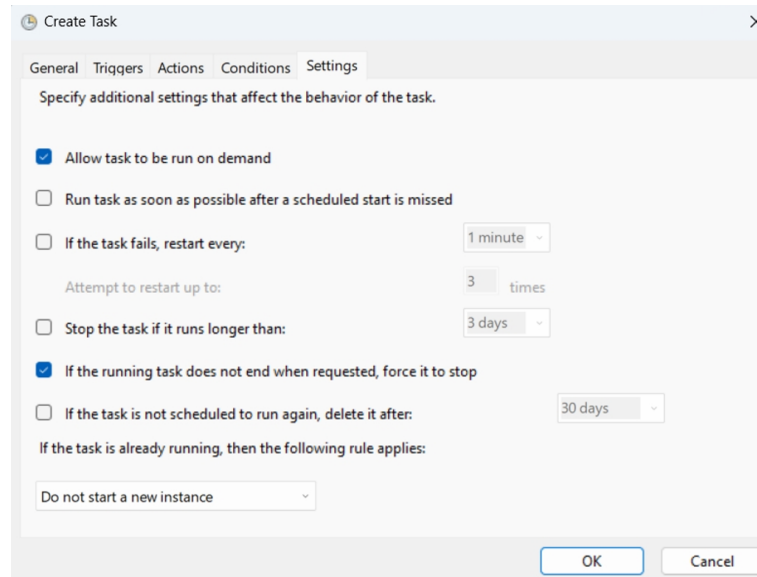
Under the Power section of the **Conditions** tab, following:

- Start the task only if the computer is on AC power: false
- Wake the computer to run this task: true

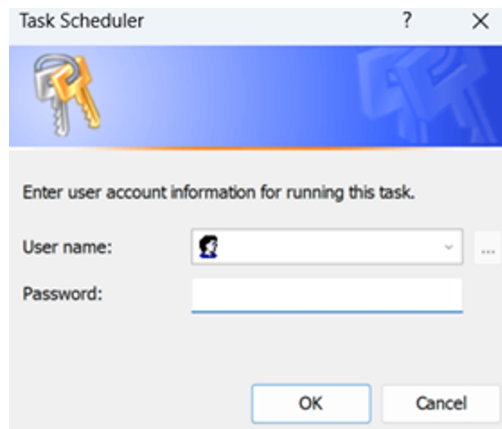


In the **Settings** tab, set the following:

- Allow task to be run on demand: true
- Stop the task if it runs longer than: false
- If the running task does not end when requested, force it to stop: true



Click **OK** to create the task, and enter the password.



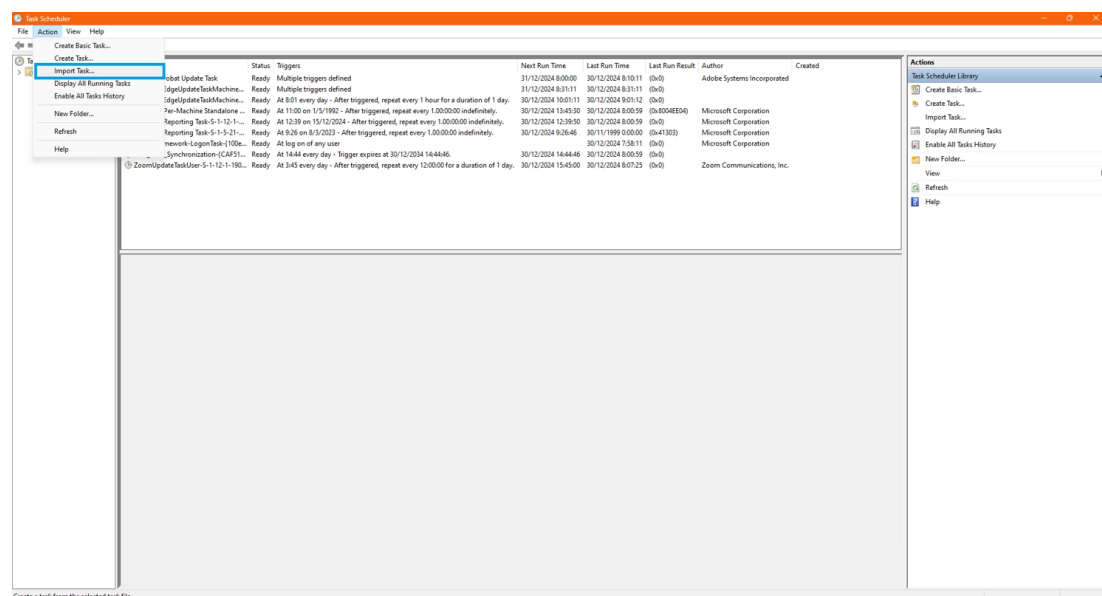
A new task is displayed in the Task Scheduler Library list.

Name	Status	Triggers	Next Run Time	Last Run Time	Last Run Result	Author	Created
Adobe Acrobat Update Task	Ready	Multiple triggers defined	31/12/2024 8:00:00	30/12/2024 8:10:11	(0x0)	Adobe Systems Incorporated	
MicrosoftEdgeUpdateTaskMachine...	Ready	Multiple triggers defined	31/12/2024 8:31:11	30/12/2024 8:31:11	(0x0)		
MicrosoftEdgeUpdateTaskMachine...	Ready	At 8:01 every day - After triggered, repeat every 1 hour for a duration of 1 day.	30/12/2024 10:01:11	30/12/2024 9:01:12	(0x0)		
OneDrive Per-Machine Standalone...	Ready	At 11:00 on 1/5/1992 - After triggered, repeat every 1.00:00:00 indefinitely.	30/12/2024 13:45:30	30/12/2024 8:00:59	(0x8004EE04)	Microsoft Corporation	
OneDrive Reporting Task-S-1-12-1-...	Ready	At 12:39 on 15/12/2024 - After triggered, repeat every 1.00:00:00 indefinitely.	30/12/2024 12:39:50	30/12/2024 8:00:59	(0x0)	Microsoft Corporation	
OneDrive Reporting Task-S-1-5-21-...	Ready	At 9:26 on 8/3/2023 - After triggered, repeat every 1.00:00:00 indefinitely.	30/12/2024 9:26:46	30/11/1999 0:00:00	(0x41303)	Microsoft Corporation	
SensorFramework-LogonTask-100e...	Ready	At log on of any user		30/12/2024 7:58:11	(0x0)	Microsoft Corporation	
Suite-startup	Ready			30/11/1999 0:00:00	(0x41303)		30/12...
User_Feed_Synchronization-[CAF51...	Ready	At 14:44 every day - Trigger expires at 30/12/2024 14:44:46.	30/12/2024 14:44:46	30/12/2024 8:00:59	(0x0)		
ZoomUpdateTaskUser-S-1-12-1-190...	Ready	At 3:45 every day - After triggered, repeat every 12:00:00 for a duration of 1 day.	30/12/2024 15:45:00	30/12/2024 8:07:25	(0x0)	Zoom Communications, Inc.	

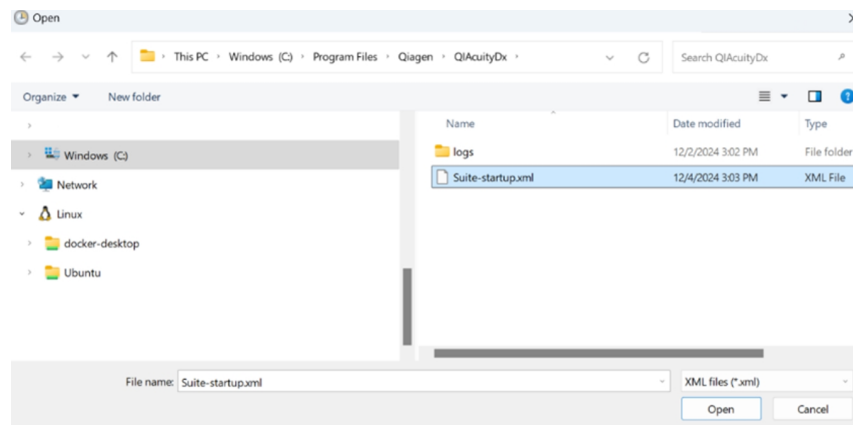
Import the configuration

In case the XML file needs to configure the Task Scheduler, proceed with the following process.

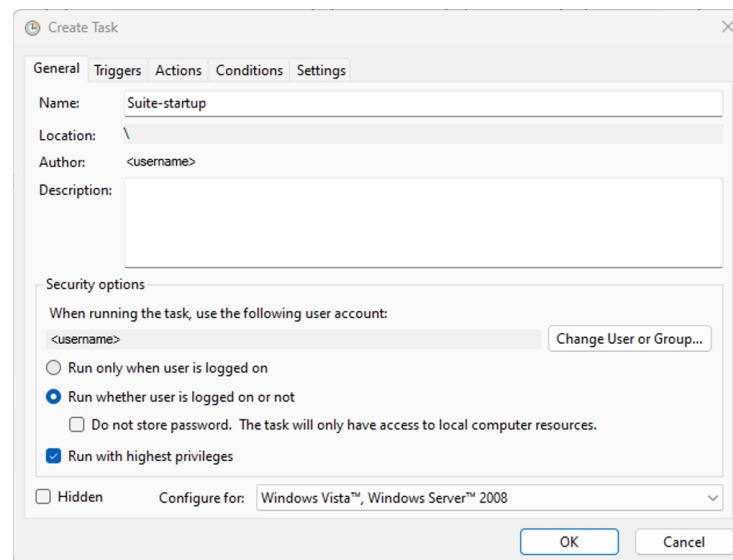
1. Open the Task Scheduler as described in the previous section.
2. Right-click on **Task Scheduler Library** on the top-left menu; select the **Import Task...** option.



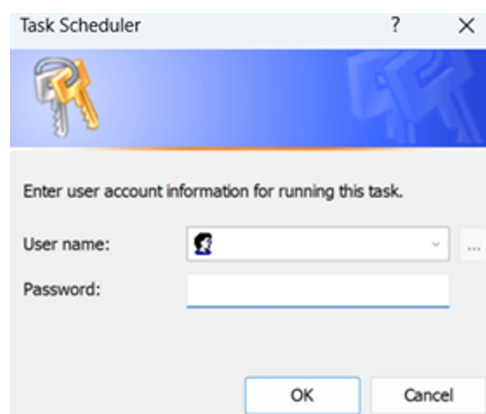
3. Select the XML file location, and click **Open**.



4. Click **OK** to create the task.

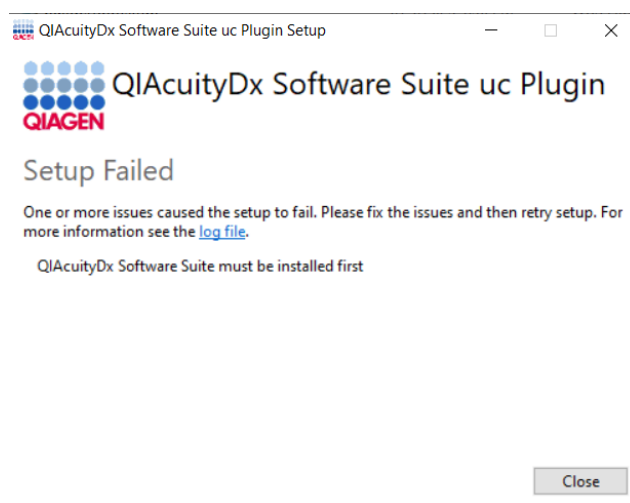


5. Enter the password, and click **OK**.



4.10. Installing the QIAcuityDx Software Assay Plugin

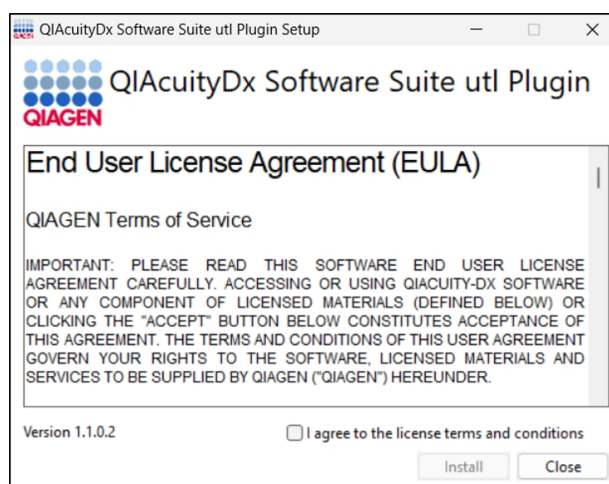
The Software Suite must be installed in the same environment (LAN) / Notebook where the QIAcuityDx Software Assay Plugin will be installed. Failure to do this will result in the following error message:



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

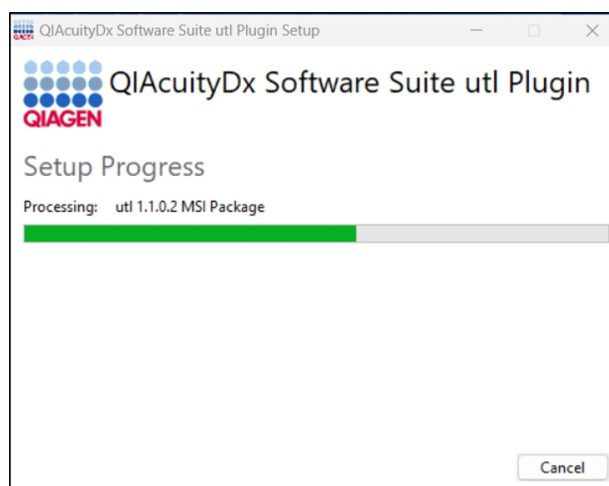
Note: The QIAcuityDx Software Assay Plugin installer(s) will be provided by a field service engineer.

1. Ensure that all the instructions described in Section 4.9 have been followed and that the Software Suite is currently running (automatically started when the notebook is turned on).
2. Double-click the plugin installer file to start the installation process.
3. The QIAcuityDx Software Assay Plugin License Agreement will be displayed. Check the checkbox and click the **Install** button.

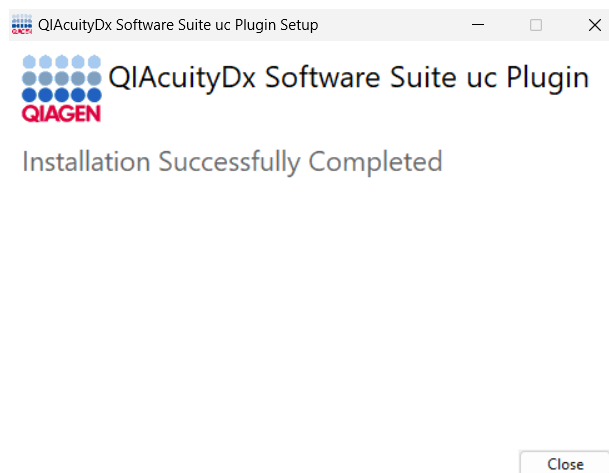


4. In case a prompt requesting Administrator rights is displayed, grant Administrator permissions to continue.

5. The QIAcuityDx Software Assay Plugin installation will begin.



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



Once completed, it may take a minute before the installed Plugin can be selected in QIAcuityDx Software Suite to create new plates.

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



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]`.

These files will be detected and used by the QIAcuityDx Software Suite to start and stop installed plugins.

When turning the notebook on, the QIAcuityDx Software Suite is automatically started, alongside the installed QIAcuityDx Software Assay Plugin(s). When the Software Suite starts, the notebook checks whether all services related to the Software Suite and Assay Plugins have been installed properly and those services are started.

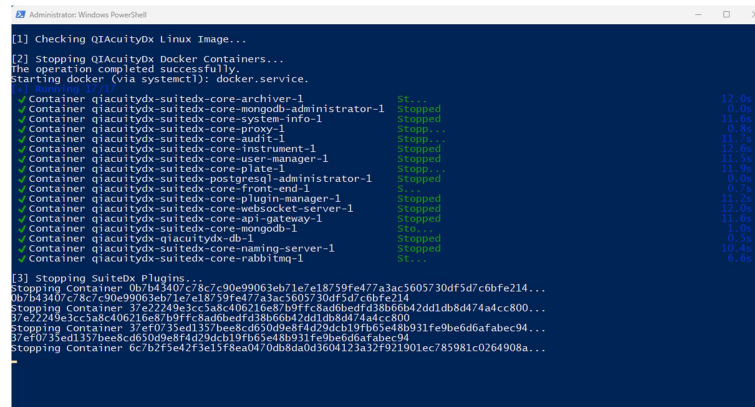
```
Administrator: Windows PowerShell
[1] Checking QIAcuityDx Linux Image...
[2] Checking 'suitedx-core-host-resources service'...
[3] Setting up QIAcuityDx Environment...
[4] Initializing QIAcuityDx Docker Containers...
The operation completed successfully.
Starting docker (via systemctl): docker.service,
Starting Core Service 'suitedx-postgresql-administrator'...
Running 2/0
Container qiacuitydx-qiacuitydx-db-1 Started 0.4s
Container qiacuitydx-suitedx-postgresql-administrator-1 Started 0.7s
Starting Core Service 'suitedx-core-mongodb-administrator'...
Running 2/0
Container qiacuitydx-suitedx-core-mongodb-1 Started 0.6s
Container qiacuitydx-suitedx-core-mongodb-administrator-1 Started 0.9s
Starting Core Service 'suitedx-core-proxy'...
Running 2/0
Container qiacuitydx-suitedx-core-rabbitmq-1 Started 0.5s
Container qiacuitydx-suitedx-core-naming-server-1 Running 0.0s
Container qiacuitydx-suitedx-core-api-gateway-1 Running 0.0s
Container qiacuitydx-suitedx-core-websocket-server-1 Running 0.0s
Container qiacuitydx-suitedx-core-proxy-1 Started 0.9s
Starting Core Service 'suitedx-core-naming-server'...
Running 2/0
Container qiacuitydx-suitedx-core-rabbitmq-1 Running 0.0s
Container qiacuitydx-suitedx-core-naming-server-1 Running 0.0s
Starting Core Service 'suitedx-core-api-gateway'...
Running 3/0
Container qiacuitydx-suitedx-core-rabbitmq-1 Running 0.0s
Container qiacuitydx-suitedx-core-naming-server-1 Running 0.0s
Container qiacuitydx-suitedx-core-api-gateway-1 Running 0.0s
Starting Core Service 'qiacuitydx-db'...
Running 1/0
Container qiacuitydx-qiacuitydx-db-1 Running 0.0s
Starting Core Service 'suitedx-core-mongodb'...
Running 1/0
Container qiacuitydx-suitedx-core-mongodb-1 Running 0.0s
Starting Core Service 'suitedx-core-rabbitmq'...
Running 1/0
Container qiacuitydx-suitedx-core-rabbitmq-1 Running 0.0s
Starting Core Service 'suitedx-core-front-end'...
Running 1/0
Container qiacuitydx-suitedx-core-front-end-1 Started 0.5s
Starting Core Service 'suitedx-core-audit'...
```

Installed plugins can be selected in the **Assay** drop-down menu at Plate Creation View for the plugin's related mode:

The screenshot shows the 'New plate' form in the QIAcuityDx application. The form is divided into several sections: 'General data', 'dPCR Parameters', 'Reaction mixes', 'Samples & Controls', and 'Plate layout'. The 'Assay' dropdown menu is set to 'Utility Mode (1.1.0.2)'. The 'Plate name' field is empty. The 'Plate barcode' field is empty. The 'Plate type' dropdown menu is set to 'admin1 admin1'. The 'Ownership' dropdown menu is set to 'admin1 admin1'. The 'Labels' field is empty. The 'Description' field is empty. The 'NEXT' button is visible at the bottom right of the form.

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 is automatically stopped when the notebook is turned off. 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:



```
[1] Checking QIAcuityDx Linux Image...
[2] Stopping QIAcuityDx Docker Containers...
The operation completed successfully.
Starting docker (via systemctl): docker.service.
Container qiacuitydx-suitedx-core-archiver-1 Stopped 12.0s
Container qiacuitydx-suitedx-core-mongodb-administrator-1 Stopped 9.0s
Container qiacuitydx-suitedx-core-system-info-1 Stopped 11.4s
Container qiacuitydx-suitedx-core-proxy-1 Stopped 0.5s
Container qiacuitydx-suitedx-core-audit-1 Stopped 11.2s
Container qiacuitydx-suitedx-core-instrument-1 Stopped 12.6s
Container qiacuitydx-suitedx-core-user-manager-1 Stopped 11.5s
Container qiacuitydx-suitedx-core-plate-1 Stopped 11.9s
Container qiacuitydx-suitedx-postgresql-administrator-1 Stopped 0.0s
Container qiacuitydx-suitedx-core-front-end-1 Stopped 9.2s
Container qiacuitydx-suitedx-core-plugin-manager-1 Stopped 11.2s
Container qiacuitydx-suitedx-core-websocket-server-1 Stopped 12.4s
Container qiacuitydx-suitedx-core-api-gateway-1 Stopped 11.8s
Container qiacuitydx-suitedx-core-mongodb-1 Stopped 1.0s
Container qiacuitydx-qiacuitydx-db-1 Stopped 0.2s
Container qiacuitydx-suitedx-core-naming-server-1 Stopped 10.4s
Container qiacuitydx-suitedx-core-rabbitmq-1 Stopped 6.6s
[3] Stopping SuiteDx Plugins...
Stopping Container 0b7b43d07c78c790e99063eb71c7e18759fe477a3ac5605730df5d7c6bfe214...
0b7b43d07c78c790e99063eb71c7e18759fe477a3ac5605730df5d7c6bfe214
Stopping Container 37e2249e3cc5a8c406216e87b9ffc8ad6bedfd38b66b42dd1db8d474a4cc800...
37e2249e3cc5a8c406216e87b9ffc8ad6bedfd38b66b42dd1db8d474a4cc800
Stopping Container 37ef0735ed1357bee8cd650d9e8f4d29dcb19fb65e48b931fe9be6d6afabec94...
37ef0735ed1357bee8cd650d9e8f4d29dcb19fb65e48b931fe9be6d6afabec94
Stopping Container 6c7b2f9e47f3c15f8ea0470db8da0a3604123a32f921901ec785981c0264908a...
```

4.10.3. Upgrading the QIAcuityDx Software Assay Plugin

Software Suite Assay Plugins are not upgraded. Each version of the same plugin is considered a different product.

When having more than one plugin installed, depending on the plugin's mode, the usability may be different:

- **IVD Mode:** The newest plugin version is selected by default as Assay for new Plates. When installing a newer plugin version, existing plugins become unelectable and enter in read-only mode. Every plate created with older plugin versions remains accessible, but no new plates can be created with older plugin versions.
- **Utility Mode:** There are no restrictions. All installed plugins for Utility Mode can be selected as Assay regardless of the version when creating a plate.

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.

Note: If ambient temperature is below 17°C (63°F), an equilibration phase of 30–60 minutes might be required.

5. 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.

4.11.3. QIAcuityDx Four instrument standard log in

Before logging into the QIAcuityDx Four instrument, as described in the section above, user shall be created in the QIAcuityDx Software Suite instance to which the instrument shall be properly connected; the same credentials used to login in the Software Suite can be used on the instrument. To login, simply enter the login and password information in the instrument login view:

Users that have logged in the QIAcuityDx Four instrument will be able to login even if the Software Suite is temporally disconnected (user credentials are cached for 24 hours).

4.11.4. QIAcuityDx Four instrument one-time access log in

To login into the instrument when it is offline (e.g., the Suite IP address was changed and the instrument can no longer connect to it), the one time access procedure can be used following the steps below:

1. From the QIAcuityDx Four instrument login page, click on the **ONE TIME ACCESS** link in the bottom right corner.
2. The one-time access page is loaded showing the Device serial number and the Control code (an example below).

QIAcuityDx CSW 0.0.0.0 CONNECTED DISK 09/01/2024 15:49

QIAGEN

One Time Access log in

Device serial number
QiaCuity-FLASH-001D

Control code
584606

Security code

Call QIAGEN Technical Services to receive security code

← BACK LOG IN

Sample to Insight © QIAGEN 2013–2024. All rights reserved.

3. Contact the QIAGEN Technical Services indicating the need for the One Time Access **Security Code** and provide them with the Serial Number and the Control code shown in the One Time Access login page.
4. Once obtained the code, insert it into the Security Code field and click the **Log In** button (the code will be valid only for one login).
5. Update the Network or Suite Connection configuration as described in Section 4.9.

Add on => automated startup for hiding admin privilege

prerequisites for this

Procedure to set task scheduler

(White paper similar need to be added)

Add on => backup via scheduler (not yet tested)

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)
QIAcuityDx 26k 24-well Nanoplate Kit	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 26k 24-well Nanoplate Kit (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 plate types.

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 type is mandatory 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 plate types.

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 plate types.

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 plate types.

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, set up in a standard PCR pre-plate or microtubes is recommended. 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 30 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.

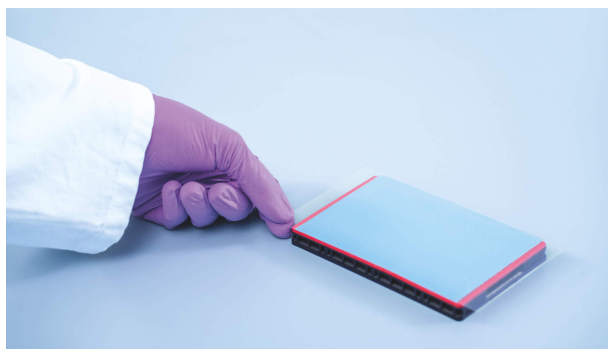
3. Apply the Top seal that comes with the nanoplates as follows to ensure good filling of the wells and to prevent evaporation and contamination:

The top nanoplate seal consists of 3 layers, the Top seal, and 2 protective foils (top and bottom). 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 Top 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 Top 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 Top 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 Top seal are turned down and well attached to the plate frame and that the barcode is not covered. Do not apply pressure to the Top 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.

When reimaging a plate, the total of overall dPCR steps cannot be greater than 8. 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.

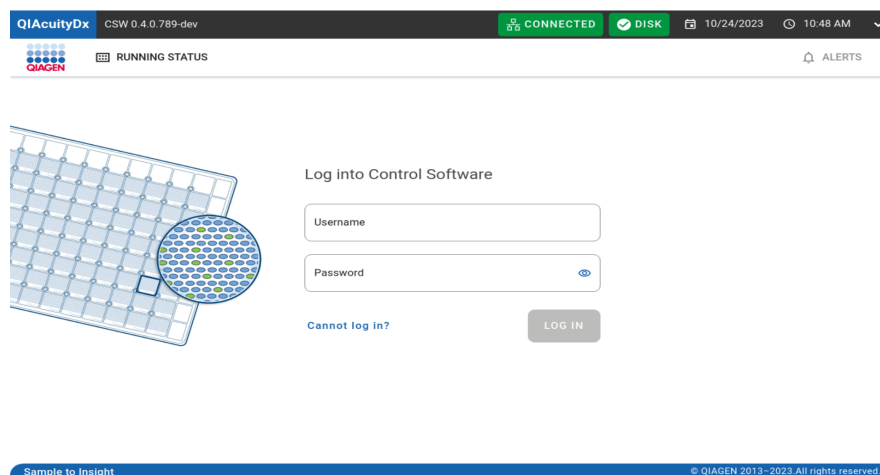
Note: The fluorescent intensity and Top seal integrity can be affected for plates that are stored incorrectly, which could lead to contamination of the laboratory. Store processed plates according to these guidelines or dispose of them properly after processing.

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.

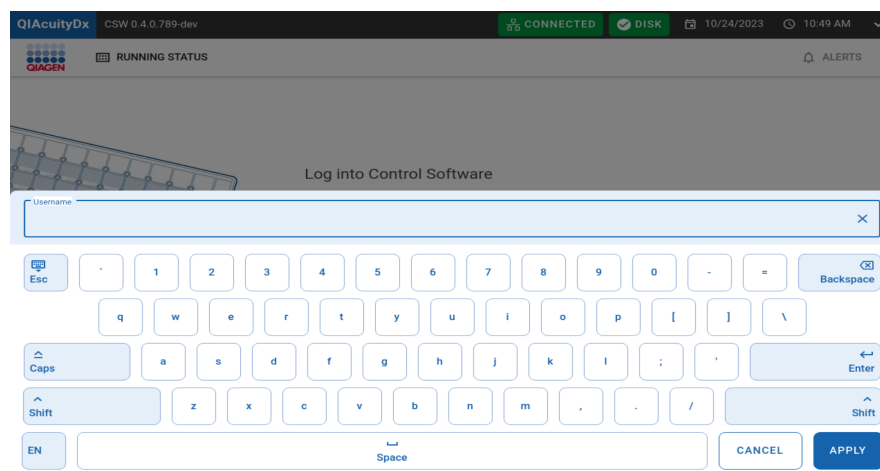
5.8. Instrument set-up

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.

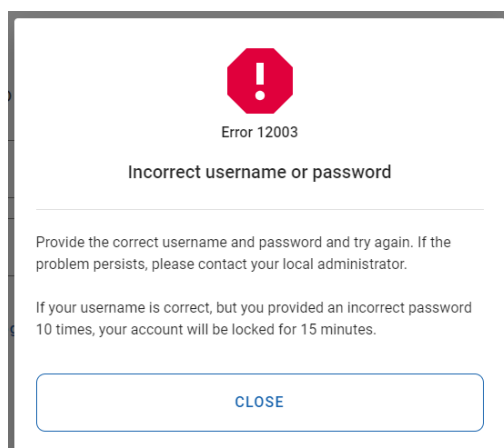


Log into the instrument. The QIAcuityDx is operated through a touchscreen pad.

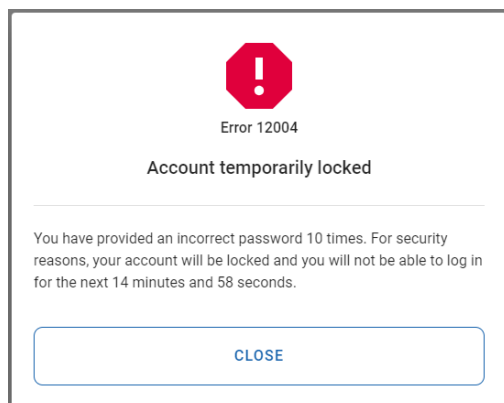


Enter your credentials in the Username and Password fields.

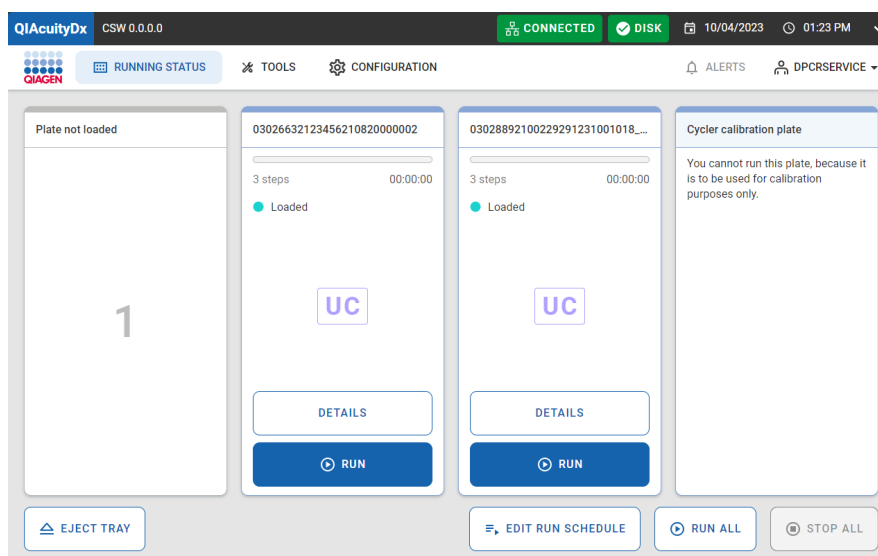
If the user enters the wrong login or password, they should receive information about incorrect login or password.



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.



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.

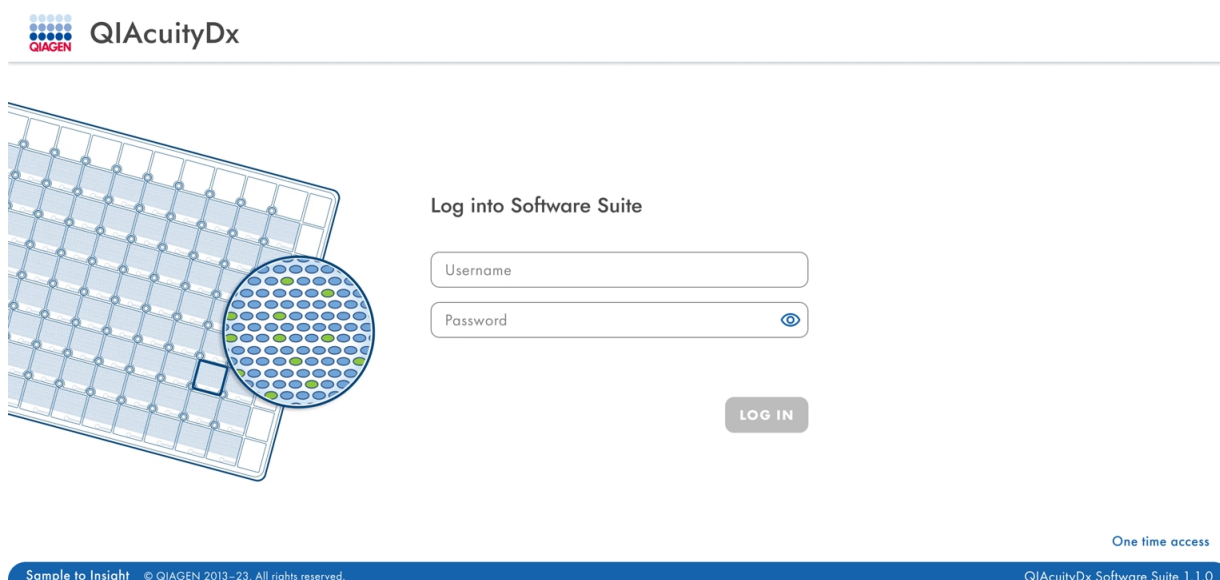
5.9. QIAcuityDx Software Suite set-up

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, Mozilla Firefox, or Microsoft Edge.
2. Type <https://<suiteServerIPAddress>:8687> (e.g., <https://10.99.240.62:8687>) into the address bar.

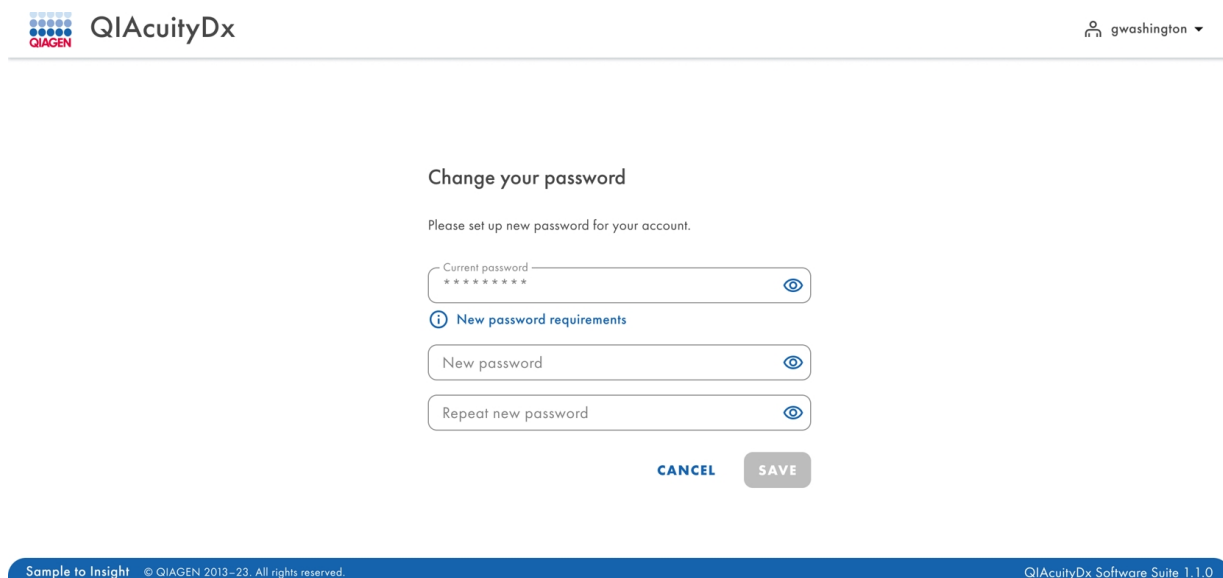
Upon accessing the Software Suite, a security warning may be shown. Follow the prompt to proceed to website.

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.

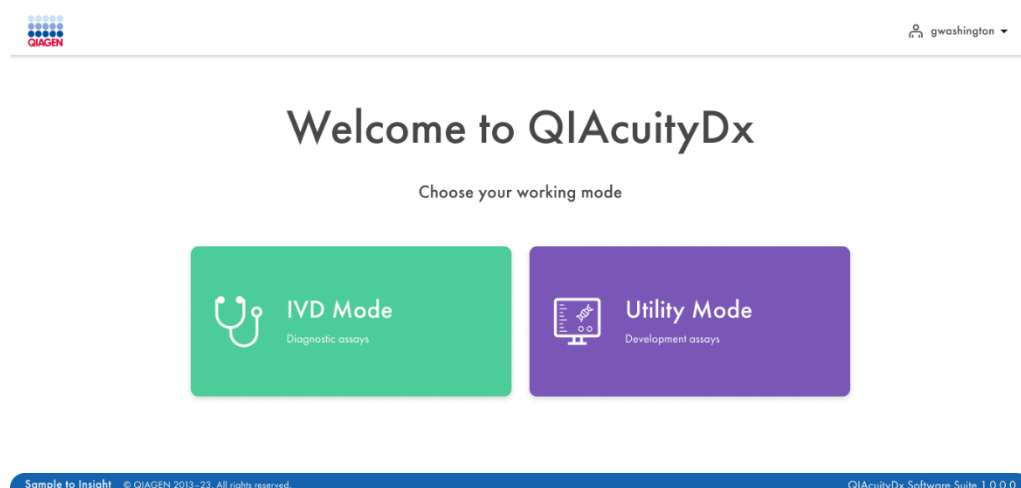
5. Upon the first login, it is required to change the provided password:



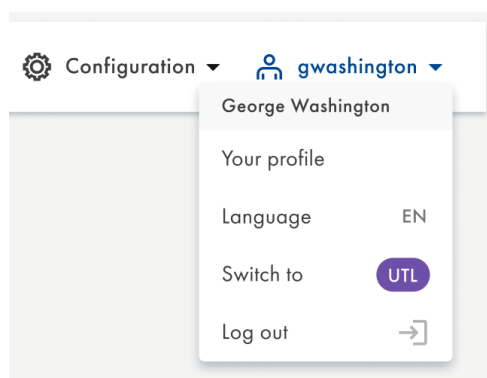
The screenshot shows the QIAcuityDx login interface. At the top left is the QIAcuityDx logo with the QIAGEN logo below it. At the top right is the user name 'gwashington' with a dropdown arrow. The main heading is 'Change your password'. Below it is the instruction 'Please set up new password for your account.' There are three password input fields: 'Current password' (masked with asterisks), 'New password', and 'Repeat new password'. Each field has an eye icon to toggle visibility. Between the first and second fields is a link 'New password requirements' with an information icon. At the bottom are 'CANCEL' and 'SAVE' buttons. A blue footer bar contains 'Sample to Insight © QIAGEN 2013–23. All rights reserved.' on the left and 'QIAcuityDx Software Suite 1.1.0' on the right.

Note: The Change your password screen is also displayed whenever the password expires.

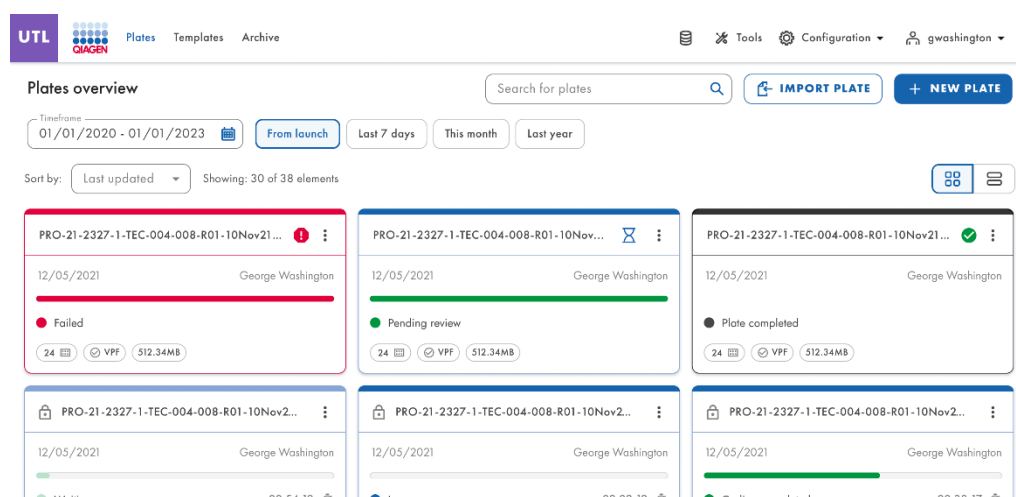
6. The mode should then be selected. If only the Utility Mode plugin has been installed, it should be **Utility Mode**:



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.



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



8. The Software Suite should be accessible via any PC/notebook/tablet that is connected to the internet.
9. 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 from the **Your profile** menu. Passwords expire after 90 days; if they are not changed before their expiration, the Software Suite triggers the password change as in after the first log in.

The screenshot shows the 'Your profile' page in the IVD software suite. The page has a header with the IVD logo, 'Plates' and 'Archive' tabs, and a user menu for 'g.washington'. The main content area is titled 'Your profile' and contains two sections: 'User information' and 'Roles'. The 'User information' section has input fields for 'Name' (George) and 'Surname' (Washington). The 'Roles' section lists 'IVD Mode - Operator' and 'Utility Mode - Operator'. Below these is the 'Change password' section, which includes a 'New password requirements' tooltip, a 'Your current password' field, a 'New password' field, and a 'Repeat password' field. At the bottom are 'CANCEL' and 'SAVE' buttons.

- 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 (8–100 characters, contain at least one upper case letter, at least one lower case letter, contain at least one number, and at least one symbol [- ! \$ ^ & * () _ + | ~ = ` { } " ; < > ? . , / # ' : \ [] @]).
- The user must reconfirm their new password.
- Rules of the current password policy are displayed upon hovering over “New password requirements”.

This screenshot is similar to the previous one, but it highlights the 'New password requirements' tooltip. The tooltip lists the following requirements: 8 - 100 characters, at least one upper case letter, at least one lower case letter, one number, and one symbol from the set [- ! \$ ^ & * () _ + | ~ = ` { } " ; < > ? . , / # ' : \ [] @]. The tooltip is positioned over the 'New password' field.

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 screenshot shows the 'Your profile' page in the IVD Software Suite. The page has a header with the IVD logo, a navigation bar with 'Plates' and 'Archive', and a user menu with 'Tools', 'Configuration', and 'g.washington'. The main content area is divided into two columns: 'User information' and 'Roles'. Under 'User information', there are input fields for 'Name' (George) and 'Surname' (Washington). Under 'Roles', there are two roles listed: 'IVD Mode - Operator' and 'Utility Mode - Operator'. The 'Change password' section is highlighted with a red border and contains a red error message: 'Your current password is incorrect. Provided password is incorrect.' Below this, there are input fields for 'New password' and 'Repeat password', both with a red border. At the bottom of the page, there are 'CANCEL' and 'SAVE' buttons.

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

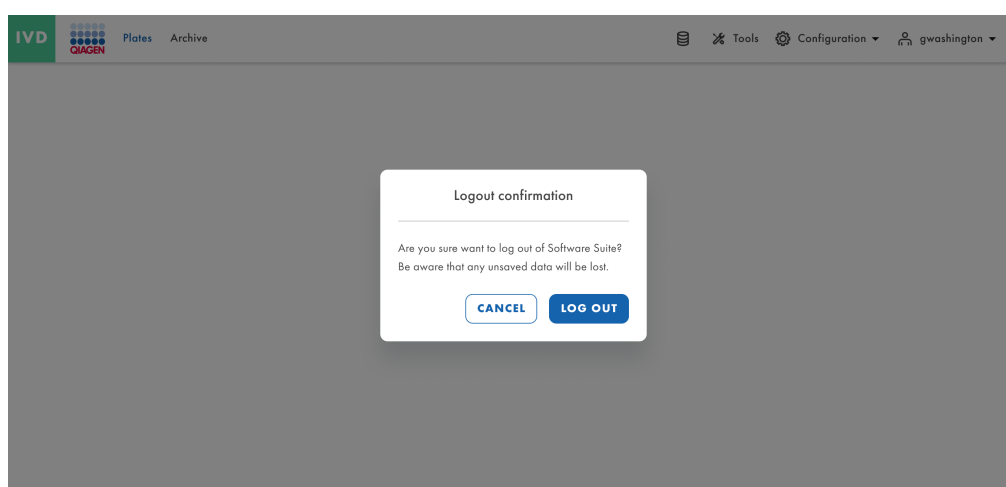
The screenshot shows the 'Your profile' page in the IVD Software Suite after a successful password change. The page layout is identical to the previous screenshot, but the 'Change password' section now has a green border and a green success message: 'Changes have been saved'. The 'New password' and 'Repeat password' fields are now empty. At the bottom of the page, there are 'CANCEL' and 'SAVE' buttons.

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.

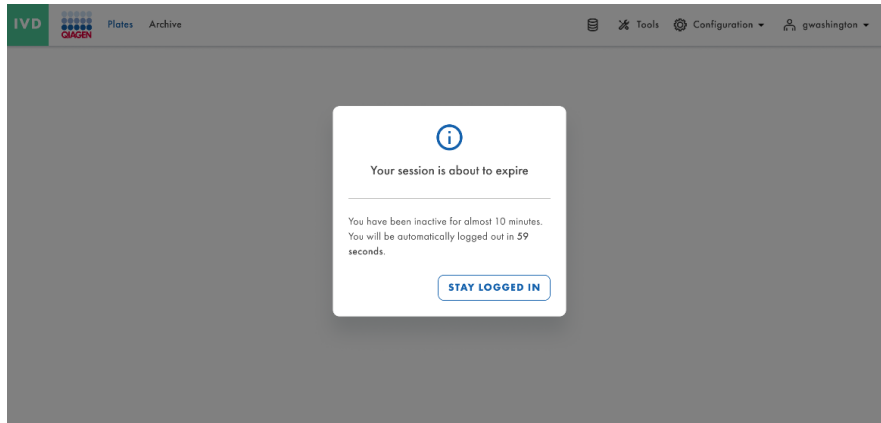


When a logged-in user has more than one open tab of the Software Suite subsystem and successfully logs out from it in one tab, the user is logged out from all of them and redirected to the Login page in all open tabs, from the same or different browser windows.

Once the user logs in again, they are taken to the last screen they were in or into a page higher in the software structure.

5.9.3. Automatic logout

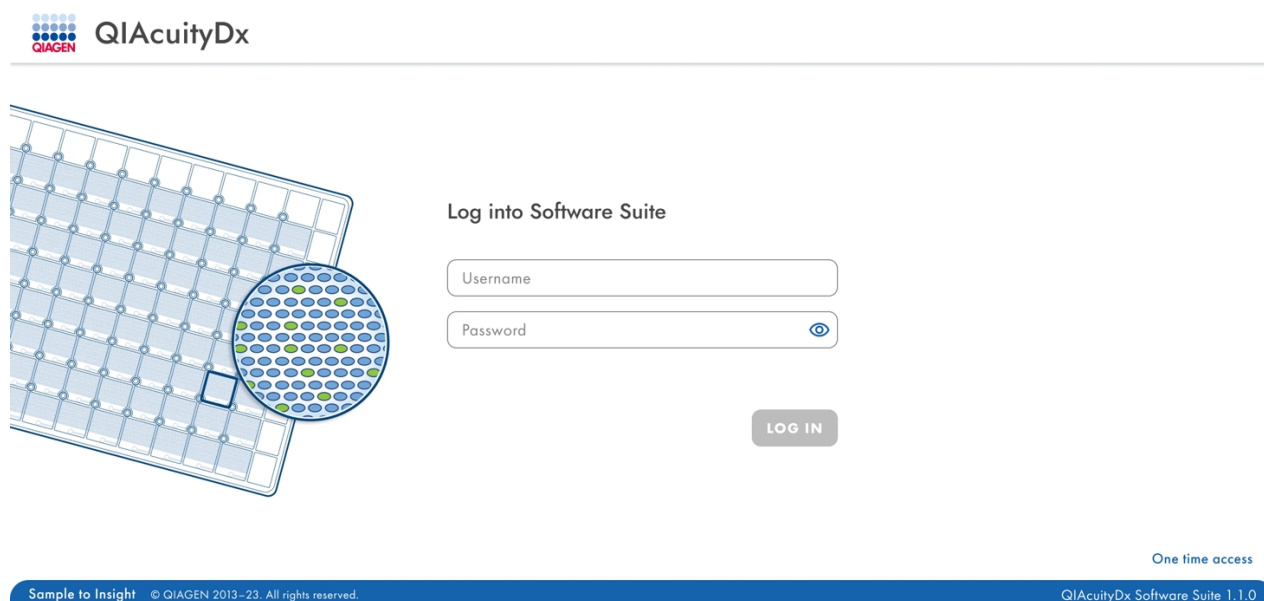
Each user will be logged out after 10 minutes of inactivity on Software Suite. The 10 minute counter restarts after every user action. After logging in, users are taken to the last screen they were in, or into a page higher in the software structure. One minute before the user is logged out, a pop-up message is displayed with a counter warning that they will be automatically logged out in X seconds as well as a **Stay logged in** button that would restart the counter. The automatic logout counter is displayed in all the tabs or windows opened by the user (i.e., they are logged in). Any activity in any of the tabs or windows impacts all of them. 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.



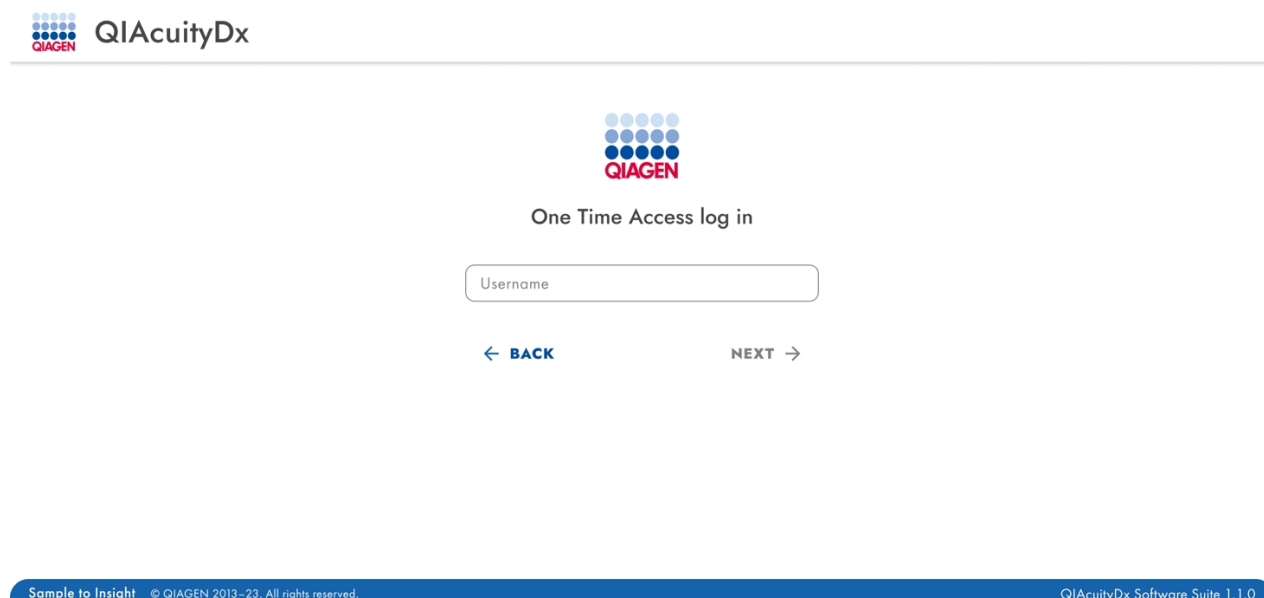
Important: Implementing network modifications may result in users being automatically logged out by the system, thereby posing a potential risk of loss for unsaved information. Ensure that no user is actively working on the system during the implementation of network modifications.

5.9.4. One time access

Whenever a user forgets their password, they can access the One time access screen available in the lower right side of the login page to generate a new password.



When clicking the **One time access** button, the One Time Access log in screen is displayed, in which the user must enter their username and click **Next**. If **Back** is clicked, they are brought to the Login screen.



Upon clicking **Next**, users are brought to the next One Time Access log in screen, comprised by their username, Software Suite subsystem's serial number, a control code (which is randomly generated), and a field for entering the security code. A new control code is automatically generated every time the user accesses the One Time Access screen. The security code is provided by QIAGEN Technical Services, as indicated by the tooltip available in the info icon of the Security code field. All three values are needed to generate the security code. If **Back** is clicked, they are brought to the previous screen.



One Time Access log in

Username
gwashtington

Serial number
QIAcuityDxSuite-1234567890

Control code
123456

Security code *

← BACK

LOG IN

Call QIAGEN Technical Services to receive security code.

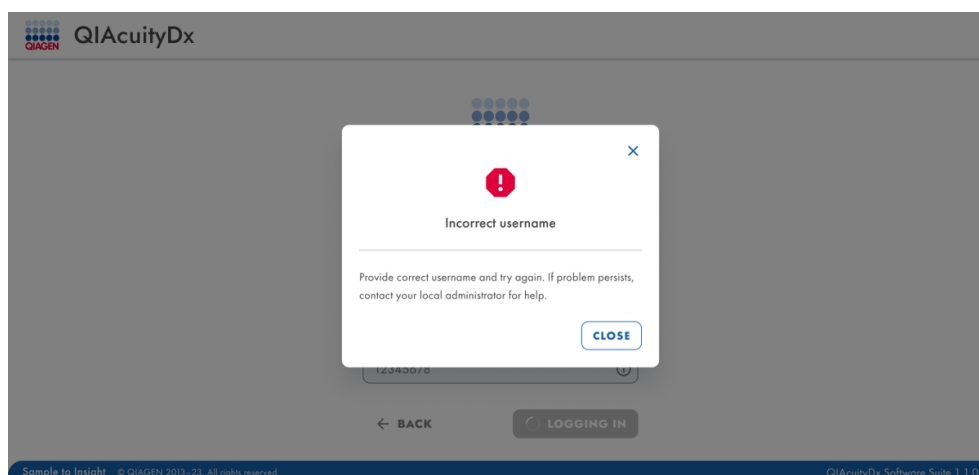
Security code *



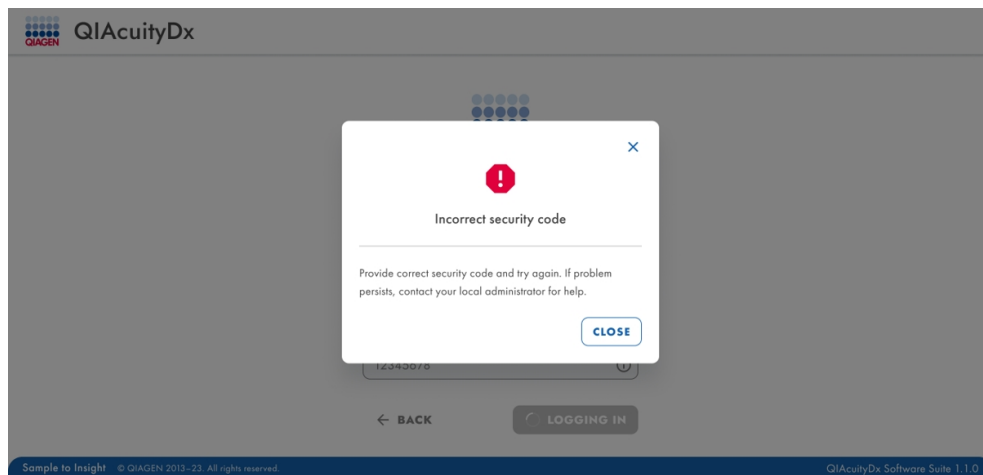
After entering the security code provided by QIAGEN Technical Services and clicking **Log in**, Software Suite verifies that the username exists and has not been deactivated meanwhile checking whether the security code is correct.

If there is an error and it is not possible to continue with the one time access, the following error messages are displayed:

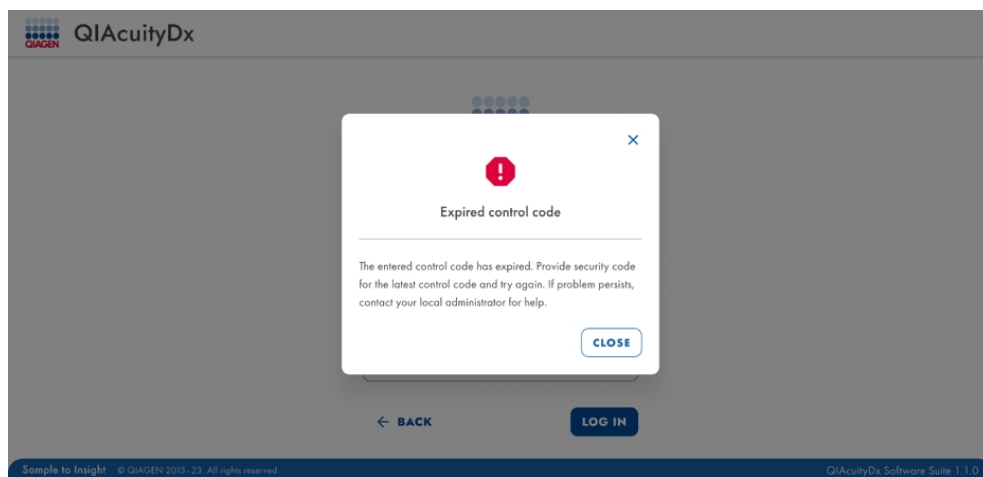
- For incorrect usernames:



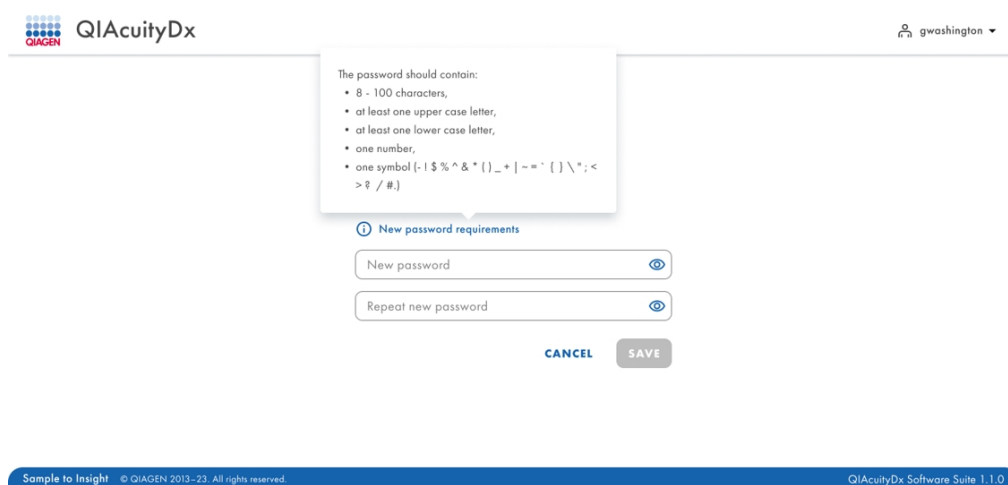
- For incorrect security codes:



- For expired control codes:



In case the entered username is correct, the user is not deactivated, and the security code is also correct, the user is brought to the Change your password screen, with the password requirements available as a tooltip:



By clicking **Cancel**, the user is brought to the Login screen again, the password is not changed, and then the whole workflow would need to be restarted in case a new One Time Access code is required.

QIAcuityDx

g.washington

Change your password

Please set up new password for your account.

New password requirements

New password

Repeat new password

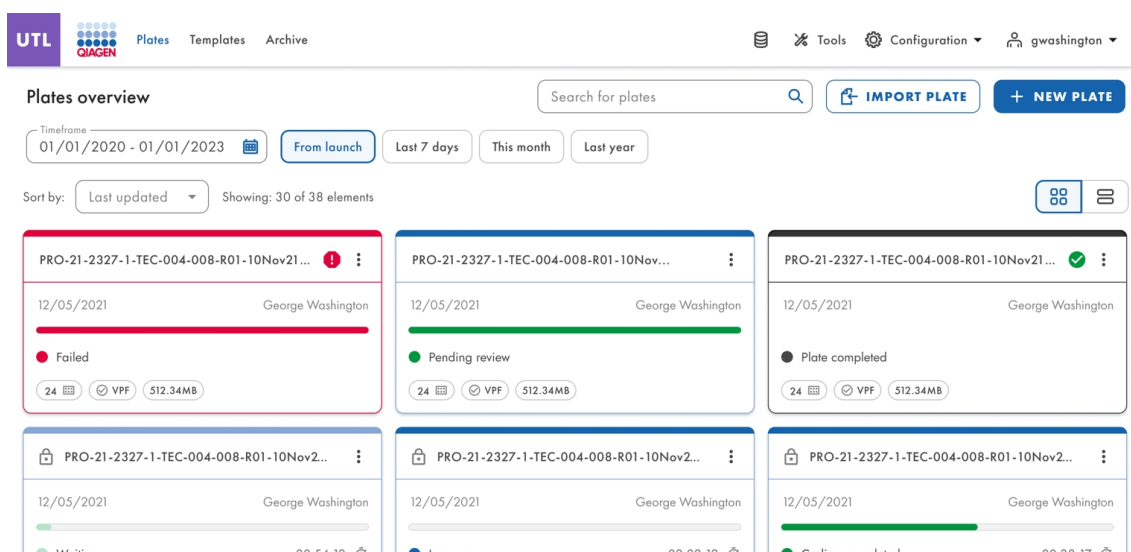
CANCEL SAVE

Sample to Insight © QIAGEN 2013-23. All rights reserved. QIAcuityDx Software Suite 1.1.0

Upon defining a new password, which must be compliant with the password requirements, the password is updated and the user is brought to the Login page to log in with the new credentials. It is mandatory to log in and enter the new credentials to access the Software Suite.

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



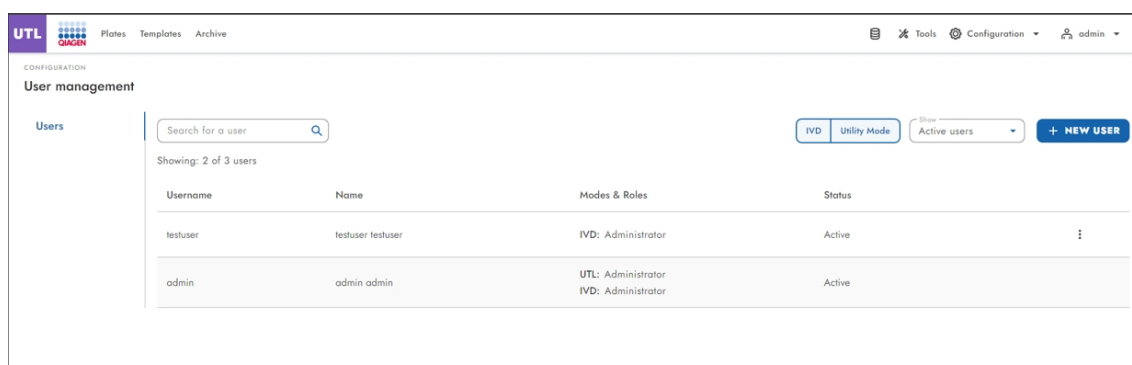
5.10.2. User management

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 Control 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, Modes & Roles, and Status, and to filter by mode (both enabled by default). It is possible to search users by Username, Name, and Surname by entering 3 or more characters into the Search box. It is not needed to press Enter to start the search.



Elements of user account

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

The screenshot shows the 'New user' form in the IVD (Quagen) interface. The form is divided into two sections: 'User information' and 'Permissions'. The 'User information' section contains fields for Username, Name, Surname, New password, and Repeat password. The 'Permissions' section is currently empty. The form has a 'CANCEL' button and a 'NEXT' button.

User information

Username *

Name *

Surname *

New password setup

New password

Repeat password

Permissions

CANCEL **NEXT**

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

Users must have 1 role assigned per mode. Possible default roles are Administrator, Operator, Lab Leader, Group Leader, Supervisor, and Quality Assurance. There can be additional roles added by IVD Software Assay Plugins (Assay-specific roles) for IVD Mode. The list of permissions for each role and its description are available when assigning a role.

Note: It is recommended to have several administrator users with all configurable permissions assigned.

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 clear 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, analyze a plate, 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, analyze a plate, 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 plate template.
 - **Edit Template:** User can edit an existing plate template.
 - **Read Template:** User can read information about existing templates and use them while creating and editing plates (if also has appropriate plate permissions).
 - **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. These permissions can be found under the IVD and Utility Mode in the Permissions screen, and include the following note “General permissions are independent of roles and mode-agnostic. Review the General permissions list carefully and assign only the permissions that the user is supposed to have.” informative note:

- 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

An administrator is responsible for overall configuration of the system, including management of general permissions for individual user access/rights. In addition to the permissions already assigned to administrator level, it is recommended to assign all configurable permissions to this role.

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

An operator has extensive access to all general QIAcuityDx Control Software and Software Suite functionalities required to process, analyze, and report results. The Operator role is configured without permission to delete plates but is different from the Supervisor role as an Operator has permission to delete reports but does not have permission to delete templates.

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
 - Run Experiment
 - 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

A lab leader role has extensive access to all QIAcuityDx Control Software and Software Suite functionalities required to process, analyze, and report results. The Lab Leader has the same pre-configured permissions as the Administrator role. The configuration of general permissions by the Administrator can be used to remove some aspects of system use for this role.

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
 - Run Experiment
 - 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

A group leader has access to QIAcuityDx Control Software and Software Suite functionalities required to process, analyze, and report results from plates owned by them. In addition to the restricted permissions applied to both Supervisor and Operator roles, the Group Leader role is configured without permission for running, editing, analyzing, or reading Plates not owned by them.

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
 - Run Experiment
 - 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

A supervisor has extensive access to all QIAcuityDx Control Software and Software Suite functionalities required to process, analyze, and report results. The Supervisor role is configured without permission to delete plates but is different from the Operator role as a Supervisor has permission to delete templates but does not have permission to delete reports.

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
 - Run Experiment
 - 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

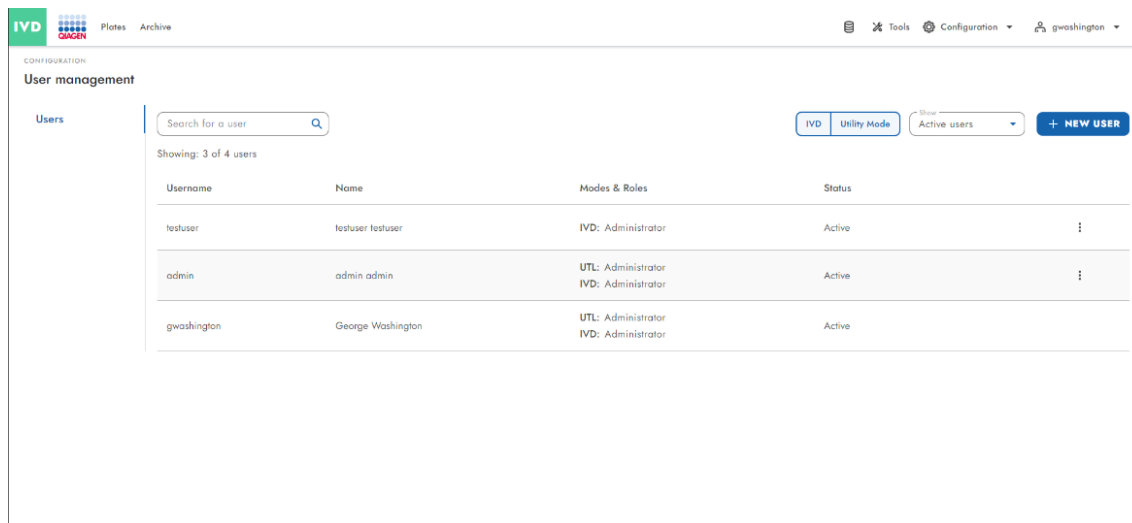
The Quality Assurance role has the least available pre-configured permissions of any role, as users assigned this role are not expected to create, edit, or run plates. This role still has permissions to read/import plates, create/sign reports (Utility Mode only), and read Templates, as well as having access to archives with the option to recover Plates. An administrator may consider assigning View Audit Trail permission to this role.

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). Username is case-sensitive. The password requirements (8–100 characters, at least one upper case letter, at least one lower case letter, at least one number, at least one symbol [- ! \$ % ^ & * () _ + | ~ = ` []]) are displayed when hovering the New Password requirements text. It is possible to switch steps before saving.

Note: It is required to assign one of the default roles (Operator, Supervisor, Administrator, Lab leader, Group leader, Quality Assurance) as well when assigning the IVD Signer role in IVD mode, to be able to log in to the QIAcuityDx Software Suite.

The screenshot shows the 'New user' form in the IVD software. It includes fields for Username, Name, Surname, New password, and Repeat password. There are also buttons for 'CANCEL' and 'NEXT'.

User information

1 User information

2 Permissions

Username *

Name *

Surname *

New password setup

New password requirements

New password

Repeat password

CANCEL **NEXT**

Password change

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

The screenshot shows the QIAcuityDx web application interface. At the top left is the QIAcuityDx logo. At the top right is a user profile icon and the name 'gWASHINGTON'. The main heading is 'Change your password'. Below it is a message: 'Please set up new password for your account.' followed by an information icon. There are three input fields: 'Your current password', 'New password', and 'Repeat new password'. Each field has a toggle icon on the right. A tooltip is visible over the 'New password' field, stating: 'The password should contain: 8 - 100 characters, at least one upper case letter, at least one lower case letter, one number, one symbol [- ! \$ % ^ & * () _ + | ~ = ` { } \ " ; < > ? / #.]'. At the bottom are 'CANCEL' and 'SAVE' buttons. The footer contains 'Sample to Insight © QIAGEN 2013–23. All rights reserved.' and 'QIAcuityDx Software Suite 1.0.0.0'.

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

The screenshot shows the QIAcuityDx web application interface. At the top left is the QIAcuityDx logo. At the top right is a user profile icon and the name 'gWASHINGTON'. The main heading is 'Change your password'. Below it is a message: 'Please set up new password for your account.' followed by an information icon. There are three input fields: 'Your current password', 'New password', and 'Repeat new password'. Each field has a toggle icon on the right. The 'New password' field is highlighted with a red border and contains a red exclamation mark icon, indicating an error. Below the 'New password' field is a message: 'Password doesn't meet security requirements.' At the bottom are 'CANCEL' and 'SAVE' buttons. The footer contains 'Sample to Insight © QIAGEN 2013–23. All rights reserved.' and 'QIAcuityDx Software Suite 1.0.0.0'.

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

The screenshot shows the 'User management' screen for the 'QA testuser'. The interface includes a sidebar with 'User information' and 'Permissions' tabs. The 'User information' tab is active, displaying the following fields:

- Username: QAtestuser
- Name: QA
- Email: testuser
- Change password: (toggle)
- New password: (password field)
- Repeat password: (password field)

At the bottom of the screen, there are 'CANCEL' and 'SAVE' buttons.

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.

The screenshot shows the 'User management' screen for the 'UTL' system. The interface includes a sidebar with 'Users' and 'Permissions' tabs. The 'Users' tab is active, displaying a search bar and a table of users.

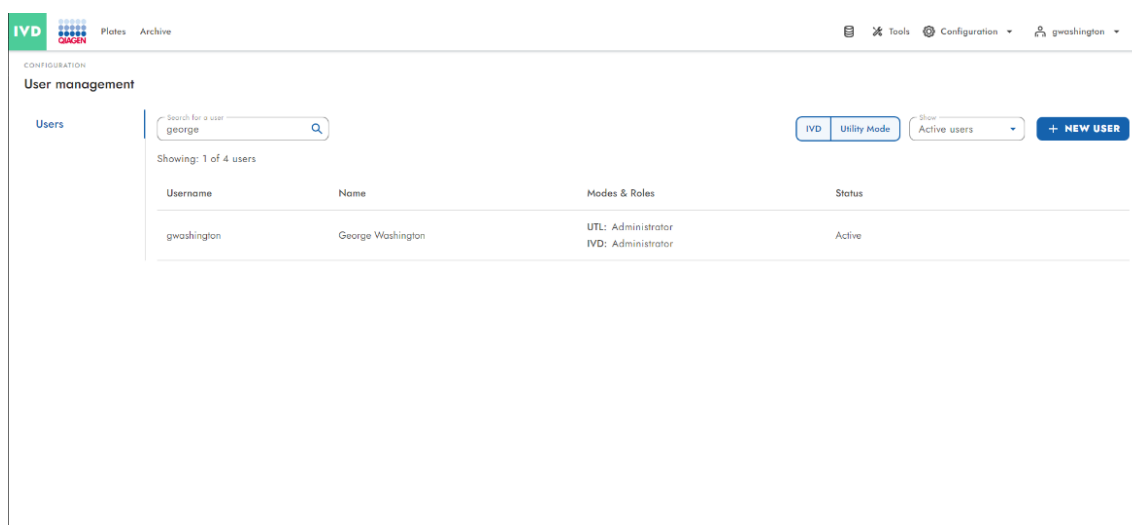
Search for a user: [Search bar]

Showing: 1 of 2 users

Username	Name	Modes & Roles	Status
admin	admin admin	UTL: Administrator IVD: Administrator	Active

At the bottom of the screen, there are 'CANCEL' and 'SAVE' buttons.

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

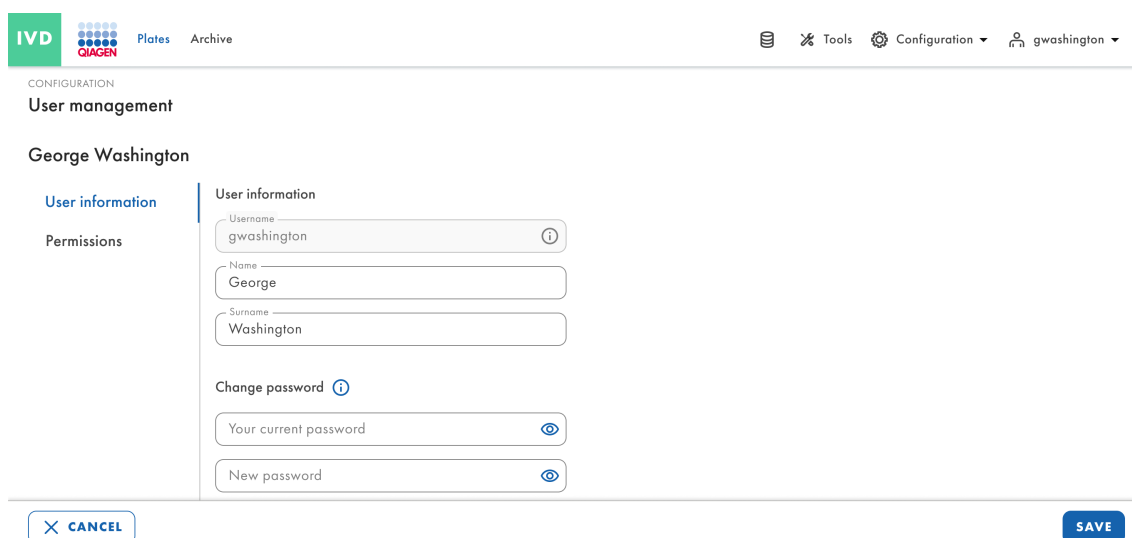


The screenshot shows the 'User management' section of the IVD Configuration interface. A search bar at the top left contains the text 'george'. Below the search bar, it says 'Showing: 1 of 4 users'. A table lists the user 'gwashington' with the name 'George Washington' and roles 'UTL: Administrator' and 'IVD: Administrator'. The status is 'Active'. On the right, there are buttons for 'IVD', 'Utility Mode', a dropdown for 'Show Active users', and a '+ NEW USER' button.

Username	Name	Modes & Roles	Status
gwashington	George Washington	UTL: Administrator IVD: Administrator	Active

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.



The screenshot shows the 'Edit user' form for 'George Washington' in the IVD Configuration interface. The form has two tabs: 'User information' and 'Permissions'. The 'User information' tab is active, showing fields for 'Username' (gwashington), 'Name' (George), and 'Surname' (Washington). There is also a 'Change password' section with fields for 'Your current password' and 'New password'. At the bottom, there are 'CANCEL' and 'SAVE' buttons.

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.

IVD

PlatesArchive

ToolsConfigurationgwwashington

CONFIGURATION

User management

Users

Search for a user

IVDUtility ModeShowActive usersNEW USER

Showing: 3 of 4 users

Username	Name	Modes & Roles	Status	
testuser	testuser testuser	IVD: Administrator	Active	Edit Deactivate
admin	admin admin	UTL: Administrator IVD: Administrator	Active	
gwwashington	George Washington	UTL: Administrator IVD: Administrator	Active	

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 fully registered due to incongruences with the contract is displayed with Reg. Status "Not compliant" with further details on the incomppliance shown when hovering over the "Not compliant" status.

Plugin name	Version	Reg. status	Status	Automatic validation	Labels
BCR-ABL 1	0.0.1	Validated	Active	On	CE; UDL_ID
ABC XYZ	2.6.1	In development	Enabled	N/A	
Lorem ipsum dolor sit amet	2.6.1	Not compliant	Disabled	N/A	Lorem ipsum; Dolor sit amet

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.

Plugin update

A Windows user with Windows administrator rights can install a newer version of an already installed Plugin. Plugin upgrades do not overwrite previously installed Plugins. The new Plugin will appear on the **Configuration > Plugin Management** screen after a successful installation.

To install a new version of an already installed IVD plugin, Software Suite automatically deactivates the previous installed version, as Software Suite does not support having two active versions of the same IVD plugin. Both versions remain installed.

The following applies to the deactivated, previously installed version:


- It is possible to:
 - Access all previously run plates (the plate configuration, plate review, and reports screens)
 - For plates in Drafted status, it is possible to change the assigned plugin and save the changes.
 - Archive, restore, import, and export plates
 - Download the plate support package

- It is not possible to:
 - Create and run new plates, as the plugin has gone into read-only mode
 - Generate a new report
 - Sign a report
 - Send results to LIMS

The following applies to the new installed version:


- It is possible to:
 - Create and run new plates
 - Access all plates (the plate configuration, plate review, and reports screens)
 - Archive, restore, import, and export plates
 - Download the plate support package
 - Generate a new report
 - Sign a report
 - Send results to LIMS
- It is not possible to:
 - Change the assigned plugin of a plate to a deactivated plugin version

Prior to installing an updated version of a specific IVD plugin, the user first needs to confirm that there are no plates associated with the plugin that are still running, as such plates would get stuck in an unstable state. Furthermore, whenever the preconditions for deactivating an IVD plugin (not having all plates of that plugin version in Drafted status, Failed status with report generated, or Invalidated or Completed status with report generated and signed) are not fulfilled, the Plugin cannot be deactivated. In such cases, on attempting to update the IVD Plugin, the following error notification is displayed.



Plugin can't be deactivated

Plugin can only be deactivated if all plates are either in Drafted status, Failed with report generated and Invalidated or Completed with report generated and signed.

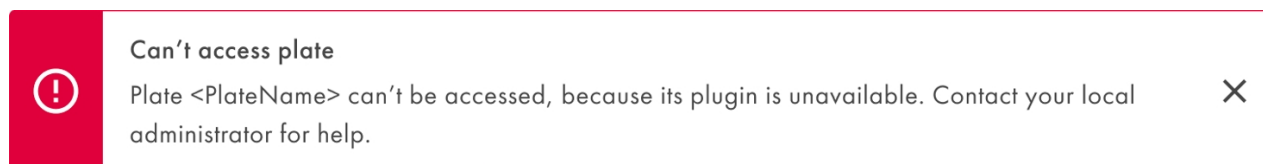


In contrast to the above, several versions of a Utility Mode plugin can coexist in the same Software Suite instance. After having installed a new version of a Utility Mode plugin, it is possible to (as long as the plugin is enabled):

- Access all existing plates (the plate configuration, analysis, and reports screens) with both plugins
 - For plates in Drafted or Defined status, it is possible to change the assigned plugin and save the changes.
 - Each plate is linked to a plugin and can only be analyzed with that specific plugin version.
- Create and run plates with both plugins
- Archive, restore, import, and export plates of both plugins
- Download the plate support package

- Generate reports with both plugins
- Sign reports with both plugins
- Send results to LIMS with both plugins
- Delete plates of both plugins

If not possible to reach the plugin when consulting a plate from a plugin, the following error message is displayed to the user.

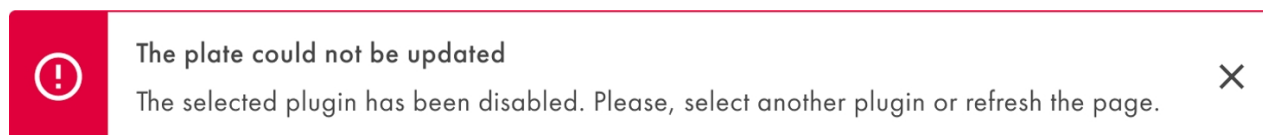


For Utility Mode, it is possible to create plates with any installed Utility Mode plugins regardless of the version. However, there are a few minor limitations to be aware of:

- Plates created with Software Assay Plugin Utility Mode v1.0
 - Reports and LIMS functionalities are not available.
- Plates whose linked plugin is disabled
 - In Plates Overview, only **Edit/Details** is available.
 - In the Plate Configurator, the Assay drop-down menu includes the plugin name and version, together with "(not available)".
 - For plates in Drafted or Defined status, the Assay drop-down menu is enabled; it is possible to change the plugin and save the plate. Afterwards, the disabled plugin version is not available in the Assay drop-down menu.
 - It is not possible to edit the plate with the same disabled plugin and save the changes.
 - For plates in a status different than Drafted/Defined, the Assay drop-down menu is disabled and the "(not available)" suffix is added to the plugin name and version.
 - In Archive Overview, **Restore** and **Delete** options are available.
 - It is possible to delete the plate.
 - When trying to restore the plate, an error is displayed.

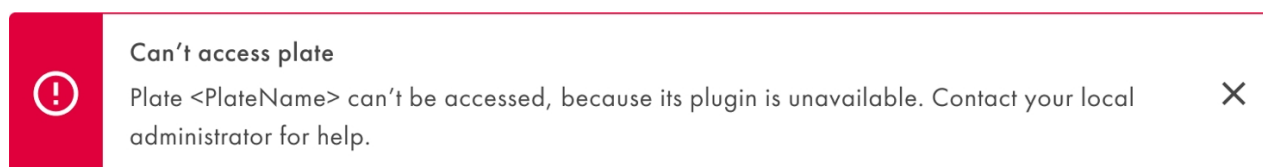
Disabled Utility mode plugins

System administrators can enable and disable Utility mode plugins via the scripts included with the plugin installation package, which is provided by QIAGEN's Field Service Engineers and QIAGEN Technical Services. Each plugin has a unique script for enabling the plugin and a unique script for disabling the plugin. It is not recommended to disable a plugin unless instructed by QIAGEN Technical Services, as plates whose plugins are disabled do not have the analysis available and cannot be edited. When trying to save changes to such plate, the following error message is displayed:



It is not possible to assign a disabled plugin to a plate during plate creation or edition.

When trying to type the Analysis URL (i.e., adding "/Analysis" as a suffix in the address bar) for a plate whose plugin is disabled, then the following error notification is displayed and the user is brought back to the plates overview screen:



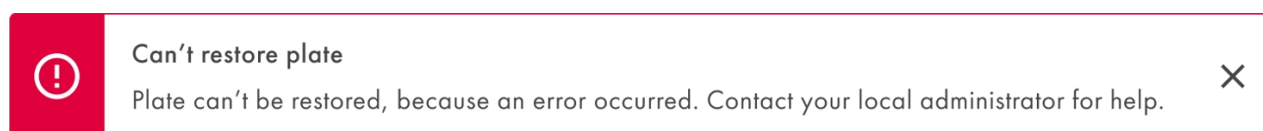
If a plugin is disabled, all the links/buttons are hidden in Plates Overview, apart from:

- **Edit** option for plates in Drafted/Defined status (so that the disabled plugin assigned to the drafted/defined plate can be changed)
- **Details** option for any other plates associated with the disabled plugin

When editing a plate in Drafted/Defined status that is linked to a disabled Utility Mode plugin, it is not possible to select a disabled plugin in the assay drop-down menu; either when editing for the first time before the assay has been changed (and then it is not possible to save the plate), or after having saved the plate subsequent to changing the selection to an active assay plugin (following which the disabled assay plugin is no longer visible to select from the drop-down menu).

For plates linked to a disabled plugin in Archive Overview, the **Restore** and **Delete** buttons are available.

When trying to restore a Utility Mode plate created in the Software Suite subsystem v1.0 whose plugin is currently disabled (or not available due to any technical inconvenience), the following generic error is displayed:

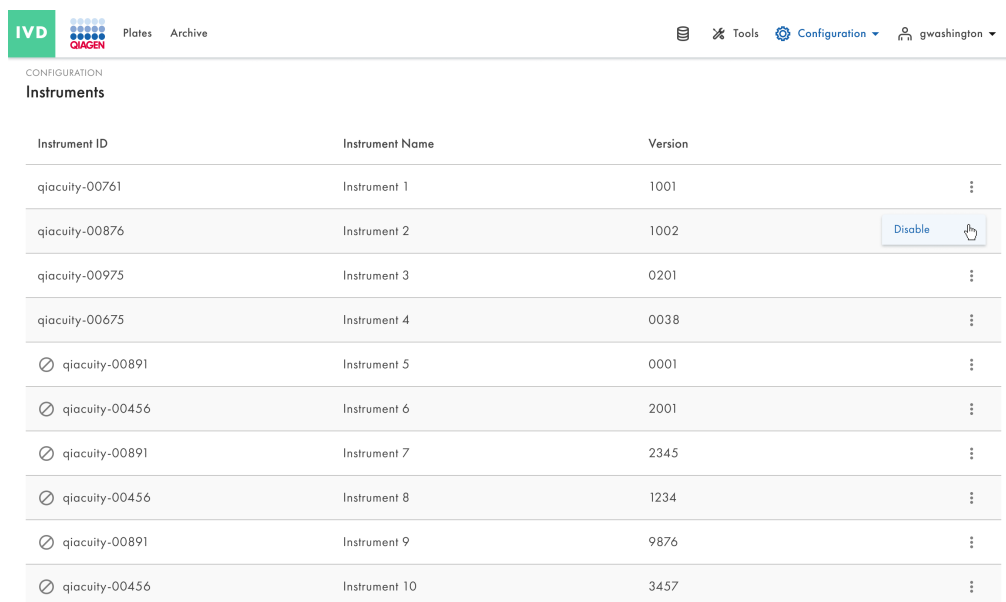


When trying to restore a Utility Mode plate created in the Software Suite subsystem v1.1 or higher whose plugin is currently disabled (or not available due to any technical inconvenience), the **Restore** option is not available. In other words, it is not possible to restore a Utility Mode plate linked to a Utility Mode Plugin that is currently disabled.

5.10.4. Instruments

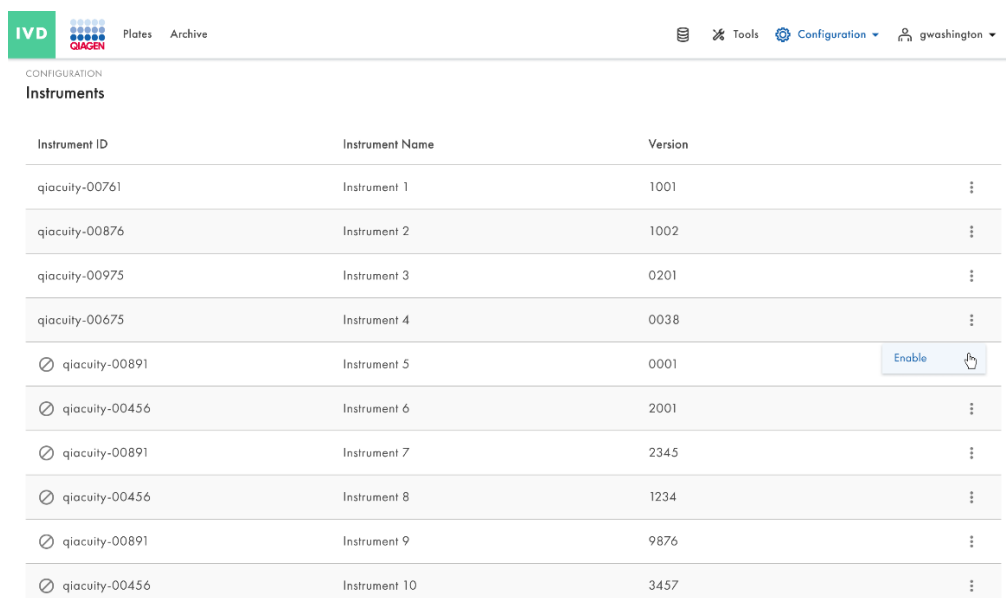
Users with Registered Instruments permission can see the list of registered instruments, which consists of the instrument ID, the instrument name, and the version. The list is read-only.

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.



Instrument ID	Instrument Name	Version
qiacuity-00761	Instrument 1	1001
qiacuity-00876	Instrument 2	1002
qiacuity-00975	Instrument 3	0201
qiacuity-00675	Instrument 4	0038
❌ qiacuity-00891	Instrument 5	0001
❌ qiacuity-00456	Instrument 6	2001
❌ qiacuity-00891	Instrument 7	2345
❌ qiacuity-00456	Instrument 8	1234
❌ qiacuity-00891	Instrument 9	9876
❌ qiacuity-00456	Instrument 10	3457

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.



Instrument ID	Instrument Name	Version
qiacuity-00761	Instrument 1	1001
qiacuity-00876	Instrument 2	1002
qiacuity-00975	Instrument 3	0201
qiacuity-00675	Instrument 4	0038
❌ qiacuity-00891	Instrument 5	0001
❌ qiacuity-00456	Instrument 6	2001
❌ qiacuity-00891	Instrument 7	2345
❌ qiacuity-00456	Instrument 8	1234
❌ qiacuity-00891	Instrument 9	9876
❌ qiacuity-00456	Instrument 10	3457

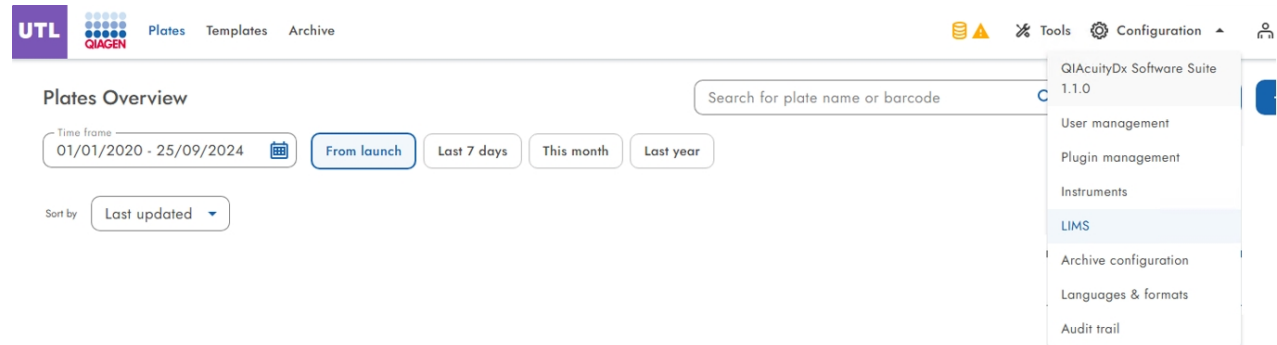
Note: Connecting an instrument to a different Software Suite instance does not automatically disable it in the previous Software Suite instance; it has to be manually disabled.

5.10.5. LIMS configuration

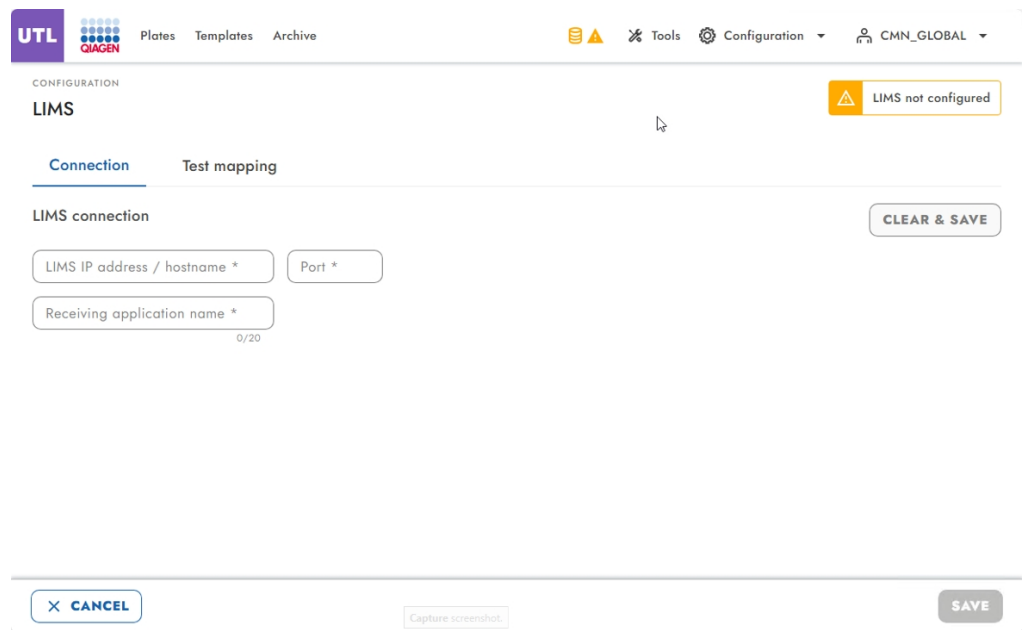
LIMS connection

It is possible to configure the address, port, and a receiving application name of the external LIS/HIS/LIMS for users who have the Manage LIMS Connector permission.

The configuration page is on **Configuration > LIMS > Connection** tab.



The authorized user enters the address, port, and receiving application name of the external LIS/HIS/LIMS.



The 3 fields are mandatory for the configuration, and its format will be validated. After introducing it and clicking the **SAVE** button, the LIMS connection will be configured and connection status will be periodically checked.

The screenshot shows the UTL (Universal Test Library) configuration interface for LIMS. The top navigation bar includes 'Plates', 'Templates', and 'Archive'. The main header shows 'CONFIGURATION' and 'LIMS'. A green notification box at the top center displays a checkmark and the text 'LIMS connection configured'. Below this, the 'LIMS connection' section is active, showing two input fields: 'LIMS IP address / hostname' (containing 'localhost') and 'Port' (containing '8080'). A 'Receiving application name' field is also present, containing 'LISName'. A 'CHECKING CONNECTION...' button is visible on the right. At the bottom, there are 'CANCEL' and 'SAVE' buttons.

If the connection with the external LIS/HIS/LIMS is established, then a “LIMS connected” icon will be displayed.

This screenshot shows the same UTL LIMS configuration interface as the previous one, but with the status updated. The green notification box now displays a checkmark and the text 'LIMS connected'. The 'LIMS connection' section remains the same, with 'localhost' in the IP field, '8080' in the Port field, and 'LISName' in the Receiving application name field. The 'CHECKING CONNECTION...' button is still present. The 'CANCEL' and 'SAVE' buttons are at the bottom.

If the connection cannot be established or after successfully established the connection is lost, then a “LIMS not connected” icon will be displayed.

The screenshot shows the UTL (Universal Test Library) interface for LIMS configuration. The top navigation bar includes 'Plates', 'Templates', and 'Archive'. The main header area displays 'CONFIGURATION' and 'LIMS'. A red status bar at the top right indicates 'LIMS not connected'. Below this, the 'Connection' tab is active, showing the 'LIMS connection' section. It contains three input fields: 'LIMS IP address / hostname *' with the value 'localhost', 'Port *' with the value '80', and 'Receiving application name *' with the value 'LISName'. A 'CLEAR & SAVE' button is located to the right of the input fields. At the bottom left, there is a 'CANCEL' button, and at the bottom right, there is a 'SAVE' button.

To clear the configuration, and consequently disconnect from the external LIS/HIS/LIMS, click **CLEAR & SAVE**. This action will clear the configuration.

The screenshot shows the UTL (Universal Test Library) interface for LIMS configuration. The top navigation bar includes 'Plates', 'Templates', and 'Archive'. The main header area displays 'CONFIGURATION' and 'LIMS'. A yellow status bar at the top right indicates 'LIMS not configured'. Below this, the 'Connection' tab is active, showing the 'LIMS connection' section. It contains three input fields: 'LIMS IP address / hostname *', 'Port *', and 'Receiving application name *'. A 'CLEAR & SAVE' button is located to the right of the input fields. At the bottom left, there is a 'CANCEL' button, and at the bottom right, there is a 'SAVE' button. A 'Capture screenshot' button is also visible at the bottom center.

LIMS test mapping

It is possible to consult the USI (Universal Service Identifier) to be used with LIS/HIS/LIMS in the LIMS **Test mapping** tab for users that have the Manage LIMS Connector permission.

The Test mapping page is on **Configuration > LIMS > Test mapping**.

The screenshot displays the 'LIMS' configuration page with the 'Test mapping' tab selected. It features a table with the following data:

Mode	Assay Name	Parameter Name	Type	LIMS Test ID	LIMS Alternative Test ID
IVD	TESTIVD 1.0.0.0	Order 1	Order	XXXXXX-X^TEST1^LN	777777^TEST I^99QIA
		Obs 1	Observation	NNNNN^Test2^LN	22222^Test II^99QIA
		Obs 2	Observation	YYYYY^Test3^LN	ZZZZZZ^TEST III^QIA99
		Obs 3	Observation	AAAAA^Test4^LN	BBBBBB^TEST IV^99QIA
UTL	utl 1.1.0.0	utl-1.1.0.0	Order		utl Plugin 1.1.0.0
		Absolute Quantification	Observation		Read manual to know utl-1.1.0.0 observation identifiers.

IVD Mode parameters

- The column LIMS Test ID indicates the value to be used in the OBR record, field 4, components 1, 2, and 3, respectively, in case of the Order type parameters. On the other hand, for the Observation type parameters, the values are intended to be used in the OBX record, field 3, components 1, 2, and 3, respectively.
- The column LIMS Alternate Test ID indicates the value to be used in the OBR record, field 4, components 4, 5, and 6, respectively, in case of the Order type parameters. On the other hand, for the Observation type parameters, the values are intended to be used in the OBX record, field 3, components 4, 5, and 6, respectively.
- In case LIMS Test ID shows no data, it is considered empty. Hence, 3 carets (^^^) must be used.

Examples:

OBR||2342343325||XXXXXX-X^TEST1^LN^777777^TEST I^99QIA|||20230731143656.457

OBX|1|NM|NNNNN^Test2^LN^22222^Test II^99QIA||1337||||F|||20230731143656.457||operator|^Order
1|SN123456789|20230731143656.457

UTL Mode parameters

- In case of Order type parameters, the column LIMS Alternate Test ID indicates the value to be used in the OBR record, field 4, components 4, 5, and 6, respectively.
- In case of Observation type parameters, the compounding of the Observation identifier for results obtained in UTL mode follows a logic based on its well or hyperwell ID, imaging step, reaction mix name, target name or selected channel, and its plugin version.
- In case LIMS Test ID shows no data, it is considered empty. Hence, 3 carets (^^^) must be used.

Element name	Description	Allowed values	Comment, example
Prefix	Indicates that the observation identifier is related to UTL mode	UTL	Fixed as "UTL"
Separator	Separator character	_	Fixed as "_" (Underscore)
Well or hyperwell ID	Indicates the well or hyperwell on the plate of the observation	The ones used in the plate	Examples: HW1, A1, A3, B4, HW5
Separator	Separator character	_	Fixed as "_" (Underscore)
Imaging step	Indicates the imaging step related to the observation. Represented as IS + the imaging step number (from 1 to 7)	IS1, IS2, IS3, IS4, IS5, IS6, IS7	
Separator	Separator character	_	Fixed as "_" (Underscore)
Reaction mix name	Indicates the name of the Reaction mix related to the observation	User defined	User defined
Separator	Separator character	_	Fixed as "_" (Underscore)
Target name or Channel	Indicates the name of the Target or the Channel related to the observation	Target: user defined. Channel: Green, Yellow, Orange, Red, Crimson	Target: user defined. Channel: Green, Yellow, Orange, Red, Crimson
Separator	Separator character	_	Fixed as "_" (Underscore)
Plugin version	Indicates the plugin version related to the observation		Example: 1.1.0.1

- UTL_ + Well ID or Hyperwell ID + _ + Imaging step + _ + Reaction mix name + _ + target name or channel + _ + plugin version.

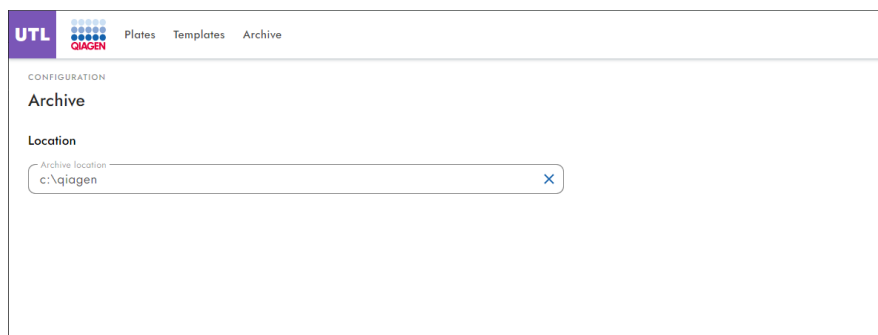
Example: UTL_A1_IS1_Reactionmix1_Target2_1.1.0.0

UTL OBX example: OBX|1|NM|^^^UTL_A1_IS1_Reactionmix1_Target2_

1.1.0.0^^^QIA99||101|copies/μl||||F|||20231129002433.5932||operator|^UTL Plugin|76431234|20220620054042.8074

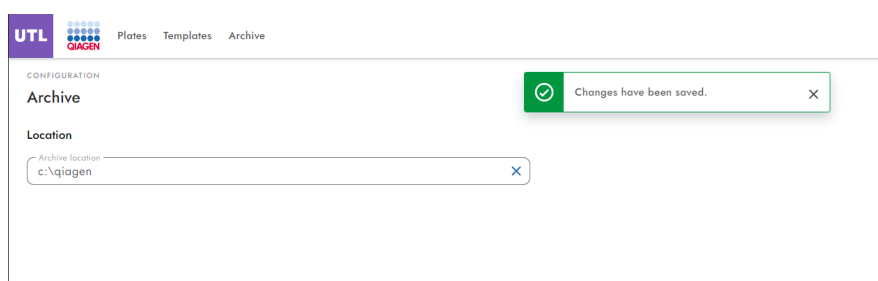
5.10.6. Archive location

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.



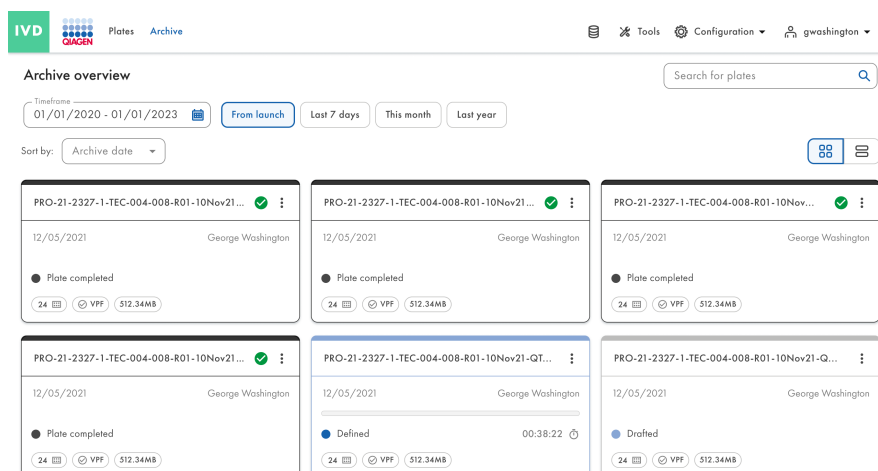
The screenshot shows the UTL (Qiagen) software interface. The top navigation bar includes 'UTL', 'Plates', 'Templates', and 'Archive'. The 'Archive' section is selected, displaying the 'Archive' configuration page. Under the 'Location' heading, there is an input field labeled 'Archive location' containing the text 'c:\qiagen'. A green 'Save' button is located to the right of the input field.

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.



This screenshot shows the same UTL Archive configuration page as before, but with a green notification box at the top right that reads 'Changes have been saved.' The 'Archive location' field still contains the path 'c:\qiagen'.

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.



The screenshot shows the IVD (Qiagen) software interface. The top navigation bar includes 'IVD', 'Plates', and 'Archive'. The 'Archive' section is selected, displaying the 'Archive overview' page. The page shows a grid of plate cards. The first three cards are 'Plate completed' and the last one is 'Drafted'. Each card displays the plate ID, date, and user.

Plate ID	Date	User	Status
PRO-21-2327-1-TEC-004-008-R01-10Nov21...	12/05/2021	George Washington	Plate completed
PRO-21-2327-1-TEC-004-008-R01-10Nov21...	12/05/2021	George Washington	Plate completed
PRO-21-2327-1-TEC-004-008-R01-10Nov21...	12/05/2021	George Washington	Plate completed
PRO-21-2327-1-TEC-004-008-R01-10Nov21-QT...	12/05/2021	George Washington	Drafted

5.10.7. 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. By default, QIAcuityDx is set up in English (United States). It is required to install the language packs for being able to select the language in the Languages & formats screen. There are language packs for Software Suite, Control Software, and each Software Assay Plugin.

Note: The language, date format, and number format are applied to all users and propagated to all the connected instruments. Ensure all users are aware of the selected date and number format.

IVD QIA GEN Plates Archive Tools Configuration gwashington

CONFIGURATION

Languages & formats

Language

☒ English (United States) EN-US

Date format

☒ DD/MM/YYYY 21/07/2023

☐ DD.MM.YYYY 21.07.2023

☐ D/M/YYYY 21/7/2023

☐ M/D/YYYY 7/21/2023

☐ YYYY/M/D 2023/7/21

☐ YYYY-MM-DD 2023-07-21

☐ YYYY-MM 2023-7-21

☐ YYYY#MM#DD日 2023年07月21日

Number format

☒ 1,234,567.89

☐ 1 234 567,89

☐ 1 234 567.89

☐ 1.234.567,89

5.10.8. 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

IVD

Plates

Archive

Tools

Configuration

gwashington

CONFIGURATION

Audit trail

Affected plate name or ID / instrument ID / username

Time frame

01/01/2020 - 11/01/2022

Any

Instrument

Plate

Suite

Event type

Any

Initiated by

George Washington

Clear all

10 events

EXPORT TO PDF

Date / time (UTC +01:00)	Initiated by	Category	Event type	Affected plate / user	Instrument ID
05/05/2022 13:35:15	gwashington	Plate	Plate experiment finish	<div><div></div>Generic_Plate_24well_8.5K - Upgraded d53f26c5-488d-4d93-a2f2-2eebd196b234</div>	qiacyuity-00761 <div><div></div>PDF</div>
05/05/2022 13:35:15	gwashington	Suite	User activation	<div><div></div>alincolln</div>	qiacyuity-00761 <div><div></div>PDF</div>
05/05/2022 13:35:15	gwashington	Plate	Plate update	<div><div></div>PRO-21-2327-1-TEC-004-008-R01-10Nov21-QTY-005-KO d53f26c5-488d-4d93-a2f2-2eebd196b234</div>	- <div><div></div>PDF</div>
05/05/2022 13:35:15	-	Suite	System version change	-	- <div><div></div>PDF</div>
05/05/2022 13:35:15	gwashington	Plate	Plate experiment finish	<div><div></div>PRO-21-2327-1-TEC-004-008-R01-10Nov21-QTY-005-KO d53f26c5-488d-4d93-a2f2-2eebd196b234</div>	qiacyuity-00761 <div><div></div>PDF</div>

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.

IVD

Plates Archive

Tools Configuration gwashington

CONFIGURATION

Audit trail

Affected plate name or ID / instrument ID / username

Time frame 01/01/2020 - 11/01/2022

Any Instrument Plate Suite

Event type Any

Initiated by George Washington

Clear all

10 events

EXPORT TO PDF

Date / time (UTC +01:00)	Initiated by	Category	Event type	Affected plate / user	Instrument ID	
05/05/2022 13:35:15	gwashington	Plate	Plate experiment finish	Generic_Plate_24well_8.5K - Upgraded d53f26c5-488d-4d93-a2f2-2eebd196b234	qiacuity-00761	PDF
05/05/2022 13:35:15	gwashington	Suite	User activation	alincolln	qiacuity-00761	PDF
05/05/2022 13:35:15	gwashington	Plate	Plate update	PRO-21-2327-1-TEC-004-008- R01-10Nov21-QTY-005-KO d53f26c5-488d-4d93-a2f2-2eebd196b234	-	PDF
05/05/2022 13:35:15	-	Suite	System version change	-	-	PDF
05/05/2022 13:35:15	gwashington	Plate	Plate experiment finish	PRO-21-2327-1-TEC-004-008- R01-10Nov21-QTY-005-KO d53f26c5-488d-4d93-a2f2-2eebd196b234	qiacuity-00761	PDF

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.

IVD

Plates Archive

Tools Configuration gwashington

Audit trail

Affected plate name or ID / instrument ID / username

01/01/2020 - 11/01/2022

Any Instrument Plate Suite

Event type

Any

Initiated by

gwashington

Clear all

10 events

EXPORT TO PDF

Date / time (UTC +01:00)	Initiated by	Category	Event type	Affected plate / user	Instrument ID	
05/05/2022 13:35:15	gwashington	Plate	Plate experiment finish	Generic_Plate_24well_8.5K - Upgraded d53f26c5-488d-4d93-a2f2-2eebd196b234	qiacyuity-00761	PDF
05/05/2022 13:35:15	gwashington	Suite	User activation	alincolln	qiacyuity-00761	PDF
05/05/2022 13:35:15	gwashington	Plate	Plate update	PRO-21-2327-1-TEC-004-008- R01-10Nov21-QTY-005-KO d53f26c5-488d-4d93-a2f2-2eebd196b234	-	PDF
05/05/2022 13:35:15	-	Suite	System version change	-	-	PDF
05/05/2022 13:35:15	gwashington	Plate	Plate experiment finish	PRO-21-2327-1-TEC-004-008- R01-10Nov21-QTY-005-KO d53f26c5-488d-4d93-a2f2-2eebd196b234	qiacyuity-00761	PDF

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

IVD

Plates Archive

Tools Configuration gwashington

Audit trail

Affected entity ID

01/01/2020 - 11/01/2022

Any Instrument Plate Suite

Event type

Any

Initiated by

gwashington

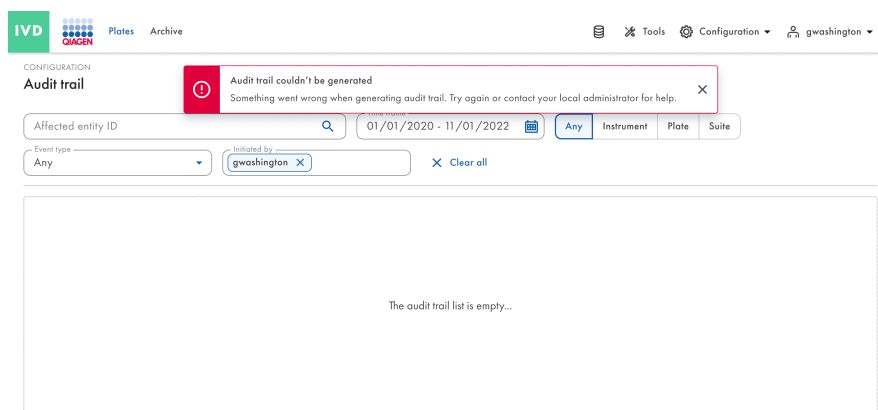
Clear all

Audit trail unavailable

Audit trail is not responding. Try again later, or contact your local administrator for help.

The audit trail list is empty...

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

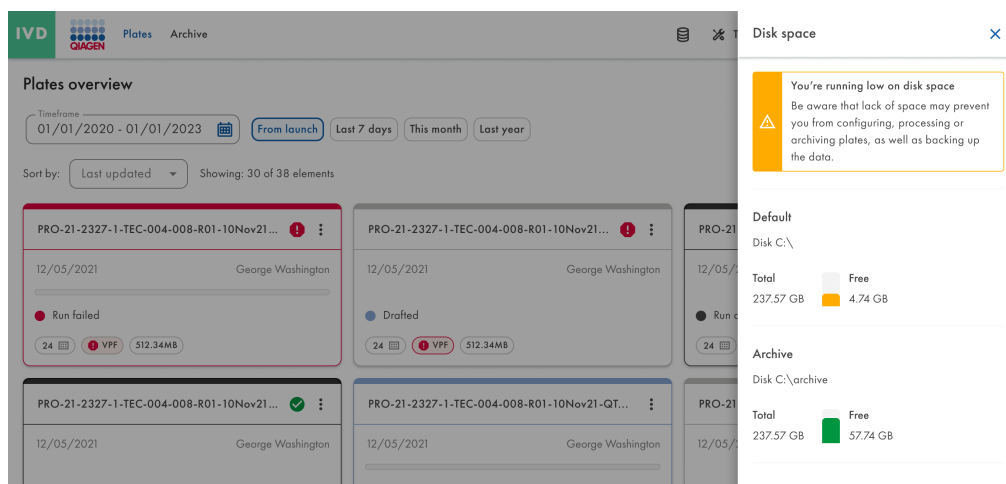
New value

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

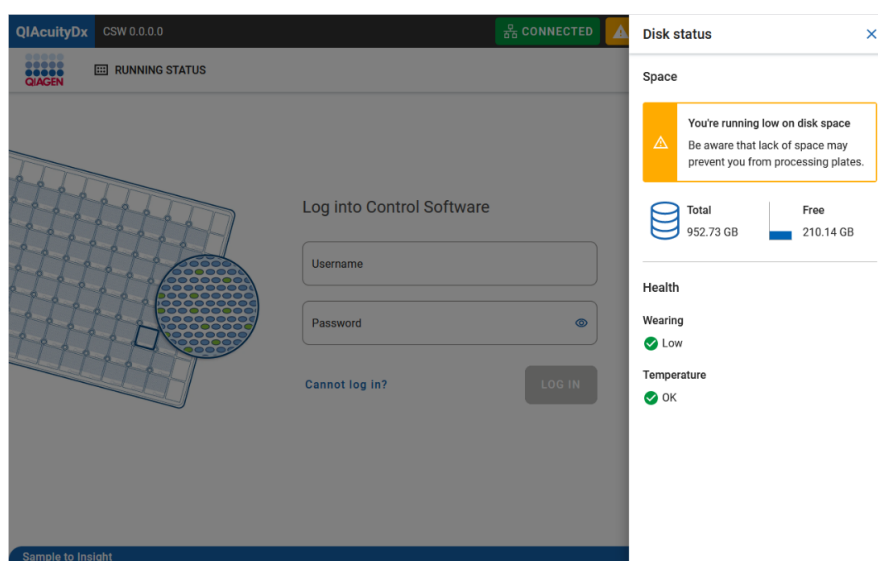
The Software Suite allows authorized users to monitor the disk space of the Software Suite storage and all external storage used for external files. The Software Suite notifies the user about insufficient storage space and prevents users executing any step of the IVD workflow (create plate, archive plate) 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:



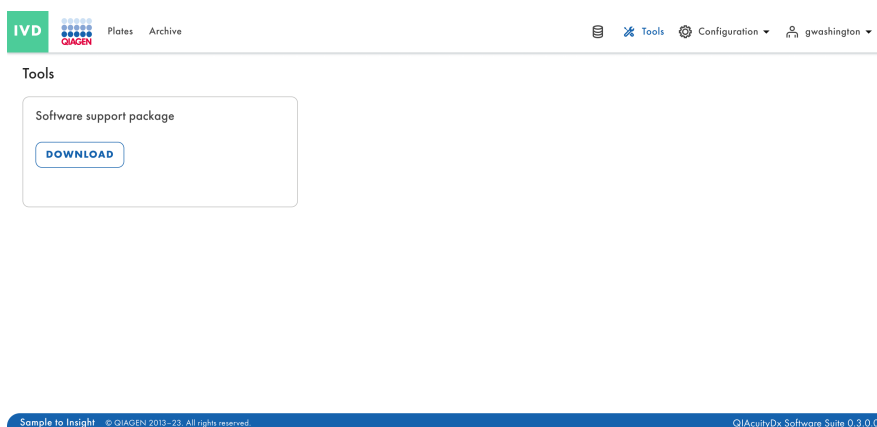
If the instrument is unable to connect to the Software Suite, raw image data will be stored in the instrument storage. Once the connection is restored the instrument will automatically upload the stored images to the Software Suite. In some cases, the number of images temporarily stored in the instrument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

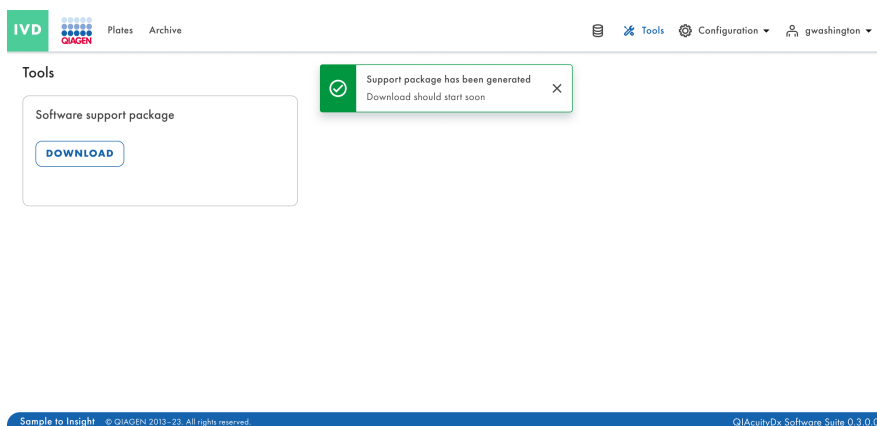
5.13. QIAcuityDx support packages

5.13.1. QIAcuityDx Software Suite support packages

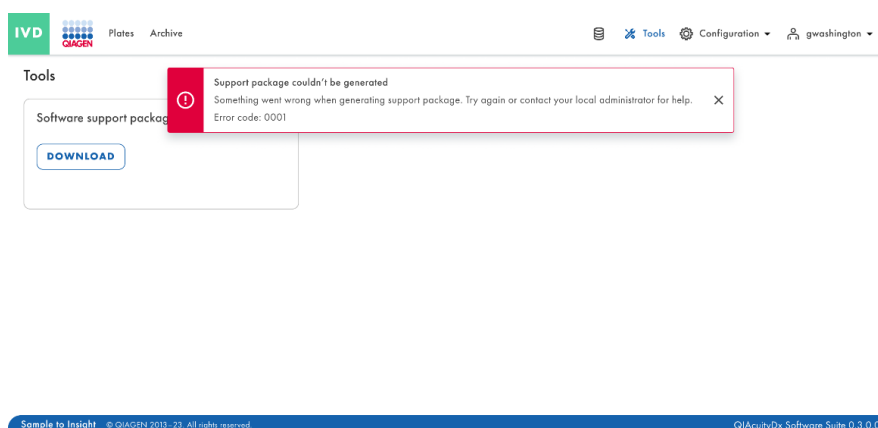
Any user logged into the Software Suite is able to create and download support packages containing the system logs by clicking the **Download** button in **Tools > Support Package**. The generated zip file is password protected and contains the log file(s).



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



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



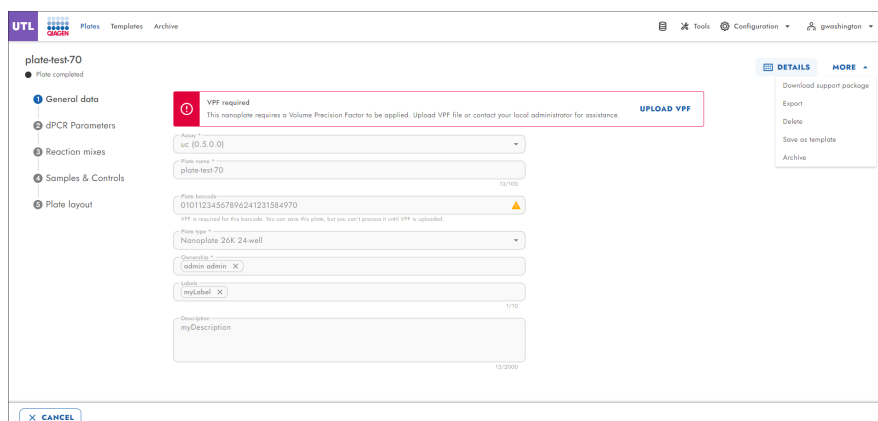
CAUTION Loss of sensitive information



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, define the package type (standard or extended) and the date range to be considered.

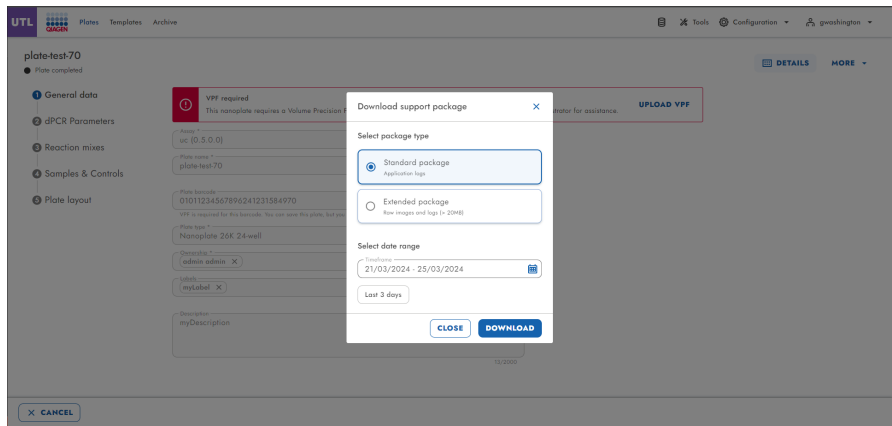
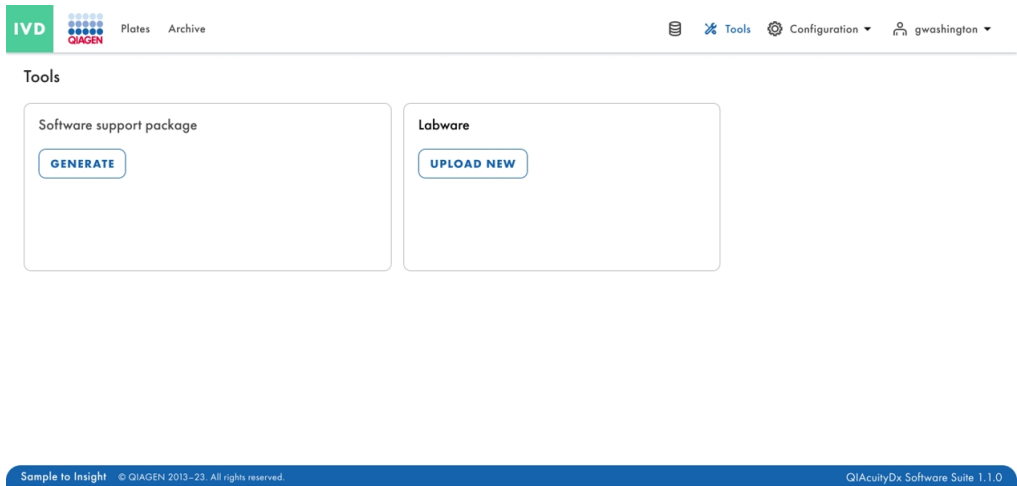


Plate support packages include the CSV files for Absolute Quantification per channel, Absolute Quantification per target, and RFU for troubleshooting.

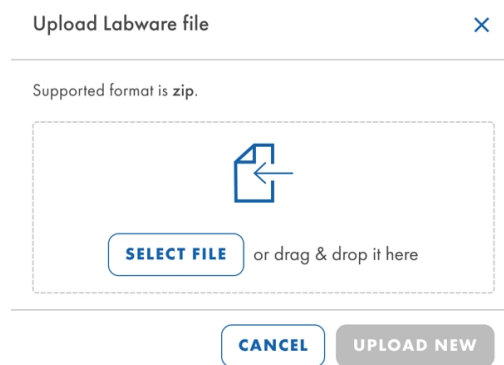
5.13.3. Upload labware files

The upload of labware files from the application applies the implicit security policy.

Each authorized user with Upload Labware file permission can upload labware files from the Tools screen, by clicking the **Upload New** button in the Labware section.



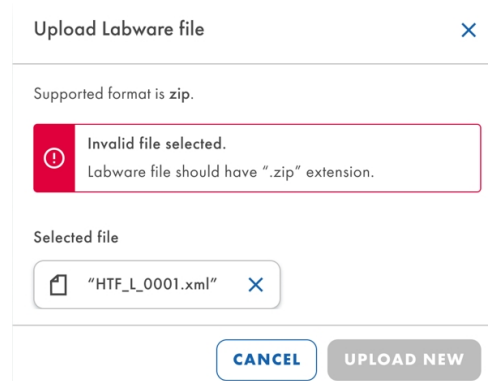
Then the Upload Labware file pop-up window is displayed:



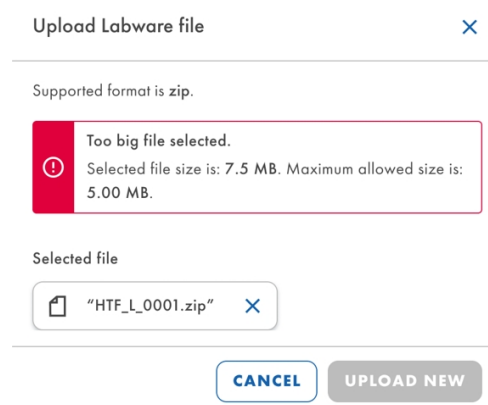
After selecting a file or dragging and dropping it into the pop-up window, the Software Suite validates the size and format of the file.

The following error messages can be displayed:

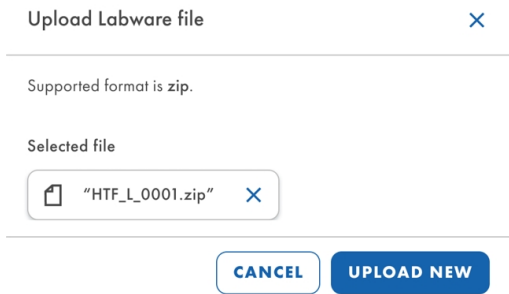
- Invalid file selected



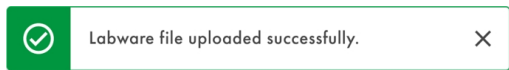
- File too big



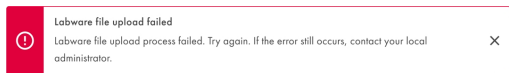
For files that comply with both the format and the size, the **UPLOAD NEW** button is enabled and the upload can be performed:



The Software Suite displays a success notification after the labware file has been successfully uploaded:

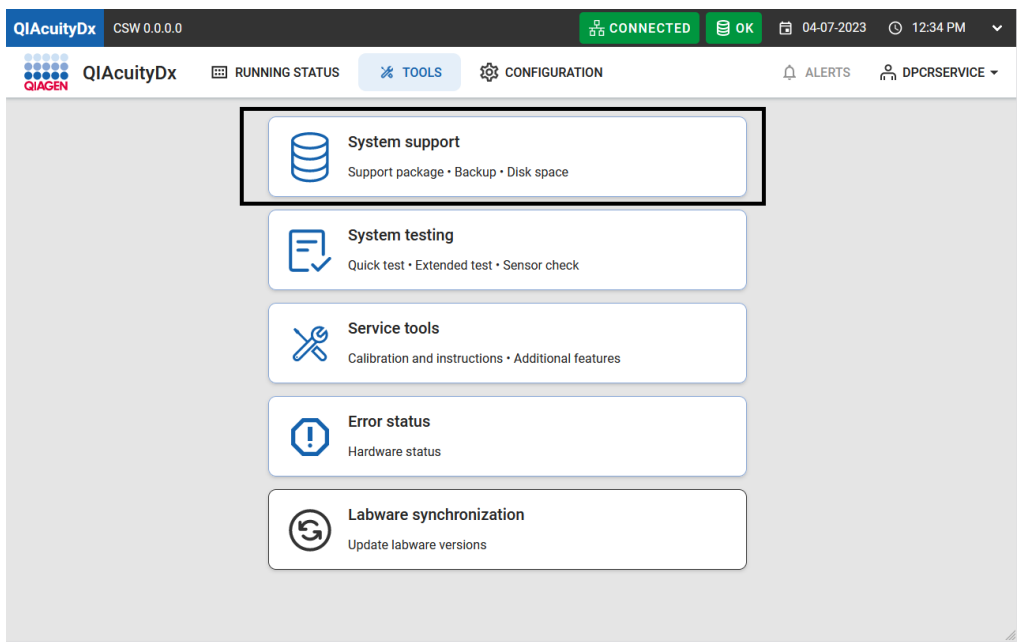


In case there is an error during the file upload, the following error notification is displayed:



5.13.4. Instrument support packages

The instrument GUI allows 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.

Support package

LAST 3 DAYS

LAST 2 WEEKS

Time frame
08/01/2022 - 08/24/2022

EXPORT TO USB

EXPORT TO SUITE

Selected: 09/08/2023 - 09/11/2023

September 2023

October 2023

Su	Mo	Tu	We	Th	Fr	Sa	Su	Mo	Tu	We	Th	Fr	Sa
					1	2	1	2	3	4	5	6	7
3	4	5	6	7	8	9	8	9	10	11	12	13	14
10	11	12	13	14	15	16	15	16	17	18	19	20	21
17	18	19	20	21	22	23	22	23	24	25	26	27	28
24	25	26	27	28	29	30	29	30	31				

CANCEL

SELECT

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.

UTL

Plates Templates Archive

Tools

Configuration

g.washington

Search for templates

+ NEW TEMPLATE

Name ↑	Creation date	Created by	Last modification ↓	Modified by
Template lorem ipsum dolor sit amet	12/05/2021, 12:55	George Washington	12/05/2021, 12:55	George Washington
Template lorem ipsum dolor sit amet	12/05/2021, 12:55	George Washington	12/05/2021, 12:55	George Washington
Template lorem ipsum dolor sit amet	12/05/2021, 12:55	George Washington	12/05/2021, 12:55	George Washington
Template lorem ipsum dolor sit amet	12/05/2021, 12:55	George Washington	12/05/2021, 12:55	George Washington

Sample to Insight

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QIAcuityDx Software Suite 1.0.0.0

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

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

UTL QIAcuity Dx System

Plates Templates Archive

Tools Configuration gwashington

New template

- General data
- dPCR Parameters
- Reaction mixes
- Samples & Controls
- Plate layout

Template name *
Template name * Characters left: 100

Plate name
Plate name Characters left: 100

Plate type
Plate type

Labels
Labels

Description
Description

CANCEL NEXT

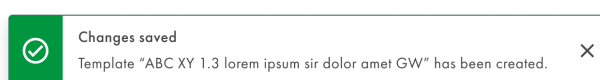
In the dPCR Parameters screen, the user can define the partitioning, cycling, and imaging.

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

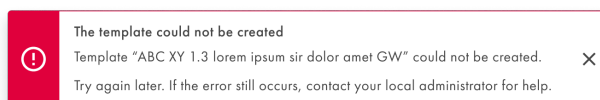
In the Samples & Controls screen, the user can define samples, controls, and NTCs.

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.

UTL **Plates** Templates Archive Tools Configuration gwashington

New plate

1 General data 2 dPCR Parameters 3 Reaction mixes 4 Samples & Controls 5 Plate layout

Plate name * Characters left: 100

Plate type *

Assay

Ownership *

Plate barcode *
Enter barcode number manually or scan the barcode with handheld scanner

Labels

Description

TEMPLATES Use template Save as template

CANCEL **NEXT**

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

Save as template ✕

Template name * Characters left: 100

CANCEL **SAVE**

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

Save as template ✕

Template name *
Lorem ipsum template Characters left: 71

CANCEL **SAVE**

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.

Save as template

Template name *

Lorem ipsum template

This name already exists. Choose another one.

Characters left: 71

CANCEL

SAVE

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

Changes saved

Template "ABC XY 1.3 lorem ipsum sir dolor amet GW" has been created.

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

The template could not be created

Template "ABC XY 1.3 lorem ipsum sir dolor amet GW" could not be created.
Try again later. If the error still occurs, contact your local administrator for help.

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

UTL

Plates Templates Archive

Tools Configuration gwashington

Templates

Search for templates

+ NEW TEMPLATE

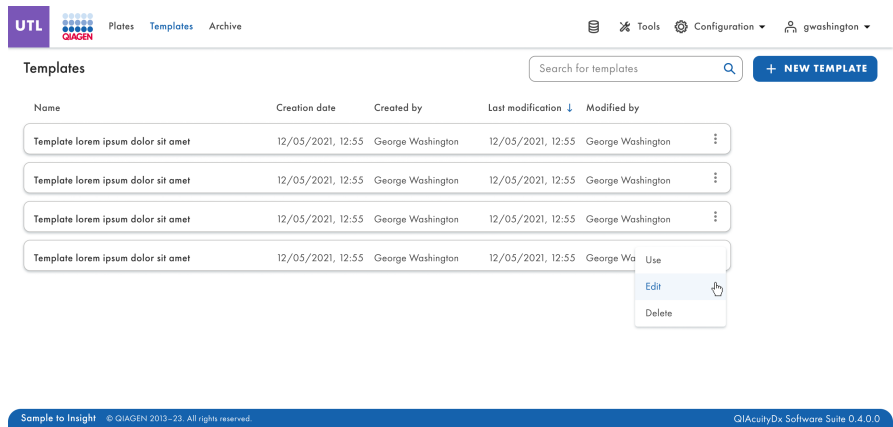
Name	Creation date	Created by	Last modification	Modified by	
Template lorem ipsum dolor sit amet	12/05/2021, 12:55	George Washington	12/05/2021, 12:55	George Washington	
Template lorem ipsum dolor sit amet	12/05/2021, 12:55	George Washington	12/05/2021, 12:55	George Washington	
Template lorem ipsum dolor sit amet	12/05/2021, 12:55	George Washington	12/05/2021, 12:55	George Washington	
Template lorem ipsum dolor sit amet	12/05/2021, 12:55	George Washington	12/05/2021, 12:55	George Washington	<div><div>Use</div><div>Edit</div><div>Delete</div></div>

Sample to Insight

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QIAcuityDx Software Suite 0.4.0.0

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 screenshot shows the 'Template configuration' screen for 'Template lorem ipsum dolor'. The top navigation bar includes 'UTL' and 'QIAGEN' logos, and tabs for 'Plates', 'Templates', and 'Archive'. A search bar and a '+ NEW TEMPLATE' button are on the right. Below the navigation bar is a sidebar with a list of steps: '1 General data', '2 dPCR Parameters', '3 Reaction mixes', '4 Samples & Controls', and '5 Plate layout'. The main area contains a form with fields for 'Template name' (with a value of 'Template lorem ipsum dolor' and a character count of '26/100'), 'Plate name' (with a character count of '0/100'), 'Plate type' (a dropdown menu), 'Labels' (with a character count of '0/10'), and 'Description' (with a character count of '0/2000'). At the bottom, there are 'CANCEL' and 'NEXT' buttons.

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.

UTL QIAAGEN Plates Templates Archive

Template lorem ipsum dolor sit amet

REPORTS MORE

1 General data
2 dPCR Parameters
3 Reaction mixes
4 Samples & Controls
5 Plate layout

Template name *
Template lorem ipsum dolor sit amet 35/100

Plate name 0/100

Plate type

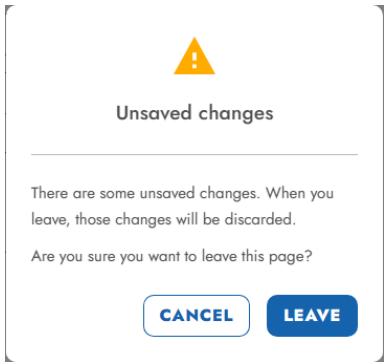
Labels 0/10

Description 0/2000

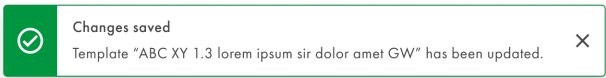
CANCEL

Save changes
Save and exit
NEXT

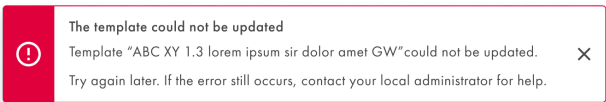
Whenever the user has modified a template and clicks the **Cancel** button without saving first, a warning confirmation pop-up is displayed:



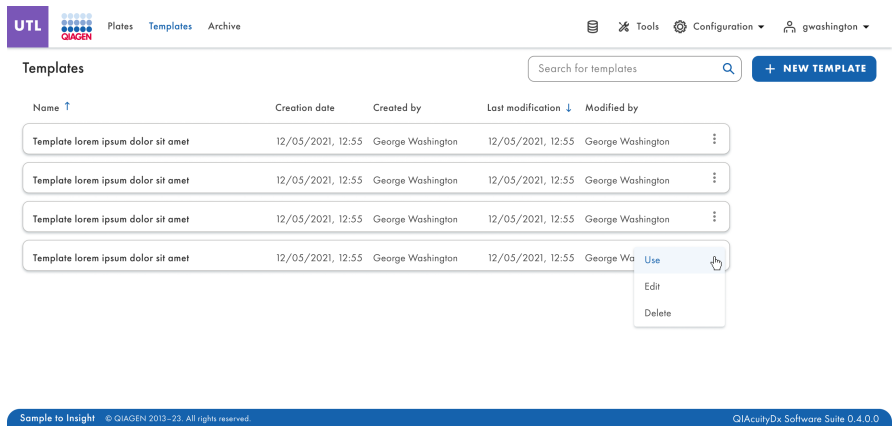
After updating an already created template, a success notification pop-up is displayed:



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

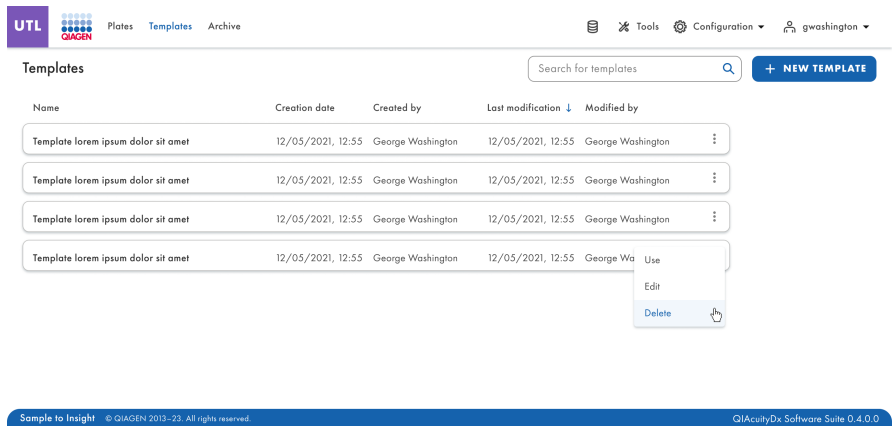


The authorized user with Read Template permission can view the details of the plate template. The template configuration screen appears when the user clicks the template name or selects **Use** or **Edit** from the 3-dot menu.

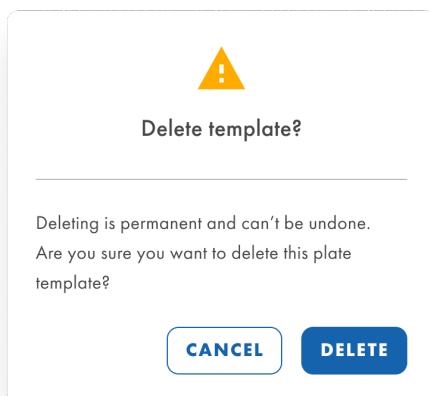


The split button on the bottom of the screen switches to the following template editing step and saving remains disabled until the changes are done.

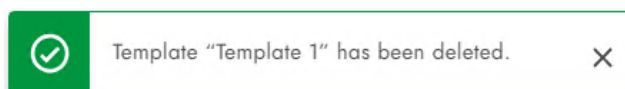
The authorized user with Delete Template permission can delete plate templates.



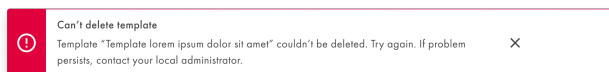
When the user selects **Delete** from a 3-dot menu, a warning confirmation pop-up message is displayed, informing the user that deleting a template is permanent.



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.

UTL **Plates** Templates Archive

Tools Configuration g.washington

New plate

1 General data 2 dPCR Parameters 3 Reaction mixes 4 Samples & Controls 5 Plate layout

Plate name * Characters left: 100

Plate type *

Assay

Ownership *

Plate barcode *

Enter barcode number manually or scan the barcode with handheld scanner

Description

TEMPLATES

Use template

Save as template

CANCEL NEXT

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.

Use template

Template

Using a template means overwriting all the current plate data

CANCEL USE

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

Use template

Template

Lorem ipsum

Lorem ipsum 1

Lorem ipsum 2

Lorem ipsum 3

CANCEL USE

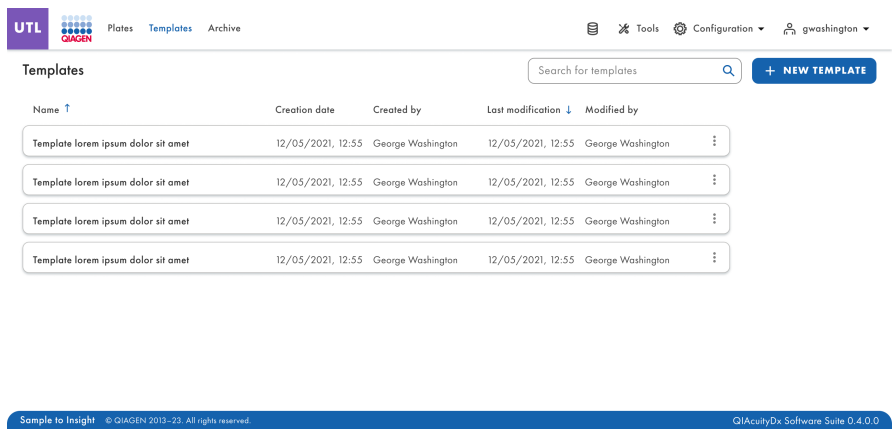
Use template

Template

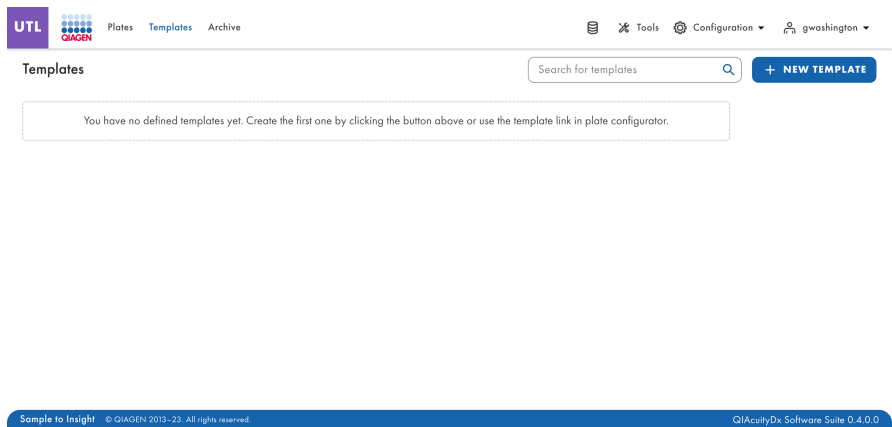
Lorem ipsum 1

CANCEL USE

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.

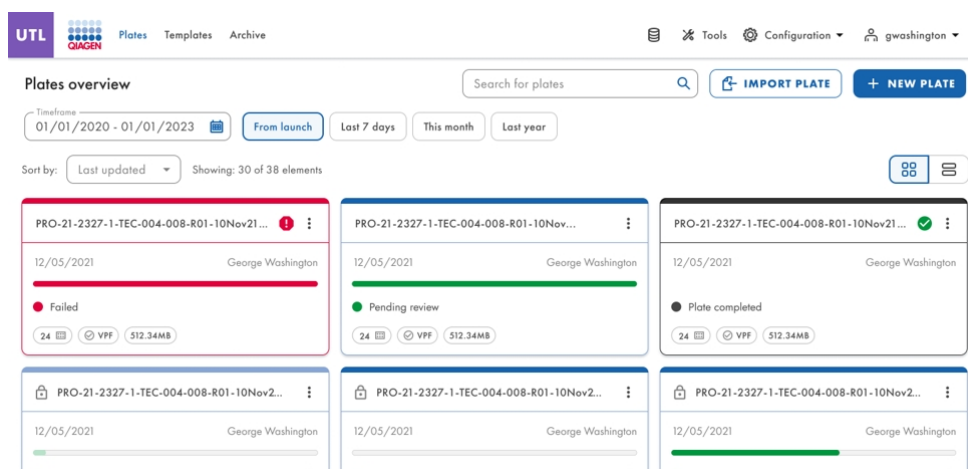


If no templates have been created yet, the following message is displayed:



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 (Utility Mode [1.1.0.0] 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.

Note: When the barcode field already has a barcode present, the field is not updated when scanning a different barcode until the previously entered barcode is deleted.

- Plate Ownership can only be modified by users with Set Plate Ownership permission. Multiple plate owners are supported. Only active users can be defined as plate owners. It is mandatory to have at least one owner. By default, the user creating the plate is assigned as Plate Owner.

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:

- 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.
- 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.

Channel	Exposure	Gain
Green	500 ms	8
Orange	500 ms	8
Yellow	500 ms	8
Red	500 ms	8
Crimson	500 ms	8

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

- The default exposure times and gain settings are applied automatically. Depending on the assay, different settings may be required and so can be altered.
- 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.

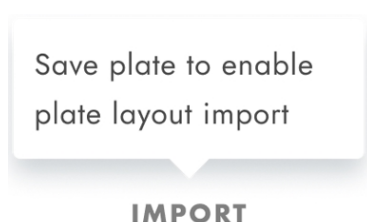
Reaction mix name	Target	Dye	Channel	IC
Reaction Mix 1	Target A Lorem ipsum target	FAM -	Green Orange	- ✓
Reaction Mix 2	Target B Target C	FAM -	Green Orange	

7. To create a reaction mix, click on the **Reaction mix** tab. Define the reaction mix name, the target name, and the detection channel. The following characters are not supported for the reaction mix name: ~ ' " ! ? @ ^ * () = { } [] , ; < > | / \ & . The reaction mix name can have up to 100 characters. The Target name can have up to 40 characters. 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. A Sample ID can have up to 100 characters, its description can have up to 1000 characters, and each sample ID can have up to 10 labels. A control and an NTC can have up to 100 characters. Characters not recognizable by external systems using HL7 protocol (| ^ ~ \ & .) cannot be used in Sample IDs, controls, or NTCs. The regular expression of the accepted characters is `^[a-zA-ZÀ-ÿ0-9\s!\"'·$%&\\/()=?_{}@#~`'+\[\]\{\}~.:.,;<>¡*µ£§°β])+$.`

9. Once the samples, controls and NTCs have been created, allocate wells in the plate.

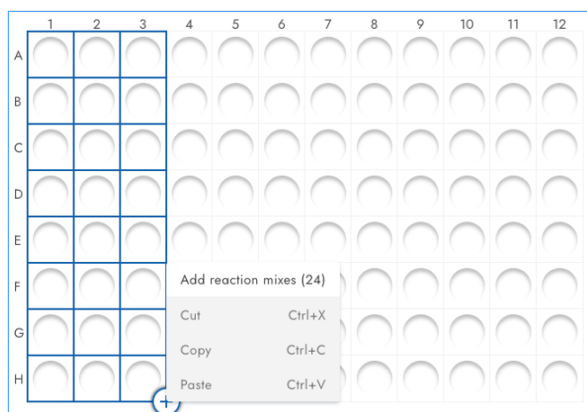
Note: It is not possible to import a plate layout while creating a plate; the **Import** button is disabled and, when hovering, the following message is displayed:



10. 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**.

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

- a. First, click the well required that will contain the sample, control, or NTC.



- 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.

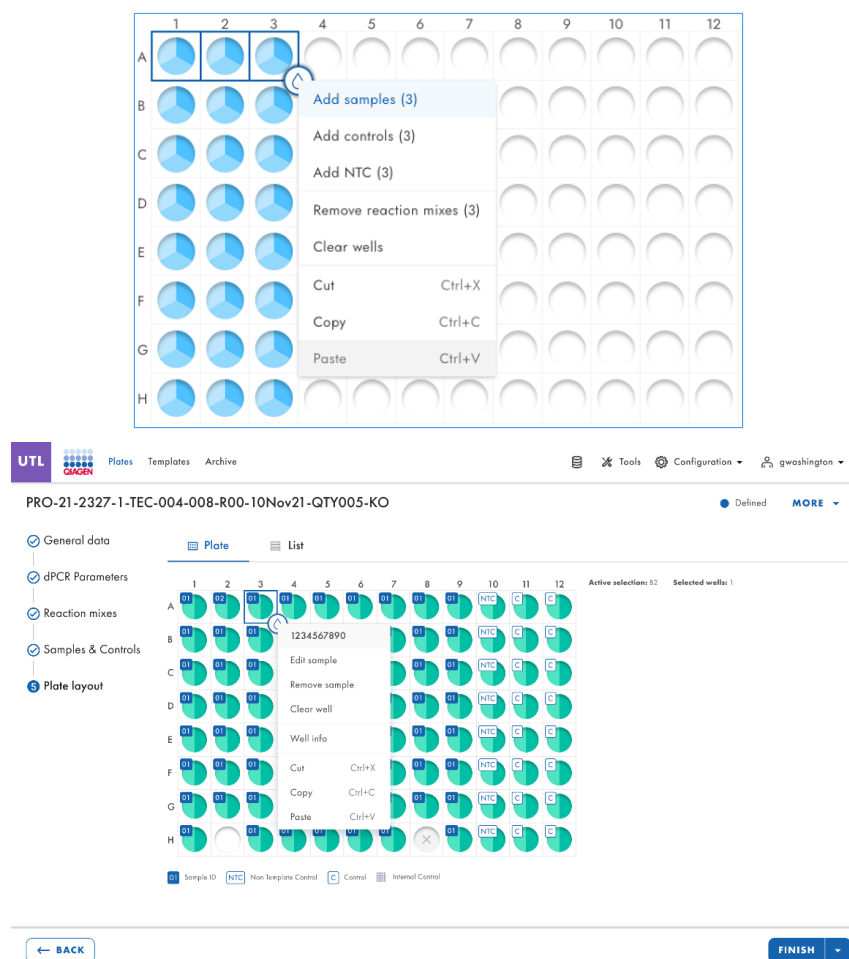
Create new reaction mix ✕

Reaction mix name * 0/100 ✎

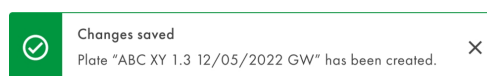
Target name *	Dye	Channel *	
<input type="checkbox"/> Target XYZ	EvaGreen	Green	<input type="checkbox"/> Internal Control ✕
<input type="text"/> Target name	Dye	Channel	<input type="checkbox"/> Internal Control ✕
<input type="text"/> Target name	Dye	Channel	<input type="checkbox"/> Internal Control ✕
<input type="text"/> Target name	Dye	Channel	<input type="checkbox"/> Internal Control ✕
<input type="text"/> Target name	Dye	Channel	<input type="checkbox"/> Internal Control ✕

CANCEL SAVE

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



- 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:

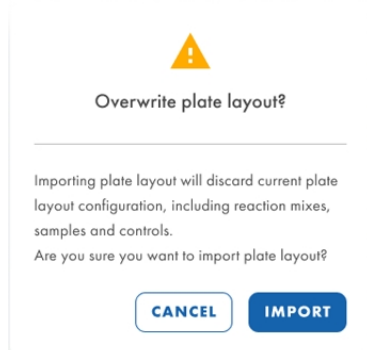


- If any of the mandatory fields has not been defined, there is not at least one sample defined in the plate layout or the plate barcode has not been defined, or the plate is saved with status Drafted, return to the run layout and check the data input and re-define. Once done, click the **Save** button again.
- To return to the Plate overview screen, click **Done**. The run should now have a status of "Defined".

15. It is possible to export and import a plate layout in CSV format for plates that have already been created, using the **Import** and **Export** buttons in the plate layout step of the plate configurator:



16. When clicking **Import**, a pop-up window for selecting the plate layout file is opened. Only CSV files are supported.
17. When trying to import a plate layout if there are already reaction mixes, controls, or samples configured, a warning dialog is displayed informing the user that importing a plate layout will discard all plate layout configuration, including reaction mixes, samples, and controls. When clicking **Cancel**, the user is brought back to the current plate layout:

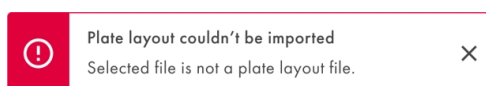


18. The following validation of fields is performed when importing a plate layout:
- Well position:** Depends on the number of wells of the selected plate type.
 - SampleID:** EMPTY or same validation as in plate layout.
 - Type:** Only Sample, NTC, and Control is allowed. EMPTY is only allowed if SampleID is EMPTY.
 - SampleDescription:** EMPTY or same validation as in plate layout.
 - SampleLabels:** EMPTY or same validation as in plate layout.
 - ReactionMixName:** EMPTY or same validation as in plate layout.

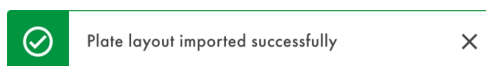
- g. **Channel1**: EMPTY if ReactionMixName is EMPTY, or only GREEN, YELLOW, ORANGE, RED, and CRIMSON are allowed.
- h. **Target1**: EMPTY if ReactionMixName is EMPTY, or same validation as in plate layout.
- i. **Dye1**: EMPTY or only FAM, SYBR Green, EvaGreen, VIC, HEX, TAMRA, ROX, and Cy5 are allowed.
- j. **InternalControl1**: EMPTY if ReactionMixName is EMPTY, or TRUE and FALSE are allowed.
- k. **ControlType1**: if Type is CONTROL, then only positive and negative are allowed. If Type is not CONTROL, then only EMPTY is allowed.

Note: the Channel#, Target#, Dye#, InternalControl#, and ControlType# block are repeated until 5.

In case the content of the plate layout does not comply with the validation of fields, an error is displayed:



In case the plate layout is successfully imported, a success notification is displayed:



19. The plate is now ready to run on the instrument.

CAUTION Sample mismatch



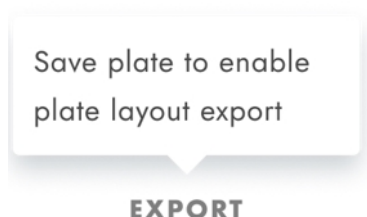
To avoid potential sample mismatches, please be careful when assigning samples in the plate layout during Plate Creation. Ensure that the layout created in the application corresponds to the layout of the samples dispensed in the Nanoplate.

Users with Read Plate permissions can export a plate layout from the Plate details screen in Utility Mode (it is not possible to export a plate layout in IVD Mode).

When clicking **Export**, the **To CSV** option is displayed. After selecting **To CSV**, Software Suite automatically downloads the plate layout in a CSV file.



It is not possible to export a plate layout while creating or editing a plate without saving; the **Export** button is disabled and, when hovering, the following message is displayed.

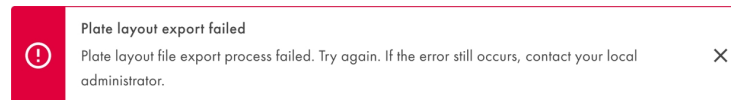


The exported plate layout contains the following data, separated by comma:

- Well
- Sample ID
- Type
- Sample description
- Sample labels
- Reaction mix name
- Channel 1
- Target 1
- Dye 1
- Internal control 1
- Control type 1
- Channel 2
- Target 2
- Dye 2
- Internal control 2
- Control type 2
- Channel 3
- Target 3
- Dye 3
- Internal control 3
- Control type 3
- Channel 4
- Target 4
- Dye 4
- Internal control 4

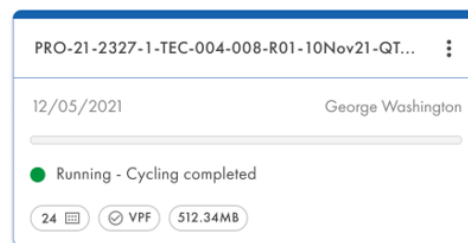
- Control type 4
- Channel 5
- Target 5
- Dye 5
- Internal control 5
- Control type 5

In case the plate export fails due to a different cause, the following generic error notification is displayed:



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

- Plate title
- Plate type
- Plate status
- Last update date
- Plate size
- 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 Mode. To create new plates in IVD Mode, the following fields are mandatory to be filled in **General data**:

- Assay
- Plate name
- Barcode

Note: When the barcode field already has a barcode present, the field is not updated when scanning a different barcode until the previously entered barcode is deleted.

- Plate type
- Kit information
 - Kit ID or catalog number
 - IS-CAL (if applicable)

- Ownership

Plate Ownership can only be modified by users with Set Plate Ownership permission. Multiple plate owners are supported. Only active users can be defined as plate owners. It is mandatory to have at least one owner. By default, the user creating the plate is assigned as Plate Owner.

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

- Labels
- Description

IVD QIAGEN Plates Archive

Tools Configuration gwashington

New plate Drafted DETAILS

1 General data

2 Samples & layout

Assay *

Plate name *

Plate barcode

Enter barcode number manually or scan the barcode with handheld scanner

Plate type *

Primer / probe kit

Kit ID or Catalogue number is required

Kit ID *

Enter ID manually or scan the Qicard

Catalogue number *

CANCEL NEXT

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.

IVD Plates Archive

Tools Configuration gwashington

New plate

1 General data

2 Samples & layout

Assay * bcr-abl1 (1.0)

Plate name * KO 12/05/2021 - 002

Plate barcode * 00000123456789012345678901

Enter barcode number manually or scan the barcode with handheld scanner

Plate type * QIAcuityDx Nanoplate 26k 24-well

Primer / probe kit

Kit ID or Catalogue number is required

Kit ID *

Enter ID manually or scan the Qcard

Catalogue number *

Expiration date * Lot no * IS-CAL *

Mastermix kit

Kit ID or Catalogue number is required

Kit ID *

Enter ID manually or scan the Qcard

Catalogue number *

Expiration date * Lot no * IS-CAL *

+ Add another kit

Description

CANCEL **NEXT**

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

IVD Plates Archive

Tools Configuration gwashington

New plate

1 General data

2 Samples & layout

VPF required

This nanoplate requires a Volume Precision Factor to be applied. Upload VPF file or contact your local administrator for assistance. **UPLOAD VPF**

Assay * BCR-ABL 1.1

Plate name * KO 12/05/2021 - 002

Plate barcode * 1234567899012345678901234556

VPF is required for this barcode. You can save this plate, but you can't process it until VPF is uploaded.

Plate type * QIAcuityDx Nanoplate 26k 24-well

Primer / probe kit

Kit ID * 1234567890

CANCEL **NEXT**

Possible error and warning scenarios regarding the plate barcode:

- If the barcode format is invalid (i.e. does not consist of 26 digits), the “Invalid Barcode” error is displayed and the user cannot proceed with the plate creation.
- If the plate is expired, a warning message states that the nanoplate is expired is displayed and the user cannot proceed with the plate creation.
- If the plate expires tomorrow, a warning message states that the nanoplate expires tomorrow is displayed and the user can proceed with the plate creation.
- If the plate type does not match with the barcode:
 - When the barcode is set first and afterwards the plate type is selected, then a warning pop-up that the plate type does not match the barcode is displayed.
 - When the plate type is selected first and afterwards the barcode is entered, then a warning pop-up that the barcode does not match the selected plate type is displayed.

The following error messages can occur:

- When an invalid character is used or the barcode does not consist of 26 digits:

Plate barcode 
Invalid barcode

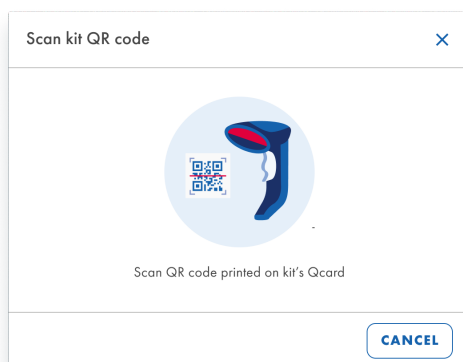
- When a QIAcuity Nanoplate is used instead of a QIAcuityDx Nanoplate:

Plate barcode 
Nanoplate with this barcode is not suitable for Dx use. Use a different nanoplate.

- When a plate with this barcode already exists within Software Suite system:

Plate barcode 
This barcode doesn't match selected plate type

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: Lot Num, Expiry Date, Kit ID, IS-CAL Value
- Master Mix Kit: Lot Num, Expiry Date, Kit ID

Note: The catalog number is reported in the Q-Card but not in the data matrix; therefore, it has to be manually entered. The catalog number is not required if the kit ID (GTIN) is fulfilled.

Note: It is recommended to enter the primer/probe kit and master mix kit information using the handheld scanner when available. When not possible, it is advised to review the manually entered data to ensure its traceability and correctness.

IVD Plates Archive

New plate

1 General data

Assay * BCR-ABL 1.1

Plate name * KO 12/05/2021 - 002

Plate barcode 00000123456789012345678901

Enter barcode number manually or scan the barcode with handheld scanner

Plate type * QIAcuityDx Nanoplate 26k 24-well

2 Samples & layout

Primer / probe kit

Kit ID *

Enter ID manually or scan the Qcard

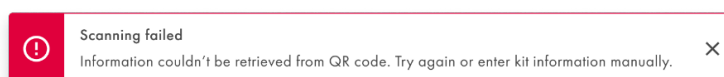
Catalogue number *

Expiration date * Lot no * IS-CAL *

Mastermix kit

CANCEL NEXT

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



IVD Plates Archive

KO-12/05/21-1

1 General data

2 Samples & layout

Reaction mix and controls required

This plate requires a reaction mix, 4 controls (x2 replicates) and 8 samples (x2 replicates) to be specified.

Select well(s), click on a droplet icon and select option to add specific type of content.

Reaction mix has to be added to wells, before samples and controls can be specified.

Plate layout

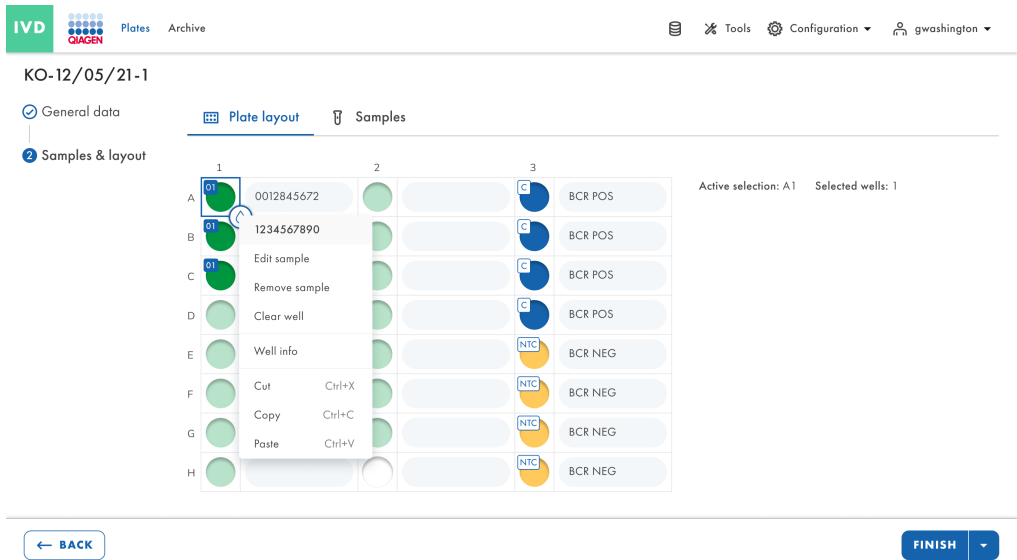
	1	2	3
A			
B			
C			
D			
E			
F			
G			
H			

BACK FINISH

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.

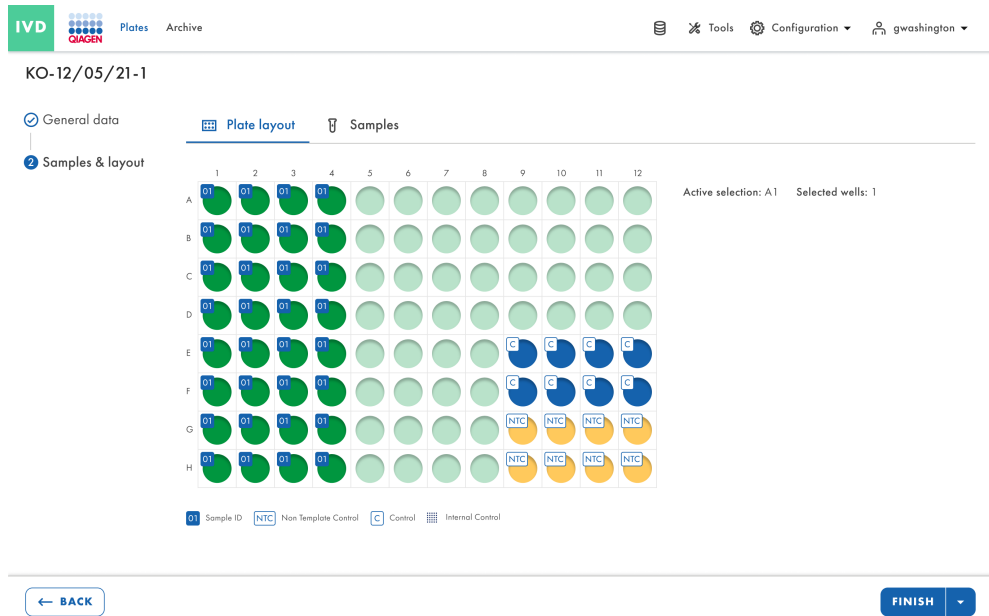
To define a well's contents, click on a well, select the droplet icon, and select the option to add specific type of reaction mix. A reaction mix has to be added to the wells, before samples and controls can be specified.

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:

KO-12/05/21-1

General data | Plate layout | **Samples [2]**

2 Samples & layout

[+ NEW SAMPLE](#)

	Name	Well(s)
01	1234567890	A1
02	1112223334	-
02	1112223334	A1, A2, A3, A4, B2, B4, C3, C4, D1, D3, E1, E5

[← BACK](#) [FINISH](#)

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
- Reports

Loaded, In queue, Waiting, and Running status:

- Details
- Reports

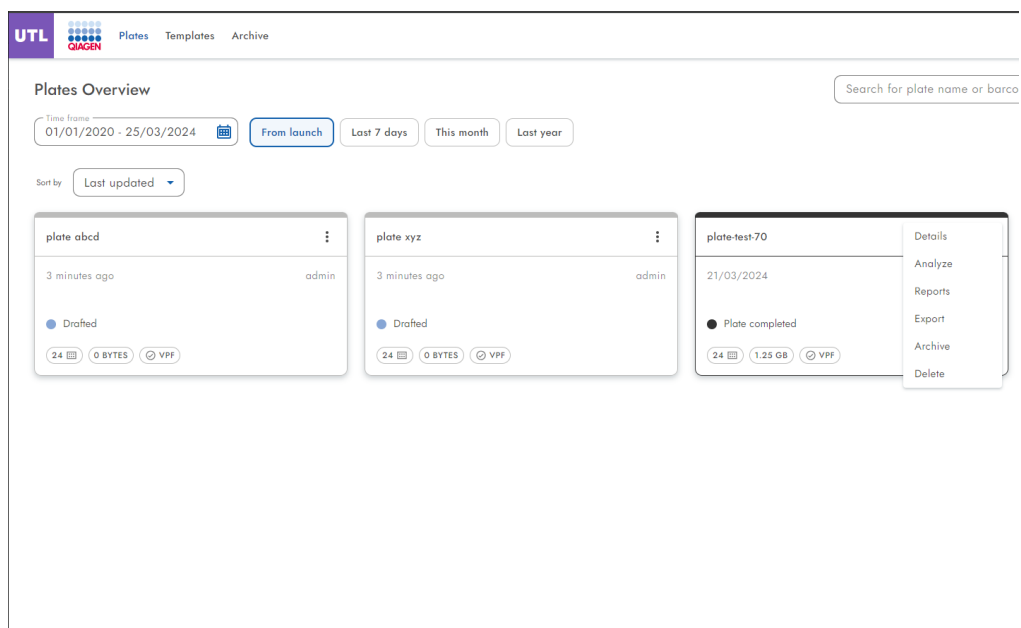
Plate Completed status:

- Details
- Export
- Archive
- Delete
- Analyze
- Reports

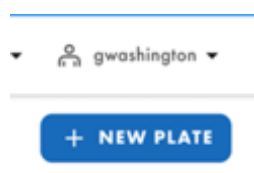
Failed or Invalidated status:

- Details
- Export
- Archive
- Delete
- Analyze
- Reports

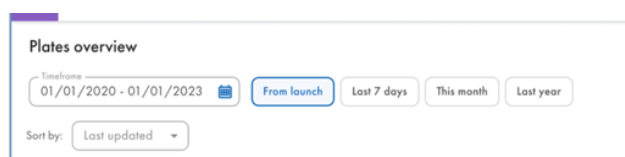
Note: The **Archive** plate option is only available if an archive location has been configured.



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.

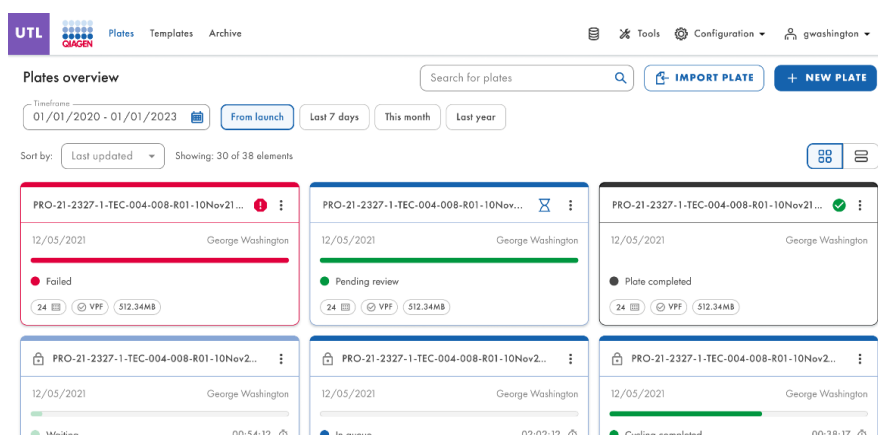


Users can also sort plates by various other criterion, by clicking on “sort by” drop-down menu. This enables users to sort plates by last update, plate name, or plate status.



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.

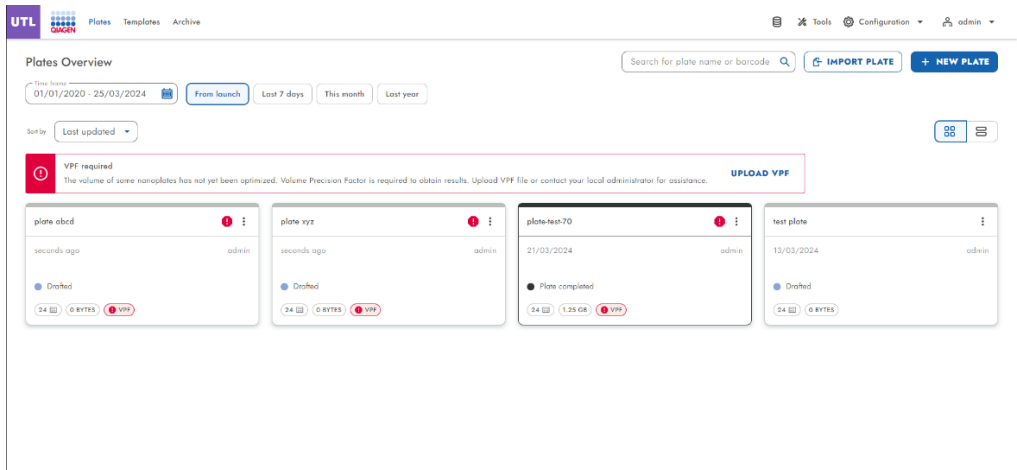
New sets of VPFs will be published during production of the nanoplate batches and can be downloaded from the QIAGEN website.

The new VPF must be uploaded to the Software Suite.

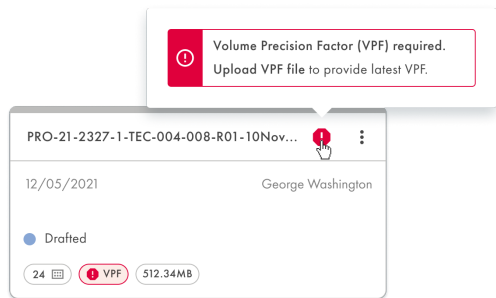
The Software Suite applies the uploaded VPF to the plate for calculating the partition volume variations when determining the concentration. The file is required to optimize the partition volumes of the Nanoplates to obtain results.

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.

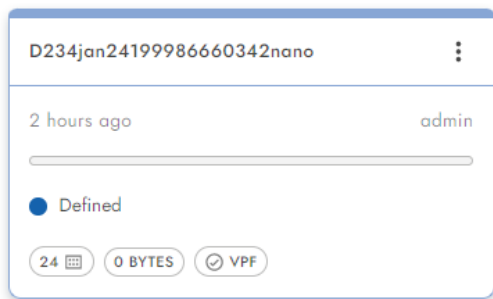
An inline warning message is displayed to all users to upload VPF files if any of the created plates are missing a VPF file.



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.

UTL **Plates** Templates Archive

Tools Configuration gwashington

New plate

TEMPLATES

- 1 General data
- 2 dPCR Parameters
- 3 Reaction mixes
- 4 Samples & Controls
- 5 Plate layout

VPF required

This nanoplate requires a Volume Precision Factor to be applied. Upload VPF file or contact your local administrator for assistance. [UPLOAD VPF](#)

Assay *
Utility Channel 1.1

Plate name *
ABC XY 1.3 12/05/2022 GW

Plate barcode *
1234567899012345678901234556

VPF is required for this barcode. You can save this plate, but you can't process it until VPF is uploaded.

Plate type *
Nanoplate 24-wells (26K)

Ownership *
George Washington

Description

[CANCEL](#) [NEXT](#)

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.

UTL **Plates** Templates Archive

Tools Configuration admin

Plates Overview

Search for plate name or barcode

[IMPORT PLATE](#) [NEW PLATE](#)

From launch Last 7 days This month Last year

Sort by Last updated

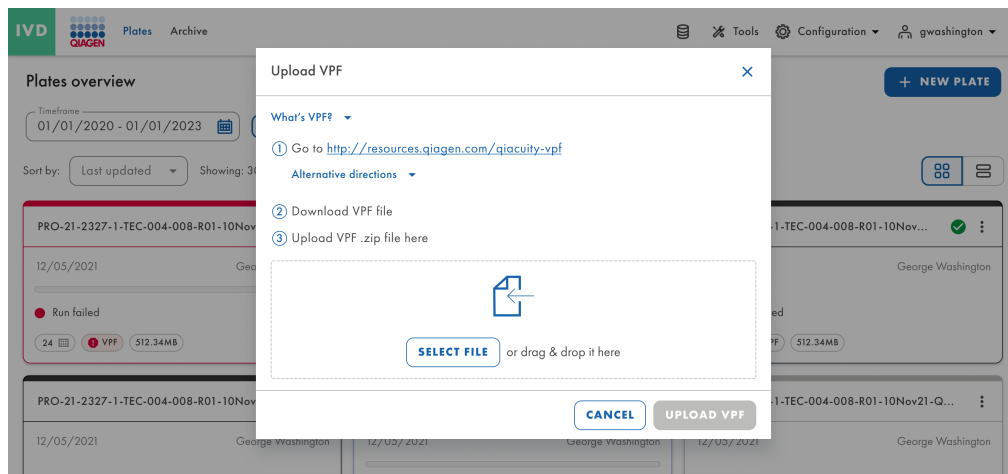
VPF required

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](#)

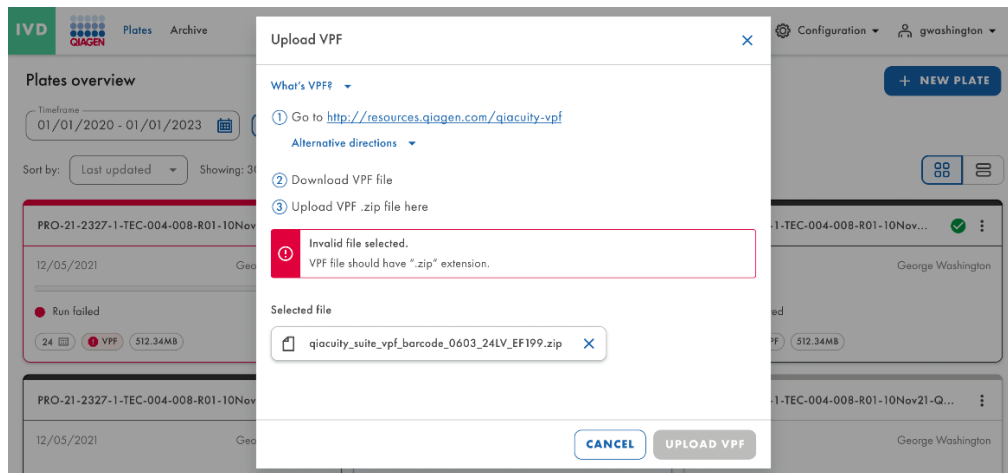
<p>plate abcd</p> <p>seconds ago admin</p> <p>Drafted</p> <p>24 BYTES VPF</p>	<p>plate xyz</p> <p>seconds ago admin</p> <p>Drafted</p> <p>24 BYTES VPF</p>	<p>plate-test-70</p> <p>21/03/2024 admin</p> <p>Plate completed</p> <p>24 BYTES 1.25 GB VPF</p>	<p>test plate</p> <p>13/03/2024 admin</p> <p>Drafted</p> <p>24 BYTES</p>
---	--	---	--

[IMPORT PLATE](#) [NEW PLATE](#)

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.

UTL **Plates** Templates Archive Tools Configuration gwashington

New plate

VPF required
This nanoplate requires a Volume Precision Factor to be applied. Upload VPF file or contact your local administrator for assistance. **UPLOAD VPF**

General data
dPCR Parameters
Reaction mixes
Samples & Controls
Plate layout

Assay *
Utility Channel 1.1

Plate name *
ABC XY 1.3 12/05/2022 GW

Plate barcode *
1234567899012345678901234556

VPF is required for this barcode. You can save this plate, but you can't process it until VPF is uploaded.

Plate type *
Nanoplate 24-wells (26K)

Ownership *
George Washington

Description

CANCEL **NEXT**

The Upload VPF pop-up is displayed.

UTL **Plates** Templates Archive Tools Configuration gwashington

New plate

VPF required
This nanoplate requires a Volume Precision Factor to be applied. Upload VPF file or contact your local administrator for assistance. **UPLOAD VPF**

General data
dPCR Parameters
Reaction mixes
Samples & Controls
Plate layout

Assay *
Utility Channel 1.1

Plate name *
ABC XY 1.3 12/05/2022 GW

Plate barcode *
1234567899012345678901234556

VPF is required for this barcode. You can save this plate, but you can't process it until VPF is uploaded.

Plate type *
Nanoplate 24-wells (26K)

Ownership *
George Washington

Description

CANCEL **NEXT**

Upload VPF

What's VPF? **What's VPF?**

① Go to <http://resources.qiagen.com/qiacuity-vpf>
Alternative directions

② Download VPF file

③ Upload VPF .zip file here

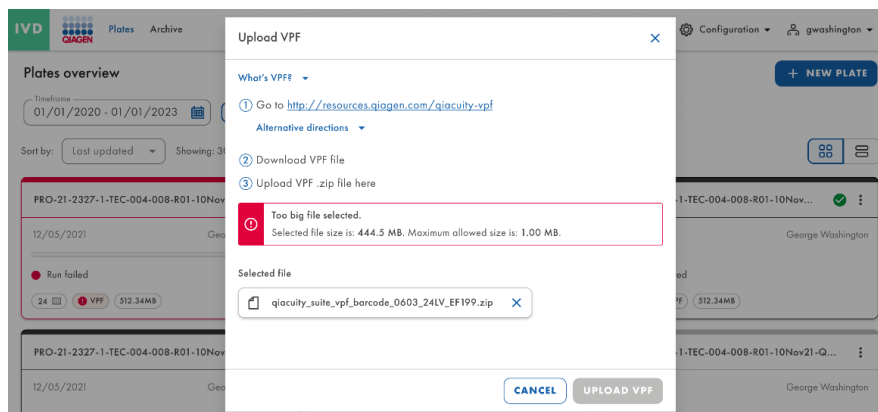
SELECT FILE or drag & drop it here

CANCEL **UPLOAD VPF**

The pop-up warning message above 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.

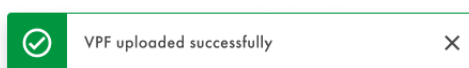


If the size of the file uploaded is less than 1MB, a validity check will be performed.

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**



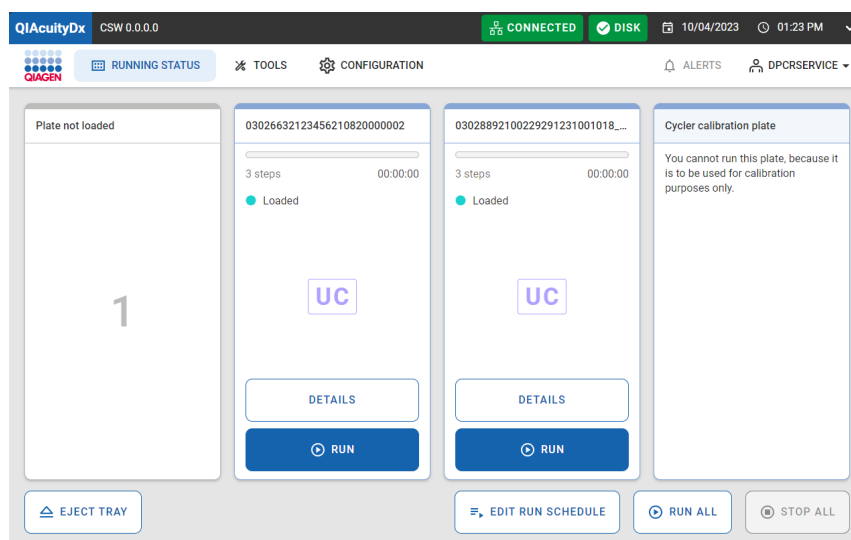
User should ensure the nanoplate is flat when loaded into the instrument drawer. Failure to do so may cause a collision.

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.

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



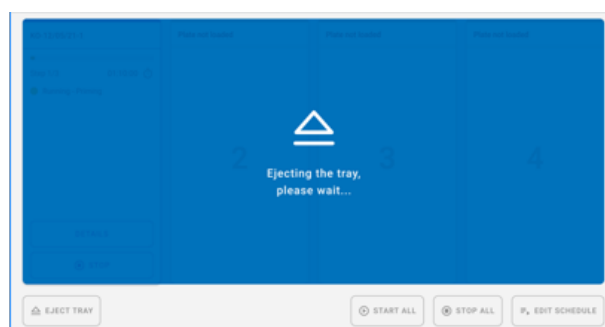
The upper **Network** button with a green tick  or **CONNECTED**  shows that the instrument and Software Suite are connected.

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.

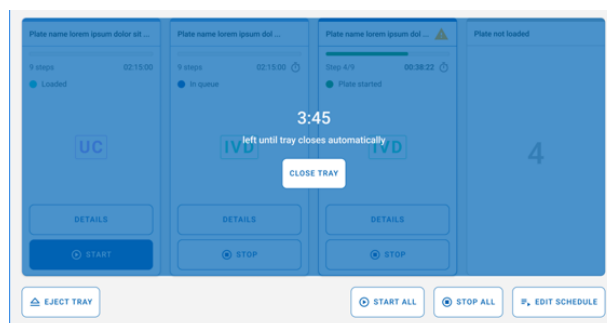
Note: Before loading a plate into the instrument, the plate run configuration shall be completed ("Defined") in the connected Software Suite. If no plate definition is found matching the barcode of the plate loaded, an error will be shown.

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 alphanumeric 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.

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



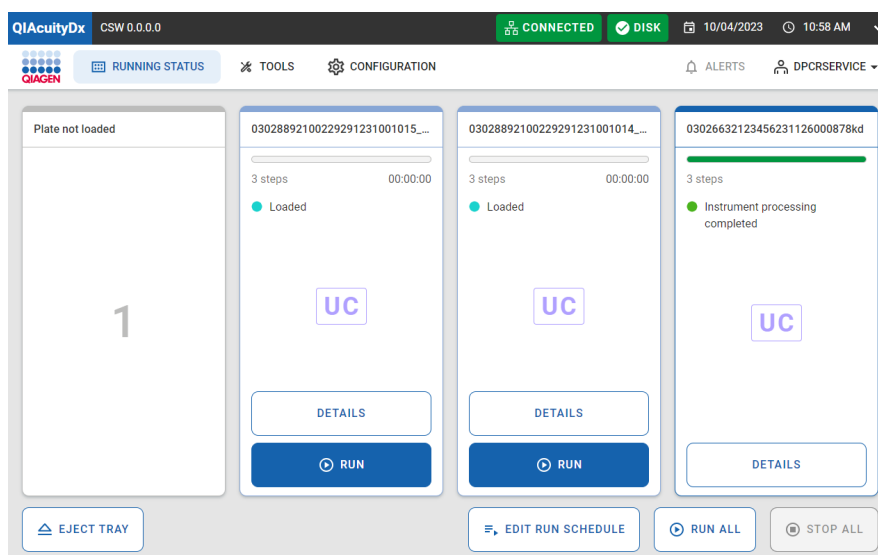
- Remove the Nanoplate from the tray by using the GUI or physical tray release button. Place the Nanoplate into one of the free slots (not highlighted by an LED light) of the instrument with the barcode facing the device.



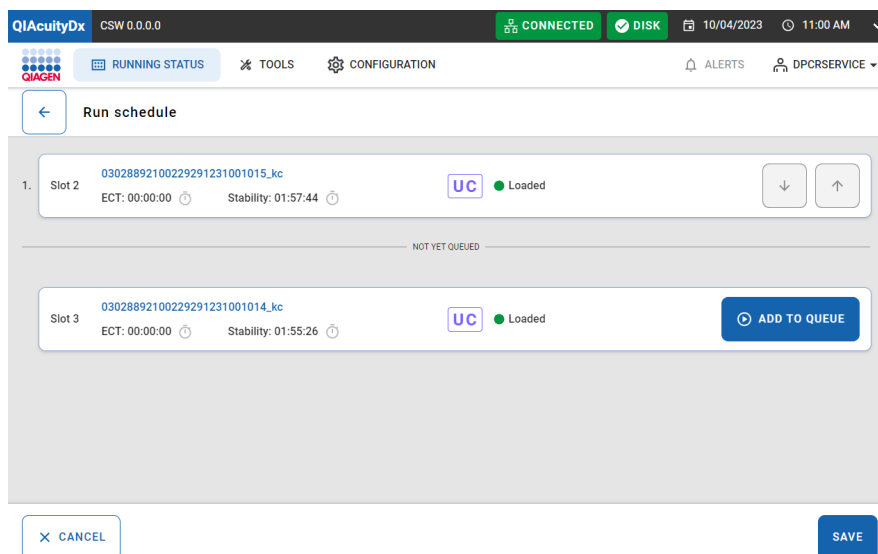
- Press the **CLOSE TRAY** button to close the drawer once the plate is in place. If the button is not pressed, after the timer ends, it will close automatically.
- LED lights will show different colors depending on the status of the instrument:
 - Blue:** for Nanoplates loaded but not started and while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

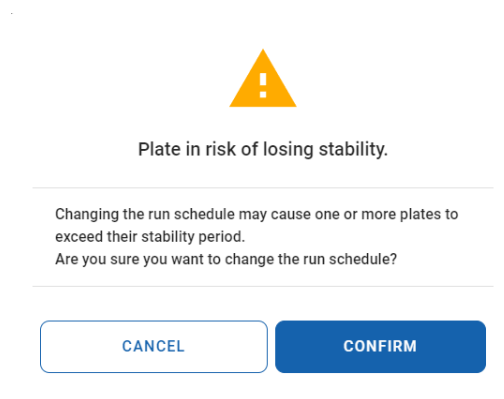
The Run schedule screen has 2 sections: one for scheduled plates and another for unscheduled ones. If there are no plates in one of these two, then that section is not displayed at all.

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.

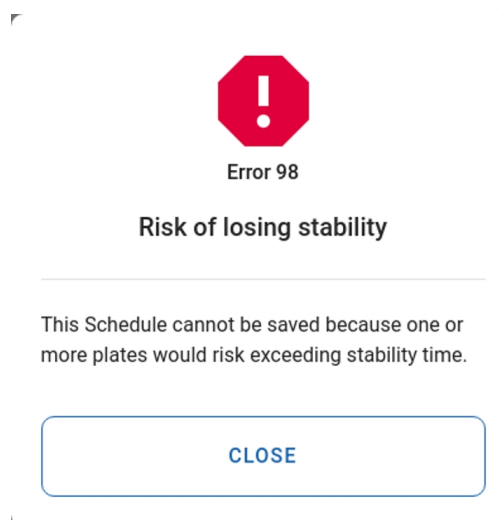
All the changes are only processed once the user clicks on the **Save** button and gets a successful response. Therefore, reordering operations can be performed without effectively altering the schedule as long as the **Save** button is not pressed. Moreover, any modifications carried out in scheduling 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.

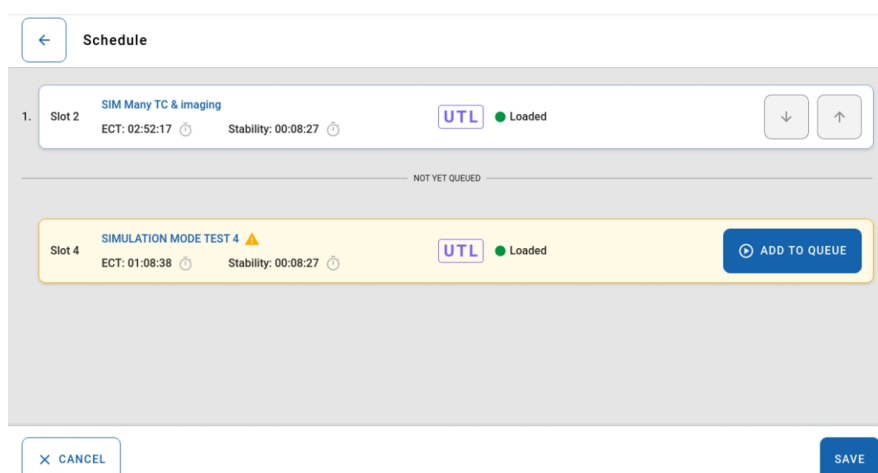
In **Utility Mode**, the user will see the following dialog.



In case the selected run order does not allow to run all remaining plates within their onboard stability times, the following dialog will be shown and it would not be possible to save the current schedule.



In such case, those plates in risk of losing their onboard stability will also be shown with a warning icon in the schedule view.



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).

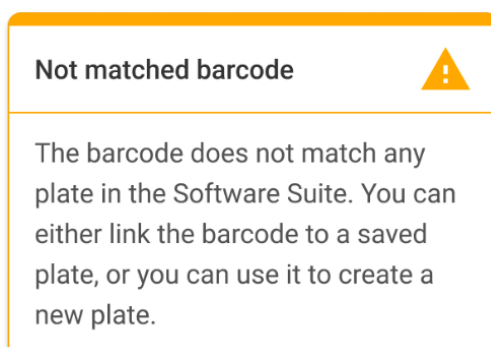
The onboard stability of the nanoplate can be seen as a dynamic metric, as it varies depending on the processing step the plate is at. There are 3 stages over which the onboard stability is timed:

- Post-loading: waiting to be primer rolled (3 hour stability time)
- Post-priming: awaiting for thermocycling (9 hour stability time, counting down)
- Post-thermocycling: waiting to be imaged (240 hour [10 days] 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

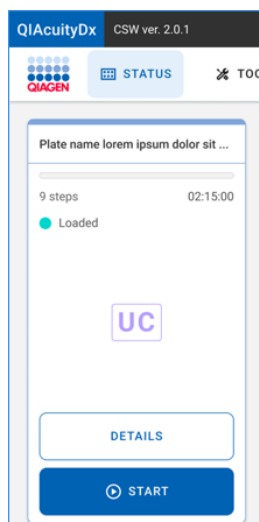
Once the QIAcuityDx Nanoplate is in place, the instrument will scan the barcode on the plate and the instrument tray LED lights will light up with a blue light.

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:

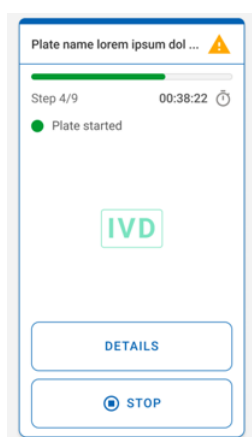


Note: If the barcode has not been predefined in the Software Suite, the plate must be removed from the instrument and the barcode must be scanned into plate configurator in the Software Suite (see Sections 5.15 Create a new plate in Utility Mode and 5.16 Create a new plate in IVD mode).

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



When the plate is processing 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 processing

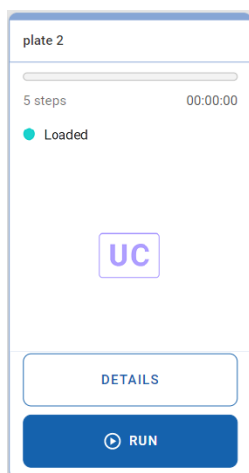
The plate is processed in the primary loading module, and the reaction mix of each well is partitioned into individual reactions. Then, a PCR is performed in the thermocycler. A positive fluorescence signal indicates the presence of suitable template material within a particular partition, which is detected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

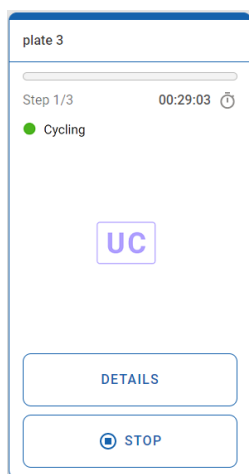
In the instrument's Running Status screen, each slot view can render a plate in any of its different possible states (thus, with different actions available for each case):

- 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



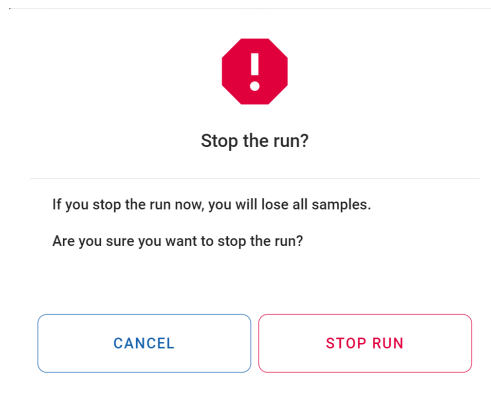
If a plate run is in progress, one of the following states can be displayed:

- Plate started
- Partitioning
- Partitioning completed
- Waiting – partitioning completed
- Imaging
- Imaging completed

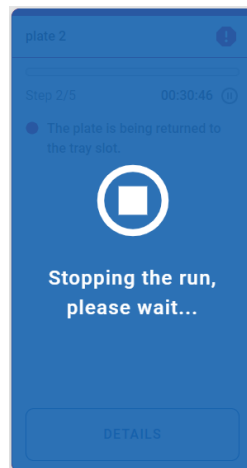
- Waiting – imaging completed
- Cycling
- Cycling completed
- Waiting – cycling completed

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

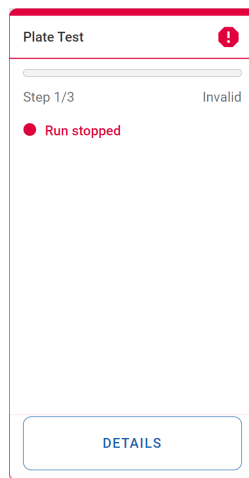
When clicking on the **Stop** button, the user has then to confirm that action via a confirmation dialog.



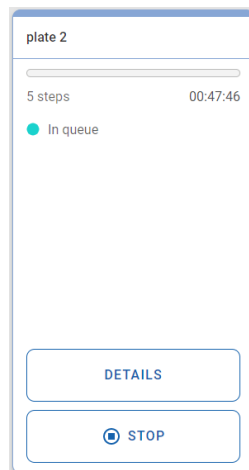
When a plate run is stopped, the plate is transported back to the tray (to its original slot) and, while that is happening, a blue overlay is displayed over its tile.



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



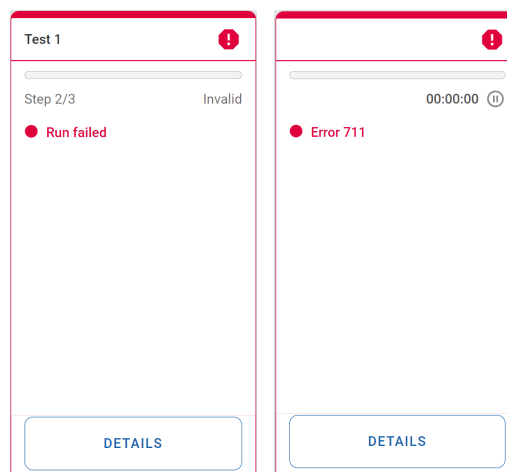
When a plate is "in queue", it can be stopped. If so, it immediately changes its state back to "loaded". In such case, as no run has started, the plate can still be run.

- Completed



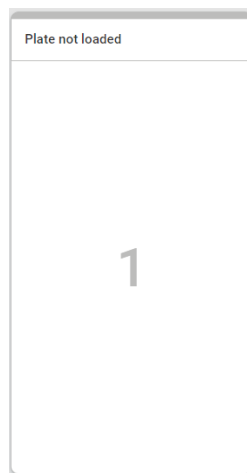
This tile is visible when a plate run is successfully completed.

- Error/Failed



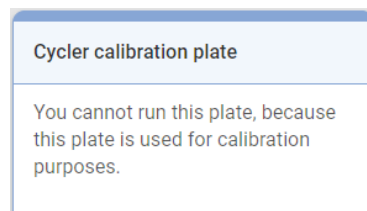
These tiles are visible when a plate run failed or when there is another error affecting the plate tile status (e.g., Error 711 – Software Suite Connectivity Issues).

- Plate not loaded



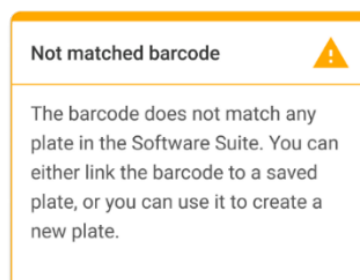
This tile is visible when the tray slot does not have any plate loaded.

- 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 details

Loaded

Run Steps

1

Partitioning

2

Cycling

3

Imaging

Plate name

03026632123456250203000555

Assay

uc-0.4.0.0

Plate barcode

03026632123456250203000555

Loaded

Owner(s)

admin

Est. run duration

00:00:00

Stability time

Time left to start Partitioning

01:41:11

Plate type

96 UC

CANCEL

- Plate is in queue

Plate details

In queue

Run Steps

1

Partitioning

2

Cycling

3

Imaging

Plate name

03026632123456250203000555

Assay

uc-0.4.0.0

Plate barcode

03026632123456250203000555

Loaded

Owner(s)

admin

Est. run duration

00:00:00

Stability time

Time left to start Partitioning

01:41:11

Plate type

96 UC

CANCEL

- Plate is processing

Plate details

×

● Plate started

Run Steps

1 Partitioning

2 Cycling

3 Imaging

Plate name

03026632123456250820000044

Assay

uc-0.4.0.0

Plate barcode

03026632123456250820000044

Loaded

09/22 07:38 AM by DPCRSERVICE

Owner(s)

admin

Est. completion time

01:03:41

Stability time

Time left to start Partitioning
01:42:18 ⓘ

Plate type

96

UC

- Plate processing in the instrument is completed

Plate details

Instrument processing completed

Run Steps

✓

Partitioning

✓

Cycling

✓

Imaging

Plate name

03026632123456250820000033

Completion time

00:59:41

Assay

uc-0.4.0.0

Plate type

96

UC

Plate barcode

03026632123456250820000033

Loaded

-

Owner(s)

admin

CANCEL

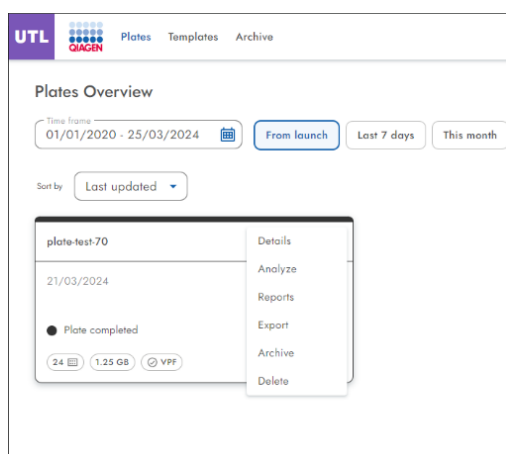
5.19.5. Check if images have a good quality or are over-saturated (only available in Utility mode)

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.

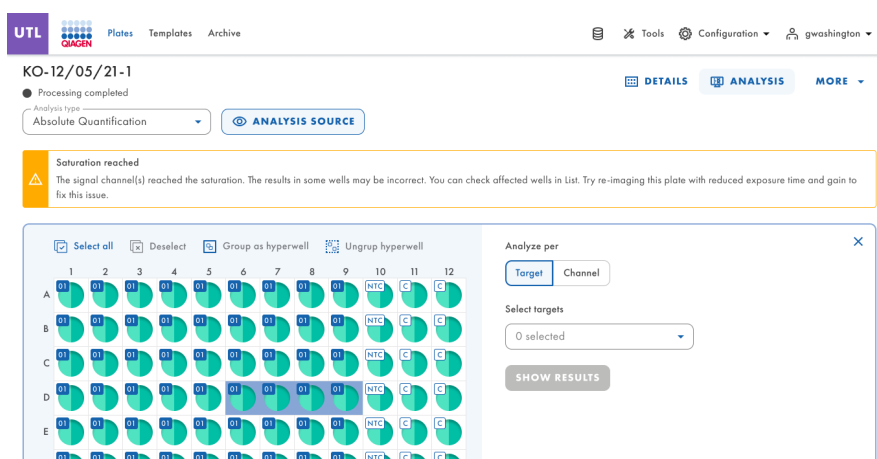
For analysis, click on the plate and select **Analyze** from the drop-down menu bar.

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.



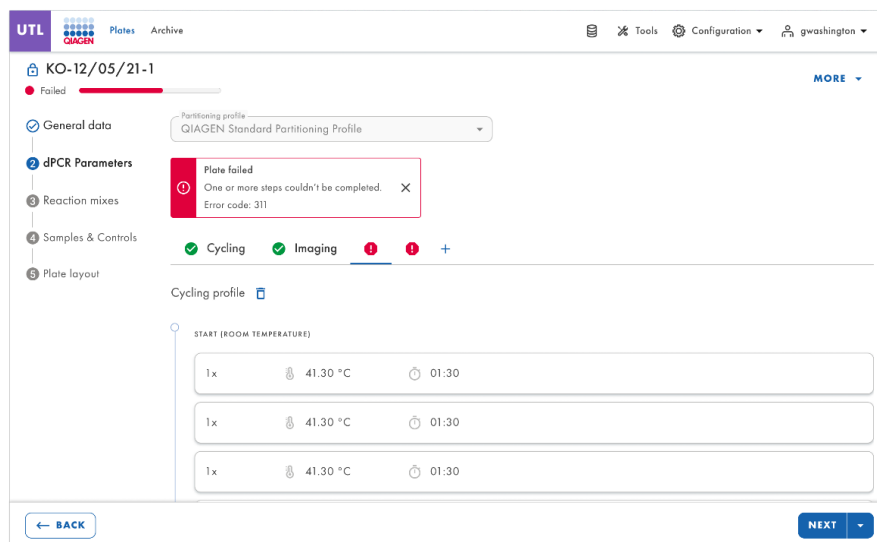
Note: If the signal for channels reached saturation, they will be highlighted in yellow. It is therefore recommended to reimage the plate with 30% lower exposure time.



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 8 steps, including the existing imaging steps, are allowed.



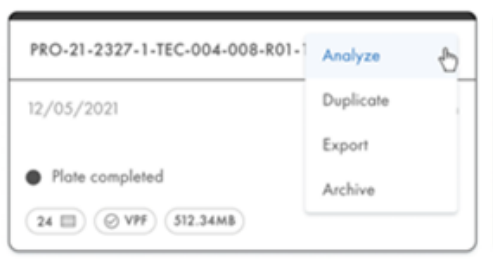
After adding the desired additional imaging steps, click **Save**. The plate status will remain as “Completed”.

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

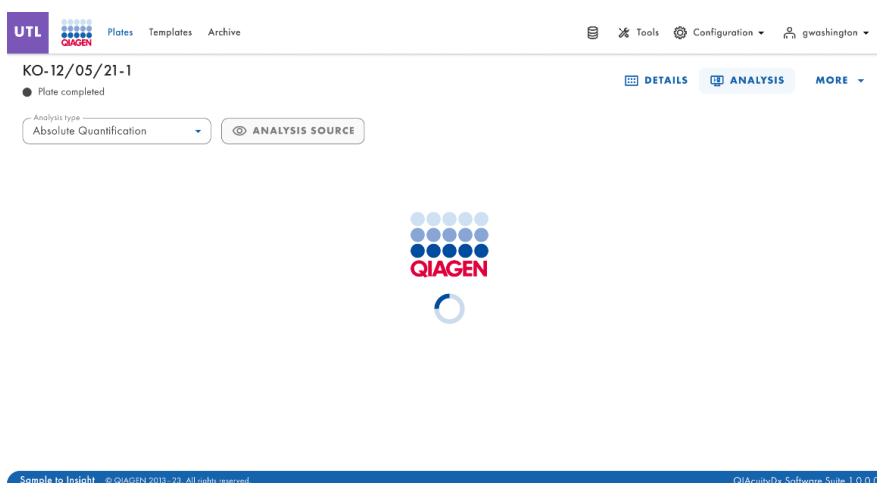
After the instrument has performed the additional imaging steps, no more additional steps are allowed to be added.

5.19.6. Run analysis in Utility Mode

Using Utility Mode, 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.

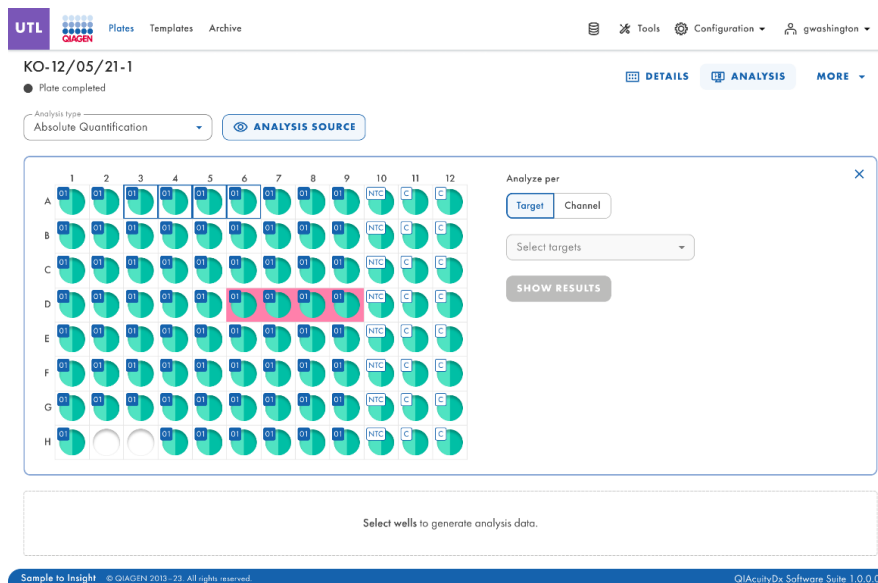


It is also possible to access the Plate Analysis environment from inside the plate, by entering in the plate and clicking the **Analysis** button. A loader page with the QIAGEN logo is displayed.



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.

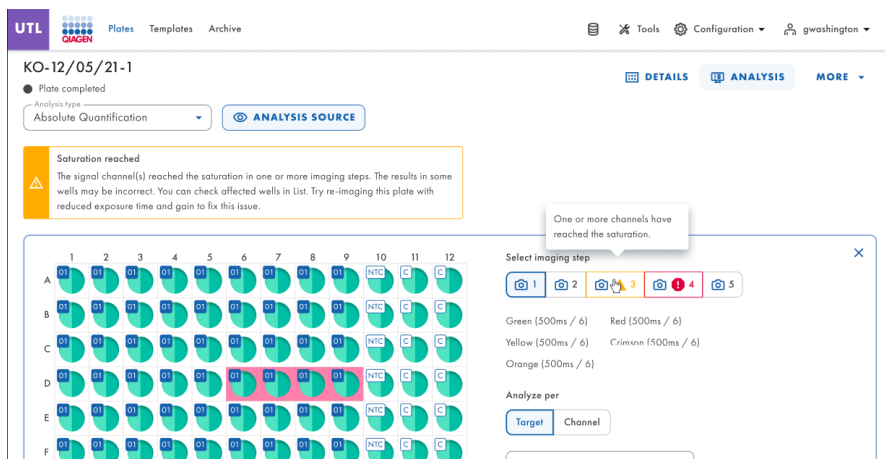
Authorized users can analyze the plate's wells processed by the instrument by selecting the analysis type.

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.

The screenshot shows the 'Results - list' table in the UTL software. The table has columns for Well, Name / ID, Reaction mix, Target, IC, Control type, Concentration *, CI, Partitions, and Threshold. A tooltip for well A3 shows the selected imaging step (3) and lists the channels: Green (500ms / 6), Red (500ms / 6), Yellow (500ms / 6), and Orange (500ms / 6). The 'Analyze per' section has 'Target' and 'Channel' buttons.

Well	Name / ID	Reaction mix	Target	IC	Control type	Concentration *	CI	Partitions	Threshold
			Name			copies/μL	[9]	Positive	Negative
A1	1234567890	Reaction Mix 1	Target A	-	POS	1220.1	3.3%	7646	2871
A2	1234567890	Reaction Mix 1	Target B	-	POS	1220.1	3.3%	7646	2871
A3	1234567890	Reaction Mix 1	Target C	-	POS	1220.1	3.3%	7646	2871

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.

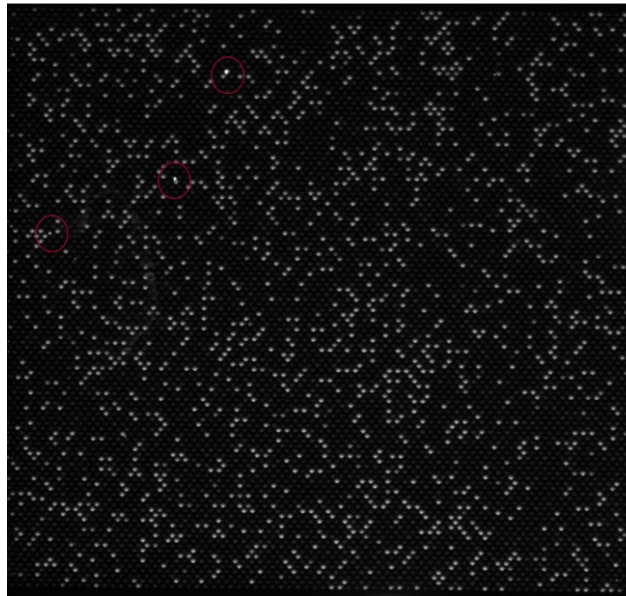


Figure 12. Raw image of a well showing dust particles (marked with red circles).

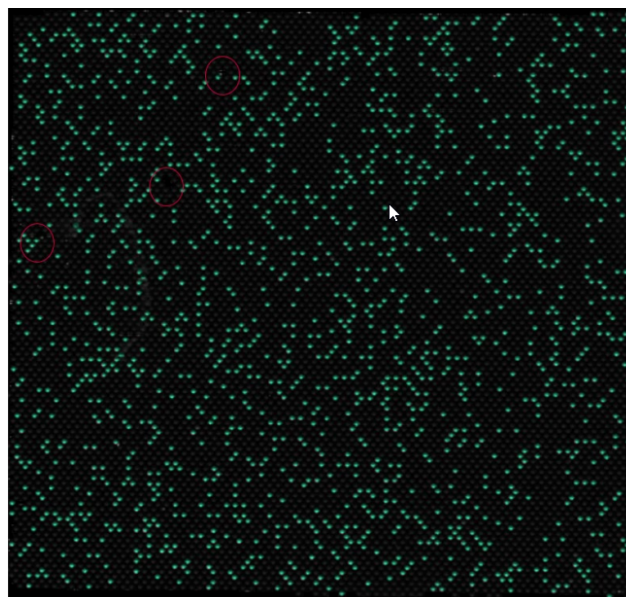


Figure 13. Signal map of the dust-corrected image.

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.

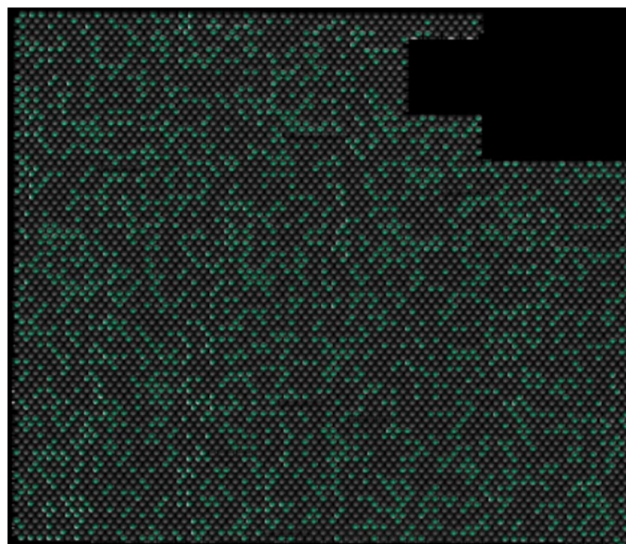


Figure 14. Signal map of an image with blacked-out low amplification areas.

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.

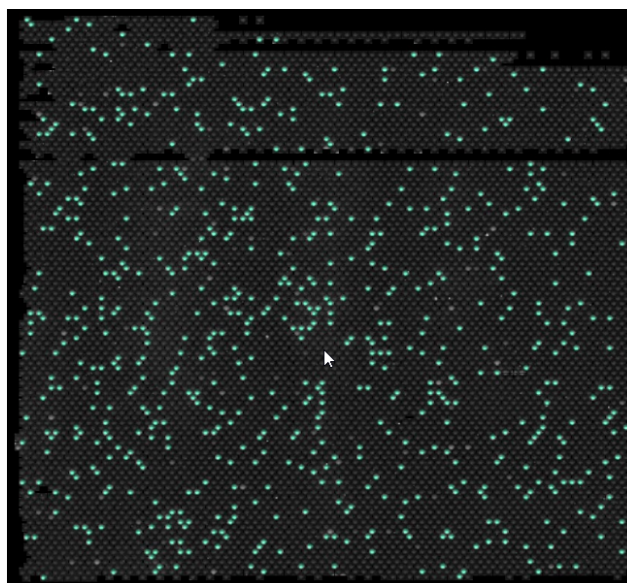


Figure 15. Signal map of an image showing areas of bad filling.

Crosstalk correction algorithm

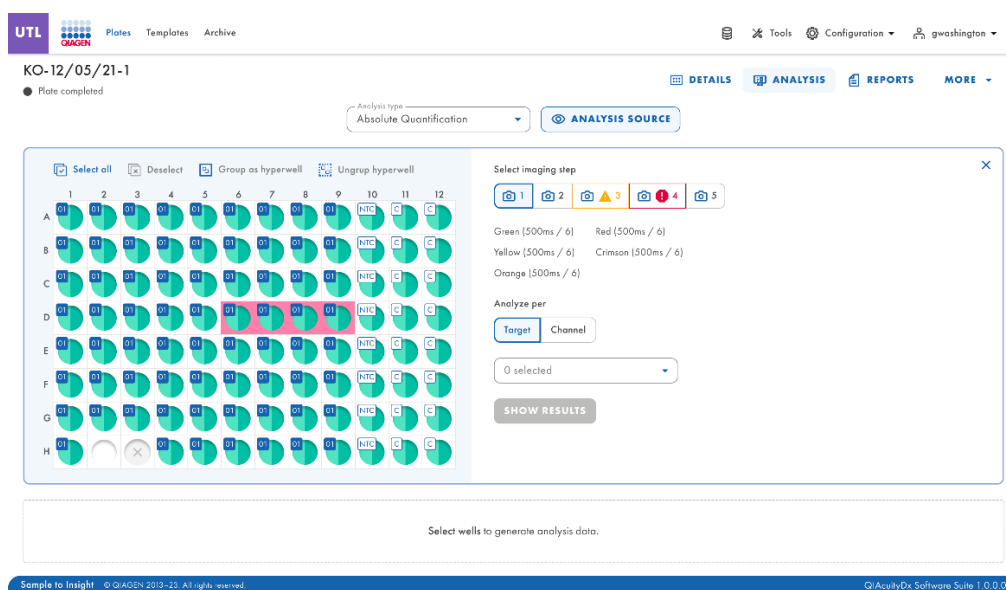
The QIAcuityDx instrument can detect 5 fluorescent channels. To compensate for the spectral overlap between the fluorescent dyes, a crosstalk correction algorithm is implemented in the Software Suite. This correction is done automatically by the software and does not require any user action. The bleed-through 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:

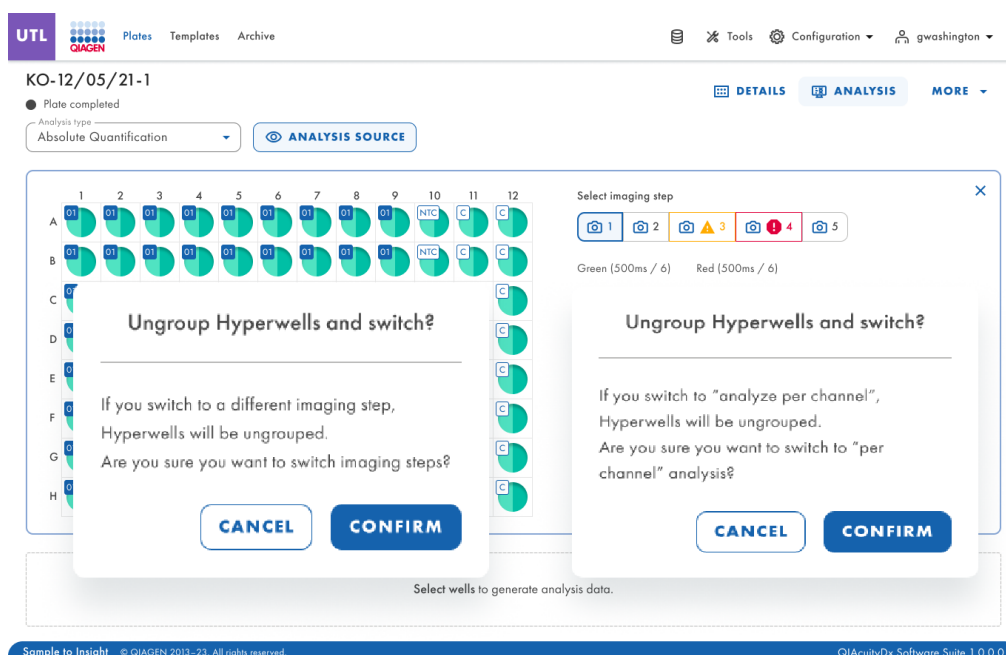
- Header
 - Well information — <Well ID>
- Subheader
 - Reaction mix name
 - Sample ID
 - Sample Name
- Table
 - Column 1 : Target number
 - Column 2: Target name
 - Column 3: IC
 - Column 4: Dye
 - Column 5: Channel

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.

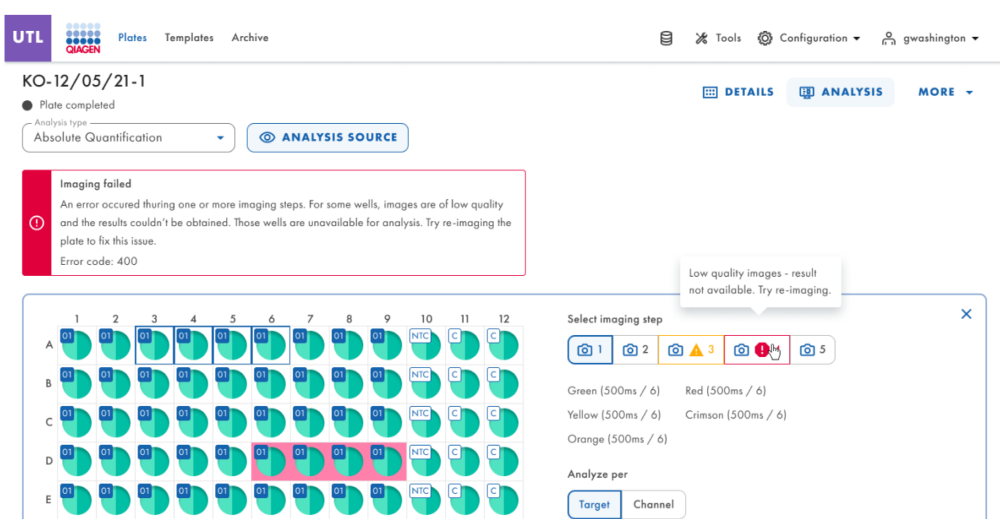


Diagram option

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.

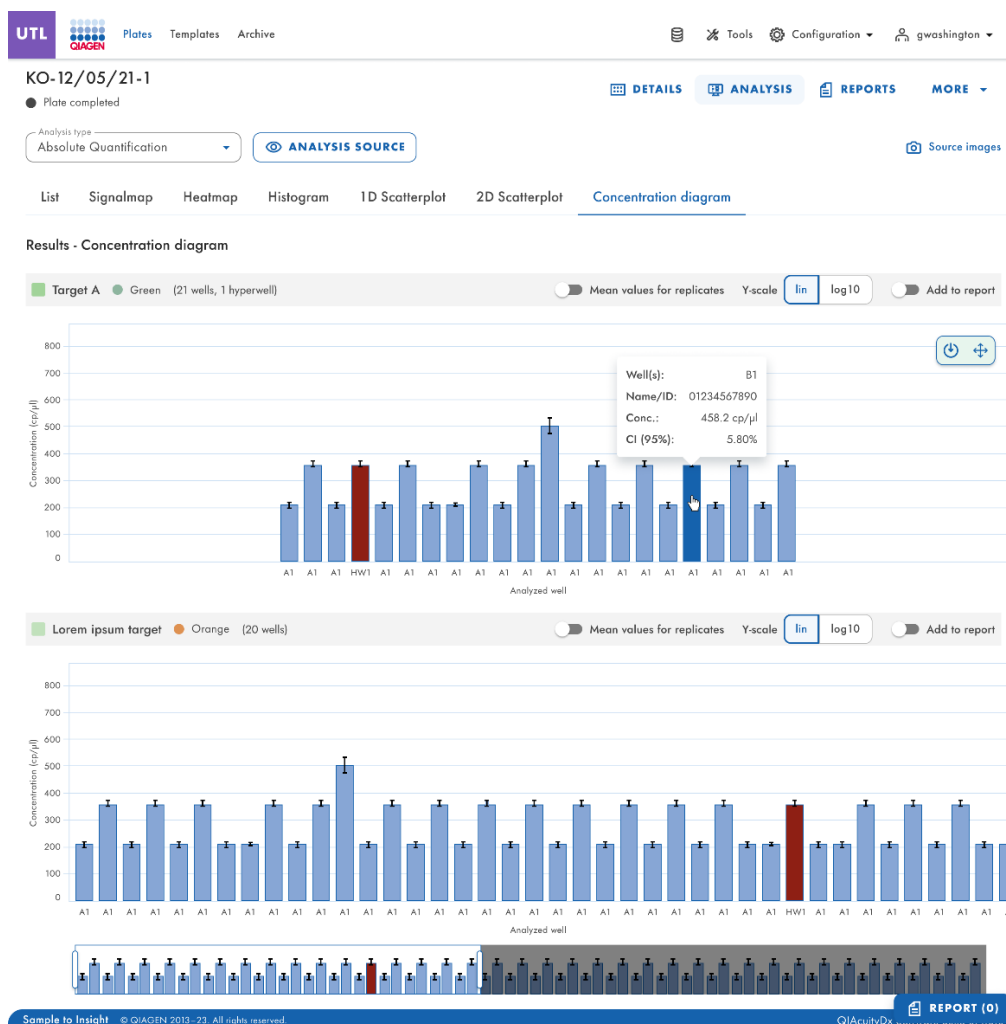


Figure 16. Example of a range slider below a chart.

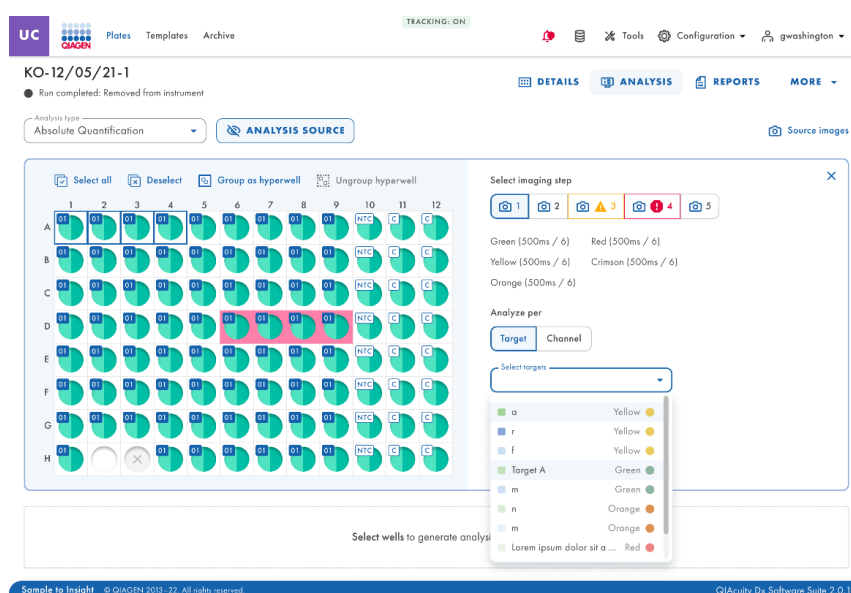
The highlighted area of the slider shows the portion of the chart that is currently displayed. The gray part of the slider is a preview of the rest of the chart. To view another part of a diagram, click the highlighted area of the slider and drag to the part that you want to view. To adjust the range 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

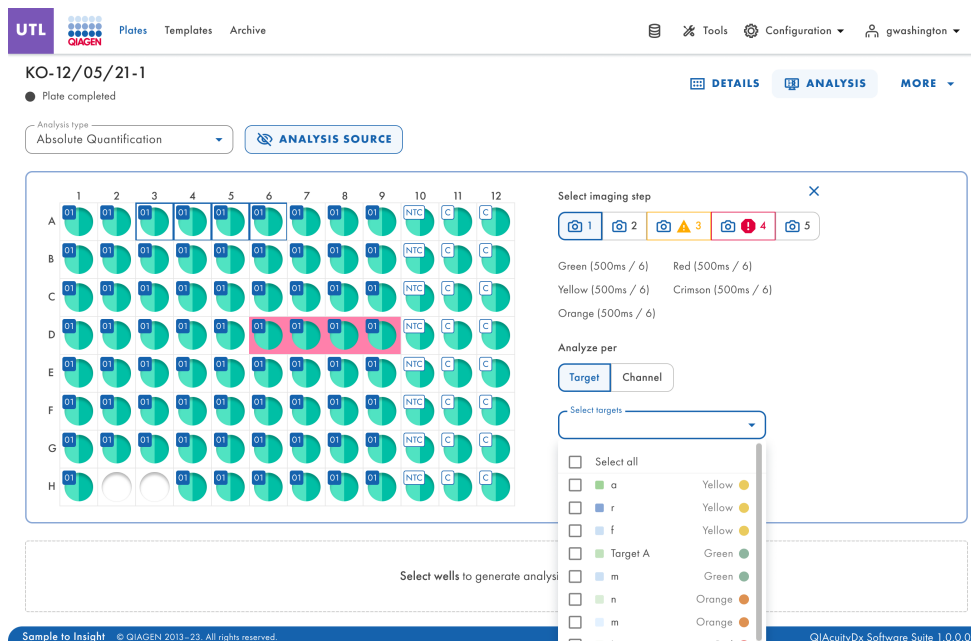
The Absolute Quantification Analysis is the first option in the Analysis drop-down. After selecting the wells to be analyzed, you can view lists, signal maps, heatmaps, histograms, 1D scatterplots, 2D scatterplots, and concentration diagrams in this option.

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/ μ L)** – 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.

Note: Wells that only have a Reaction Mix assigned or that do not have a Reaction Mix assigned at all are not included in the list.

UTL

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gwwashington

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● Plate completed

Analysis type

Absolute Quantification

ANALYSIS SOURCE

⚠

Saturation reached

The signal channel(s) reached the saturation. The results in this wells may be incorrect. You can check affected wells in List. Try re-imaging this plate with reduced exposure time and gain to fix this issue.

List

Signalmap

Heatmap

Histogram

1D Scatterplot

2D Scatterplot

Concentration diagram

Results - list

Export to CSV

Well	Name / ID	Reaction mix	Target Name	IC		Concentration * copies/µL	CI (95%)	Partitions			Threshold
					Control type			Valid	Positive	Negative	
A1	1234567890	Reaction Mix 1	Target A	✓	POS	1220.1	3.3%	7646	2871	5342	Variable
A1	1234567890	Reaction Mix 1	Target A	-	POS	1220.1	3.3%	7646	2871	5342	Variable
A1	1234567890	Reaction Mix 1	Lorem ipsum target	-	POS	1220.1	3.3%	7646	2871	5342	Variable
			Dolor sit	-	POS	1220.1	3.3%	7646	2871	5342	Variable
HW1	1234567890	Reaction Mix 1	Target A	-	POS	1220.1	3.3%	7646	2871	5342	Variable
HW1	1234567890	Reaction Mix 1	Target A	-	POS	1220.1	3.3%	7646	2871	5342	Variable
A1	1234567890	Reaction Mix 1	Target B	-	POS	1220.1	3.3%	7646	2871	5342	Variable
A1	1234567890	Reaction Mix 1	Target C	-	POS	1220.1	3.3%	7646	2871	5342	Variable
			Lorem ipsum target	-	POS	1220.1	3.3%	7646	2871	5342	Variable
A1	1234567890	Reaction Mix 1	Target C	-	POS	1220.1	3.3%	7646	2871	5342	Variable
			Lorem ipsum target	-	POS	1220.1	3.3%	7646	2871	5342	Variable

Sample to Insight

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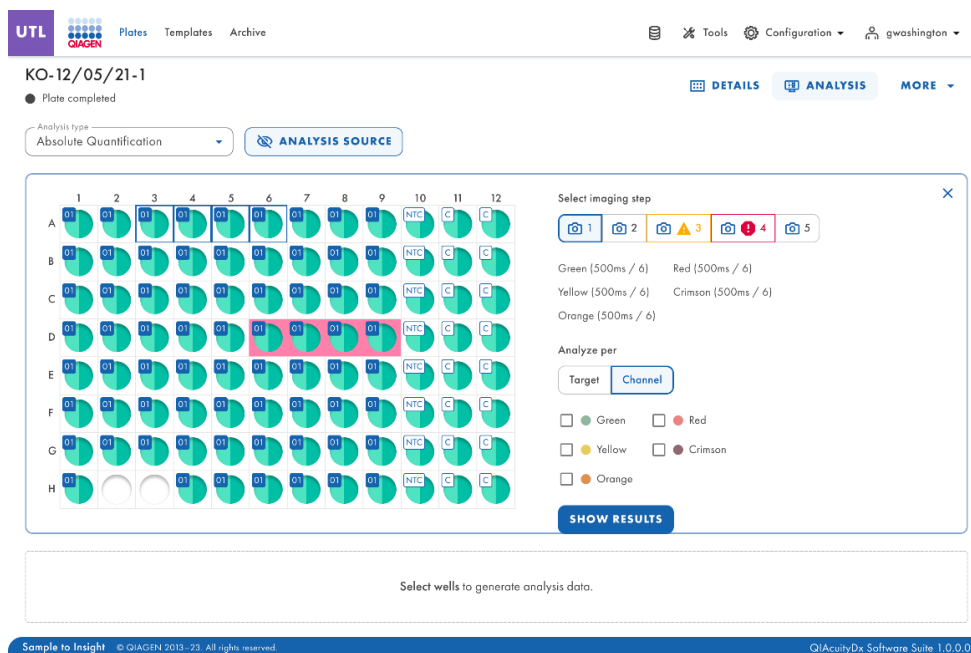
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Analyze per channel

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/ μ L)** – 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.

Note: Wells that do not have a reaction mix assigned are not included in the list.

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● Plate completed

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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		Concentration * copies/μL	CI (95%)	Valid	Partitions		Threshold	
				IC	Control type				Positive	Negative		
A1	OB 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	OB 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	OB 1234567890	Reaction Mix 1	Green		✓	POS	1220.1	3.3%	7646	2871	5342	Variable
A3	OB 1234567890	Reaction Mix 1	Yellow	-	-	POS	1220.1	3.3%	7646	2871	5342	Variable
			Crimson	-	-	POS	1220.1	3.3%	7646	2871	5342	Variable
			Red	-	-	POS	1220.1	3.3%	7646	2871	5342	Variable
A1	OB 1234567890	Reaction Mix 1	Green		✓	POS	1220.1	3.3%	7646	2871	5342	Variable
A1	OB 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	OB 1234567890	Reaction Mix 1	Yellow		-	POS	1220.1	3.3%	7646	2871	5342	Variable

Sample to Insight

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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).

The screenshot shows the QIAcuity Dx Software Suite interface. At the top, there's a header with 'UTL' and 'QIAcuity Dx' logos, followed by 'Plates', 'Templates', and 'Archive'. Below this, the sample ID 'KO-12/05/21-1' is displayed, along with a status 'Plate completed' and buttons for 'DETAILS', 'ANALYSIS', and 'MORE'. A dropdown menu for 'Analysis type' is set to 'Absolute Quantification', and there's a button for 'ANALYSIS SOURCE'. Below this, a row of tabs includes 'List', 'Signalmap', 'Heatmap', 'Histogram', '1D Scatterplot', '2D Scatterplot', and 'Concentration diagram'. The 'List' tab is active, showing a table of results. On the right side of the table, there's a button labeled 'Export to CSV' which is circled in red. The table has columns for 'Well', 'Name / ID', 'Reaction mix', 'Channel', 'IC', 'Control type', 'Concentration *', 'CI', 'Yield', 'Partitions', and 'Threshold'. The data rows show various wells (A1, A3) and their corresponding results.

Well	Name / ID	Reaction mix	Channel	IC	Control type	Concentration *	CI	Yield	Partitions	Threshold	
A1	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	1234567890	Reaction Mix 1	Green	✓	POS	1220.1	3.3%	7646	2871	5342	Variable
A1	1234567890	Reaction Mix 1	Yellow	✓	POS	1220.1	3.3%	7646	2871	5342	Variable
A1	1234567890	Reaction Mix 1	Orange	✓	POS	1220.1	3.3%	7646	2871	5342	Variable
A1	1234567890	Reaction Mix 1	Green	✓	POS	1220.1	3.3%	7646	2871	5342	Variable
A3	1234567890	Reaction Mix 1	Yellow	-	POS	1220.1	3.3%	7646	2871	5342	Variable
A3	1234567890	Reaction Mix 1	Crimson	-	POS	1220.1	3.3%	7646	2871	5342	Variable
A3	1234567890	Reaction Mix 1	Red	-	POS	1220.1	3.3%	7646	2871	5342	Variable
A1	1234567890	Reaction Mix 1	Green	✓	POS	1220.1	3.3%	7646	2871	5342	Variable
A1	1234567890	Reaction Mix 1	Green	✓	POS	1220.1	3.3%	7646	2871	5342	Variable
A1	1234567890	Reaction Mix 1	Yellow	✓	POS	1220.1	3.3%	7646	2871	5342	Variable
A1	1234567890	Reaction Mix 1	Orange	✓	POS	1220.1	3.3%	7646	2871	5342	Variable
A3	1234567890	Reaction Mix 1	Yellow	-	POS	1220.1	3.3%	7646	2871	5342	Variable

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

The screenshot shows a dropdown menu for 'Export to CSV'. The menu is open, displaying two options: 'Current results' and 'RFU values'. The 'Current results' option is highlighted.

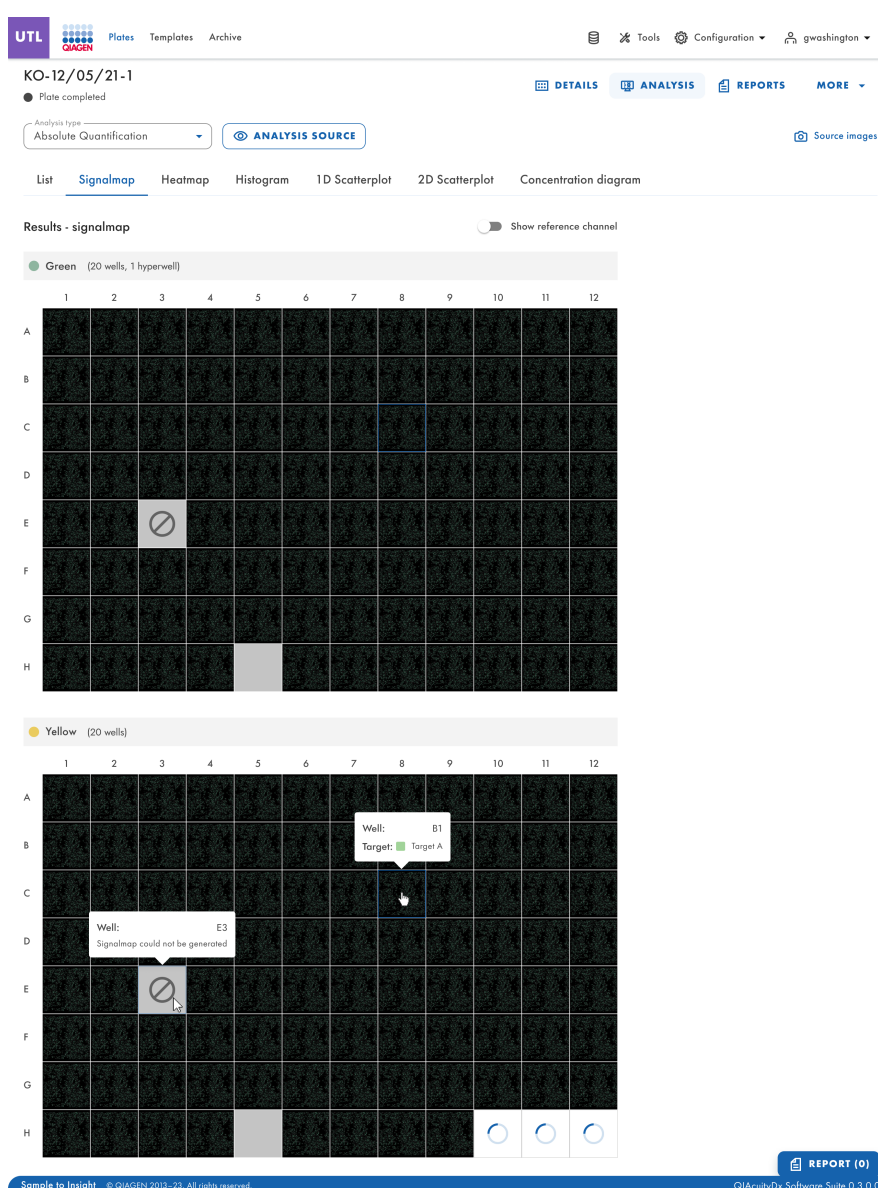
By selecting **Current results**, a list view of the current results per sample for selected wells will be downloaded as a CSV file.

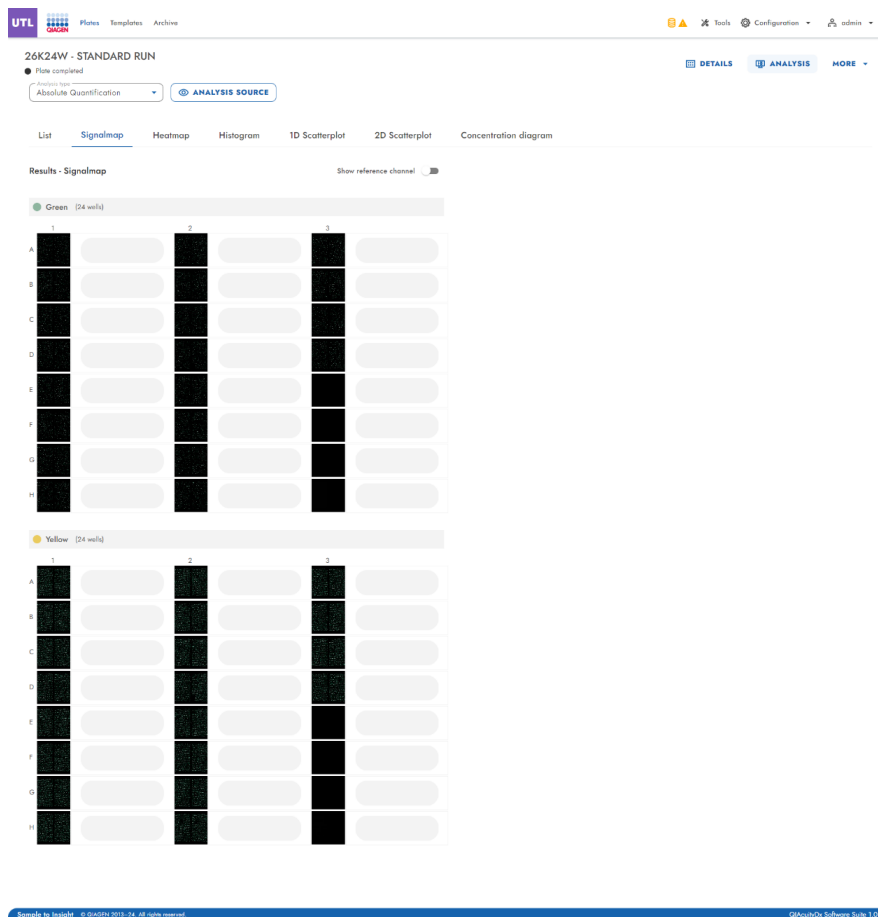
By selecting **RFU values**, a list view of the RFU values (compact version) per partitions for selected wells will be downloaded as a CSV file.

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 only available for Field Service Engineers. 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.

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● Run completed

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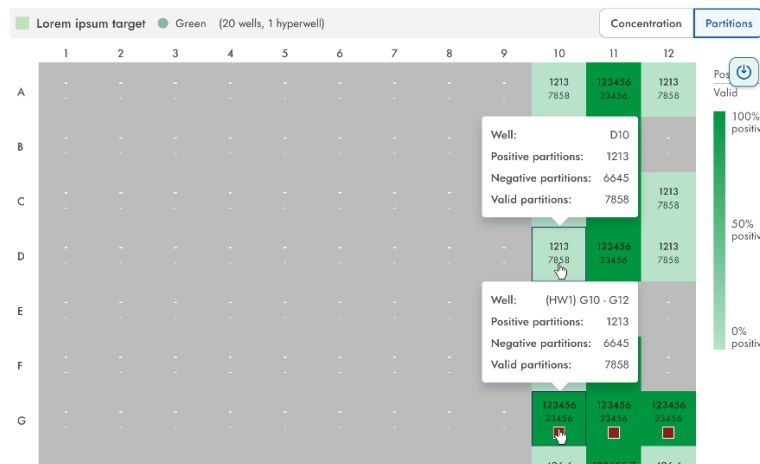
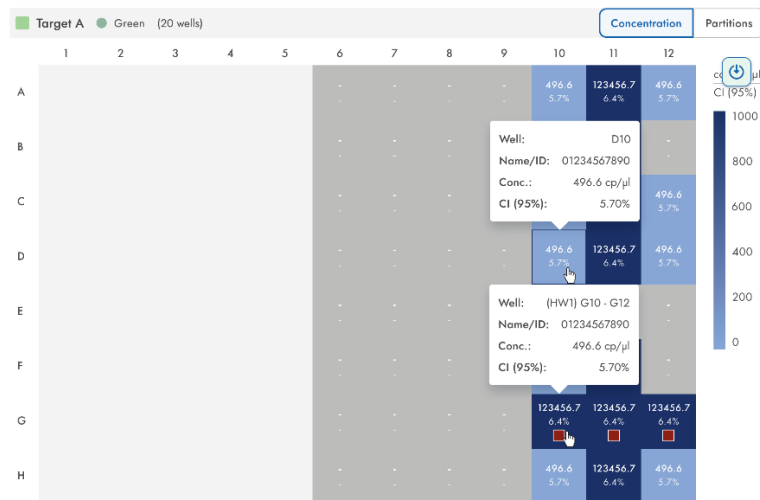
Analysis type
 Absolute Quantification

[ANALYSIS SOURCE](#)

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[Heatmap](#)
[Histogram](#)
[1D Scatterplot](#)
[2D Scatterplot](#)
[Concentration diagram](#)

Results - heatmap



[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.

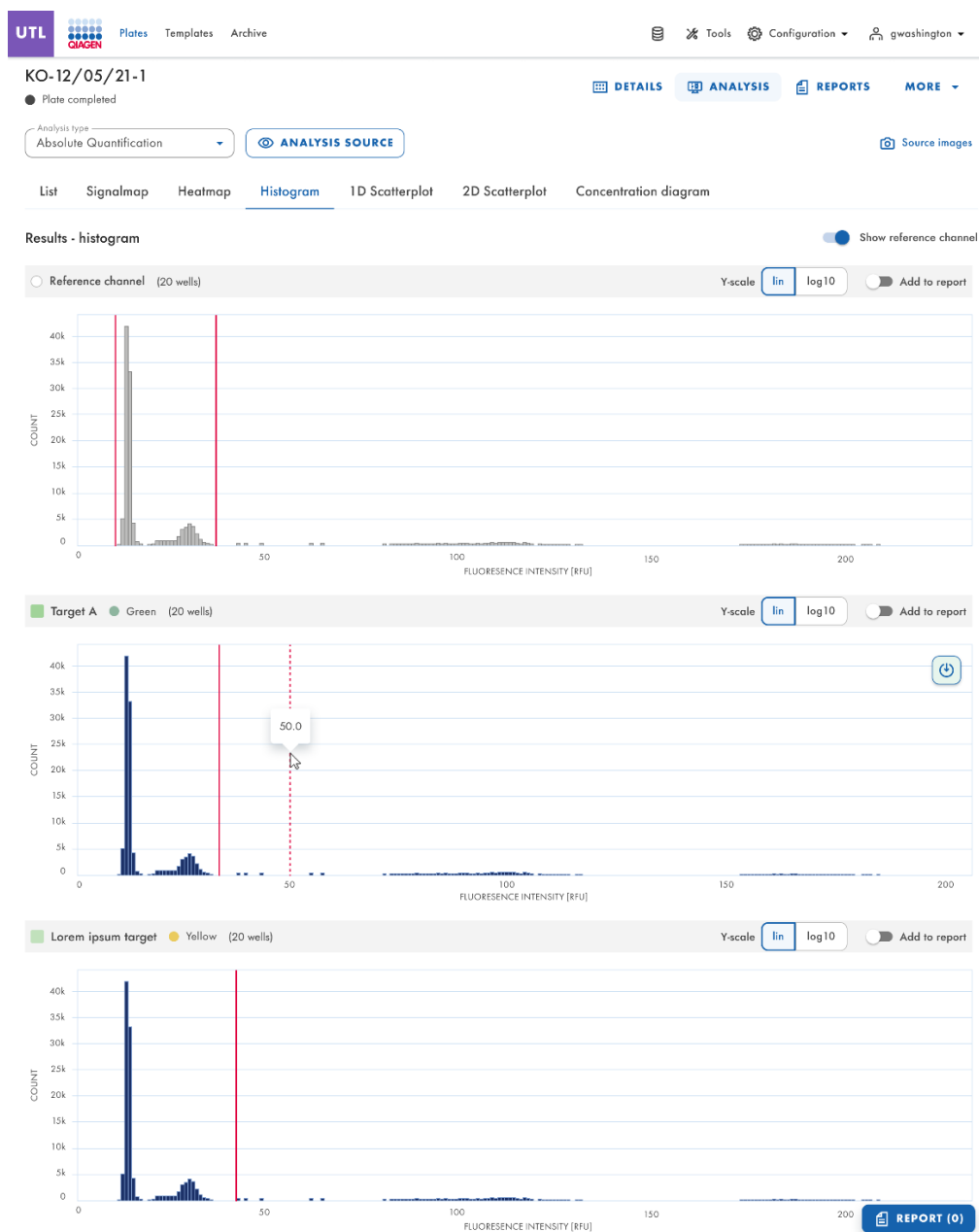
To view an additional toolbar that enables actions related to the diagram, such as downloading the plot, hold the cursor over the diagram. For more details about the toolbar, refer to the “Diagram option” section.

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 only available for Field Service Engineers. 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.

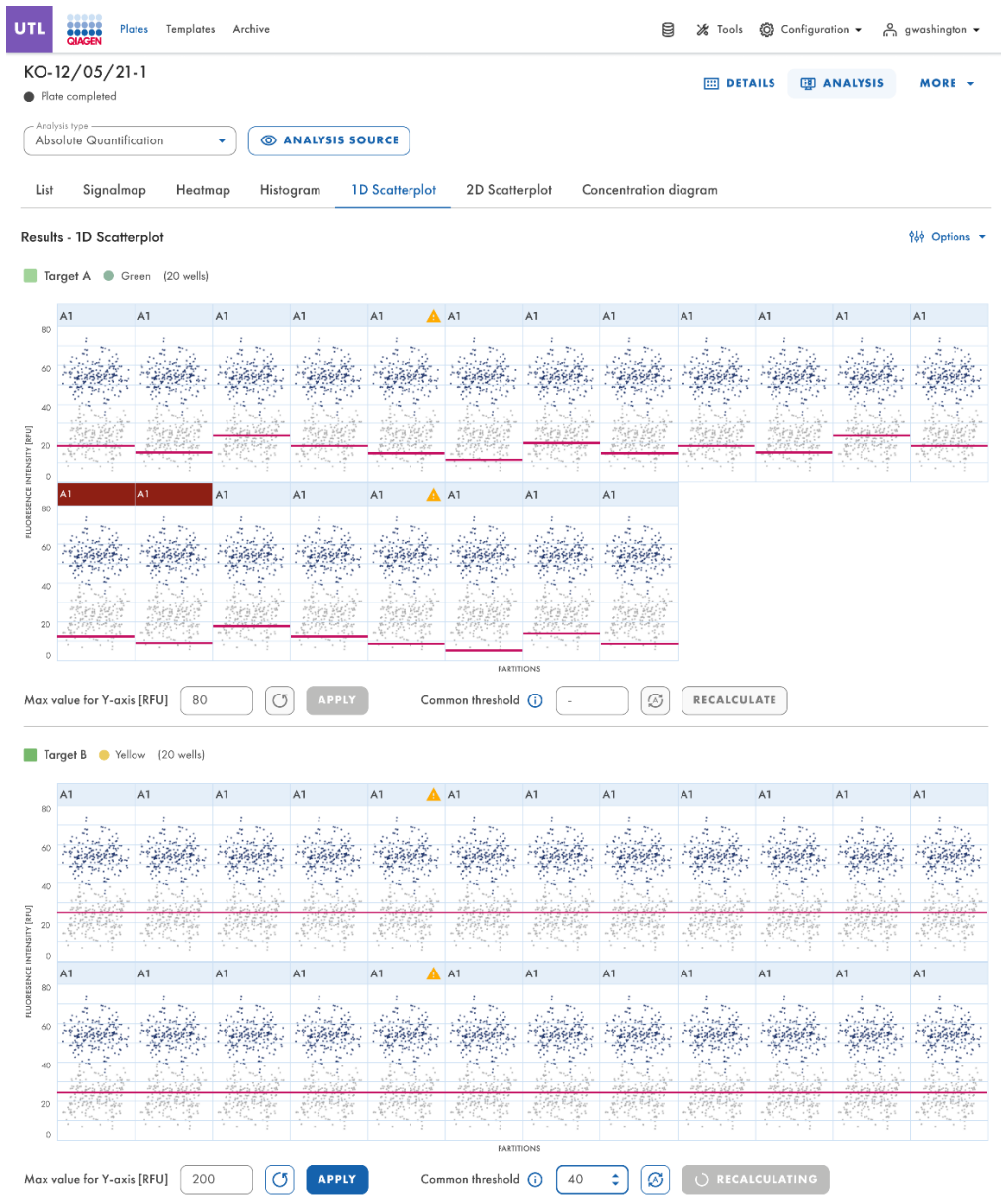


1D Scatterplot

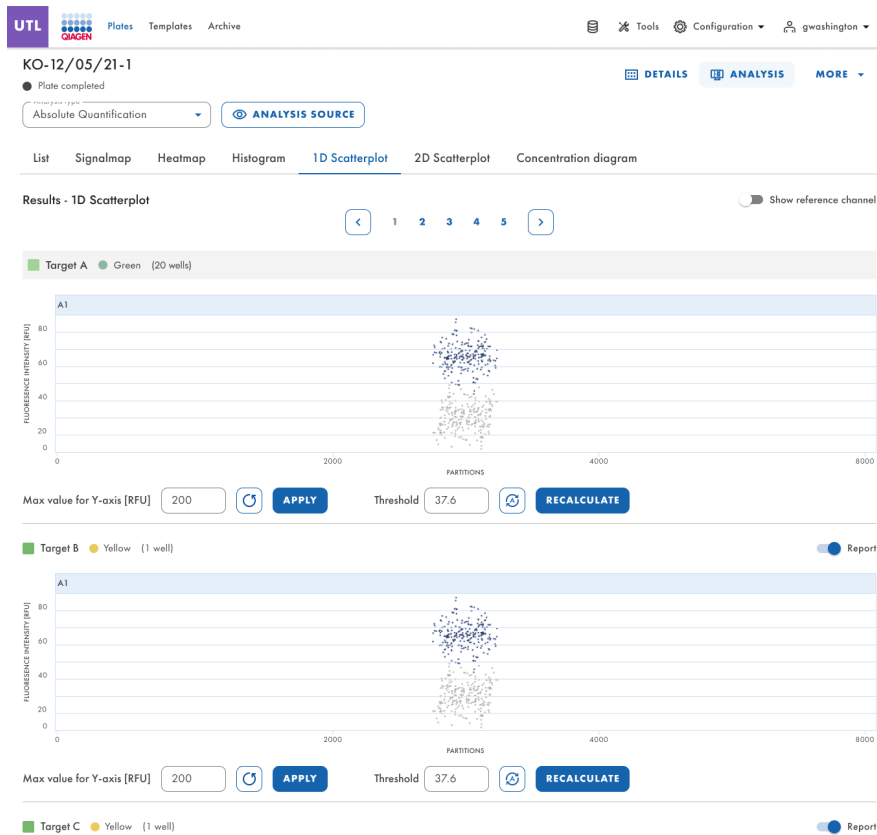
The **Absolute Quantification** tab is the first tab in the Analysis environment. After selecting the wells to be analyzed, the user can view the list and the **1D Scatterplot** tab.

- 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.

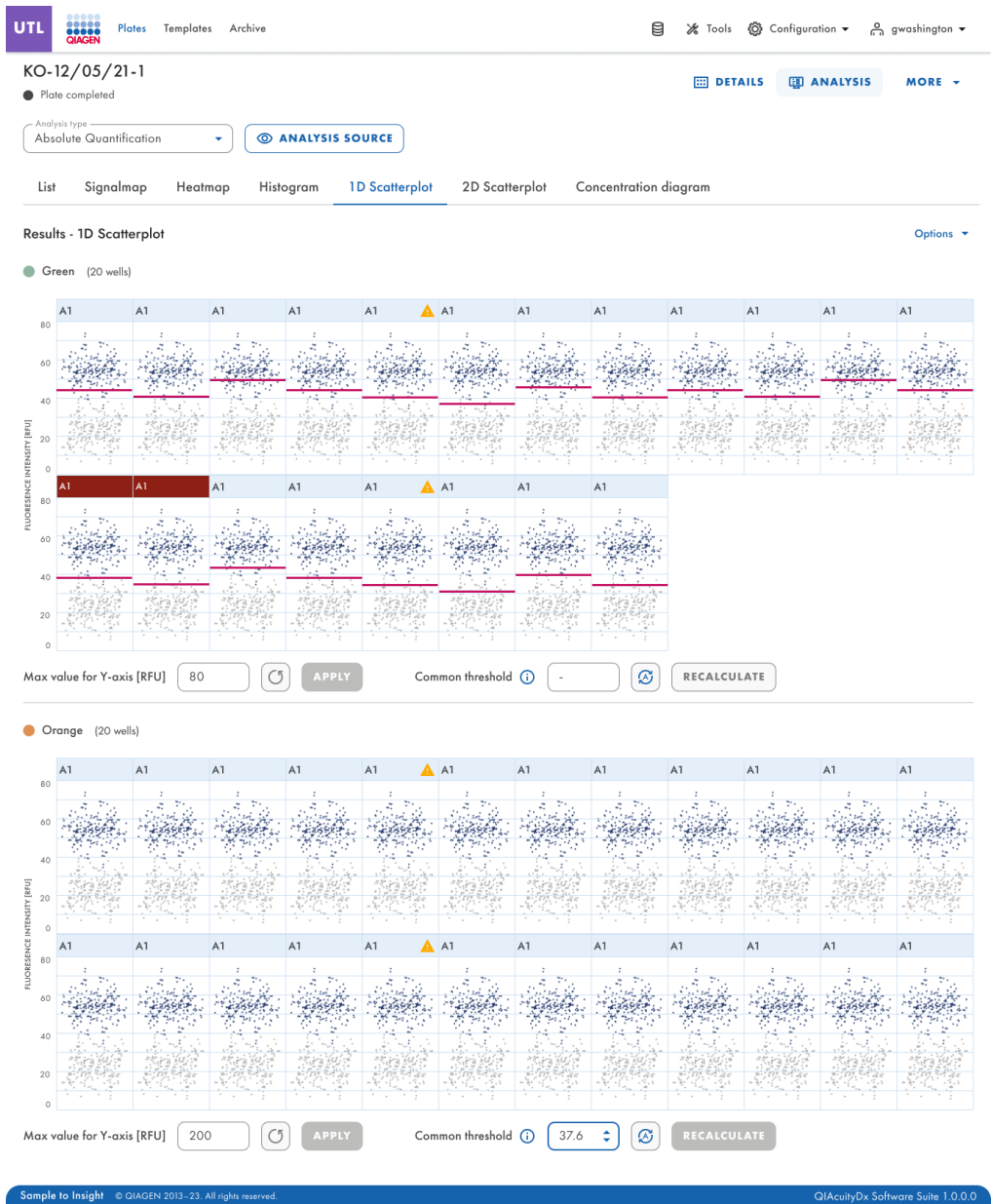
If the 1D Scatterplot is analyzed by target (the DNA/RNA sequence or molecule for which the copy number/ μL is detected), the user will see the following structure:



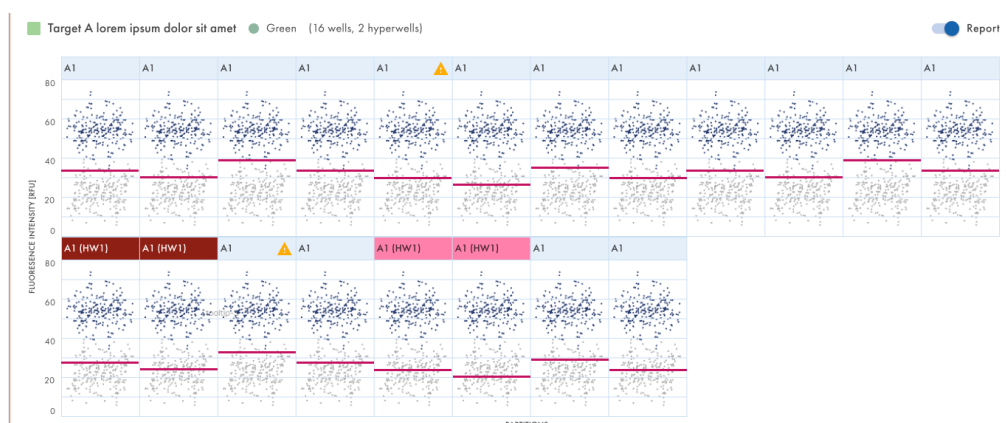
If the analysis done by channel data is presented based upon the wavelength filters used during image acquisition, the user will see an output such as:



It is important to mention that this analysis can be also done in multiple wells simultaneously. If there is no common threshold for the presented wells, a hyphen is displayed in the Common threshold field.



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

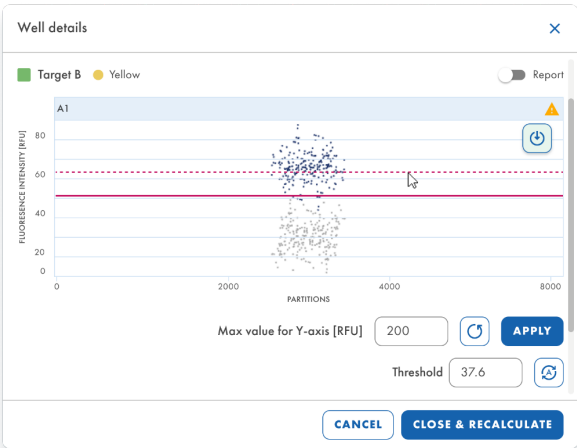
1. To change the threshold individually per well, click on the appropriate header of the well in the 1D Scatterplot view. A window opens and the threshold can be changed by pointing over the chart, which triggers the appearance of a dotted line.
2. Once the dotted line is in the appropriate spot, click 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.

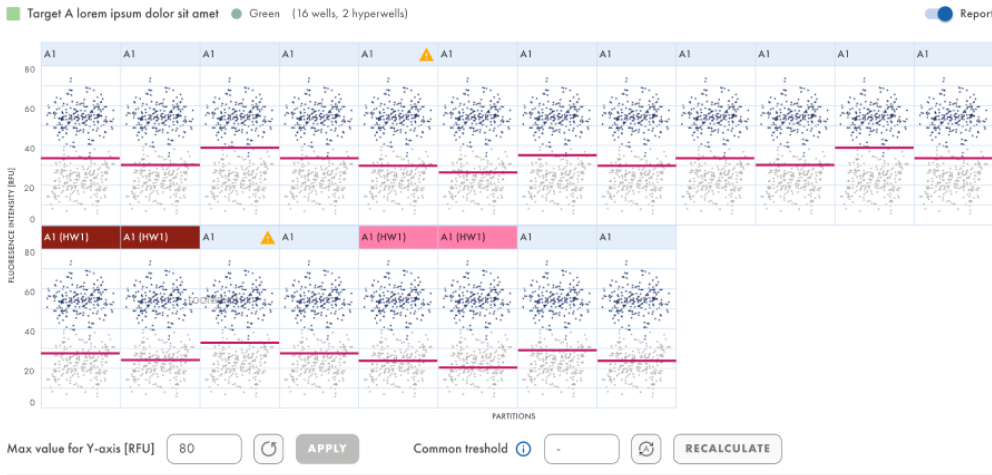
4. Click **CLOSE & RECALCULATE** to trigger the re-analysis of data and to close the window. Click **Cancel** to close the window without any changes.



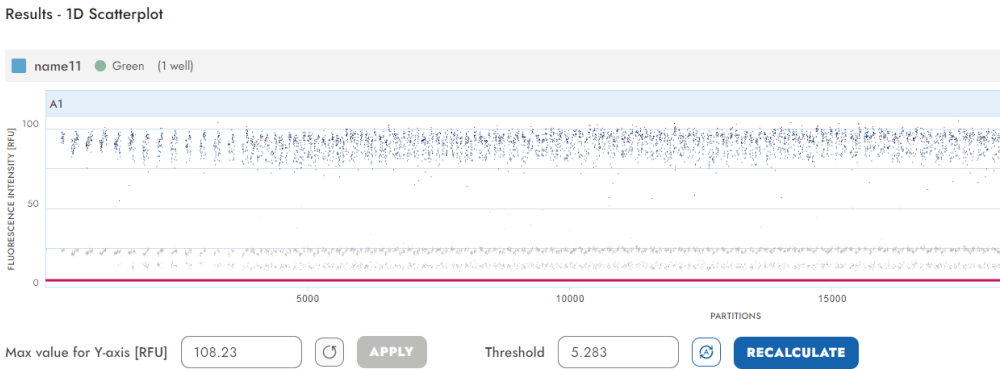
Dotted threshold line when dragging it over the graph:



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



Clicking 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.

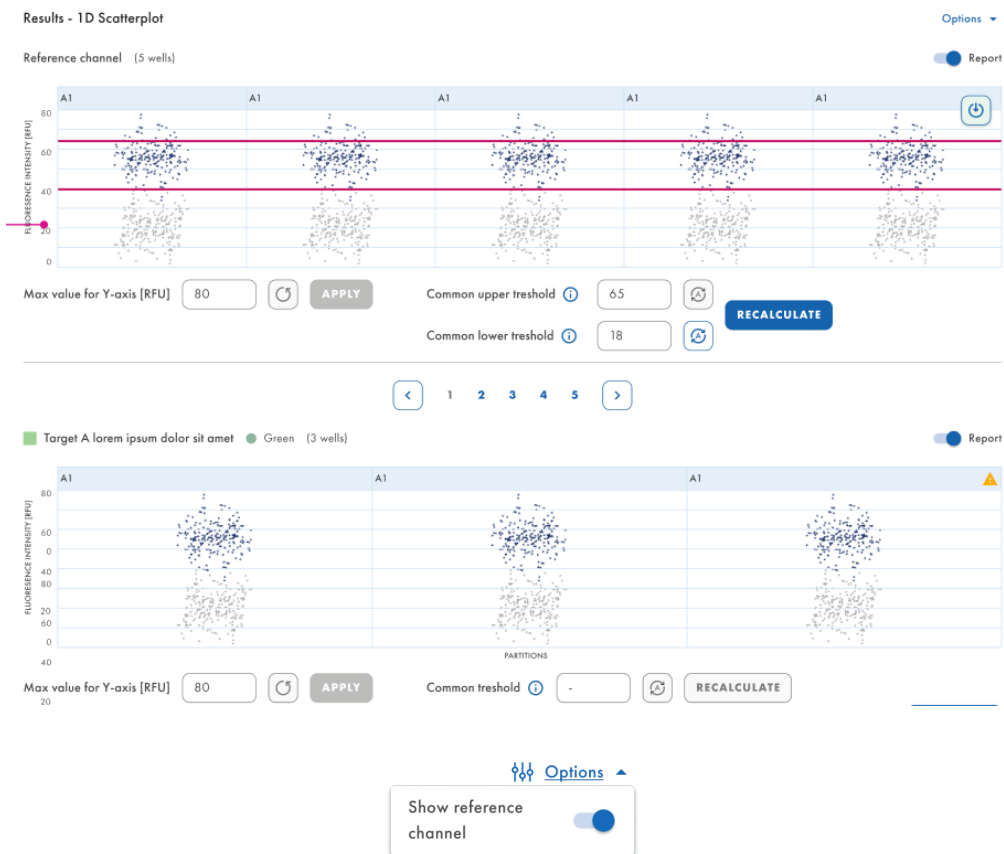
If a value higher than 300 is entered, an input validation error is shown.



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. When clicking recalculate, the whole page is reloaded and any other entered (and unsaved) changes are lost. The recalculation has to be done one by one.

Reference channel on 1D Scatterplot

The reference channel 1D Scatterplot is displayed for every selected well for Field Service Engineers running a 1D Scatterplot analysis with “Show reference channel” enabled. Standard users do not see 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

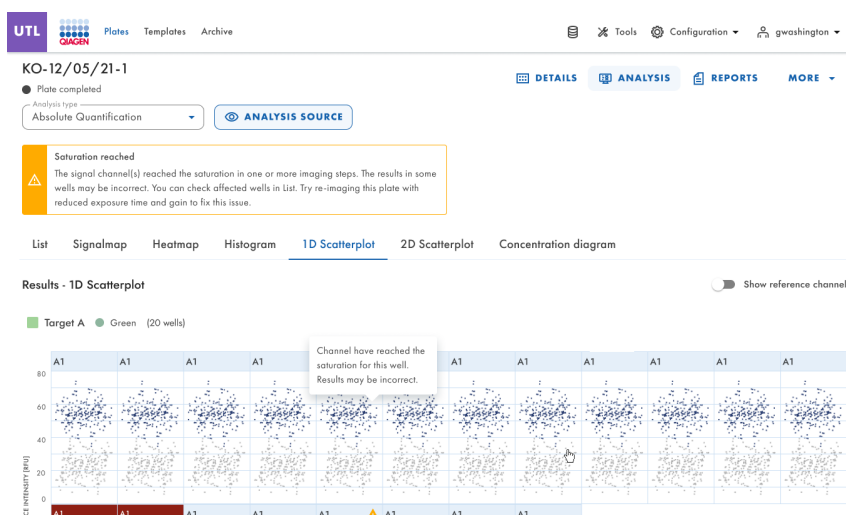
It is possible to download 1D Scatterplots when running a 1D Scatterplot analysis.

Download graph

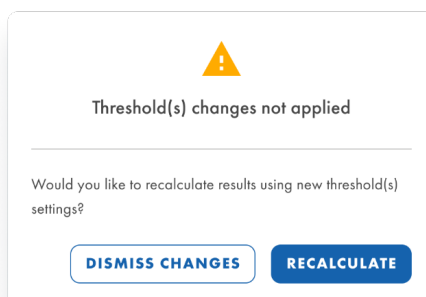


Warnings

- 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."



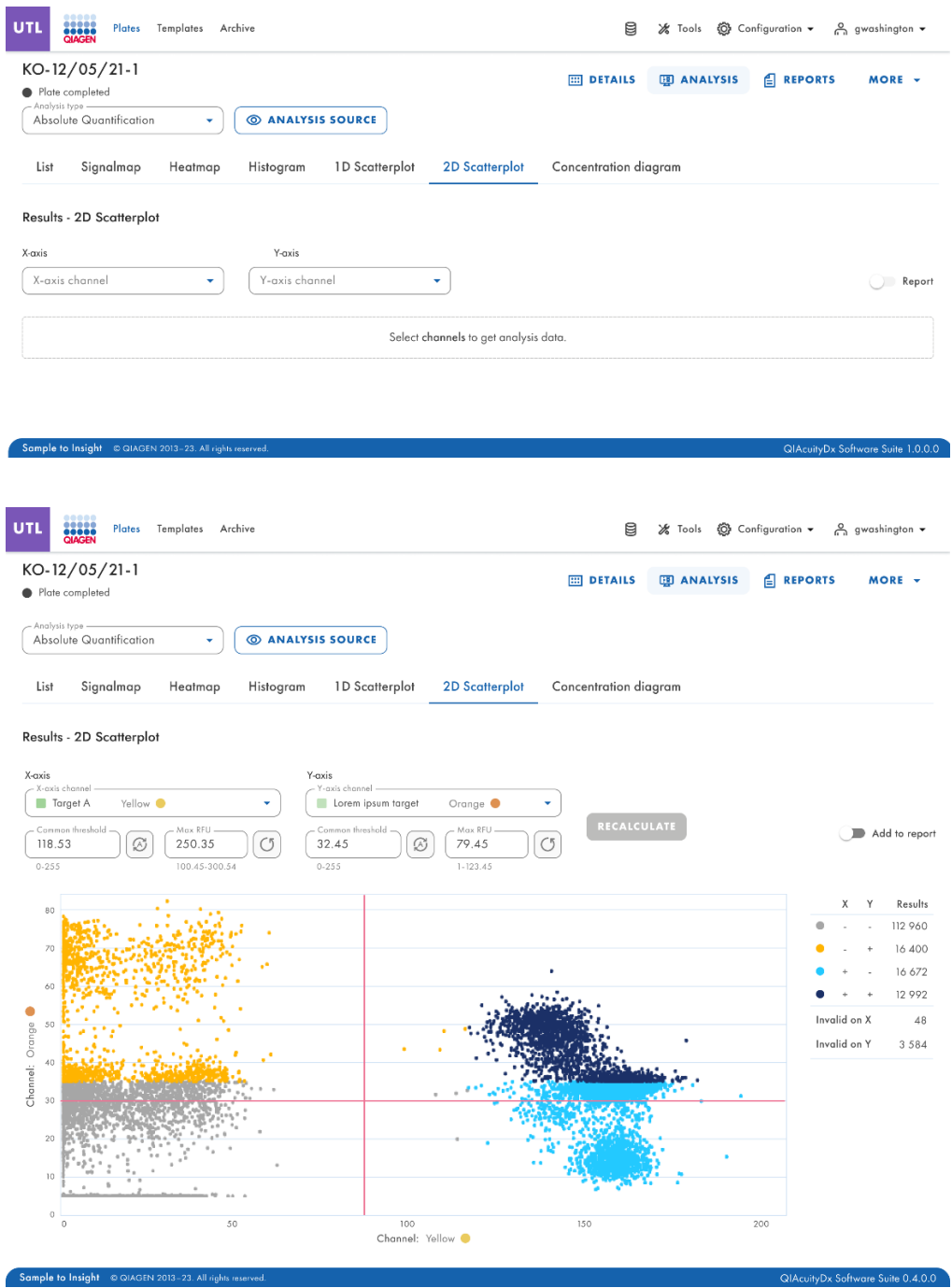
- The QIAcuityDx Software Assay Plugin displays a modal window whenever the threshold input has been changed, and the results are not recalculated before selecting another well in the plate layout, going to the List tab or selecting another scatterplot from the list.



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.

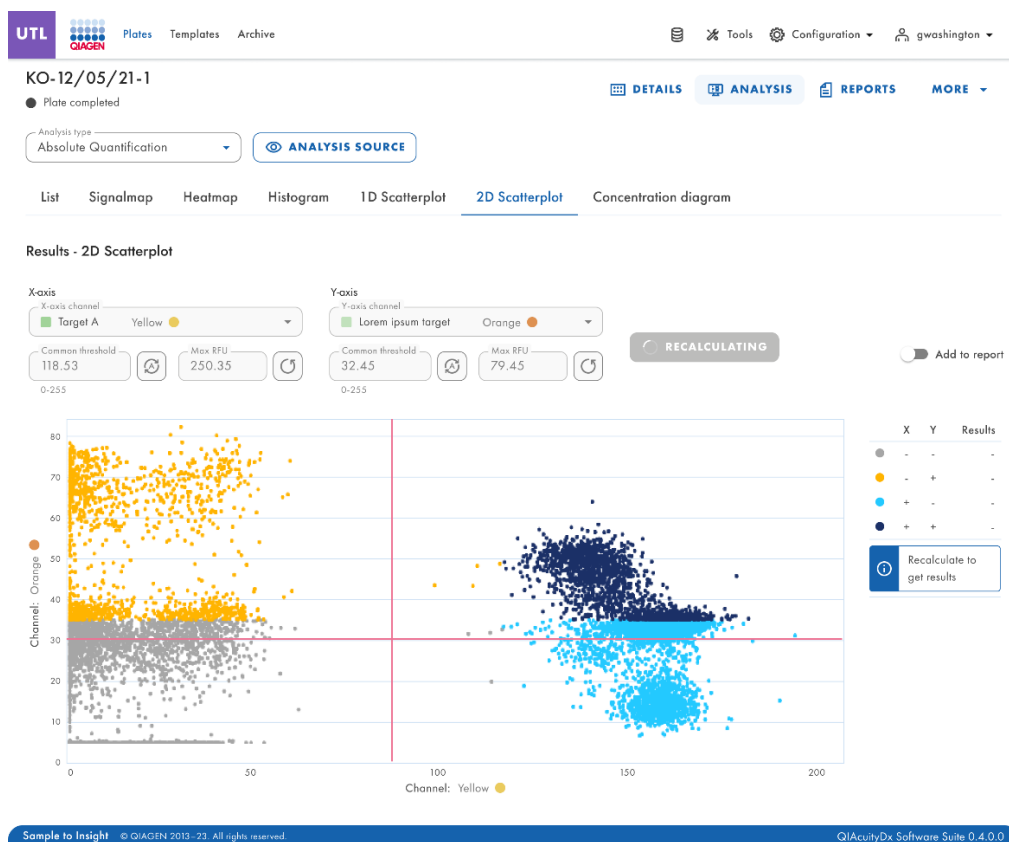
After the user selects the targets from the Select Targets list or the channels from the Select Channels list and clicks the **Show results** button, the analysis results must be assigned to x- and y-axes in the **2D Scatterplot** tab.



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-axis 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:

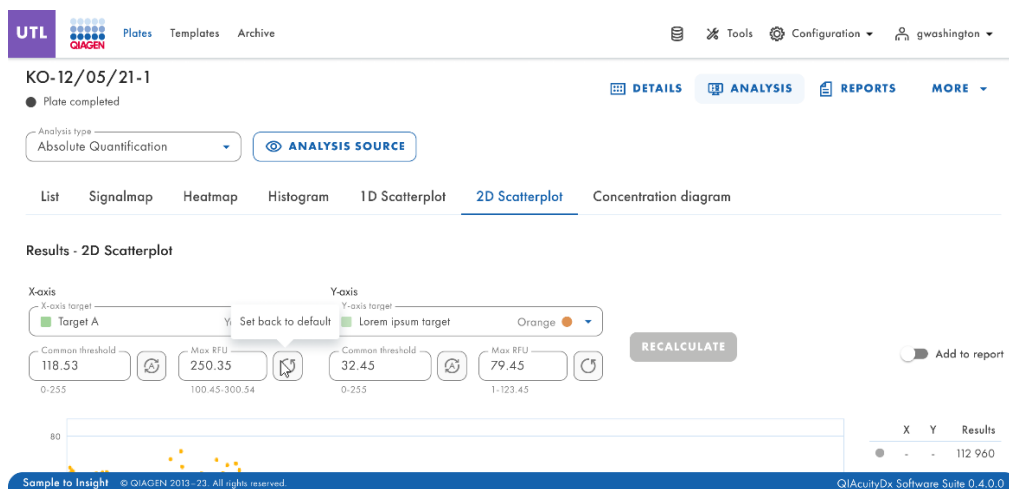
- ++ partition n is positive on both X and Y channels (dark blue).
- +- partition n is positive on X but negative on Y channel (light blue).
- -- partition n is negative on both X and Y channels (gray).
- -+ partition n is negative on X, but positive on Y channel (yellow).

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.

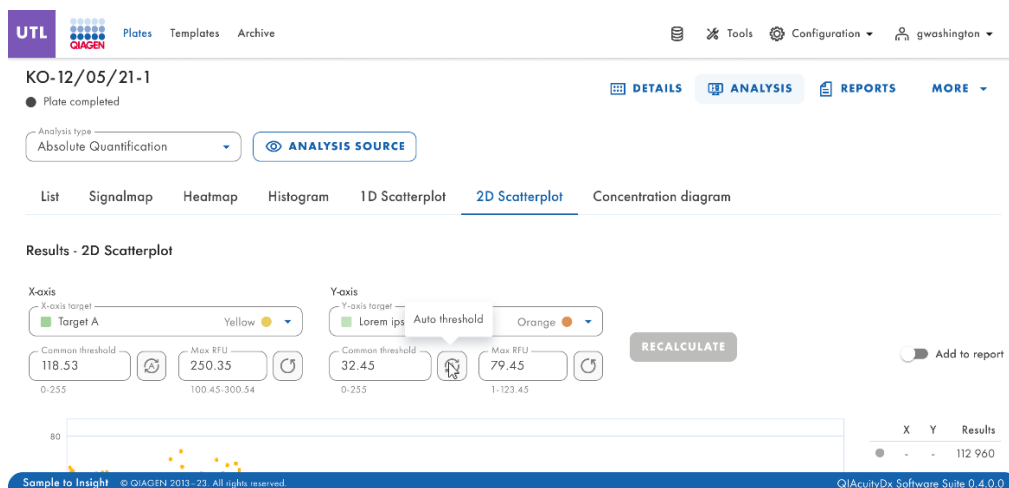
A "Recalculate to get results" notification is shown in the legend.

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.

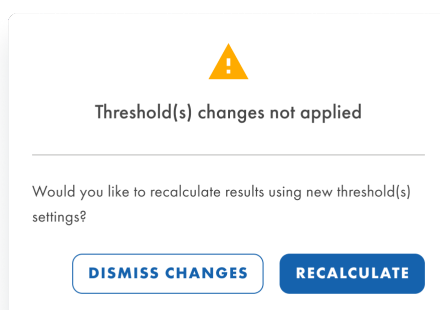


The prompt on leaving without recalculating with the changed thresholds appears when the user:

- 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.

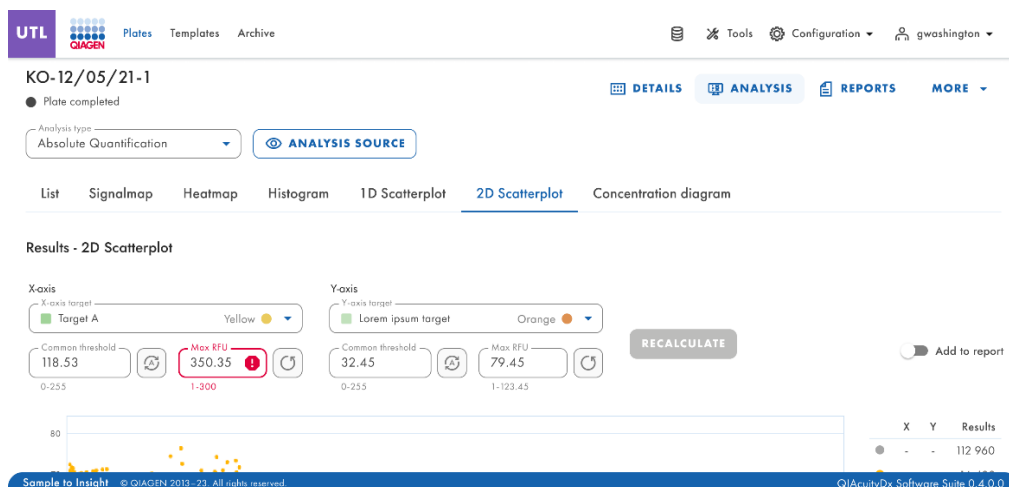


Recalculation is triggered when the user moves to a different tab. The pop-up window appears with a warning.



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

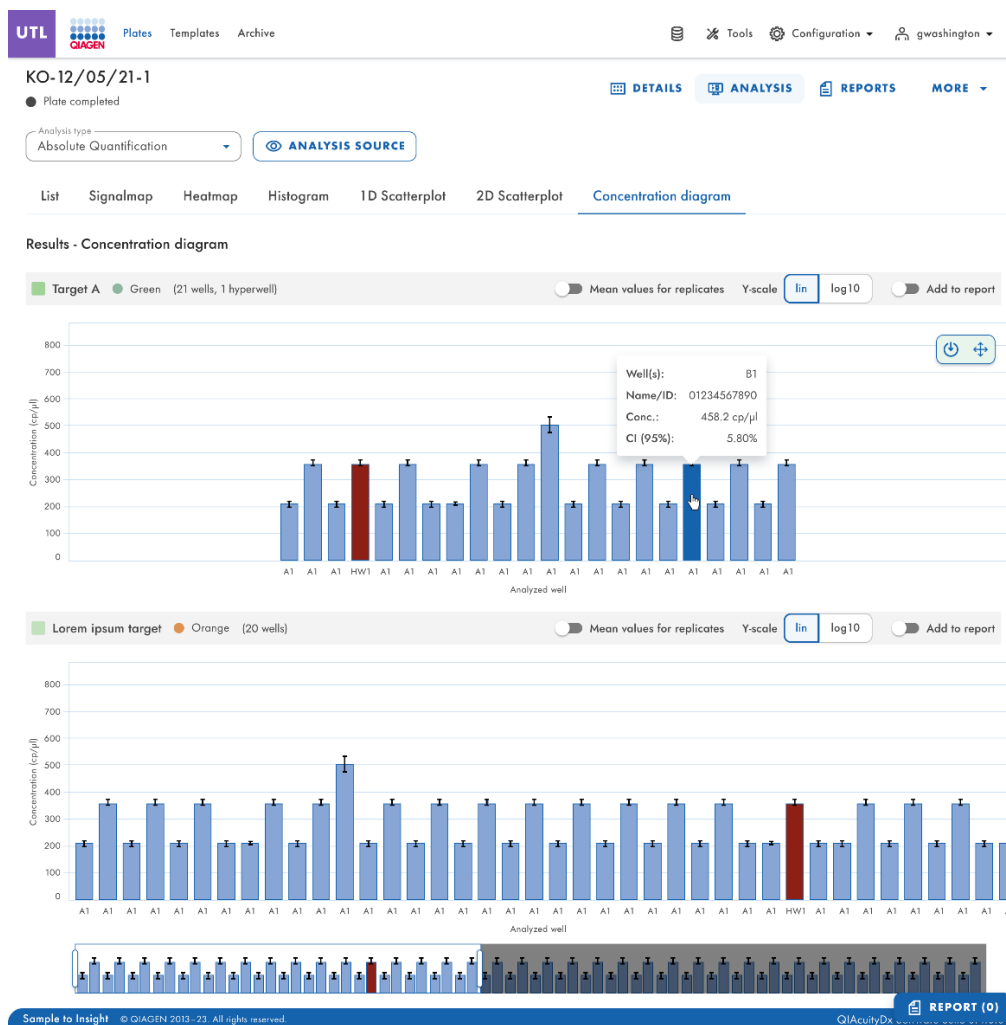
The **Concentration diagram** tab shows the diagrams that display the distribution of concentration values and confidence intervals. One diagram is created for each selected target or channel. A concentration diagram has 2 axes. The x-axis shows the analyzed wells, and the y-axis represents the concentration 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.

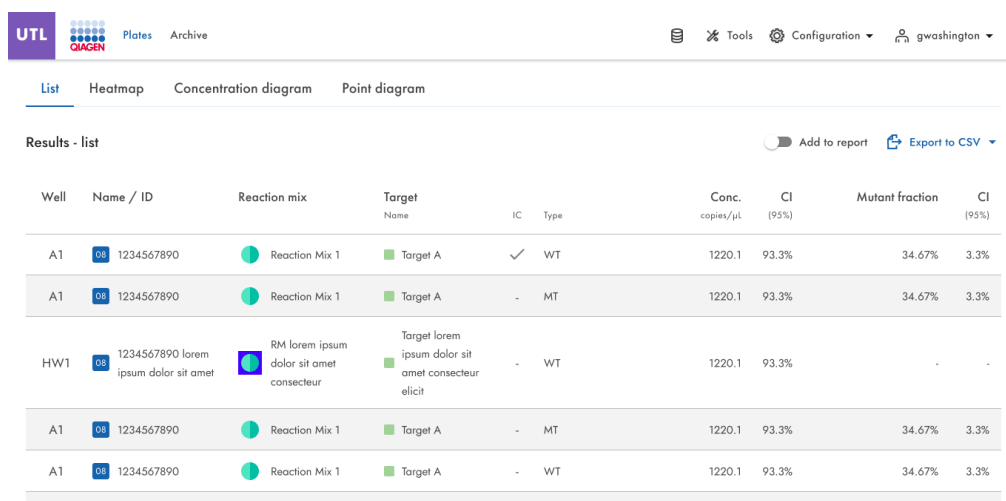
Setting up a mutation detection analysis

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.



The screenshot shows the QIAcuity Dx software interface. At the top, there's a navigation bar with 'UTL' and 'QIAGEN' logos, and tabs for 'Plates' and 'Archive'. Below this, there's a toolbar with icons for 'Tools', 'Configuration', and a user profile 'g.washington'. The main area has four tabs: 'List', 'Heatmap', 'Concentration diagram', and 'Point diagram'. The 'List' tab is active, showing a table of results. The table has columns for Well, Name / ID, Reaction mix, Target, IC, Type, Conc. (copies/μL), CI (95%), Mutation fraction, and CI (95%). The data is organized into rows, with some rows having a 'Target' column that is expanded to show details like 'Target lorem ipsum dolor sit amet consectetur elicit'.

Well	Name / ID	Reaction mix	Target	IC	Type	Conc. (copies/μL)	CI (95%)	Mutation fraction	CI (95%)
A1	1234567890	Reaction Mix 1	Target A	✓	WT	1220.1	93.3%	34.67%	3.3%
A1	1234567890	Reaction Mix 1	Target A	-	MT	1220.1	93.3%	34.67%	3.3%
HW1	1234567890 lorem ipsum dolor sit amet	RM lorem ipsum dolor sit amet consectetur	Target lorem ipsum dolor sit amet consectetur elicit	-	WT	1220.1	93.3%	-	-
A1	1234567890	Reaction Mix 1	Target A	-	MT	1220.1	93.3%	34.67%	3.3%
A1	1234567890	Reaction Mix 1	Target A	-	WT	1220.1	93.3%	34.67%	3.3%

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

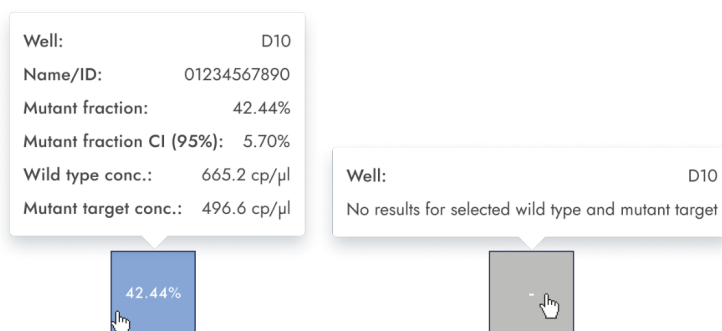


Heatmap tab for mutation detection

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.



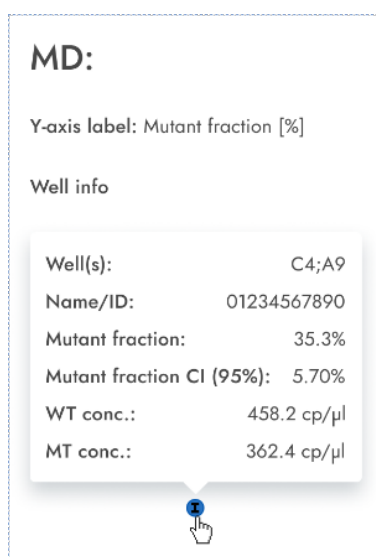
Point diagram tab for mutation detection

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.

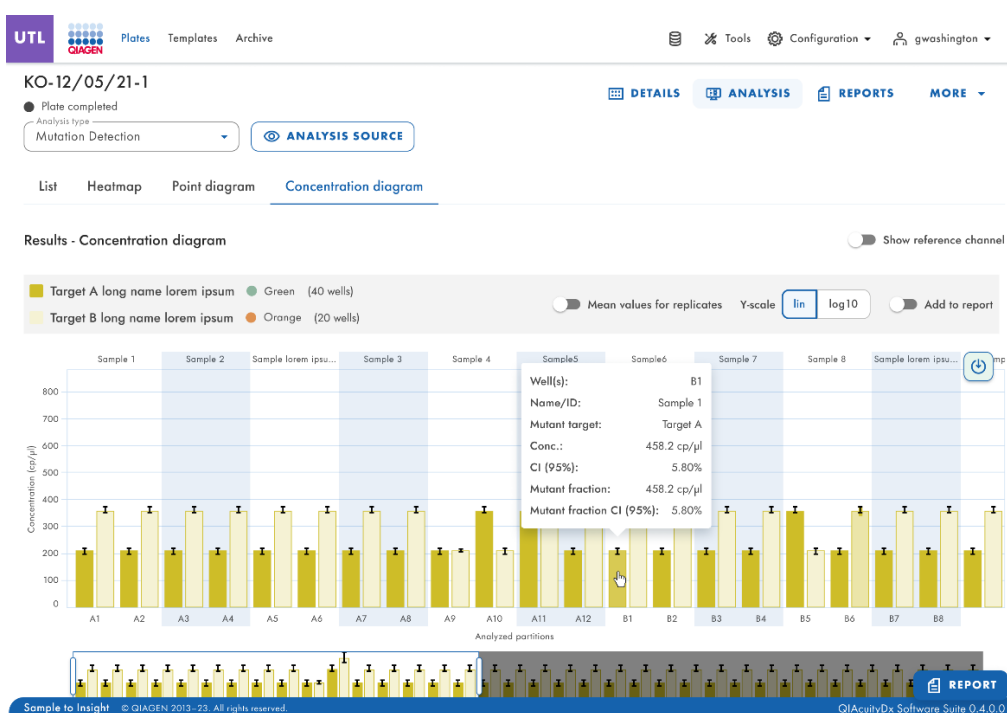


Concentration diagram for mutation detection

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.

Genome editing

Select imaging step

1 2 3 4 5

Wild type target *

a Yellow

Edited target *

Lorem ipsum dolor sit a... Red

SHOW RESULTS

Wild type target

t	Crimson
Target A	Green
n	Orange
Lorem ipsum dolor sit a...	Red
r	Yellow
f	Red
m	Green
m	Orange
s	Crimson

- Sort by RM
- Edited target: Only show targets that are available for selection, based on Wild type target selection

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**.

UTL

Plates

Archive

Tools

Configuration

g.washington

List

Heatmap

Concentration diagram

Point diagram

Results - list

Add to report

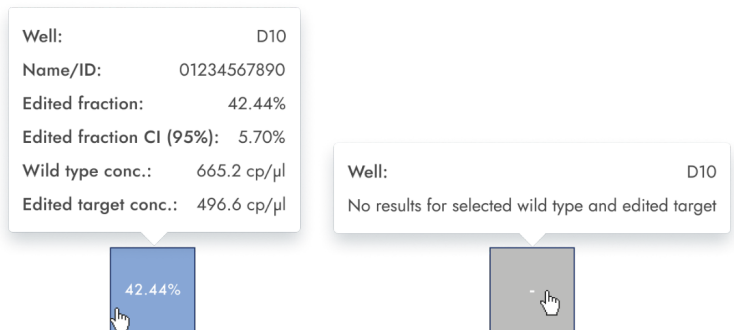
Export to CSV

Well	Name / ID	Reaction mix	Target Name	IC	Type	Conc. copies/μL	CI (95%)	Edited fraction	CI (95%)
A1	08 1234567890	Reaction Mix 1	Target A	✓	WT	1220.1	93.3%	34.67%	3.3%
A1	08 1234567890	Reaction Mix 1	Target A	-	ET	1220.1	93.3%	34.67%	3.3%
HW1	08 1234567890 lorem ipsum dolor sit amet	RM lorem ipsum dolor sit amet consectetur	Target lorem ipsum dolor sit amet consectetur elicit	-	WT	1220.1	93.3%	34.67%	-
A1	08 1234567890	Reaction Mix 1	Target A	-	ET	1220.1	93.3%	34.67%	3.3%
A1	08 1234567890	Reaction Mix 1	Target A	-	WT	1220.1	93.3%	34.67%	3.3%

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.

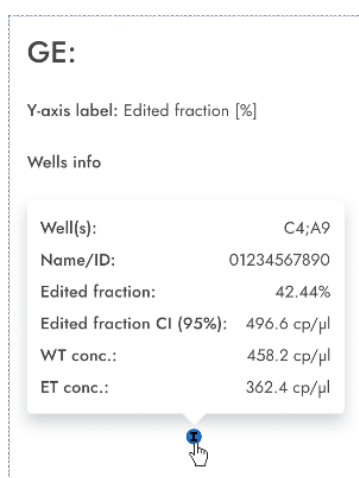


Point diagram tab for genome editing

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.

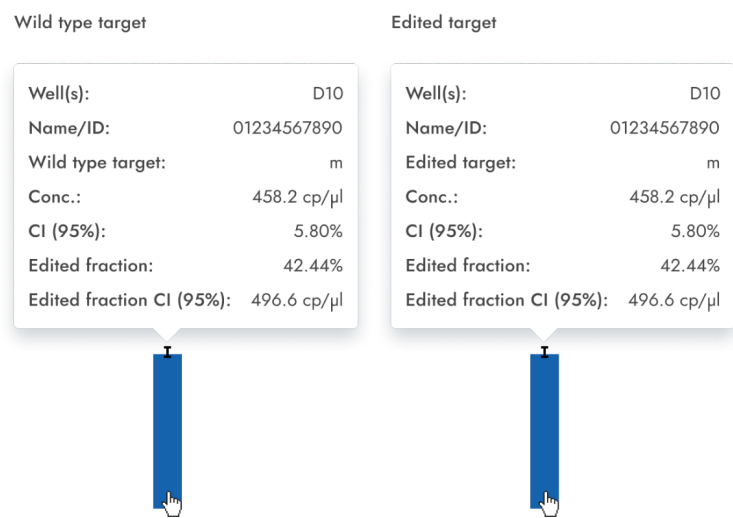


Concentration diagram tab for genome editing

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/ μ L)** – 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.

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Concentration diagram

Point diagram

Results - list

Mean values for replicates

Add to report

Export to CSV

Well	Name / ID	Reaction mix	Target	IC	Type	Conc.	CI	Copies/genome	CI
			Name			copies/μl	(95%)		(95%)
A1	<div>08</div> 1234567890 (REF)	<div><div></div></div> Reaction Mix 1	<div></div> Target A	-	TOI	14.1	93.3%	44.00	3.3%
			<div></div> Target B	✓	REF	1220.1	67%	44.00	3.3%
			<div></div> Target C	-	TOI	29.7	56%	44.00	3.3%
			<div></div> Target D	✓	REF	1220.1	93.3%	44.00	3.3%
			<div></div> Target E	✓	REF	15.9	21.3%	44.00	3.3%
		<div><div></div></div> Reaction Mix 2	<div></div> Target 1	✓	REF	1220.1	93.3%	44.00	3.3%
			<div></div> Target 2	-	REF	1220.1	16.7%	44.00	3.3%
			<div></div> Target 3	✓	TOI	78.9	93.3%	44.00	3.3%
			<div></div> Target 4	✓	TOI	1363.1	0.5%	44.00	3.3%
			<div></div> Target 5	-	REF	1220.1	93.3%	44.00	3.3%
A1	<div>08</div> 1234567890	<div><div></div></div> Reaction Mix 1	<div></div> Target A	-	REF	1220.1	93.3%	62.20	3.3%
HW1	<div>08</div> 1234567890 lorem ipsum dolor sit amet	<div><div></div></div> RM lorem ipsum dolor sit amet consectetur	<div></div> Target lorem ipsum dolor sit amet consectetur elicit	-	TOI	1220.1	93.3%	-	-
A1	<div>08</div> 1234567890	<div><div></div></div> Reaction Mix 1	<div></div> Target A	-	TOI	1220.1	93.3%	44.00	3.3%
A1	<div>08</div> 1234567890	<div><div></div></div> Reaction Mix 1	<div></div> Target A	-	REF	1220.1	93.3%	44.00	3.3%
A1	<div>08</div> 1234567890	<div><div></div></div> Reaction Mix 1	<div></div> Target A	-	-	1220.1	93.3%	34.67%	3.3%

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.

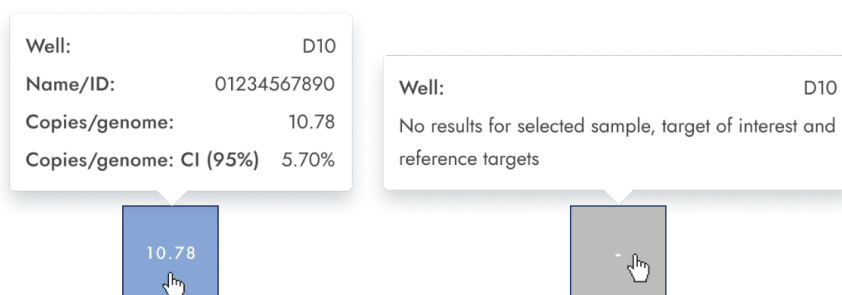
To export the results of the list view to a CSV file, click **Export to CSV**.

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.

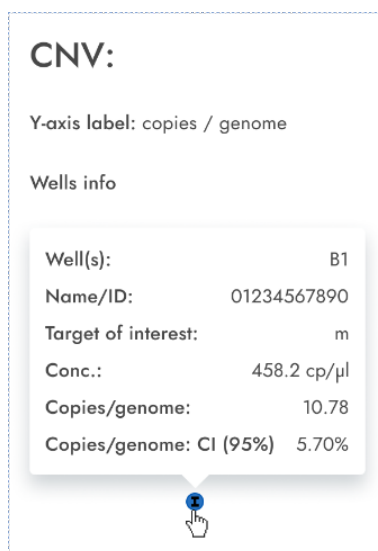
The samples are sorted by sample ID but the reference sample of a test is always shown. The well IDs and sample IDs are labeled on the x-axis.

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/ μ L)** – 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.

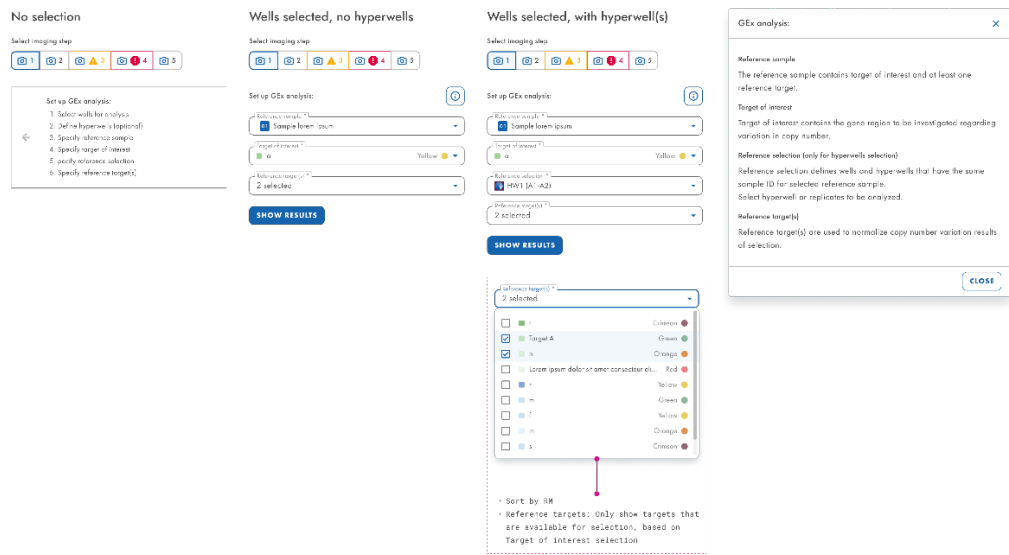
Replicates are treated different for multiplex and simplex test setup:

- 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**.

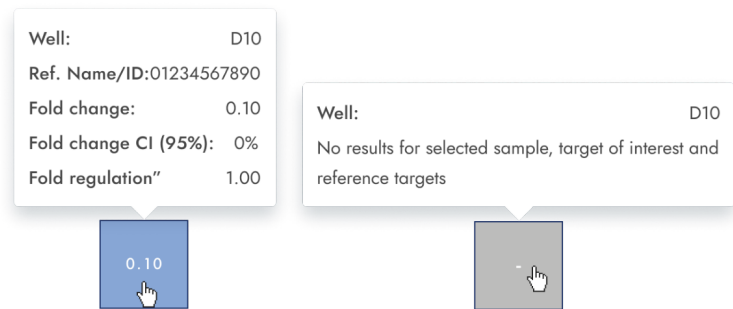


Heatmap for gene expression

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.

GEx:

Y-axis label: Fold change

Wells info

Well(s):	B1
Name/ID:	01234567890
Fold change:	0.44
Fold change CI (95%):	14.1%
Fold regulation:	-2.25



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.

Target of interest	Reference target
Well(s): D10	Well(s): D10
Name/ID: 01234567890	Name/ID: 01234567890
Target of interest: a	Reference target: a
Conc.: 458.2 cp/μl	Conc.: 458.2 cp/μl
CI (95%): 5.80%	CI (95%): 5.80%
Fold change: 0.79	Fold change: 0.79
Fold change CI (95%): 67.4%	Fold change CI (95%): 67.4%
Fold regulation: -1.27	Fold regulation: -1.27



5.19.7. Create a report in Utility 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.

Creating a report with default content

Each authorized user with Create Report for Analysis permission can generate PDF reports of plates in status Completed, Failed, or Invalidated that can later be downloaded in the Software Suite.

Generated PDF report contents include only results from samples that are valid.

- Content included by default in the PDF report:
 - Run details
 - Start and end time
 - Run status
 - Plate general data
 - Plate name
 - Plate type
 - Plate description
 - Labels
 - Plate owners
 - Plate barcode
 - Report name

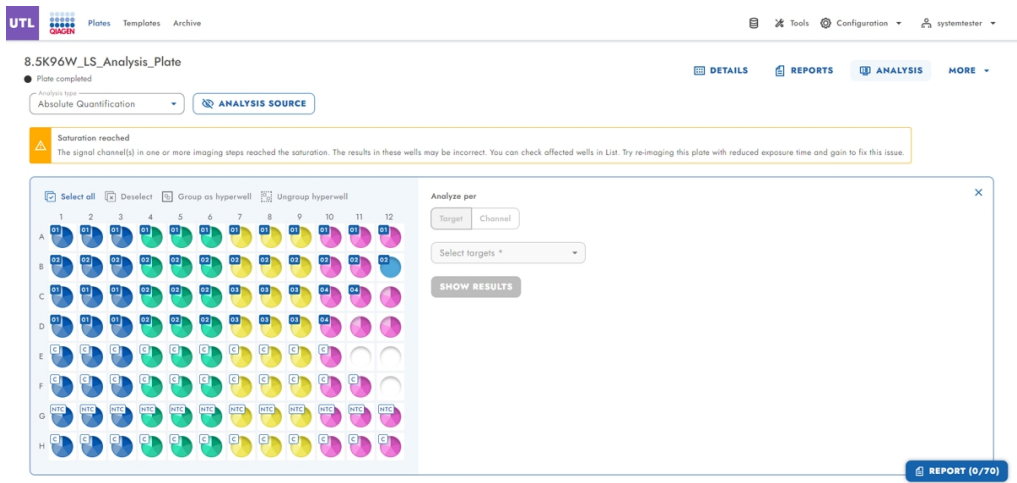
- Sample IDs included in the Plate (Plate layout)
- Assay (version) used per sample
- Result information per sample (Absolute Quantification)
- dPCR Parameters (*only for UTL Mode reports*)
- Used controls and/or calibrators incl. lot numbers
- Number of samples and controls/calibrators per Nanoplate
- Used consumables incl. lot numbers (*only for IVD Mode reports*)
- Used instrument incl. serial number
- Used Control software incl. software version
- Used Software Suite version incl. configuration used for results generation
- Warnings
 - Saturation
 - Min. valid partitions level
- Audit trail information like
 - Author of run report
 - Date and Time
 - Modification of locked Nanoplate setup

Note: The List view is generated as a graph, not as a data table.

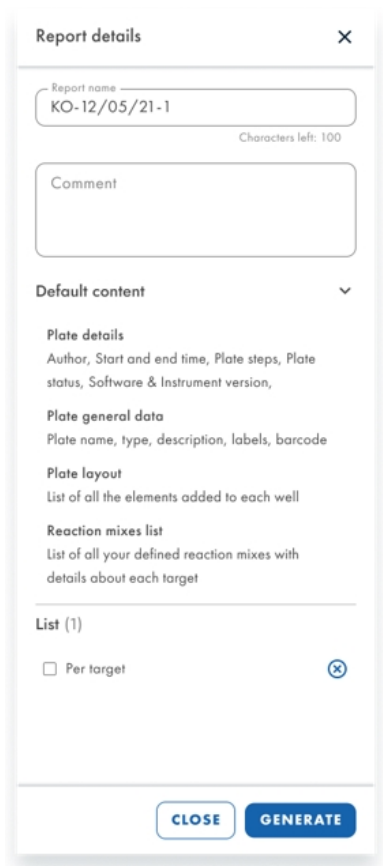
Note: The Software Suite stores the language, date, and time format configured during report generation and stores it with the report, so that every time the report is downloaded, the same language, date, and time format are used.

To download the report in a different language, it is required to create a new report with the Software Suite configured as needed.

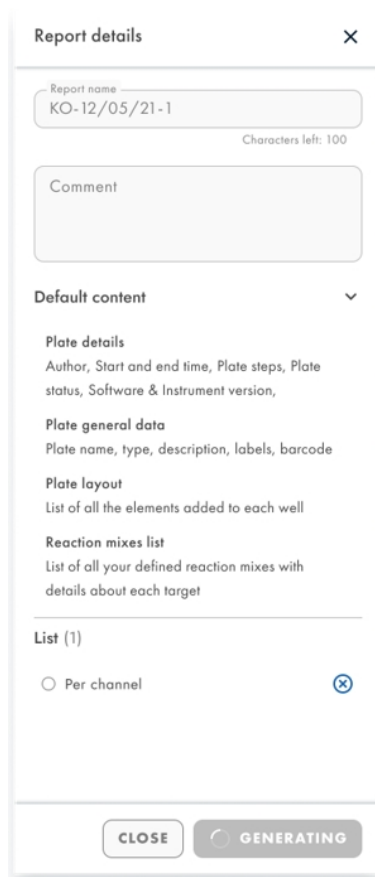
In the Analysis screen of the plate, users with Create Report for Analysis permission can click the **Report** button in the lower right side of the screen to generate a run report with default content:



Upon clicking **Report**, the Report details side panel is displayed, where the user can define the Report name and add comments, if applicable. If the user does not define a report name, the report is named **<Platename>.pdf**. The default content that is included in the report is listed:

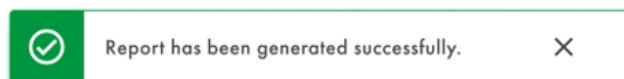


While the report is being generated, the **Generate** button is disabled and includes a spinner:



The image shows a 'Report details' dialog box. At the top, there's a title bar with 'Report details' and a close button (X). Below the title bar, there's a 'Report name' field containing 'KO-12/05/21-1' and a 'Characters left: 100' indicator. Underneath is a 'Comment' text area. A section titled 'Default content' with a dropdown arrow contains several items: 'Plate details' (Author, Start and end time, Plate steps, Plate status, Software & Instrument version), 'Plate general data' (Plate name, type, description, labels, barcode), 'Plate layout' (List of all the elements added to each well), and 'Reaction mixes list' (List of all your defined reaction mixes with details about each target). Below this is a 'List (1)' section with a radio button for 'Per channel' and a blue circular icon with an X. At the bottom, there are two buttons: 'CLOSE' and 'GENERATING' (which has a spinner icon).

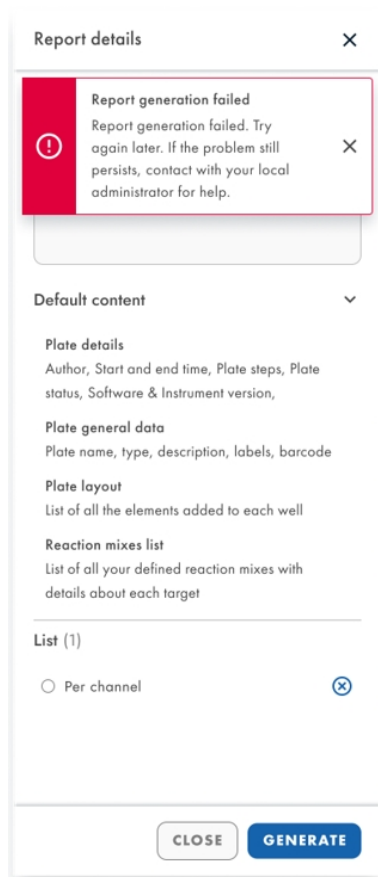
The Software Suite informs the user after the report has been successfully generated:



The Software Suite informs the user when the report is downloaded:



The Software Suite displays an error whenever the report generation fails:



Generated reports are stored in the disk.

Creating a customized report

Each authorized user with Create Report for Analysis permission can generate a previously customized report in PDF format.

When customizing reports using the side panel, the default content is also included in the generated format. If a report name is not defined, the report is generated as **<platename>.pdf**. If several reports with the same name are generated, then an incremental is added to the file name (e.g., **<platename>_1.pdf**).

Report details

Report name

KO-12/05/21-1

Characters left: 100

Comment

Default content

Absolute Quantification (28)

List (1)

☐ Per target

Histogram (3)

☒ Lorem ipsum target

☒ Target B

☒ Target C lorem ipsum dolor sit amet consectetur elit

1D Scatterplot (11)

☐ Reference channel

☒ Lorem ipsum target

☒ Lorem ipsum target

☒ Lorem ipsum target

☒ Lorem ipsum target

☒ Target B

☒ Target B

☒ Target B

☒ Target C lorem ipsum dolor sit amet consectetur elit

☒ Target C lorem ipsum dolor sit amet consectetur elit

☒ Target C lorem ipsum dolor sit amet consectetur elit

2D Scatterplot (1)

☒ Target B

☒ Target C lorem ipsum dolor sit amet consectetur elit

Concentration diagram (4)

☐ Reference channel

☒ Lorem ipsum target

☒ Target B

☒ Target C lorem ipsum dolor sit amet consectetur elit

Mutation Detection (2)

List (1)

☐ List

Point diagram (1)

☒ Target B

☒ Target C lorem ipsum dolor sit amet consectetur elit

Gene Expression (1)

List (1)

☐ List

CLOSE

GENERATE

Report details

Report name

KO-12/05/21-1

Characters left: 100

Comment

Default content

Absolute Quantification (4)

List (1)

☐ Per channel

Histogram (3)

☒ Lorem ipsum target

☒ Yellow

☒ Target C lorem ipsum dolor sit amet consectetur elit

Imaging step: 1

Remove from report

CLOSE

GENERATE

Report details

Report name

KO-12/05/21-1

Characters left: 100

Comment

Default content

Plate details

Author, Start and end time, Plate steps, Plate status, Software & Instrument version,

Plate general data

Plate name, type, description, labels, barcode

Plate layout

List of all the elements added to each well

Reaction mixes list

List of all your defined reaction mixes with details about each target

Absolute Quantification (1)

List (1)

☐ Per target

CLOSE

GENERATE

When creating a report, the “Add to Report” toggle is displayed in Absolute Quantification, Genome Editing, Mutant Detection, Gene Expression, and Copy Number Variation. It is possible to define whether the items should be included or not in the final report in the presented side panel.

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Export to CSV

Add to report

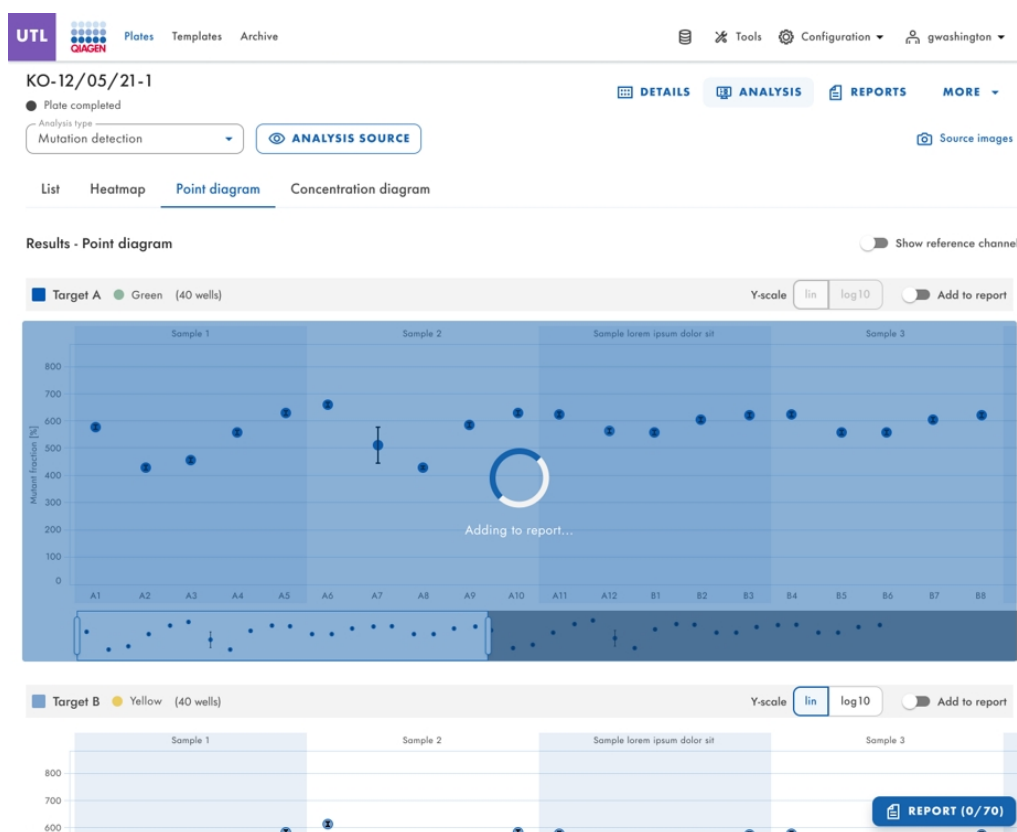
Well	Name / ID	Reaction mix	Target Name	IC	Type	Conc. copies/μL	CI (95%)	Copies/genome	CI (95%)
A1	1234567890 (REF)	<div>Reaction Mix 1</div>	Target A	-	TOI	14.1	93.3%	44.00	3.3%
			Target B	✓	REF	1220.1	67%	44.00	3.3%
			Target C	-	TOI	29.7	56%	44.00	3.3%
			Target D	✓	REF	1220.1	93.3%	44.00	3.3%
			Target E	✓	REF	15.9	21.3%	44.00	3.3%
		<div>Reaction Mix 2</div>	Target 1	✓	REF	1220.1	93.3%	44.00	3.3%
			Target 2	-	REF	1220.1	16.7%	44.00	3.3%
			Target 3	✓	TOI	78.9	93.3%	44.00	3.3%
			Target 4	✓	TOI	1363.1	0.5%	44.00	3.3%
			Target 5	-	REF	1220.1	93.3%	44.00	3.3%
A1	1234567890	Reaction Mix 1	Target A	-	REF	1220.1	93.3%	62.20	3.3%
HW1	1234567890 lorem ipsum dolor sit amet	RM lorem ipsum dolor sit amet consectetur	Target lorem ipsum dolor sit amet consectetur elicit	-	TOI	1220.1	93.3%	-	-
A1	1234567890	Reaction Mix 1	Target A	-	TOI	1220.1	93.3%	44.00	3.3%
A1	1234567890	Reaction Mix 1	Target A	-	REF	1220.1	93.3%	44.00	3.3%
A1	1234567890	Reaction Mix 1	Target A	-	-	1220.1	93.3%	34.67%	3.3%

There is a limit of 70 diagrams or tables to be included in one report, and there is a counter in the **Report** button. The counter is refreshed with the number of objects that have been selected to be added.



It is not possible to add the signalmap to the report.

While the items are being added to the report, a loader is displayed and any graph settings are disabled:



For each generated report, the Absolute Quantification List data are stored to be used for sending the results to LIMS (Well, Reaction mix, Target, Concentration, and Control True/False).

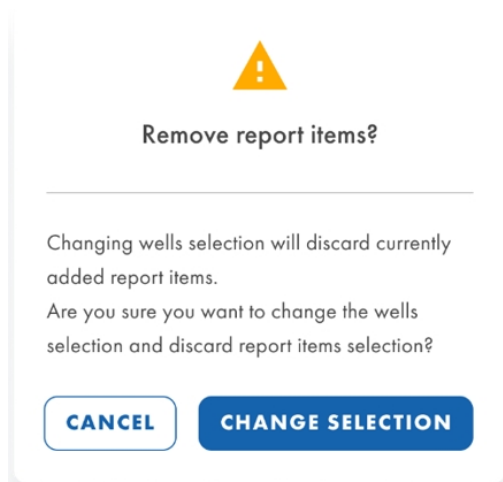
It is possible to add up to 70 items in the report with different variations of the analysis selection (changing the target selection, the channel selection, the different Secondary Analyses, etc.), except for a threshold change. Changing the threshold resets the selected items in the report, and a new selection must be made.

The generated PDF includes the sections in the same order as displayed in the side panel, and the PDF consists of A4 pages in landscape orientation. Any icons that are presented in the different diagrams and graphs in the Analysis screen are also included in the report.

For those lists that do not fit in a single page, the headers are repeated in each page containing the list.

The Comments page is only included if any comments are added.

Whenever the selection of wells/hyperwells is changed, a prompt is displayed, warning that if the selection change is confirmed, the currently added items will be discarded; therefore, the customized items need to be added once again. The default content is automatically updated, and it is only required to click the **Generate** button, whether custom items have been added or not.



Note: The Software Suite stores the language, date, and time format configured during report generation and stores it with the report, so that every time the report is downloaded, the same language, date, and time format are used.

To download the report in a different language, it is required to create a new report with the Software Suite configured with the newly desired language.

Each authorized user with Read Plate permission can download a previously created and signed Utility Mode report in PDF format in the Reports screen of the plate by clicking **Download**.

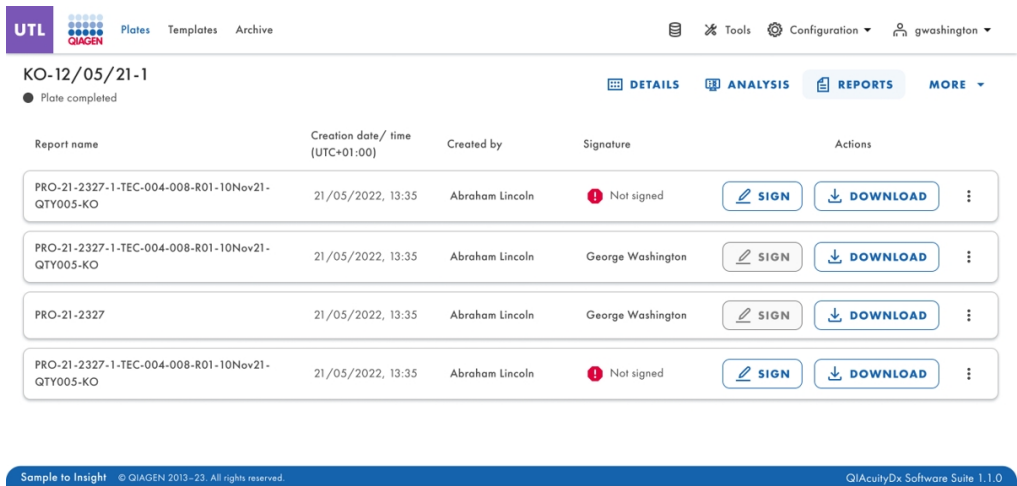
<div> <div>UTL</div> <div> <div></div> <div>QIAGEN</div> </div> </div> <div>Plates Templates Archive</div>		<div> <div></div> <div>Tools</div> <div>Configuration</div> <div>g.washington</div> </div>			
<div>KO-12/05/21-1</div> <div>● Plate completed</div>		<div> <div>LIMS connected</div> <div>DETAILS</div> <div>ANALYSIS</div> <div>REPORTS</div> <div>MORE</div> </div>			
Report name	Creation date/ time (UTC+01:00)	Created by	Signature	Results status	Actions
PRO-21-2327-1- TEC-004-008- R01-10Nov21- QTY005-KO	21/05/2022, 13:35	Abraham Lincoln	<div>Not signed</div>	<div>Sent to LIMS</div> <div>RESEND</div>	<div>SIGN</div> <div>DOWNLOAD</div>
PRO-21-2327-1- TEC-004-008- R01-10Nov21- QTY005-KO	21/05/2022, 13:35	Abraham Lincoln12345678910	George Washington	<div>Failed</div> <div>RESEND</div>	<div>SIGN</div> <div>DOWNLOAD</div>
PRO-21-2327-1- TEC-004-008- R01-10Nov21- QTY005-KO	21/05/2022, 13:35	Abraham Lincoln	<div>Not signed</div>	<div>SEND TO LIMS</div>	<div>SIGN</div> <div>DOWNLOAD</div>
PRO-21-2327-1- TEC-004-008- R01-10Nov21- QTY005-KO	21/05/2022, 13:35	Abraham Lincoln	<div>Not signed</div>	<div>SENDING TO LIMS</div>	<div>SIGN</div> <div>DOWNLOAD</div>

Upon generation of the report, the Software Suite stores the current language, date, and time format, and whenever that report is downloaded, the same language, date, and time format will be used, regardless of the configuration at that time.

It is possible to generate a new report for the new format/language.

5.19.8. Sign a report in Utility Mode

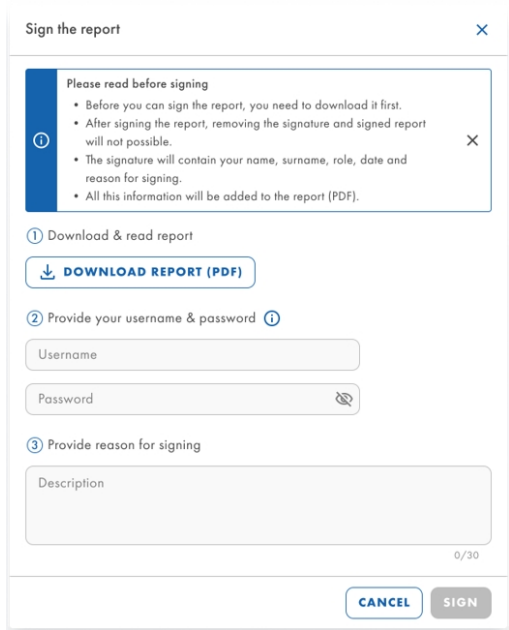
Each authorized user with Sign report permission can sign the Utility Mode reports to certify the validity of the run and results. Upon signing the report, a checksum is stored in the database to be checked against tampering. There can be only one signer per report, and after that, the **Sign** button is disabled.



The screenshot shows the QIAcuityDx Utility Mode (UTL) interface. At the top, there's a navigation bar with 'UTL', 'Plates', 'Templates', and 'Archive'. Below this, a status bar indicates 'KO-12/05/21-1' and 'Plate completed'. A table lists four reports, each with columns for 'Report name', 'Creation date/ time (UTC+01:00)', 'Created by', 'Signature', and 'Actions'. The first and fourth reports are marked 'Not signed' with a red exclamation mark, while the second and third are signed by 'George Washington'. Each row has 'SIGN' and 'DOWNLOAD' buttons. A footer bar contains 'Sample to Insight! © QIAGEN 2013-23. All rights reserved.' and 'QIAcuityDx Software Suite 1.1.0'.

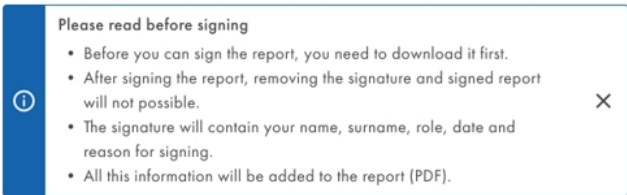
Report name	Creation date/ time (UTC+01:00)	Created by	Signature	Actions
PRO-21-2327-1-TEC-004-008-R01-10Nov21-QTY005-KO	21/05/2022, 13:35	Abraham Lincoln	Not signed	SIGN DOWNLOAD ⋮
PRO-21-2327-1-TEC-004-008-R01-10Nov21-QTY005-KO	21/05/2022, 13:35	Abraham Lincoln	George Washington	SIGN DOWNLOAD ⋮
PRO-21-2327	21/05/2022, 13:35	Abraham Lincoln	George Washington	SIGN DOWNLOAD ⋮
PRO-21-2327-1-TEC-004-008-R01-10Nov21-QTY005-KO	21/05/2022, 13:35	Abraham Lincoln	Not signed	SIGN DOWNLOAD ⋮

The user can start the signature workflow by clicking **Sign**, which opens a pop-up window:



The 'Sign the report' pop-up window contains a 'Please read before signing' section with four bullet points: 'Before you can sign the report, you need to download it first.', 'After signing the report, removing the signature and signed report will not possible.', 'The signature will contain your name, surname, role, date and reason for signing.', and 'All this information will be added to the report (PDF)'. Below this is a three-step process: 1. 'Download & read report' with a 'DOWNLOAD REPORT (PDF)' button; 2. 'Provide your username & password' with fields for 'Username' and 'Password'; 3. 'Provide reason for signing' with a 'Description' text area. At the bottom are 'CANCEL' and 'SIGN' buttons.

The user is informed about the signing process flow with the following information notification:



This is a close-up of the notification box from the previous image. It features a blue header with an information icon and the text 'Please read before signing'. It contains the same four bullet points regarding the signing process and report integrity.

The notification can be closed, and it will be displayed every time the modal is reopened.

All the fields are disabled by default, until the report has been downloaded. After downloading the report, the fields are enabled and the user can and has to enter the username and password. When the entered username does not match the logged user, the Sign button is disabled.

All information is verified instantly, and users are immediately informed of any errors, such as:

- An empty username or password ("This field cannot be empty.")

The screenshot shows a modal titled "Sign the report" with a close button (X) in the top right corner. Inside the modal, there is a section titled "Please read before signing" with a list of instructions: "Before you can sign the report, you need to download it first.", "After signing the report, removing the signature and signed report will not be possible.", "The signature will contain your name, surname, role, date and reason for signing.", and "All this information will be added to the report (PDF).". Below this, there are three steps: 1. "Download & read report" with a "DOWNLOAD REPORT (PDF)" button; 2. "Provide your username & password" with a "Username" field (containing an empty field) and a "Password" field; 3. "Provide reason for signing" with a "Description" text area. The "Username" field has a red border and a red error message: "This field cannot be empty.". At the bottom, there are "CANCEL" and "SIGN" buttons. The "SIGN" button is disabled.

- Entering a username different than the logged-in user ("This username doesn't match logged user's username"). The **Sign** button is also disabled.

The screenshot shows the same "Sign the report" modal. In this instance, the "Username" field contains the text "Admin". Below the field, there is a red error message: "This username doesn't match logged user's username.". The "SIGN" button at the bottom is disabled.

- Leaving the password field empty ("This field cannot be empty.").

Sign the report [X]

Please read before signing

- Before you can sign the report, you need to download it first.
- After signing the report, removing the signature and signed report will not possible.
- The signature will contain your name, surname, role, date and reason for signing.
- All this information will be added to the report (PDF).

① Download & read report

[↓ DOWNLOAD REPORT \(PDF\)](#)

② Provide your username & password ①

Admin

PASSWORD

This field cannot be empty.

③ Provide reason for signing

Description

0/30

[CANCEL](#) [SIGN](#)

- Entering an incorrect password ("Password is incorrect.").

Sign the report [X]

Please read before signing

- Before you can sign the report, you need to download it first.
- After signing the report, removing the signature and signed report will not possible.
- The signature will contain your name, surname, role, date and reason for signing.
- All this information will be added to the report (PDF).

① Download & read report

[↓ DOWNLOAD REPORT \(PDF\)](#)

② Provide your username & password ①

Admin

PASSWORD

Password is incorrect.

Incorrect password

You've got 1 more attempts before you are logged out.

③ Provide reason for signing

Just because

12/30

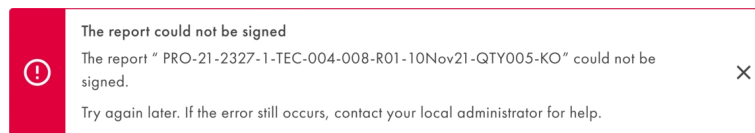
[CANCEL](#) [SIGN](#)

There are up to 3 attempts for entering the correct password before being logged out, and the error notification below the password field indicates how many attempts are left. The counter of attempts is reset after successful report sign or new log in. Any signing of any report by the same user is counted regardless of logged device, plate, and report. After the third failed attempt, the user token for the session where the signing failed is expired and all tabs using the same token are logged out. Any unsuccessful attempt and the logout are tracked in the Audit Trail.

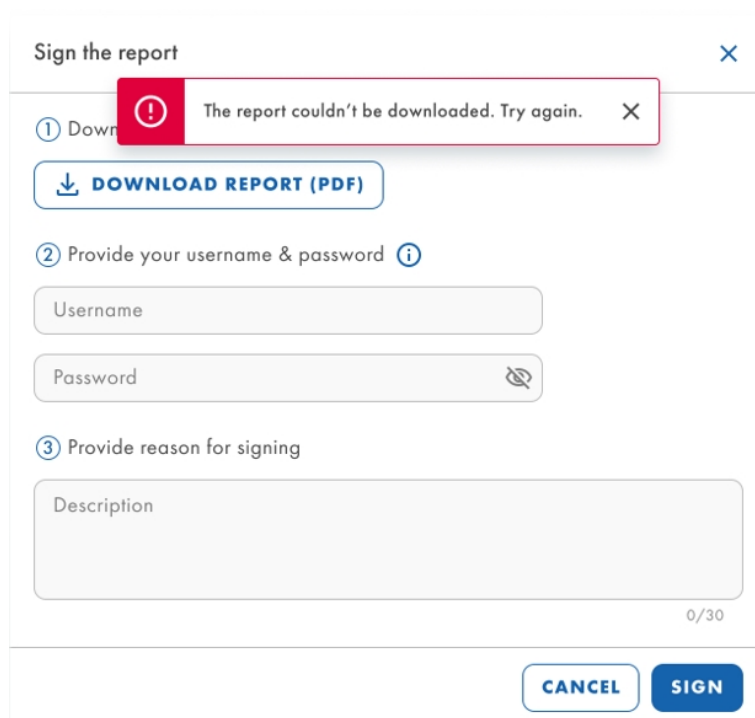
Once the report is successfully signed, the following confirmation message appears.



If an error occurs during the signing process, an error notification is displayed.



If the download of the report during signing fails, the following error notification is displayed.



5.19.9. Delete a Utility Mode Report

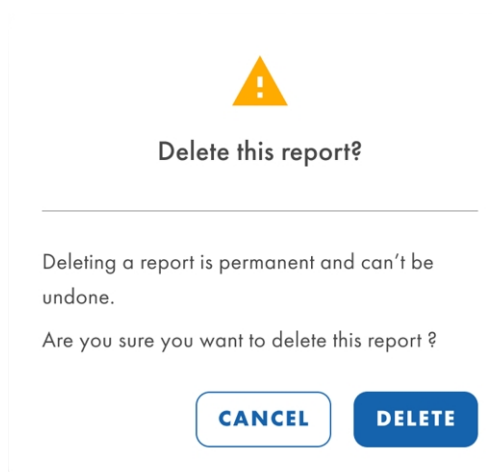
Each authorized user with Delete Report permission can delete Reports from Utility Mode plates available in the Software Suite system. It is possible to delete both signed and unsigned reports.

The **Delete** option is available in each report's context menu.

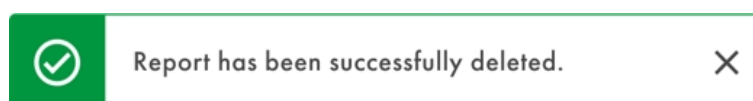
The screenshot shows the QIAGEN UTL interface. At the top, there's a navigation bar with 'UTL', 'Plates', 'Templates', and 'Archive'. On the right, there are icons for 'Tools', 'Configuration', and a user profile 'gwashington'. Below the navigation bar, the title 'KO-12/05/21-1' is displayed, followed by a status indicator 'Plate completed'. A tab bar shows 'DETAILS', 'ANALYSIS', 'REPORTS' (selected), and 'MORE'. The main content is a table with columns: 'Report name', 'Creation date/ time (UTC+01:00)', 'Created by', 'Signature', and 'Actions'. The table contains four rows of reports. The third row, 'PRO-21-2327', has a context menu open over the 'Actions' column, showing 'SIGN', 'DOW', 'Delete', and a cursor icon. The footer of the screenshot shows 'Sample to Insight © QIAGEN 2013-23. All rights reserved.' and 'QIAcultyDx Software Suite 1.1.0'.

Report name	Creation date/ time (UTC+01:00)	Created by	Signature	Actions
PRO-21-2327-1-TEC-004-008-R01-10Nov21-QTY005-KO	21/05/2022, 13:35	Abraham Lincoln	Not signed	SIGN DOWNLOAD ⋮
PRO-21-2327-1-TEC-004-008-R01-10Nov21-QTY005-KO	21/05/2022, 13:35	Abraham Lincoln	George Washington	SIGN DOWNLOAD ⋮
PRO-21-2327	21/05/2022, 13:35	Abraham Lincoln	George Washington	SIGN DOW Delete
PRO-21-2327-1-TEC-004-008-R01-10Nov21-QTY005-KO	21/05/2022, 13:35	Abraham Lincoln	Not signed	SIGN DOWNLOAD ⋮

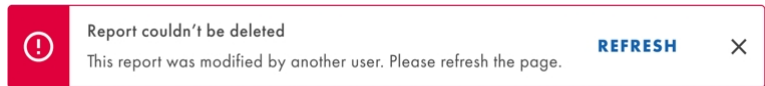
After clicking it, a confirmation pop-up is displayed. Upon clicking **Cancel**, the report deletion is canceled and the user is brought back to the Reports screen. Upon clicking **Delete**, the report is deleted and the user is brought back to the Reports screen.



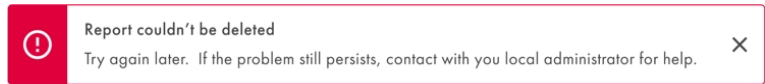
Upon user confirmation, the deletion notification is shown for successful deletions.



In case there is an error during deletion, an error notification is displayed.



If the report is deleted in another browser tab by the user or by another user, an error notification is displayed with a **Refresh** button for reloading the page.



The deletion of a report is tracked in the Audit Trail as "Report deleted" event type, with category "Plate".

5.19.10. Review results in IVD mode

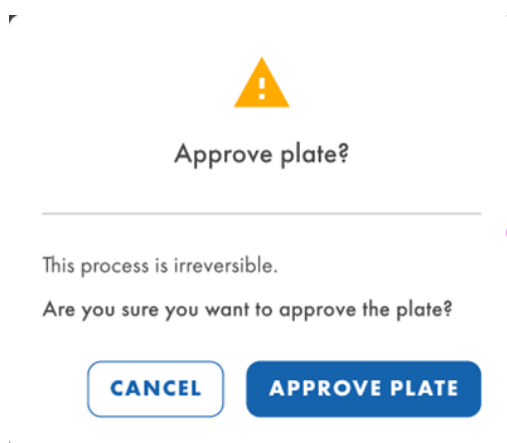
Manual validation


The screenshot shows the IVD (In Vitro Diagnostic) review interface. At the top, there's a header with "IVD" and "QIAGEN" logos, and navigation tabs for "Plates" and "Archive". Below the header, the report title "KO-12/05/21-1" is displayed, along with a "Pending review" status. There are buttons for "DETAILS", "REVIEW", "REPORTS", and "MORE". The "Plate details" section includes "REJECT" and "APPROVE" buttons. Below this is a table with columns: Well, HW, Control, NCN%, IS-NCN, and MR. The table contains four rows of data. The "Samples" section below the table has columns: Well, HW, Sample ID, NCN%, IS-NCN, and MR, with four rows of data. At the bottom right, there are "CANCEL" and "SAVE & GENERATE REPORT" buttons.

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**.




Approve plate?


This process is irreversible.

Are you sure you want to approve the plate?

CANCEL
APPROVE PLATE

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.

IVD



[Plates](#)
[Archive](#)

KO-12/05/21-1

● Plate completed

Plate details

✓ Plate approved 24/04/2023, 12:55 (UTC+01:00) by George Washington

Well	HW	Control	NCN%	IS-NCN	MR
A1-A2	HW9	HighPC	108.10	108.10	3.5
B1-B2	HW10	LowPC	105.09	106.01	4.5
C1-C2	HW11	BT Neg	101.47	105.00	2.5

If the user wants to reject the plate, after clicking **REJECT**, a rationale for the rejection will be asked for by the Software Suite.

Reject plate

✕

KO-12/05/21-1

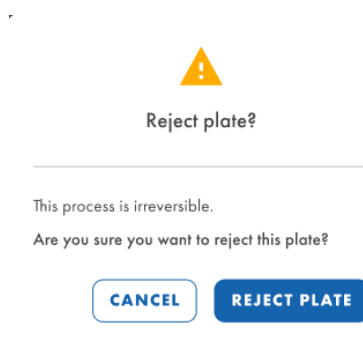
Rejection reason *

Invalid NTC and IS-NCN parameters

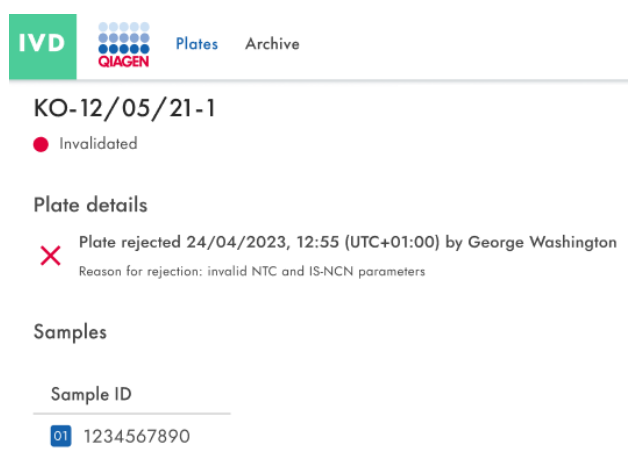
1900/2000

CANCEL
APPLY

After clicking **APPLY**, to make the rejection persistent, the user should finally click **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”.

5.19.11. 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 Mode. This is valid for the plates with status on IVD “Plate Completed”.

IVD QIAGEN Plates Archive

KO-12/05/21-1

● Plate completed

DETAILS REVIEW REPORTS MORE

Report name	Creation date/ time (UTC+01:00)	Created by
PRO-21-2327-1-TEC-004-008-R01-10Nov21-QTY005-KO	21/05/2022, 13:35	Abraham Lincoln

DOWNLOAD

If no reports are available, the “No reports available.” message is displayed to the user.

IVD QIAGEN Plates Archive

KO-12/05/21-1

● Completed

DETAILS REVIEW REPORTS MORE

No reports available.

If the download fails due to a corruption of the report, a specific error notification is displayed.

The report couldn't be downloaded

The existing report got corrupted and couldn't be downloaded. Contact your local administrator for help.

If the download of the report fails due to a different cause, the generic error notification is displayed.

The report couldn't be downloaded. Try again.

Note: Upon generation of the report, the Software Suite stores the current language, date, and time format, and whenever that report is downloaded, the same language, date, and time format will be used, regardless of the configuration at that time. It is not possible to download the report with a different format or language.

5.19.12. 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.

The screenshot shows the IVD (In Vitro Diagnostic) interface. At the top, there's a navigation bar with 'IVD', 'Plates', and 'Archive'. Below this, the header displays 'KO-12/05/21-1' and a status indicator 'Plate completed'. To the right, there are tabs for 'DETAILS', 'REVIEW', 'REPORTS' (which is active), and 'MORE'. Below the tabs, a table lists reports. The table has columns: 'Report name', 'Creation date/ time (UTC+01:00)', 'Created by', 'Signature', and 'Actions'. One report is listed: 'PRO-21-2327-1-TEC-004-008-R01-10Nov21-QTY005-KO' with a creation date of '21/05/2022, 13:35' and created by 'Abraham Lincoln'. In the 'Signature' column, it says 'Not signed' with a red exclamation mark icon. In the 'Actions' column, there are two buttons: 'SIGN' and 'DOWNLOAD'. At the bottom of the page, there's a footer with 'Sample to Insight © QIAGEN 2013–23. All rights reserved.' and 'QIAcuityDx Software Suite 1.0.0'.

If the plate has a report pending to be signed, a “Not Signed” text will be shown in the “Signature” column.

The dialog box is titled 'Sign the report'. It contains a section 'Please read before signing' with a list of instructions: 'Before you can sign the report, you need to download it first.', 'After signing the report, removing the signature and signed report will not possible.', 'The signature will contain your name, surname, role, date and reason for signing.', and 'All this information will be added to the report (PDF)'. Below this, there are three steps: 1. 'Download & read report' with a 'DOWNLOAD REPORT (PDF)' button; 2. 'Provide your username & password' with input fields for 'Username' and 'Password'; 3. 'Provide reason for signing' with a 'Description' text area. At the bottom right, there are 'CANCEL' and 'SIGN' buttons.

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.

Sign the report

Please read before signing

- Before you can sign the report, you need to download it first.
- After signing the report, removing the signature and signed report will not possible.
- The signature will contain your name, surname, role, date and reason for signing.
- All this information will be added to the report (PDF).

1

Download & read report

Download Report (PDF)

2

Provide your username & password

Username *

gwashtington

Password *

3

Provide reason for signing

Just because

12/30

CANCEL

SIGN

The report " PRO-21-2327-1-TEC-004-008-R01-10Nov21-QTY005-KO" has been signed.

To finish the signing process, click the **SIGN** button. A notification will be shown.

5.19.13. 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 Mbc

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 Mbc
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

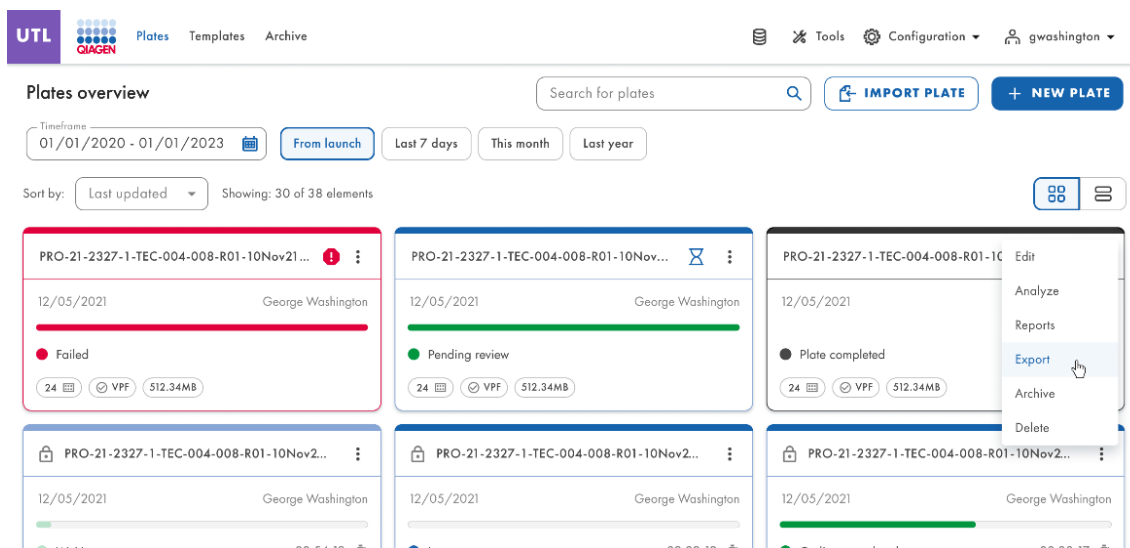
Kits

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

5.19.14. 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**.

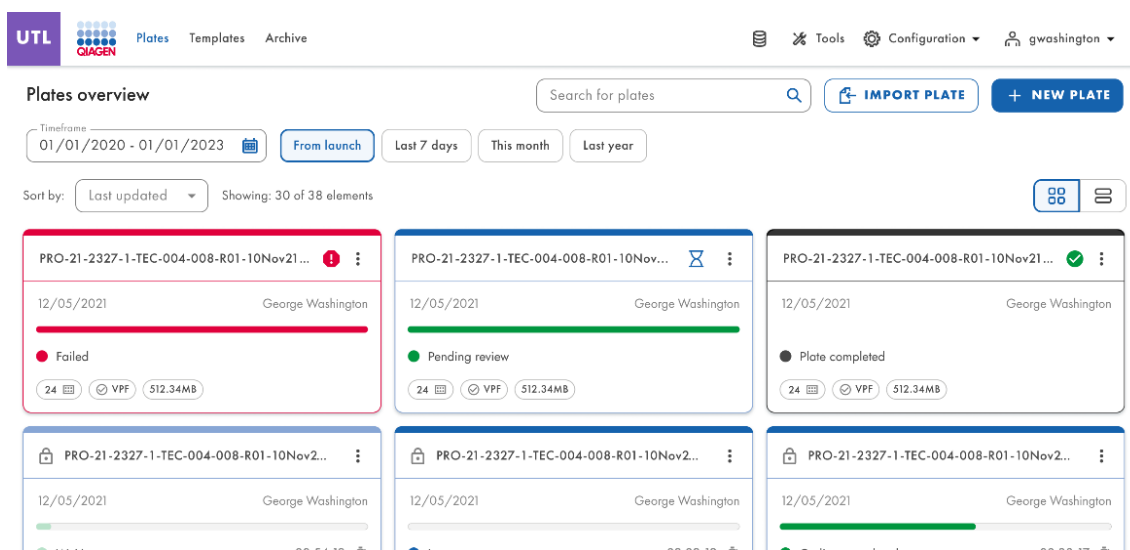
Note: Audit Trail events related to the exported plate will always remain in the original Software Suite instance. The exported plate does not contain Audit Trail information.



5.19.15. 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 notebook.

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.

The screenshot displays the 'Archive overview' interface. At the top, there's a navigation bar with 'IVD' and 'QUAGEN' logos, and tabs for 'Plates' and 'Archive'. A search bar labeled 'Search for plates' is on the right. Below the navigation, a 'Timeframe' filter is set to '01/01/2020 - 01/01/2023', with buttons for 'From launch', 'Last 7 days', 'This month', and 'Last year'. A 'Sort by' dropdown is set to 'Archive date'. The main area shows a grid of six plate cards. Each card displays a plate ID (e.g., 'PRO-21-2327-1-TEC-004-008-R01-10Nov21...'), a date ('12/05/2021'), and a user ('George Washington'). The status is indicated by a dot and text: 'Plate completed' (black dot) for the first five cards and 'Drafted' (blue dot) for the last card. Each card also shows a '24' icon, a 'VFP' icon, and a size of '512.34MB'. The middle card in the second row is highlighted with a blue border and shows a 'Defined' status with a timer at '00:38:22'.

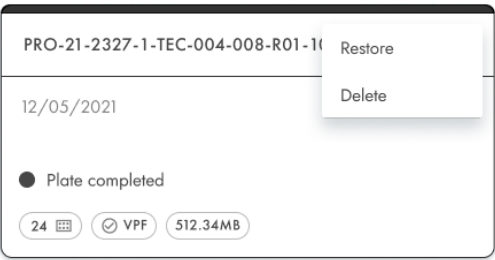
Users with Archive Overview permission can search the archived plates by plate name using the search bar in the Archive Overview screen. After deleting the text from the search bar or pressing **Esc** key, the full list of archived plates is displayed.

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.

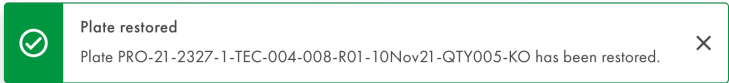
Each authorized user with Delete the Plate from Archive permission can delete archived plates from the Archive Overview list in the Utility Mode. The user can trigger the plate deletion from the context menu on the desired plate tile. It is not possible to delete plates from the IVD Mode.

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.

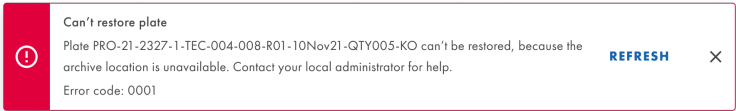
The user looks for the plate to be restored in Archive Overview, clicks the 3-dots menu and selects **Restore**.



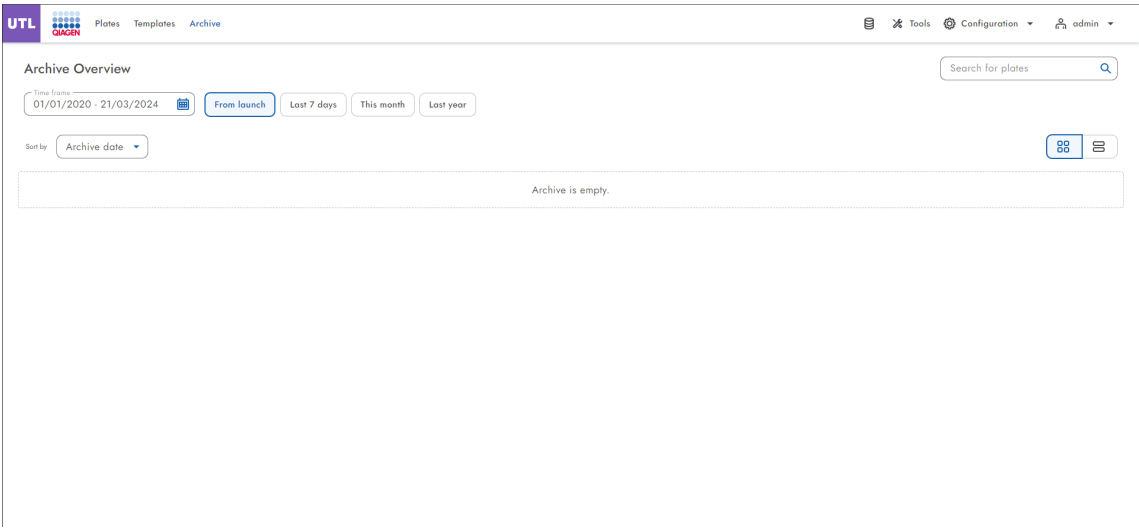
The successful restore is confirmed with the following message.



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 by Field Service Engineers only.

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

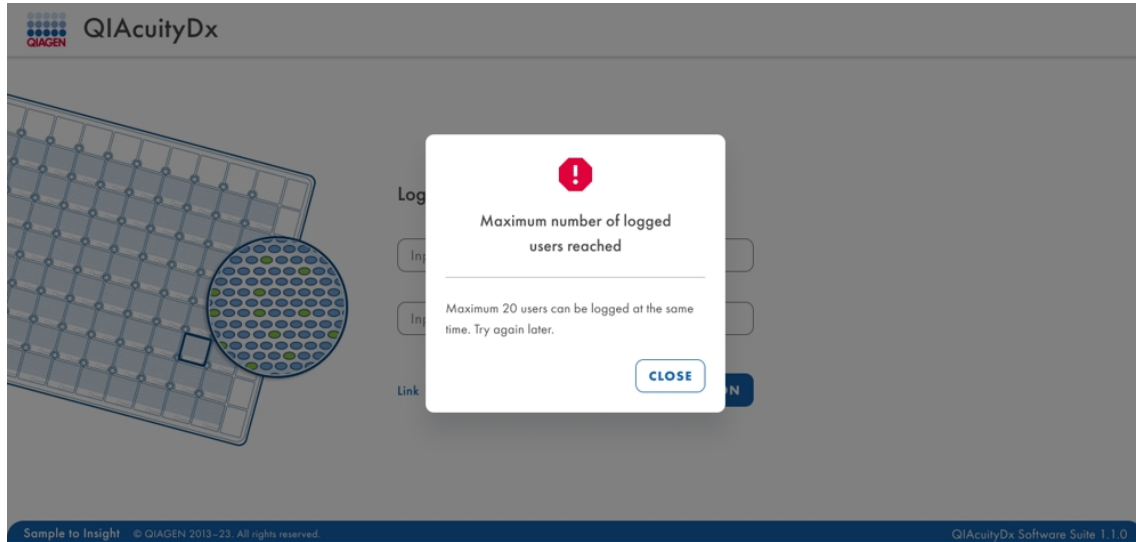
The Software Suite protects from unauthorized access to data at rest.

5.21.9. QIAidentity and LIMS Connector log rollover policy

QIAidentity and LIMS Connector have a log rollover policy of 60 days to not reach the disk capacity limit.

5.21.10. Simultaneous users connected to the Software Suite

Each Software Suite subsystem can have 20 users simultaneously connected and logged in at any given time, irrespective of their activity within the system, while having also 10 instruments simultaneously connected. Whenever the limit is reached, the next user trying to log in is displayed the following error message, with only the option to close:



It is not disclosed to the user trying to log in which users are logged in or when are the tokens freed up.

Users logged into the instruments (Control Software) are not taken into account.

Users are counted by the unique tokens, not by the usernames (i.e., if username JohnDoe has been used twice to log into the Software Suite, it is counted as 2 users).

When a user uses the One Time Access (OTP) for changing the password, the token from that action is not counted; it is only counted until they actually log in with their password.

When a user has to change their password after first login/because another user has changed it, then that token does count.

Note: If there are 20 users logged in and they close the browser at the same time (without logging out), the Software Suite prevents any user to log in for an hour, except for a Field Service Engineer.

5.21.11. File name format of files generated by the Software Suite

The files generated by the Software Suite have the following file name format:

- Software Suite Package (under Tools): **QIAcuityDx_<Suiteversion>_SWSP_YYYYMMDD_HHMMSS.zip**
- Exported plate: **exported-plate_<platename>_<plateUUID>.zip**
- Plate support package:
support_package_extended_<plateUUID>_<startdateinYYYYMMDD>_<enddateinYYYYMMDD>.zip
support_package_standard_<plateUUID>_<startdateinYYYYMMDD>_<enddateinYYYYMMDD>.zip
- Run report: user defined, or **<platename>.pdf**
- CSV files:
<platename>_DD_MM_YYYY_HH_MM_SS_UTC+00_00.csv
<platename>_RFU_compact_img<imagingstep>_<channelsincludedas g_y_r_c_o>_DD_MM_YYYY_HH_MM_SS_UTC+00_00.zip
- Audit trail: **AuditTrailReport_YYYYMMDD_HHMMSS.pdf**
- Plate Layout: **<platename>_YYYYMMDD_HHMMSS.csv**

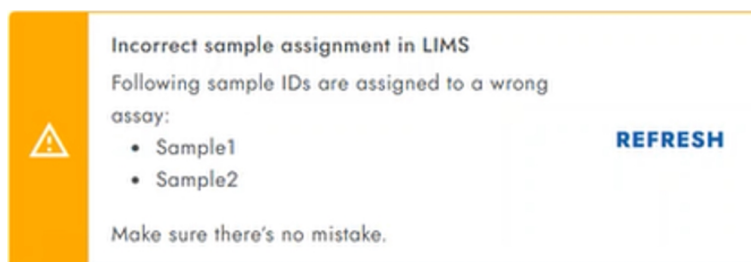
5.22. Query for pending test orders to an external LIS/HIS/LIMS

When creating or editing a plate, in either IVD or UTL mode, if a connection to LIMS is set and connected, the Software Suite will query for orders for selected samples when a user with granted permission to edit a plate, in status Drafted or Defined, and in addition, the LIMS connection is configured and is in “LIMS Connected” status. That will occur when the user assign Samples in the Plate Layout.

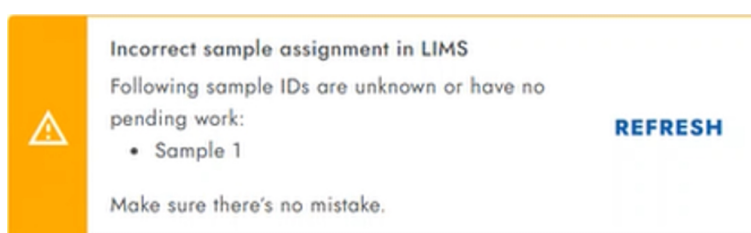
The screenshot shows the 'Demo LIMS UTL' interface in 'Drafted' status. The 'Plate layout' tab is active, displaying a grid for assigning samples to wells (A1-H3). The grid shows Sample1 assigned to A1, Sample2 to B1, and Sample 1 to C1. A warning message is displayed on the right, indicating 'Incorrect sample assignment in LIMS' for Sample1 and Sample2, with a 'REFRESH' button. The top bar shows 'LIMS connected' status and navigation buttons like BACK, FINISH, EXPORT, and IMPORT.

If the external LIMS response for the assigned sample matches the assay/plugin of the plate, no warning message will be shown.

If the external LIMS response for the assigned sample does not match the assay/plugin of the plate, a warning message will be shown indicating the discrepancy.



If the external LIMS response for the assigned sample indicates that there are no pending orders or that the sample is unknown for the LIMS, a warning message will be shown indicating the discrepancy.



In both warning message boxes, a **REFRESH** button is present to let the user query again to LIMS for the related samples.

In any case, even if the warning messages are shown, the Software Suite will not prevent the user to save the plate with the selected samples.

5.23. Sending results to an external LIS/HIS/LIMS

Each authorized user with Read Plate permission user can send the results in HL7 protocol to LIMS so that it can be managed in an external system. This action can be performed from the Reports screen. The results sent in HL7 are the same as the information expressed in the generated run reports. There are other preconditions to send the results to the LIMS, which are the following:

- The run report must be signed.
- The LIMS Connection must be configured.
- The LIMS Connection status must be in "LIMS Connected" status.
- There is at least one well selected.

For Utility Mode, the following precondition must apply to the report's content:

- The selected Utility Mode report contains one Absolute Quantification list (or more, from different imaging steps, and no other graphs/objects).

Note: The Utility Mode report does not contain reagent information (i.e., master mix/prime/probe data are not included).

If the preconditions are accomplished and the report-related results have never been attempted to be sent, then the **SEND TO LIMS** button is enabled. Otherwise, the **SEND TO LIMS** button will be disabled.

The HL7 messages are sent to LIMS after clicking the button, one per each sample assigned to the related plate.

In case the user already attempted to send the results previously, the **RESEND** button is shown, along with the Result status. For results where at least one message was not properly delivered (Failed status), the Results status is “Failed”. For results where all messages have been correctly delivered, the status displayed is “Sent to LIMS”.

The screenshot shows the QIAGEN software interface with a table of reports. The table has columns for Report name, Creation date / time, Created by, Signature, Results status, and Actions. The reports are as follows:

Report name	Creation date / time (UTC+01:00)	Created by	Signature	Results status	Actions
PRO-21-2327-1- TEC-004-008- R01-10Nov21-QTY005- KO	21/05/2022, 13:35	Abraham Lincoln	George Washington	LIMS connected	SEND TO LIMS SIGN DOWNLOAD
PRO-21-2327-1- TEC-004-008- R01-10Nov21-QTY005- KO	21/05/2022, 13:35	Abraham Lincoln	George Washington	Failed	RESEND SIGN DOWNLOAD
PRO-21-2327	21/05/2022, 13:35	Abraham Lincoln	George Washington	Sent to LIMS	RESENDING SIGN DOWNLOAD
PRO-21-2327-1- TEC-004-008- R01-10Nov21-QTY005- KO	21/05/2022, 13:35	Abraham Lincoln	Not signed	Not signed	SEND TO LIMS SIGN DOWNLOAD

Sample to Insight © QIAGEN 2013–23. All rights reserved. QIAcuityDx Software Suite 1.1.0

Clicking the contextual menu followed by “LIMS Result status” shows a detailed list of the pending samples and controls that can be sent to LIMS, together with their delivery status (response received from LIMS Connector).

The screenshot shows the QIAGEN software interface with a modal window titled "LIMS results delivery status". The modal displays a table of samples and controls with their LIMS status. The table is as follows:

Sample / Control	LIMS status
RT-NEG	-
LowPC	-
HighPC	-
ISAMR	-
Sample1	-
Sample2	-
Sample3	-

At the bottom of the modal, there are buttons for "CLOSE" and "SEND ALL TO LIMS".

From this list, it is also possible to send the pending messages to LIMS by clicking **SEND ALL TO LIMS** or **Send failed samples** by clicking on the arrow next to the button. Clicking **Send failed samples** sends only those that had a “Failed” LIMS status again.



After the result sending to LIMS has completed, the list shows the delivery status for each of the messages related to each sample or control.

LIMS results status ×	
5 of 8 sent to LIMS	
Sample / Control	LIMS status
01 3456812096	✓ Sent to LIMS
01 9842017399	! Failed
01 3489120921	! Failed
01 0912657843	! Failed
01 0192838475	🔄 In queue
C HighPC	✓ Sent to LIMS
C LowPC	✓ Sent to LIMS
CLOSE SEND ALL TO LIMS ▼	

The possible LIMS status are as follows:

- **- (dash)**: There has not been any attempt yet to send this message.
- **In queue**: The message sending is being processed.
- **Sent to LIMS**: the message has been sent, and the LIMS has responded with a positive acknowledgment message.
- **Failed**: The message has been attempted to be sent, but a failure occurred: the LIMS responded with a negative acknowledgment or the LIMS was unreachable. To know more, it is required to check the support package.

Reaction mix names and target names, which are user defined, should not contain any HL7 reserved character (| ^ ~ & \).

5.24. Performing a backup and restore of the Software Suite

This section describes how to backup and restore the data of the QIAcuityDx Software Suite using scripts. Backup and Restore processes need some background for dealing with possible errors, so this document is intended for Field Service Engineers and Administrators with knowledge about QIAcuityDx Software Suite and its Docker features.

5.24.1. Prerequisites

The following prerequisites are needed for performing the Backup and Restore processes:

- Administrator rights to execute the scripts.
- Installed and running QIAcuityDx Software Suite.

5.24.2. Backup

This process stores the current data of the QIAcuityDx Software Suite in a single ZIP file. Current data comprise User List, Plates (Raw Images and Analysis included), Logs, etc. The backup can be considered as a snapshot of the whole platform at a specific moment. The resulting file can be used for the Restore process.

Archived Plates are an exception, due to the Archived Plates not being stored in the system (they are a “backup” themselves) but in several different places from which the QIAcuityDx Software Suite has no access (it is up to the Users to configure the Archive location prior to archiving any plate).

It is crucial to understand that triggering a backup process will stop the Software Suite. This is needed for packaging all the data without disrupting any running processes, which would cause wrong or inconsistent data to be stored. Consider before performing the backup for which time slot would stopping the Software Suite have the lesser impact for the users.

The backup process consists of the following steps:

1. A System Check will be executed to determine if all the requirements are fulfilled for running the backup. Requirements checked are as follows:
 - a. Docker Daemon is running.
 - b. The Software Suite is properly installed and running.
 - c. 7zip executable is located (It is provided along with the scripts).
 - d. The Script input parameters are well-formed and valid.
2. QIAidentity Service is stopped.
3. The QIAcuityDx Software Suite is stopped.
4. Installed Plugins, if found, are stopped.
5. A password-protected ZIP file is generated with the Backup Data. A special file with the current QIAcuityDx Software Suite’s version is included.
6. The QIAcuityDx Software Suite is restarted (This step will take some minutes to be completed).
7. Installed Plugins, if found, are restarted.

8. QIAidentity Service is restarted.
9. The overall process completion status is written in the logs.

Configurable parameters

The Backup script must be executed with the following parameters:

Parameter	Description	Example
-TargetPath	<ul style="list-style-type: none"> Path where the Backup File will be generated Must be a valid Windows or Network Path <p>Note that for inputting a target folder with spaces in its name, the whole path will have to be enclosed in double quotes.</p>	<p>Windows paths:</p> <p>C:\QIAGEN\Backups D:\Scheduled\Backups\QIAGEN C:\Temp\QIAGEN Backups</p> <p>Network paths:</p> <p>\\192.168.1.5\QIAGEN\Backups \\suitedxhost\Temp\Backups</p>
-Password	<ul style="list-style-type: none"> Password to encrypt the Backup file with <p>There are restrictions or requirements for the password besides being a mandatory parameter (minimum length of 1 character).</p>	<p>Weak password: Password</p> <p>Strong password: 12Az#XasDk9x!ddW9x</p>

Execution

The backup process can be executed anytime using the provided script file "SuiteDx-Backup.ps1" located in folder "\scripts" under the QIAcuityDx Software Suite installation folder (which is c:\Program Files\Qiagen\QIAcuityDx\ by default).

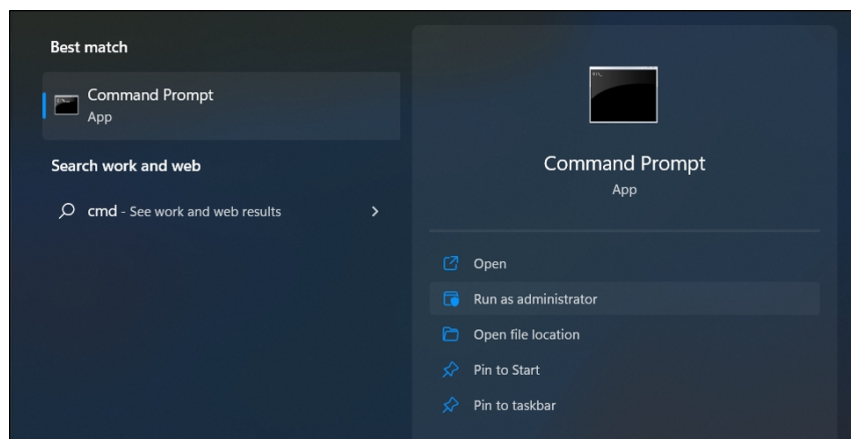
Note: The script will stop all QIAcuityDx Software Suite services; therefore, the script can only be executed once per backup.

Assuming the following parameters (as an example):

- **-TargetPath:** c:\qiagen\backup
- **-Password:** 12Az#XasDk9x!ddW9x

The steps to perform a Backup are as follows:

1. Open a Windows Command Prompt (CMD) with administrator rights by typing "cmd" in Windows' start menu:



- Go to the QIAcuityDx Software Suite installation folder (by default, c:\Program Files\Qiagen\QIAcuityDx):

```
Administrator: Command Pro x + v
Microsoft Windows [Version 10.0.22621.2134]
(c) Microsoft Corporation. All rights reserved.

C:\Users\automationuser>cd c:\Program Files\Qiagen\QIAcuityDx

c:\Program Files\Qiagen\QIAcuityDx>
```

- Execute the backup script using the following sentence:

```
Powershell.exe -executionpolicy remotesigned -File ".\scripts\SuiteDx-Backup.ps1" -TargetPath C:\qiagen\backup -Password 12Az#XasDk9x!ddw9x
```

Note: Replace the TargetPath and the Password with the corresponding values.

```
Administrator: Command Pro x + v
Backup
10% Complete:
[oooooooooooo]

TargetZip      = C:\qiagen\backup\SuiteDx_Backup_03202024_104316.zip
VersionFile    = C:\qiagen\backup\SuiteDxVersion.txt
SuiteDxHost    = https://localhost:8687/suite
7ZipExe       = C:\Program Files\Qiagen\QIAcuityDx\scripts\7za.exe
WSL Image     = QIAcuityDx
=====
Docker version 24.0.6, build ed223bc
The operation completed successfully.
Starting Docker: dockerContainer a3673d4faad900f2e3415252bdcec2abc98a4477d18df9258582ed94b2b79610 (suitedx-core-proxy) has status 'running'
Container d798a538bc1b88a29f1aecf3285eec5fdce59015b891ed5aa3f5354581c6f2e0 (suitedx-core-system-info) has status 'running'
Container cf52a99217986bca24256cd08d07c170a68e855f72e677e1c4974961f5360fdc (suitedx-core-naming-server) has status 'running'
Container 3c09880cdc4ac67f1048848eda49139ef265d29c1d048cb8c545b74a7964ed2d (suitedx-core-api-gateway) has status 'running'
QIAcuityDx Version: 0.5.0.0 - 42ea45627
Checking QIAidentity Service...
Stopping QIAidentity Service...
WARNING: Waiting for service 'QIAidentity (QIAidentity)' to stop...
Waiting until QIAidentity Service stops...
```

- Check the logs written in the Command Prompt, specifically the last trace written where the Backup final status is shown. Some of the possible script results are the following:

```
Administrator: Command Pro x + v
[+] Container suitedx-core-mongodb Running 0.0s
[+] Container suitedx-core-rabbitmq Running 0.0s
[+] Container suitedx-core-naming-server Running 0.0s
[+] Container suitedx-core-reports Started 0.0s
Starting Core Service 'suitedx-core-websocket-server'...
Waiting 10(s) for Service 'suitedx-core-audit' to be ready (attempt 59)...
Waiting 10(s) for Service 'suitedx-core-audit' to be ready (attempt 58)...
Waiting 10(s) for Service 'suitedx-core-audit' to be ready (attempt 57)...
Waiting 10(s) for Service 'suitedx-core-audit' to be ready (attempt 56)...
Waiting 10(s) for Service 'suitedx-core-audit' to be ready (attempt 55)...
Waiting 10(s) for Service 'suitedx-core-audit' to be ready (attempt 54)...
Waiting 10(s) for Service 'suitedx-core-audit' to be ready (attempt 53)...
Checking QIAcuityDx 'suitedx-core-system-info' service status...
Waiting 10(s) for Service 'suitedx-core-system-info' to be ready (attempt 59)...
Waiting 10(s) for Service 'suitedx-core-system-info' to be ready (attempt 58)...
Waiting 10(s) for Service 'suitedx-core-system-info' to be ready (attempt 57)...
Checking QIAcuityDx 'suitedx-core-archiver' service status...
Checking QIAcuityDx 'suitedx-core-plugin-manager' service status...
Checking QIAcuityDx 'suitedx-core-instrument' service status...
Checking QIAcuityDx 'suitedx-core-user-manager' service status...
Checking QIAcuityDx 'suitedx-core-plate' service status...
Checking QIAcuityDx 'suitedx-core-reports' service status...
Checking QIAcuityDx 'suitedx-core-websocket-server' service status...
Starting Plugins...
[+] Running 2/2
[+] Container suitedx-uc-0.5.0.0-plugin-fe Started 0.1s
[+] Container suitedx-uc-0.5.0.0-plugin-be Started 0.1s
[SUCCESS] Backup done successfully.
```

```

Administrator: Command Prompt
=====
SuiteDx Backup
=====
TargetPath      = NotValidPath
TargetZipName   = SuiteDx_Backup_03202024_105206.zip
TargetZip       = NotValidPath\SuiteDx_Backup_03202024_105206.zip
VersionFile     = NotValidPath\SuiteDxVersion.txt
SuiteDxHost     = https://localhost:8687/suite
7ZipExe        = C:\Program Files\Qiagen\QIAcuityDx\scripts\7za.exe
WSL Image       = QIAcuityDx
=====

Docker version 24.0.6, build ed223bc
E02: Invalid Path 'NotValidPath'. Must be a Windows or Network valid location
At C:\Program Files\Qiagen\QIAcuityDx\scripts\SuiteDx-Backup.ps1:125 char:9
+         throw "E02: Invalid Path '$TargetPath'. Must be a Windows or ...
+ ~~~~~
+ CategoryInfo          : (Error: (E02: Invalid Path 'NotValidPath'. Must be a Windows or Network valid location:String)[]) RuntimeException
+ FullyQualifiedErrorId : E02: Invalid Path 'NotValidPath'. Must be a Windows or Network valid location

```

```

Administrator: Command Prompt
=====
TargetPath      = C:\qiagen\backup
TargetZipName   = SuiteDx_Backup_03202024_105416.zip
TargetZip       = C:\qiagen\backup\SuiteDx_Backup_03202024_105416.zip
VersionFile     = C:\qiagen\backup\SuiteDxVersion.txt
SuiteDxHost     = https://localhost:8687/suite
7ZipExe        = C:\Program Files\Qiagen\QIAcuityDx\scripts\7za.exe
WSL Image       = QIAcuityDx
=====

Docker version 24.0.6, build ed223bc
The operation completed successfully.
Starting Docker: docker.
"docker container inspect" requires at least 1 argument.
See 'docker container inspect --help'.

Usage: docker container inspect [OPTIONS] CONTAINER [CONTAINER...]

Display detailed information on one or more containers
Container 'suitedx-core-proxy' has status '...'
ERROR - E08: Container suitedx-core-proxy must be running. Try to restart Suite Dx
Cleaning Up...
[ERROR] Backup not completed. Check above errors.

```

Depending on the success of the backup process, the script will write one of the following three statuses at its end:

Status	Description
[SUCCESS] Backup done successfully	Backup file was generated successfully, and the QIAcuityDx Software Suite services have been restarted including QIAidentity and the Plugins.
[WARN] Backup was done successfully, but SuiteDx Services were not restarted successfully	Backup file was generated successfully, but the QIAcuityDx Software Suite services have not been restarted. Review the script execution traces and look for code E10 in the Error codes section.
[ERROR] Backup not completed. Check above errors.	Backup file was not generated successfully. Review the script execution traces and check the Error codes section.

Error codes

Code	Message	Procedure
E01	Docker Daemon is not running	There's a problem with the Docker Daemon that is running in SuiteDx WSL image. Contact your administrator.
E02	Invalid Path [TargetPath]. Must be a Windows or Network valid location	The -TargetPath parameter provided is not a Windows or network location. Only letters, numbers, special characters '-', '_', '.', '!', '(', ')', and spaces are permitted. Windows locations must start with the drive letter followed by ":\". Network locations must start with "\\\".
E03	Invalid Path [TargetPath]	The -TargetPath provided is well-formed but points to an inaccessible location. Check the Windows permissions for that location or, for network locations, ensure that the target path is available.
E04	-TargetPath parameter must point to a Directory	The -TargetPath provided is well-formed but points to a file. Only paths to directories are valid (even if the directory does not exist).
E05	7z.exe file not found in expected path '\$7ZipExe'	7z.exe file must be present in the same folder as the scripts, as placed by the QlAcuityDx Software Suite installer. If not present, download it from https://www.7-zip.org/ and place the executable in the expected folder.
E06	Required File not found: [File]	The aforementioned file is required but has not been found. Most likely, the QlAcuityDx Software Suite was not properly installed in the system. Contact your administrator.
E07	No Docker Volumes Path Found.	The QlAcuityDx Software Suite was not properly installed in the system. Contact your administrator.
E08	Container [Container] must be running. Try to restart Suite Dx	The QlAcuityDx Software Suite is not running. Start the platform before executing the script. Note: Take into account that the QlAcuityDx Software Suite takes some minutes to be up and running.
E09	Docker containers were not stopped successfully	The QlAcuityDx Software Suite was not stopped in the expected time and the Backup process cannot start. Try to close any open tasks to release some work in the CPU and re-execute the script.
E10	Docker containers were not started successfully	The backup file has been created successfully and the QlAcuityDx Software Suite has been restarted, but services were not set up in the expected time (2 minutes by default). Try to initialize the QlAcuityDx Software Suite using the provided scripts by the installer.
E11	Please execute the script in Administrator mode	The backup script must be executed using a command line prompt with administrator rights.
E12	Usage: <script> -TargetPath [Path] -Password [Password]	Mandatory parameters were not correctly set. Check the "Configurable parameter" section for further information.

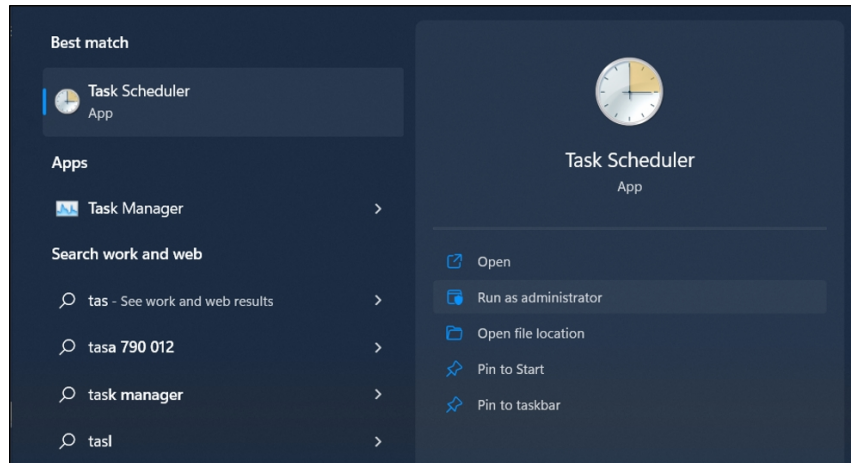
Scheduling a backup task

It is possible to schedule a recurrent execution of the backup process by using the Windows Task Scheduler tool.

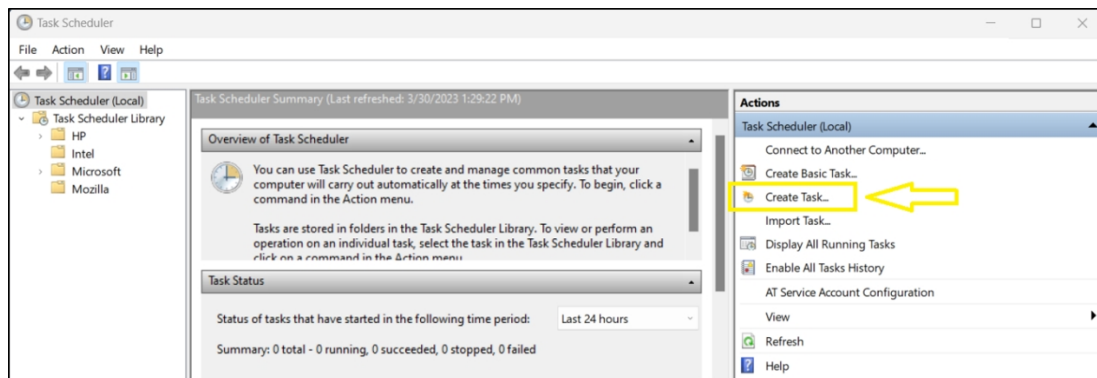
Note: It is strongly recommended to contact QIAGEN Technical Services for guidance before scheduling a backup task, due to its complexity.

Follow these steps to configure a new scheduled task:

1. Open a Windows Task Scheduler with admin rights by typing “task scheduler” in Windows’ start menu:



2. Create a new task by clicking **Create Task...** in the Actions panel:

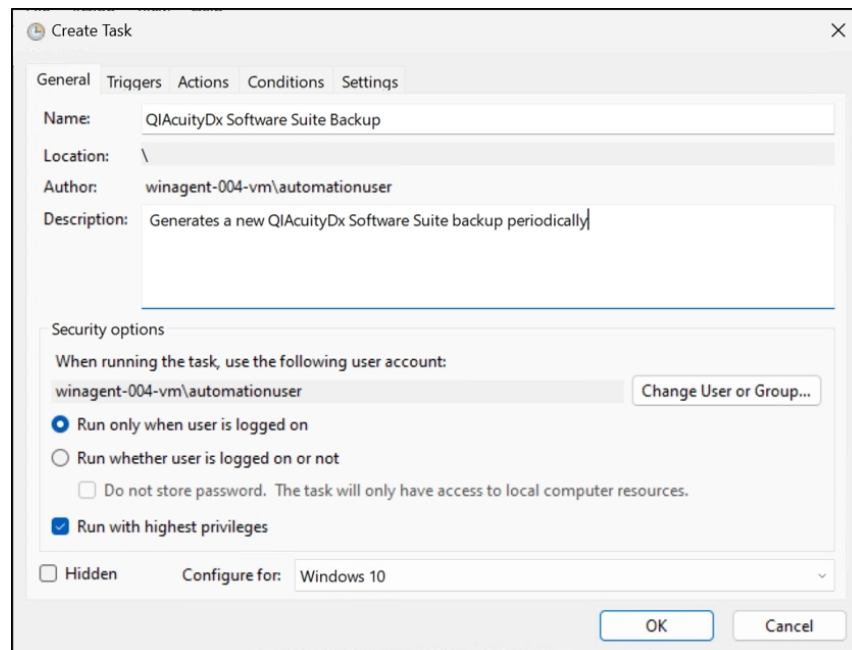


3. In **General** Tab, enter the following values for the new task:

- **Name:** QIAcuityDx Software Suite Backup
- **Description:** Generates a new QIAcuityDx Software Suite backup periodically
- **Configure For:** Windows 10 (or Windows 11, if available)

And select options:

- Run whether user is logged on or not.
- Run with highest privileges.



4. In the **Triggers** tab, click **New** to configure the recurrence entering:

- **Beginning the task:** On a schedule
- **Start:** [Select the time window where the task will start]

And select options:

- **Weekly** (as example)
- **Saturday** (as example)
- **Stop task if runs longer than:** 30 minutes.
- **Enabled**

New Trigger

Begin the task: On a schedule

Settings

☐ One time
☐ Daily
☒ Weekly
☐ Monthly

Start: 4/ 1/2023 5:00:00 AM ☐ Synchronize across time zones

Recur every: 1 weeks on:

☐ Sunday ☐ Monday ☐ Tuesday ☐ Wednesday
☐ Thursday ☐ Friday ☒ Saturday

Advanced settings

☐ Delay task for up to (random delay): 1 hour
☐ Repeat task every: 1 hour for a duration of: 1 day
☐ Stop all running tasks at end of repetition duration
☒ Stop task if it runs longer than: 30 minutes
☐ Expire: 3/30/2024 5:22:35 PM ☐ Synchronize across time zones

☒ Enabled

OK Cancel

The example shows a task that will be executed every Saturday at 5 AM. Please note that the recurrence displayed above is only an example and that the **Settings** section must be adjusted according to your backup needs.

5. In the **Actions** tab, click **New** to create a new action entering the values:

- **Action:** Start a program
- **Program/script:** cmd
- **Add arguments (optional)*:** /c Powershell.exe -executionpolicy remotesigned -File ".\scripts\SuiteDx-Backup.ps1" -TargetPath [TargetPath] -Password [Password] > [TargetPath]\Backup.log
- **Start in (optional):** C:\Program Files\Qiagen\QIAcuityDx

Edit Action

You must specify what action this task will perform.

Action: Start a program

Settings

Program/script: cmd

Add arguments (optional): /c Powershell.exe -executi

Start in (optional): C:\Program Files\Qiagen\

OK Cancel

Note: "TargetPath" and "Password" parameters must be provided according to the desired backup configuration. Using the operator ">" the output of the script will be redirected to the file indicated ([TargetPath]\Backup.log in this case) so that users can check the last traces of the scheduled script execution.

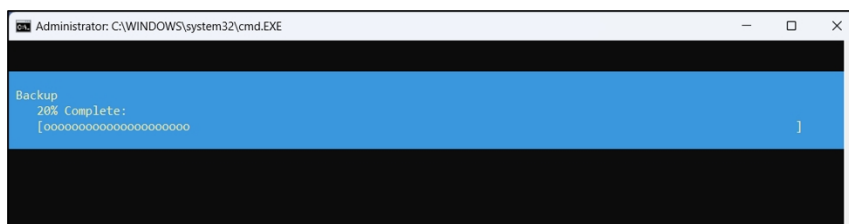
Example of valid arguments could be:

```
/c Powershell.exe -executionpolicy remotesigned -File ".\scripts\SuiteDx-Backup.ps1" -TargetPath  
C:\qiagen\backup -Password 12Az#XasDk9x!ddw9x > C:\qiagen\backup\backup.log
```

The generated log file will be overridden every time the script is executed. In case overriding the log file is not acceptable for keeping track of every execution, it is possible to generate new files each time adding a timestamp to the file's name such as:

```
/c Powershell.exe -executionpolicy remotesigned -File ".\scripts\SuiteDx-Backup.ps1" -TargetPath  
C:\qiagen\backup -Password 12Az#XasDk9x!ddw9x >  
C:\qiagen\backup\backup_%date:~10%%date:~4,2%%date:~7,2%-~time:~0,2%%time:~3,2%%time:~6,2%.log
```

6. Click **OK** to create a new task. Because the **Run whether user is logged on or not** option has been selected in the **General** tab, a prompt will appear requiring the current user's account details.
7. The Backup script will be executed at the scheduled date and time. A window with the backup process will be displayed and closed automatically:



5.24.3. Restore

This process restores all the data for User Lists, Plates (Raw Images and Plugin Analysis included), and Logs of the Software Suite to a previous version using a backup stored on a ZIP file. The backup is protected by a password, thus keep in mind to have it before starting.

The process shall be used carefully and is highly recommended to perform a manual backup before the restore because the automatic backup runs through a scheduled process task. This procedure helps to avoid losing data in the time window between backup and restore. Before starting the process, it is mandatory for the Software Suite to be up and running.

Moreover, it is crucial to understand that triggering the restore process will force the Software Suite to stop. This action is needed to recover all the data without interruptions of any running processes. Consider the best maintenance window before performing the restore that causes minimum impact to the users.

Consequently, once the restore has been successfully completed, all current data will be overridden.

Configurable parameter

Parameter	Description	Mandatory
-SourceZipFile	Full Path, including the ZIP file with the version to be restored.	Yes

Path examples for -SourceZipFile parameter:

- C:\QIAGEN\Backups\SuiteDx-20230413.zip
- D:\Scheduled\Backups\QIAGEN\SuiteDx-20230413.zip
- C:\Temp\QIAGEN Backups\SuiteDx-20230413.zip
- \\192.168.1.5\QIAGEN\Backups\SuiteDx-20230413.zip
- \\suitedxhost\Temp\Backups\SuiteDx-20230413.zip

Note: To use a target folder with spaces in its name, the whole path must be enclosed in quotation marks.

Execution

The restore process can be executed anytime using the provided script "SuiteDx-Restore.ps1", which is located in folder "\scripts" under the QIAcuityDx Software Suite installation folder (c:\Program Files\Qiagen\QIAcuityDx\ by default).

Note: It is recommended to perform a manual backup before restoring.

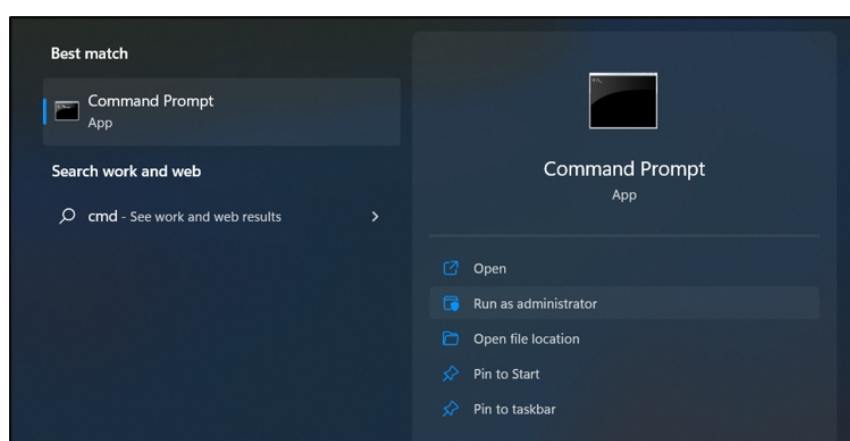
During the process, there will be information logs and a status progress bar with the most relevant information.

The following parameter will be used as an example for the procedure below:

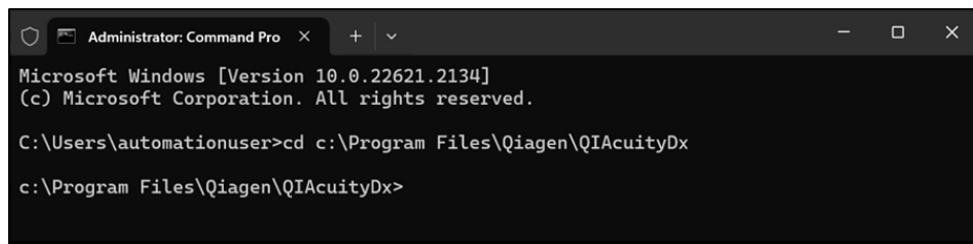
-SourceZipFile: c:\SuiteDx Backup\SuiteDx_Backup_04052023_182330.zip

The steps to perform a Restore are:

1. Open a Windows Command Prompt (CMD) with administrator rights by typing "cmd" in Windows' start menu:



2. Go to the QIAcuityDx Software Suite installation folder (c:\Program Files\Qiagen\QIAcuityDx by default):



```
Administrator: Command Prompt
Microsoft Windows [Version 10.0.22621.2134]
(c) Microsoft Corporation. All rights reserved.

C:\Users\automationuser>cd c:\Program Files\Qiagen\QIAcuityDx

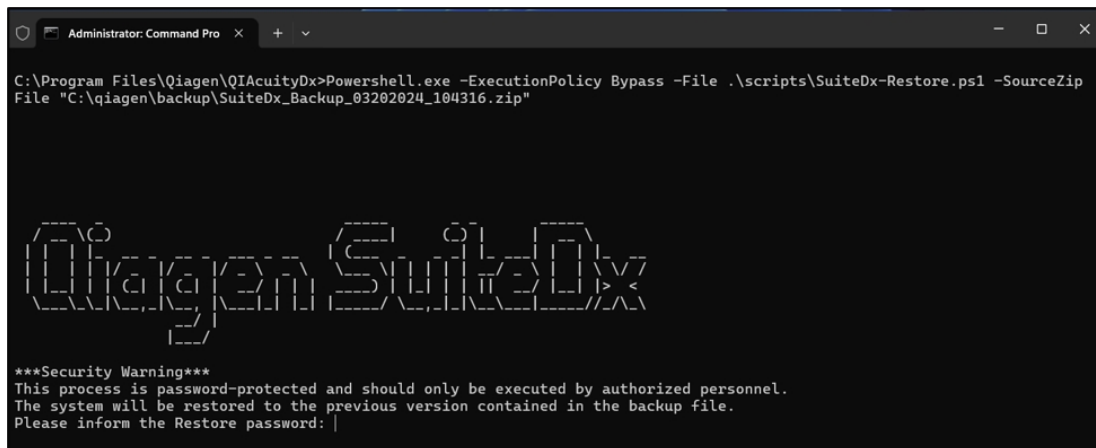
c:\Program Files\Qiagen\QIAcuityDx>
```

3. Execute the Restore script using the following sentence:

```
Powershell.exe -executionpolicy remotesigned -File ".\scripts\SuiteDx-Restore.ps1" -SourceZipFile "C:\qiagen\backup\SuiteDx_Backup_04052023_182330.zip"
```

Note: Replace the SourceZipFile with the corresponding values.

4. The restore process will prompt for the password of the backup zip file and a confirmation message:



```
Administrator: Command Prompt
C:\Program Files\Qiagen\QIAcuityDx>Powershell.exe -ExecutionPolicy Bypass -File .\scripts\SuiteDx-Restore.ps1 -SourceZipFile "C:\qiagen\backup\SuiteDx_Backup_03202024_104316.zip"

Qiagen SuiteDx

***Security Warning***
This process is password-protected and should only be executed by authorized personnel.
The system will be restored to the previous version contained in the backup file.
Please inform the Restore password: |
```

The restore process consists of the following steps:

1. The following conditions regarding these parameters are validated:
 - a. SuiteDxPath parameter:
 - Must be a valid Windows or Network location path.
 - b. SourceZipFile parameter:
 - Must be a valid Windows or Network location path.
 - The path points to a file.
 - The file's extension is ZIP.
 - c. 7ZipExe parameter:
 - 7za.exe exists.
2. The user must enter the password.
3. The user must confirm the Restore process' start.

4. A System check is performed to confirm that:
 - a. The Windows PowerShell program is running with administrator privileges.
 - b. The Docker volumes exist.
 - c. Docker is running.
 - d. The Software Suite is installed.
5. A temporary folder is created to extract the contents of the backup file.
 - a. The content of the backup file is expanded inside the temporary folder.
 - b. The QIAidentity Windows service is stopped.
 - c. All QIAcuityDx Software Suite Docker Containers are stopped.
 - d. A copy of the current QIAidentity database file is created and replaced with the backup one.
 - e. All Docker volumes related to the contents of the backup are deleted.
 - f. All the contents of the backup's temporary folder are copied to the Docker volumes' folder except for the QIAidentity database file.
 - g. The temporary folder is cleaned up.
6. Start System.
 - a. All the Docker Containers are started.
 - b. The QIAidentity Windows Service is started.
 - c. The process will wait 120 seconds for the Docker Containers to be ready.
 - d. The process checks whether the service of the QIAcuityDx Software Suite is up and running.
 - e. The process waits for the Docker Volumes' removal.
 - f. The Restore process is complete.

```

Start System
100% Complete
[Progress Bar]

Created Temp Folder: C:\Users\fead\AppData\Local\Temp\58a2a981-6627-4c31-9c7a-38c9cf598a1
Checking QIAidentity Service...
Stopping QIAidentity Service...
Waiting until QIAidentity Service stops...
Stopping SuiteDx services...
Container softwareresultdx-suite:core-audit-1 Stopped 11.35
Container softwareresultdx-suite:core-plate-1 Stopped 12.48
Container softwareresultdx-suite:core-front-end-1 Stopped 8.75
Container softwareresultdx-suite:postgresql-administrator-1 Stopped 8.11
Container softwareresultdx-suite:core-instrument-1 Stopped 12.36
Container softwareresultdx-suite:core-mongodb-administrator-1 Stopped 8.60
Container softwareresultdx-suite:core-system-info-1 Stopped 12.55
Container softwareresultdx-suite:core-plugin-manager-1 Stopped 12.66
Container softwareresultdx-suite:core-user-manager-1 Stopped 11.99
Container softwareresultdx-suite:core-archiver-1 Stopped 11.55
Container softwareresultdx-suite:core-proxy-1 Stopped 9.48
Container softwareresultdx-suite:core-websocket-server-1 Stopped 12.35
Container softwareresultdx-suite:core-api-gateway-1 Stopped 12.55
Container softwareresultdx-suite:core-mongodb-1 Stopped 8.99
Container softwareresultdx-suite:core-naming-server-1 Stopped 18.41
Container softwareresultdx-suite:core-rabbitmq-1 Stopped 6.65
Restore Completed.
Cleaning Up...
Deleted Temp Folder: C:\Users\fead\AppData\Local\Temp\58a2a981-6627-4c31-9c7a-38c9cf598a1
Restarting SuiteDx services...
Container softwareresultdx-suite:core-rabbitmq-1 Started 1.66
Container softwareresultdx-suite:core-naming-server-1 Started 0.99
Container softwareresultdx-suite:postgresql-administrator-1 Started 2.88
Container softwareresultdx-suite:core-mongodb-1 Started 1.96
Container softwareresultdx-suite:core-front-end-1 Started 0.88
Container softwareresultdx-suite:core-websocket-server-1 Started 1.25
Container softwareresultdx-suite:core-plate-1 Started 3.99
Container softwareresultdx-suite:core-audit-1 Started 4.46
Container softwareresultdx-suite:core-plugin-manager-1 Started 3.89
Container softwareresultdx-suite:core-instrument-1 Started 4.66
Container softwareresultdx-suite:core-proxy-1 Started 5.36
Container softwareresultdx-suite:core-system-info-1 Started 4.46
Container softwareresultdx-suite:core-archiver-1 Started 4.36
Container softwareresultdx-suite:core-user-manager-1 Started 3.88
Container softwareresultdx-suite:core-mongodb-administrator-1 Started 2.55
Restarting QIAidentity...
Waiting 120 seconds to allow SuiteDx to start...
Checking SuiteDx services status...
SuiteDx restored to version: 0.3.0.0-develop@2024
Removing orphan volumes...
Total reclaimed space: 88
Waiting 30 seconds to allow Docker to prune orphan volumes...
[SUCCESS] Restore done successfully.
  
```

Final status

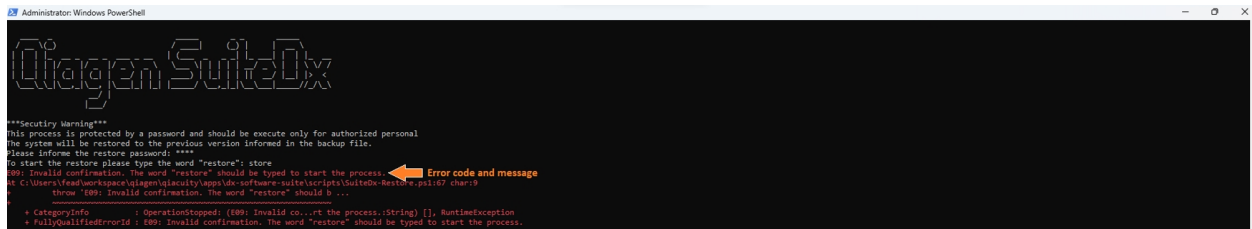
Upon completion of the Restore process and depending on its outcome, one of the following statuses is printed:

Status	Description
[SUCCESS] Restore was done successfully	Restore recovered all data successfully, and the QIAcuityDx Software Suite services have been restarted including QIAidentity and the Plugins.
[WARN] Restore was done successfully, but SuiteDx Services were not restarted successfully	Restore recovered all data successfully, but the QIAcuityDx Software Suite services have not been restarted. Review the script execution traces and look for code E15 in the Error codes section.
[ERROR] Restore not completed. Check above errors.	Restore failed was not generated successfully. Review the script execution traces and check the Error codes section.

Error codes

Whenever something goes wrong during the Backup Process, the script will write a trace with an error code and a brief description of the error upon finishing.

Example:



Possible codes are as follows:

Code	Message	Procedure
E01	Invalid Path [SuiteDxPath]. Must be a Windows or Network valid location	The path parameter provided is not a Windows or Network Location. Only letters, numbers, special characters '-', '_', '.', '!', '(', ')' and spaces are permitted. Windows locations must start with the driver letter followed by ":", Network locations must start with "\\".
E02	Invalid Path [SuiteDxPath]	The path provided is well-formed, but points to an inaccessible location. Check the Windows permissions for that location or, for network locations, ensure that the target path is available.
E03	Invalid Path [SourceZipFile]. Must be a Windows or Network valid location	The path parameter provided is not a Windows or Network Location. Only letters, numbers, special characters '-', '_', '.', '!', '(', ')' and spaces are permitted. Windows locations must start with the driver letter followed by ":", Network locations must start with "\\".
E04	Invalid Path [SourceZipFile].	The path provided is well-formed, but points to an inaccessible location where it is not possible to access. Check the Windows permissions for that location or, for network locations, ensure that the target path is available.
E05	The path [SourceZipFile] points to a Directory a backup with '.zip' extension file should be informed.	The path informed should point to a backup archive with .zip extension.
E06	Backup File [SourceZipFile] not found.	The full path archive provided is well-formed but could not be found (check the filename and whether the path is correct).
E07	The extension of the file is invalid. Only '.zip' files are allowed.	The file informed is not a zip file.
E08	7za.exe file not found in expected path [\$?ZipExe]	7za.exe file must be present in the same folder as the scripts, as placed by the QIAcuityDx Software Suite installer. If not present, download it from https://www.7-zip.org/ and place the executable in the expected folder.

Code	Message	Procedure
E09	Invalid confirmation. The word "restore" should be typed to start the process.	When the system asks to a confirmation the word restore shall be typed.
E10	No Docker Volumes Path Found.	The QlAcuityDx Software Suite was not properly installed in the system. Contact your administrator.
E11	Please execute the script in Administrator mode	The backup script must be executed using a command line prompt with administrator rights.
E12	Docker Daemon is not running	There's a problem with the Docker Daemon which is running in QlAcuityDx Software Suite WSL image. Contact your administrator.
E13	Required File not found: -[SuiteDxPath]\-docker-compose.yml. Verify if Software Suite Dx is installed	The file required to restore process has not been found. Most likely QlAcuityDx Software Suite was not properly installed in the system. Contact your administrator.
E14	Docker containers were not stopped successfully	The QlAcuityDx Software Suite did not stop in the expected time and the Backup process cannot start. Try to close any open tasks to release some work in the CPU and re-execute the script.
E15	Docker containers were not started successfully	The Backup file has been created successfully and QlAcuityDx Software Suite has been restarted, but services were not set up in the expected time (2 minutes by default). Try to initialize QlAcuityDx Software Suite using the provided scripts by the installer.
E16	Invalid restore password. [ERRORS] founded.	The password informed to expand the backup compressed file password provided is not valid.
E17	Password cannot be blank	The password has to be provided.

6. Maintenance

This section describes preventive maintenance of QIAcuityDx instrument.

Note: Only use parts supplied by QIAGEN.

6.1. Weekly maintenance

Important: To ensure correct functioning of the QIAcuityDx System, power-cycling of the QIAcuityDx instrument is recommended on a weekly 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., Mikrozyd® 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 Mikrozyd 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 the QIAcuityDx.

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 drop down from the edge closest to you exposing the filter pad.



3. Remove the filter pad from the drop-down filter compartment by pinching the pad and lifting it over the metal retention clasp.



4. Replace with a new filter and push the filter compartment upwards to the top and press the button 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 cyclers, 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	<p>The plate barcode cannot be read.</p> <p>Check if the plate barcode is damaged or if the plate is incorrectly placed on the tray slot.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>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.</p>
122	<p>The system cannot detect the Top seal of the plate.</p> <p>Ensure that the Top seal is placed properly on the plate.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>Ensure that the Top seal is placed properly on the plate. If the problem still exists, please contact QIAGEN Technical Services.</p>
129	<p>Failed to initialize Barcode Scanner module</p>	<p>Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.</p>
143	<p>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.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>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.</p>
144	<p>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.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>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.</p>
160	<p>The gripper module was not able to home properly. Contact your local administrator to resolve the gripper module error. Restart the instrument.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.</p>
170	<p>The gripper module cannot move properly. Contact your local administrator to resolve the module error. Restart the instrument.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.</p>
175	<p>The gripper module detected an error while gripping. Contact your local administrator to resolve the module error. Restart the instrument.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.</p>
176	<p>There is no target position specified for the planned movement. Please contact QIAGEN Technical Services.</p>	<p>Please contact QIAGEN Technical Services.</p>
177	<p>Insufficient teaching detected.</p> <p>Please contact QIAGEN Technical Services.</p>	<p>Please contact QIAGEN Technical Services.</p>
194	<p>A motor movement cannot be performed at this time. Contact your local administrator to resolve the gripper module error. Restart the instrument.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.</p>
199	<p>Failed to initialize Hand module</p>	<p>Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.</p>
200	<p>A critical error has been detected in the partitioning module. Contact your local administrator to resolve the module error. Restart the instrument.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>Contact your local administrator to resolve the module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.</p>
201	<p>The plate type is not supported. Remove the plate from the instrument.</p>	<p>Remove the plate from the instrument.</p>
202	<p>A movement position is out of range. Contact your local administrator to resolve the partitioning module error. Restart the instrument.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>Contact your local administrator to resolve the partitioning module error. Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.</p>

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 Cyler 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	<p>The gripper was not able to grip the plate from the drawer. If applicable, allow other plates to finish the run.</p> <p>Contact your local administrator to resolve the module error. Restart the instrument.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>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.</p>
660	<p>The drawer cannot perform the homing sequence. Contact your local administrator to resolve the module error. Restart the instrument.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.</p>
675	<p>The drawer cannot eject or retract at this time. Contact your local administrator to resolve the module error. Restart the instrument.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.</p>
676	<p>The sensor detected drawer movement failure. Clear the error, restart the instrument and perform a run.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>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.</p>
699	<p>Failed to initialize Drawer module</p>	<p>Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.</p>
700	<p>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.</p>	<p>Add a new run step in the QIAcuityDx Software Suite or instrument to rerun the plate.</p>
701	<p>Plate barcode does not exist.</p>	<p>N/A</p>
702	<p>The plate name is not defined.</p>	<p>N/A</p>
704	<p>There are no dPCR parameters defined.</p>	<p>N/A</p>
706	<p>Opening/closing of drawer was requested at a time where no opening/closing is possible. Retry once again.</p>	<p>Retry once again.</p>
710	<p>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.</p> <p>Be aware that stability countdown for this plate has started.</p>	<p>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.</p>
711	<p>A connectivity issue is detected between the instrument and the Software Suite. Check your network connection settings.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>Check your network connection settings. If the problem still exists, please contact QIAGEN Technical Services.</p>
712	<p>This plate cannot be assigned to an existing experiment because some parameters are not defined.</p> <p>Remove the plate and complete its plate definition in the Software Suite.</p>	<p>Remove the plate and complete its plate definition in the Software Suite.</p>
713	<p>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.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>Check your settings and/or contact your local administrator for assistance. If the problem still exists, please contact QIAGEN Technical Services.</p>
714	<p>The configuration failed to save. Please try again.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.</p>
715	<p>The new configuration settings failed to apply. Please try again.</p> <p>If the problem still exists, please contact QIAGEN Technical Services.</p>	<p>Restart the instrument. If the problem still exists, please contact QIAGEN Technical Services.</p>

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 by Software 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	Plate {plate-Name} can't be exported because an error occurred. 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 the plate is being restored. 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 {lastCycle} 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.

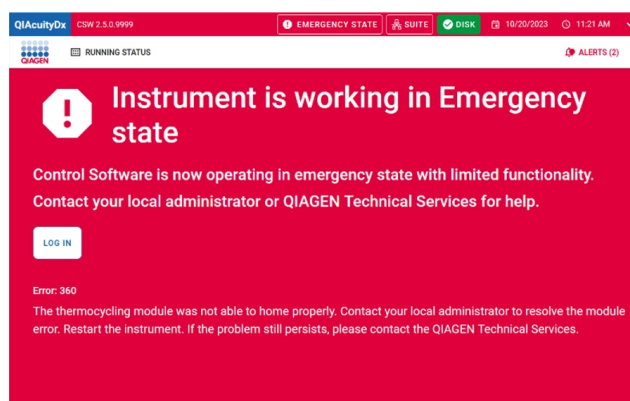
Section	Description	Action
Plate configurator	Refresh	Refresh the page
Plate configurator	Plate name is required	Enter a valid name
Plate configurator	You have already 1 plate with the same name	Enter a different plate name
Plate configurator	Enter a name without {symbols}	Enter a valid name
Plate configurator	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.

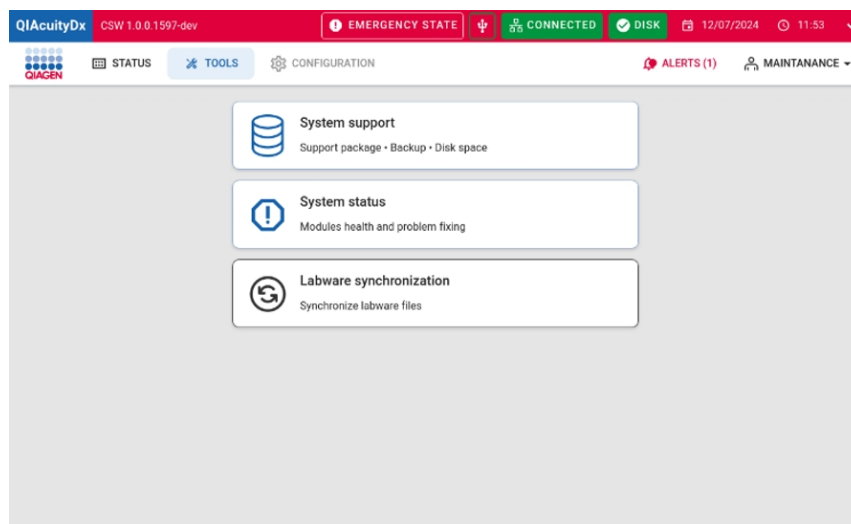
7.2.1. Clear module errors on the QIAcuityDx Four instrument

In the event of an hardware module error, the QIAcuityDx Four instruments enters in the “Emergency State” highlighted by a red error message in the Status view like in the example below.

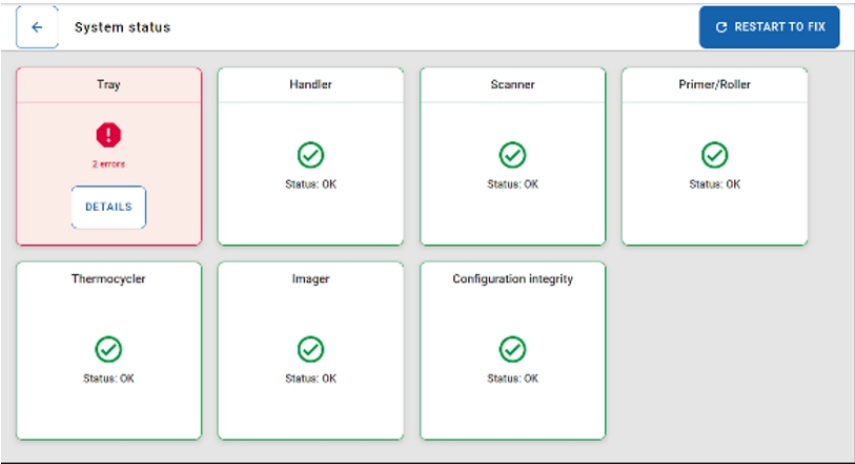


To restore the instrument functionalities, the following steps shall be used:

1. Log in with a user which has the Instrument Maintenance permission
2. Navigate to the **Tools** menu and click **System Status** button.



3. The System Status page is shown, and the module affected by the error that caused the instrument to enter the Emergency State is marked in red.



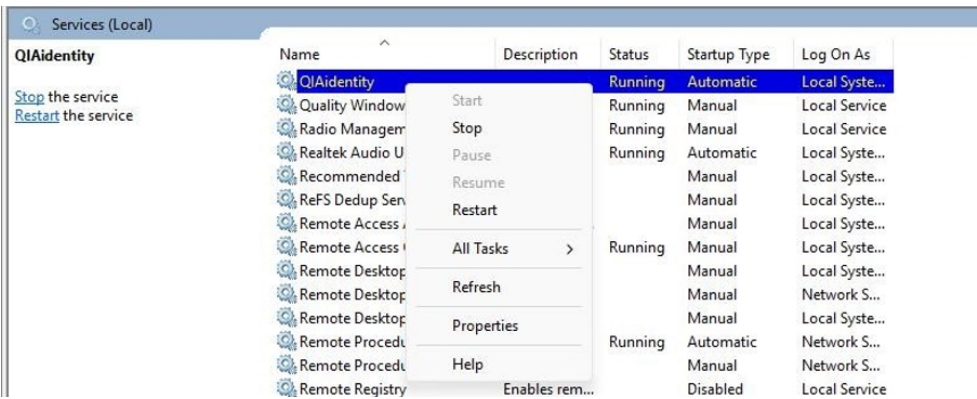
4. Click **Restart to Fix** button.
5. The QIAcuityDx Four instrument will automatically clear the module error, restart, exit from emergency state, perform the initial self-test, and ensure proper instrument functionality.

7.2.2. Undesired Software Suite log out

The user might encounter sudden undesired log outs in the Software Suite during common operations such as instrument booting and routine operations in the Software Suite due to the identity manager service. Rebooting the identity manager can help reduce the frequency of these log outs. This operation can be repeated as many times as needed.

To reboot the service, the following steps should be performed:

1. Stop Suite.
2. Search “Services” in the Windows bar and open them. Search for “QIAidentity”, right-click the “QIAidentity”, and select **Restart**.



3. Start Suite.

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 rear 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	<p>The QIAcuityDx features optics for the following optical channels:</p> <table><thead><tr><th>Channel</th><th>Green</th><th>Yellow</th><th>Orange</th><th>Red</th><th>Crimson</th></tr></thead><tbody><tr><td>Excitation (nm)</td><td>463–503</td><td>514–535</td><td>543–565</td><td>570–596</td><td>590–640</td></tr><tr><td>Emission (nm)</td><td>518–548</td><td>550–564</td><td>580–606</td><td>611–653</td><td>654–692</td></tr></tbody></table> <p>Excitation by high power white LED with average 4750 lumens Image acquisition by CMOS camera with 6.3 MP</p>	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
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														
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 as follows:

- 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*
	Conducted emissions CISPR 11	Class B, Group 1 emissions level	
	Harmonic distortion IEC 61000-3-2	As per IEC 61000-3-2	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†.
	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
T _m	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

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C:\ProgramData\QIAGEN\QIAcuityDx\licenses.rtf

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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.

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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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- f. **Patents.** One or more patents owned by QIAGEN apply to QIAcuityDx and to the features and services accessible via QIAcuityDx. Portions of the QIAcuityDx operate under license of one or more patents.

6. Support

Nothing in this agreement shall obligate QIAGEN to provide any support for the Software. QIAGEN may, but shall be under no obligation to, correct any defects in the Software and/or provide updates to licensees of the Software. User shall make reasonable efforts to promptly report to QIAGEN any defects you find in the Software, as an aid to creating improved revisions of the Software, if User has purchased support services for the QIAcuityDx equipment as identified in the relevant Ordering Document, then User shall be entitled to the QIAGEN support purchased for Software during the relevant support hours of operation.

7. Confidentiality

QIAGEN and User each agree to retain in confidence all non-public information disclosed pursuant to this Agreement that is designated as proprietary and/or confidential (the "Confidential Information"). Notwithstanding the foregoing, all Licensed Materials and the results of any evaluations or testing of Software by User shall constitute trade secrets and Confidential Information of QIAGEN without need for any marking or designation. Each party to this Agreement agrees to: (i) preserve and protect the confidentiality of the other party's Confidential Information; (ii) refrain from using the other party's Confidential Information except as expressly permitted herein; and (iii) not disclose such Confidential Information to any third party except to its employees or agents who are reasonably required to exercise its rights or perform its obligations under this Agreement and provided such third party is subject to restrictions which are at least as restrictive as the restrictions outlined in this Agreement. Notwithstanding the above, Confidential Information shall not include information that: (x) has become publicly known and made generally available other than through any act or omission of the receiving party; (y) was already or becomes known by the receiving party from a third party who was not under a duty of confidential restriction as to use or disclosure; or (z) was independently developed by the receiving party as evidenced by appropriate records. Either party may disclose Confidential Information without violating this Section 7 to the limited extent required to comply with law or

regulation, provided that the party required to disclose the Confidential Information provides prompt advance notice to enable the other party to seek a protective order or otherwise prevent such disclosure.

8. Warranty Disclaimer; User Acknowledgement

QIAGEN AND ITS SUPPLIERS PROVIDE THE LICENSED MATERIALS AND ANY SERVICES PROVIDED IN CONNECTION HERewith "AS IS" AND MAKE NO WARRANTY, EXPRESS, IMPLIED, STATUTORY, OR ARISING FROM COURSE OF PERFORMANCE, DEALING, USAGE OR TRADE, WITH RESPECT TO LICENSED MATERIALS, SERVICES DELIVERED HEREUNDER OR ANY PART THEREOF, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF TITLE, AVAILABILITY, RELIABILITY, USEFULNESS, DATA ACCURACY, COMPLETENESS, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. NEITHER QIAGEN NOR ANY OF ITS SUPPLIERS WARRANTS THAT THE LICENSED MATERIALS OR ANY PART THEREOF OR SERVICES DELIVERED HEREUNDER WILL MEET USER'S REQUIREMENTS OR BE UNINTERRUPTED, TIMELY, AVAILABLE, SECURE OR ERROR-FREE, OR THAT ANY ERRORS WILL BE CORRECTED.

9. Limitation of Liability

QIAGEN'S ENTIRE LIABILITY AND YOUR EXCLUSIVE REMEDY SHALL BE, AT QIAGEN'S OPTION, EITHER (A) RETURN OF THE PRICE PAID OR (B) REPAIR OR REPLACEMENT OF THE SOFTWARE THAT DOES NOT MEET QIAGEN'S LIMITED WARRANTY AND THAT IS RETURNED TO QIAGEN WITH A COPY OF YOUR RECEIPT. THIS LIMITED WARRANTY IS VOID IF FAILURE OF SOFTWARE HAS RESULTED FROM ACCIDENT, ABUSE OR MISAPPLICATION. ANY REPLACEMENT OF SOFTWARE WILL BE WARRANTED FOR THE REMAINDER OF THE ORIGINAL WARRANTY PERIOD OR THIRTY (30) DAYS, WHICHEVER IS LONGER. THE ABOVE RESTRICTIONS OF LIABILITY SHALL NOT APPLY IN CASES OF PERSONAL INJURY OR ANY DAMAGE RESULTING FROM WILLFUL ACTS OR GROSS NEGLIGENCE. IN NO EVENT SHALL EITHER PARTY OR ITS SUPPLIERS BE LIABLE TO THE OTHER FOR THE COST OF PROCUREMENT OF SUBSTITUTE GOODS OR TECHNOLOGY OR SERVICES, LOSS OF PROFITS, OR FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE OR INDIRECT DAMAGES ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT (INCLUDING WITHOUT LIMITATION NEGLIGENCE), STRICT LIABILITY OR OTHERWISE. EACH PARTY'S TOTAL LIABILITY ARISING OUT OF OR UNDER THIS AGREEMENT OR FOR BREACH OF THIS AGREEMENT OR IN CONNECTION WITH THE PROVISION OF ACCESS TO ANY PRODUCTS OR ANY SERVICES HEREUNDER, WHETHER IN CONTRACT, TORT (INCLUDING WITHOUT LIMITATION NEGLIGENCE), STRICT LIABILITY OR ANY OTHER LEGAL THEORY, SHALL NOT EXCEED THE AMOUNTS PAID TO QIAGEN BY USER (AND IN THE CASE OF USER'S LIABILITY ANY AMOUNTS PAID OR DUE) IN CONNECTION WITH THIS AGREEMENT. THE FOREGOING LIMITATIONS SHALL NOT APPLY TO ANY FEES DUE TO QIAGEN HEREUNDER OR ANY BREACH OF SECTIONS 2 (RIGHTS OF ACCESS AND USE), 3 (USER RESTRICTIONS, OBLIGATIONS AND LIMITATIONS) OR 7 (CONFIDENTIALITY), OR EITHER PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 10. THE LIMITATIONS SET FORTH IN THIS SECTION SHALL APPLY EVEN IF A PARTY IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGE, AND NOTWITHSTANDING THE FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS SECTION 9, QIAGEN IS ALSO NOT LIABLE FOR ACTS OF SIMPLE NEGLIGENCE (UNLESS THEY CAUSE INJURIES TO OR DEATH OF ANY PERSON), EXCEPT WHEN THEY ARE CAUSED BY A BREACH OF ANY SUBSTANTIAL CONTRACTUAL OBLIGATIONS (VERTRAGSWESENTLICHE PFLICHTEN) .

10. Indemnification

- a. User as indemnitor will indemnify, defend and hold harmless QIAGEN, its directors, officers, employees and representatives as indemnitees from and against any and all third-party losses, damages, liability, costs and expenses

awarded by a court or agreed upon in settlement, as well as all reasonable and related attorneys' fees and court costs, arising out of any third party claim alleging that User's use of the Software in violation of this Agreement violates, infringes, misappropriates third party right or violates applicable laws.

- b. The forgoing obligations are subject to (i) the indemnitee promptly notifying the indemnitor in writing of the third party proceeding or action, (ii) the indemnitee giving the indemnitor full authority and control of the action with counsel of indemnitor's choice, and (iii) the indemnitee providing the indemnitor information and assistance for defence of such claim.

11. Termination

QIAGEN has the right to (i) suspend your access to the Software at any time based on the status of your account under the Ordering Document, or (ii) terminate this Agreement at any time if the terms of this Agreement are breached by User and such breaching party fails to remedy such breach within ten (10) days after written notice thereof. User understands that if their account is suspended or terminated, User may no longer have access to the content that is stored within the Software. Upon termination, User must cease all use of Licensed Materials and must destroy all copies of the Licensed Materials in User possession or control. Except as otherwise expressly provided herein, the rights and obligations of QIAGEN and User in Sections 1 (Definitions), 3 (User Restrictions, Obligations and Limitations), 4 (Payment), 5 (Intellectual Property), 7 (Confidentiality), 8 (Warranty Disclaimer), 9 (Limitation of Liability), 10 (Indemnification), 11 (Term and Termination), and 12 (General) shall survive termination or expiration of this Agreement. Nothing contained herein shall limit any other remedies that either party may have for the default of the other party under this Agreement nor relieve the other party of any of its obligations incurred prior to such termination.

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 26k 24-well Nanoplate Kit(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 MgCl ₂ , 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 MgCl ₂ , 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 mL 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
R1, July 2024	Initial release of the User Manual
R2, February 2025	Version 1.1 release

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