Digital LightCycler® System

User Assistance

Publication version 1.1

Software version 1.0

Publication information

Publication version	Software version	Revision date	Change description
1.0	1.0	February 2022	First version
1.1	1.0	September 2022	US-specific publication version with added US-specific compliance information. What is new in US-specific publication version 1.1 (13)

Revision history

Edition notice

This publication is intended for users of the Digital LightCycler® System.

Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, the manufacturer of this product may need to update the publication information as output of product surveillance activities, leading to a new version of this publication.

Where to find information

The **User Assistance** contains all information about the product, including the following:

- Routine operation
- Maintenance
- Safety
- Troubleshooting information
- Software reference
- Configuration information
- Background information

The **Safety Guide** contains important safety information. You must read the Safety Guide before operating the instruments.

The **User Guide** focuses on routine operation and maintenance. The content is organized according to the normal operation workflow.

Privacy notice

When you use User Assistance online, viewing events (topics viewed and searches performed) and IP addresses are logged.
The data collected is for Roche internal use only and is never forwarded to third parties. It is anonymized, and after one year it is automatically deleted.
Viewing events are analyzed to improve User Assistance content and search functionality. IP addresses are used to classify regional behavior.

⚠ General attention

To avoid serious or fatal injury, ensure that you are familiar with the system and safety information before you use the system.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the instruments in a way that is not described in this publication.
- Store all publications in a safe and easily accessible place.

⚠ Incident reporting

- Inform your Roche representative and your local competent authority about any serious incidents which may occur when using this product.

Training

Do not carry out operation tasks or maintenance actions unless you have received training from Roche Diagnostics. Leave tasks that are not described in the user documentation to trained Roche Service representatives.

Images

The images in this publication have been added exclusively for illustration purposes. Configurable and variable data in screenshots, such as tests, results, or path names visible therein must not be used for laboratory purposes.

Warranty

Any customer modification to the system renders the warranty or service agreement null and void.

For conditions of warranty, contact your local sales representative or refer to your warranty contract partner.

Always leave software updates to a Roche Service representative, or perform such updates with their assistance.

Copyright

License information

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Digital LightCycler® System may include components or modules of commercial or open-source software. For further information on the intellectual property and other warnings, as well as licenses pertaining to the software programs included in Digital LightCycler® System, refer to the electronic distribution included with this product.

This open-source and commercial software and Digital LightCycler® System as a whole can constitute a device regulated in accordance with applicable law. For more detailed information, refer to the corresponding user documentation and labeling.

Note that the respective authorization is no longer valid according to the corresponding legislation should any unauthorized changes be made to Digital LightCycler® System.

Trademarks

The following trademarks are acknowledged:

LIGHTCYCLER is a trademark of Roche.

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Feedback

Every effort has been made to ensure that this publication fulfills the intended use. All feedback on any aspect of this publication is welcome and is considered during updates. Contact your Roche representative, should you have any such feedback.

Approvals

The Digital LightCycler® System meets the requirements laid down in:

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

To view the full text of the 2014/53/EU declaration of conformity, go to the Roche DiaLog global website (*dialogportal.roche.com*) and choose the eLabDoc link. If you are unable to access Roche DiaLog, contact a Roche Service representative.

Compliance with the applicable directives is provided by means of the declaration of conformity.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
FCC ID for Digital LightCycler® Partitioning Engine: 2A6AL-RWR2.

The following marks demonstrate compliance:

For *in vitro* diagnostic use.

Complies with the provisions of the applicable EU regulations.

Issued by Nemko for Canada and the US.

'Laboratory Equipment' is the product identifier as shown on the name plate.

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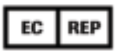

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A list of all Roche affiliates can be found at:

www.roche.com/about/business/roche_worldwide.htm

eLabDoc

Electronic user documentation can be downloaded using the eLabDoc e-service on Roche DiaLog:

dialogportal.roche.com

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Table of contents

Intended use

The Digital LightCycler® System supports a semi-automated workflow to run Polymerase Chain Reaction (PCR) based Nucleic Acid Testing (NAT). The system performs digital endpoint PCR analysis of microfluidic partitions, combining the functionalities of instrumentation, consumables, reagents, and data management to provide an efficient workflow from sample partitioning to result interpretation.

The Digital LightCycler® System is a semi-automated system for detection and absolute quantification of nucleic acid target copy number, intended for *in vitro* diagnostic use by professional users in diagnostic and screening laboratories.

The system is comprised of the Digital LightCycler® Analyzer, the Digital LightCycler® Partitioning Engine, and specified consumables, core reagents and application software. All assays are developed independently of the Digital LightCycler® System.

Symbols and abbreviations

Product names

Except where the context clearly indicates otherwise, the following product names and descriptors are used.

Product name	Descriptor
Digital LightCycler® System	system
Digital LightCycler® Partitioning Engine	partitioning engine
Digital LightCycler® Analyzer	analyzer
Digital LightCycler® Analyzer Software	analyzer software
Digital LightCycler® Web Application	web application
Digital LightCycler® Development Software	development software
Digital LightCycler® Universal Nanowell Plate	universal nanowell plate
Digital LightCycler® High Resolution Nanowell Plate	high resolution nanowell plate
Digital LightCycler® High Sensitivity Nanowell Plate	high sensitivity nanowell plate
Digital LightCycler® Partitioning Fluid	partitioning fluid
Digital LightCycler® Waste Bottle	liquid waste bottle
Digital LightCycler® 5x DNA Master	DNA master reagent
Digital LightCycler® 5x RNA Master	RNA master reagent

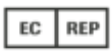
Product names

Symbols used in the publication

Symbol	Explanation
•	List item
	Cross-reference to another topic
	Figure, used in figure titles and cross-references to figures
	Table, used in table titles and cross-references to tables
	Equation, used in cross-references to equations
	Code example, used in code titles and cross-references to codes
	Tip, used for extra information on correct use or for useful hints
	Extra information within a task
	Result of an action within a task
	Frequency of a task
	Duration of a task
	Materials that are required for a task
	Prerequisites of a task

Symbols used in the publication

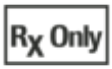
Symbols used on product

Symbol	Explanation
	Quantity contained in the package
	Global Trade Item Number
	Manufacturer
	Date of manufacture
	Authorized representative in the European Community
	Indicates the entity importing the medical device into the European Union.

Symbols used on product

Symbol	Explanation
	Distributed by
	Serial number
	Catalog number
	Unique device identifier
	Lot number
	Caution
	Protective earth
	Consult operating instructions
	Temperature limits
	Humidity limits
	Keep upright
	Fragile handle with care
	Keep dry

Symbols used on product

Symbol	Explanation
	Do not stack
	Keep away from sunlight
	Used to indicate that the equipment is suitable for alternating current only; to identify relevant terminals
	Expiry date
	To indicate that the device requires a prescription to use

Symbols used on product

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
µL	Microliter
Abs Quant **AbsQuant**	Absolute quantification
AC	Alternating current
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
CFR	Code of Federal Regulations
CI	Confidence interval
CISPR	Comité International Spécial des Perturbations Radioélectriques (International Special Committee on Radio Interference)
CNV	Copy number variation
cp	Copies
DC	Direct current
EC	European Community
EDI	External device interface
EMC	Electromagnetic compatibility
ft	Foot
GB	Gigabyte
GUID	Globally unique identifier
HL7	Health Level Seven
IEC	International Electrical Commission

Abbreviations

Abbreviation	Definition
in.	Inch
indel **Indel** **InDel**	Insertion-deletion
IP	Internet Protocol
ISO	International Organization for Standardization
IVD	*In vitro* diagnostic
IVDR	*In vitro* diagnostics regulation
LAN	Local area network
lbs	Pound
LDT	Laboratory-developed test
LIS	Laboratory information system
MLLP	Minimal Lower Layer Protocol
n/a	Not applicable
N/A	Not available
NAT	Network Address Translation
PCR	Polymerase chain reaction
RAM	Random access memory
RF	Radio frequency
RFID	Radio frequency identification
RT	Reverse transcription
SD	Standard deviation
TOI	Target of interest
UNG	Uracil DNA glycosylase
UPS	Uninterruptible power supply
WLAN	Wireless LAN

Abbreviations

What is new in US-specific publication version 1.1

Approvals US-specific compliance information was added.

Approvals (4)

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Safety

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General safety information

In this chapter 1

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Introduction

⚠ General attention

To avoid serious or fatal injury, read this publication thoroughly before you use the system.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the system in a way that is not described in this publication.
- Keep this publication in a safe place to ensure that it is not damaged and remains available for use.
- This publication must always be easily accessible.

Safety classifications

The safety precautions and important user notes are classified according to the applicable standards. Familiarize yourself with the following meanings and icons:

Safety alert

- The safety alert symbol is used to alert you to potential physical injury hazards. Obey all safety messages that follow this symbol to avoid possible damage to the system, injury, or death.

These symbols and signal words are used for specific hazards:

WARNING!

Warning…

- …indicates a hazardous situation that, if not avoided, could result in death or serious injury.

CAUTION!

Caution…

- …indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

NOTICE!

Notice...

- ...indicates a hazardous situation which, if not avoided, may result in damage to the system.

Important information that is not safety relevant is indicated with the following icon:

Tip...

...indicates additional information on correct use or useful tips.

Safety precautions

In this section

Installation and transport

Errors in installation

Error during installation of a new system or new parts can cause malfunctions.

- Leave installation activities to Roche Service representatives.

Damage during transport

Damage during transport can cause malfunctions.

- Do not attempt to relocate or transport the system. Leave relocation and transportation to Roche Service representatives.

Safe and proper use of the system

Missing personal protective equipment

Working without personal protective equipment means danger to life or health.

- Wear appropriate personal protective equipment, including, but not limited to, the following items:
  - Eye protection
  - Lab coat
  - Lab gloves
- Follow laboratory best practices and regularly change lab gloves to minimize the risk of infection and contamination, especially after contact with waste or sample material.

Exchange or removal of parts

Unauthorized exchange or removal of system parts can damage the system or stop it from functioning correctly.

- Do not exchange or remove any part of the instruments. Leave replacement of all instrument parts to Roche Service representatives.

Non-specified consumables

Use of non-specified consumables can lead to incorrect results or damage the system.

- Only use consumables approved for the system.

List of available consumables and reagents (186)

Operating conditions

Unsuitable operating conditions

Operation outside of the specified ranges may lead to incorrect processing or malfunction of the system.

- Consult the specifications.
- Use the system indoors only. Avoid proximity to heat sources and high radiation, and avoid humidity outside of the specified range.
- Ensure that the system's ventilation openings always remain unobstructed.
- In case of an emergency, use the power inlets of the partitioning engine and the analyzer as the points where to quickly disconnect the instruments from the mains outlets. Ensure that the power inlets are always easily accessible.

Overview of the partitioning engine (71)

Overview of the analyzer (74)

Environmental conditions for the system (183)

Power interruption

A power failure or momentary drop in voltage may damage the system or lead to data loss.

- Operate with an uninterruptible power supply (UPS). The specification of the UPS must comply with the power requirements for the instruments. If the UPS can barely supply the required power, the instruments may automatically shut down. Do not connect other devices to the UPS.
- Ensure periodic maintenance of the UPS.
- Perform regular backups of results.
- To shut down the instruments, follow the shutdown procedures in this publication. Only if immediate shutdown is required, use the power switch of the partitioning engine or the power button of the analyzer. If you use the power switch or power button, all processes are aborted. The data (e.g., partitioning data or results) for all currently processed samples may be lost.

Electric power supply (182)

Shutting down the partitioning engine (437)

Shutting down the analyzer (440)

Electromagnetic compatibility

The system complies with the emission and immunity requirements described in the parts IEC 61326-2-6 and IEC 61326-1.

The system complies with the emission requirements described in FCC CFR 47, Part 15 Class A.

The system has been designed and tested to CISPR 11 Class A.

In a domestic environment, the system may cause electromagnetic interference, in which case you must take measures to mitigate the interference.

Non-approved accessories, transducers, and cables

Use of non-approved accessories, transducers, and cables can result in increased electromagnetic emissions and decreased electromagnetic immunity of the system. It can also result in improper operation.

- Only use accessories, transducers, and cables specified or provided by the manufacturer of this system. For more information, contact your Roche Service representative.
- Only use cable length which complies with EMC testing:
  - USB 2.0: < 3 m
  - LAN/Ethernet: < 30 m (longer cable might reduce speed performance)
  - AC power input: < 30 m (longer cable can reduce the voltage of the system)

Electromagnetic fields

Strong electromagnetic fields can result in degradation of the system performance.

- Evaluate the electromagnetic environment before operating the system.
- Do not use portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm to any part of the system, including cables specified by the manufacturer.
- Do not operate this system close to sources of strong electromagnetic fields (for example, unshielded intentional RF sources), as they may interfere with proper operation. The distance of 30 cm for portable RF devices (mobile phones, Wi-Fi) is considered as normal electromagnetic fields for the system.
- Do not use the system in proximity (< 30 cm) to sources of strong electromagnetic radiation (for example, microwave ovens, hand-held radio transmitters, electric motors, RFID emitters), as they can interfere with proper operation.
- If it is suspected that electromagnetic interference affects the performance, correct operation may be restored by increasing the distance between the equipment and the source of the interference.

Warning messages

Electrical safety

Electric shock

Removing the covers of electronic equipment can cause electric shock.

- Do not remove any cover of the system except those covers specified in the instructions.
- Do not exchange or remove any part of the instruments. Leave replacement or repair of all instrument parts to Roche Service representatives.

Fire and burns

Alcohol is a flammable substance.

- Keep all sources of ignition (such as sparks, flames, or heat) away from the system when you perform maintenance that involves alcohol.
- When you use alcohol on or around the system, use no more than 20 mL at a time.

Caution messages

In this section

Personal injury

Sharps, rough edges, and/or moving parts

Personal injury and infection due to sharps, rough edges, and/or moving parts.

- Laboratory best practices can reduce the risk of injury.
- Be aware of your laboratory environment, well-prepared, and follow this publication. Some areas of the partitioning engine and the analyzer may have sharps, rough edges, and/or moving parts.
- Wear personal protective equipment to minimize the risk of injury from bodily contact with such parts, especially in less accessible areas, or while cleaning the partitioning engine or the analyzer.
- Your personal protective equipment should be appropriate to the degree and type of potential hazard, e.g., suitable lab gloves, eye protection, lab coat, and footwear.

Skin inflammation or injury

Direct contact with master reagents or other working solutions may cause skin irritation, inflammation, or burns.

- When you handle master reagents, exercise the precautions required for handling laboratory reagents.
- Wear appropriate personal protective equipment.
- Observe the instructions given in the Instructions for Use.
- Observe the information given in the Safety Data Sheets (available for Roche Diagnostics reagents and cleaning solutions).
- If master reagents or cleaning solutions come into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant.
  Consult a physician.

Moving drawers

The nanowell plate drawer of the partitioning engine and the nanowell plate stack drawer of the analyzer open and close during operation. An opening drawer may strike you. A closing drawer may pinch your fingers.

- Keep away from the nanowell plate drawer of the partitioning engine and the nanowell plate stack drawer of the analyzer during operation.
- Do not try to close the nanowell plate drawer of the partitioning engine or the nanowell plate stack drawer of the analyzer manually by pushing against it.
- Leave sufficient free space around the partitioning engine and the analyzer to allow for unobstructed movement of the nanowell plate drawer and the nanowell plate stack drawer.

Sharp aspiration needle

The aspiration needle in the partitioning engine is sharp. Contact with the aspiration needle may result in personal injury.

- Carefully follow the instructions in this publication for replacing the bottles on the partitioning engine and for decontaminating the aspiration needle.
- When replacing the bottles on the partitioning engine or when decontaminating the aspiration needle, pay extra attention to the aspiration needle.

Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460)

Decontaminating the aspiration needle of the partitioning engine (479)

Incorrect, invalid, or delayed results

Use of incorrect nanowell plate type

The nanowell plate types are indistinguishable by their overall appearance. Using the wrong type of nanowell plates may cause incorrect, invalid, or delayed results.

- To identify the nanowell plate type, refer to the color-coded label of the nanowell plate.
- White label = Universal nanowell plate
- Violet label = High resolution nanowell plate
- Light-blue label = High sensitivity nanowell plate

Nanowell plates (159)

Improper handling of nanowell plates

Scratches, finger prints, dust, or other artifacts on the nanowell plate lanes compromise the image integrity, which may cause incorrect, invalid, or delayed results.

- Open the packing of the nanowell plates only immediately before use.
- Do not leave the nanowell plates in the open for any length of time.
- Do not touch the nanowell plate lanes.
- Handle the nanowell plates by the long sides of the nanowell plate frames only.
- Wear lab gloves when handling the nanowell plates. Regularly change lab gloves.

Untested computer configuration

Accessing the web application from a computer with an untested configuration may compromise the performance of the web application, which may cause invalid or delayed results.

- Observe the specifications for the computer used to access the web application.

Specifications for the web application (187)

Pipetting errors

Pipetting errors, e.g., confusing the positions of the reaction mixtures on a nanowell plate, may cause incorrect results.

- Carefully enter the sample IDs and nanowell plate IDs when creating a sample setup in the web application.
- Use the sample setup report from the web application as a guide for pipetting and for verification of the sample setup in the analyzer software.
- If a pipetting error may have occurred, invalidate the affected nanowell plate lane in the web application before starting the run on the analyzer.

Invalidating nanowell plate lanes and/or nanowell plates in the web application (535)

Incorrect nanowell plate ID

If the analyzer cannot read a nanowell plate ID automatically, you must enter the nanowell plate ID manually. Entering an incorrect nanowell plate ID may cause incorrect, invalid, or delayed results.

- When you must enter a nanowell plate ID manually, ensure that you scan or enter the correct nanowell plate ID.

Resolving a nanowell plate ID reading error (521)

Contamination of the partitioning engine

The partitioning fluid bottles and the liquid waste bottles are indistinguishable by their overall appearance. Loading a liquid waste bottle in the position of the partitioning fluid bottle may contaminate the partitioning engine, which may cause incorrect, invalid, or delayed results.

- Store partitioning fluid bottles and liquid waste bottles in a way to allow for proper distinction.
- Mark all waste bottles with a permanent marker as waste bottles. Mark empty or expired partitioning fluid bottles as waste bottles immediately after unloading them from the partitioning engine.
- Dispose of liquid waste bottles according to local regulations directly after unloading them from the partitioning engine.
- If you inadvertently loaded a liquid waste bottle in the position of the partitioning fluid bottle, immediately unload it again.
- Before loading a partitioning fluid bottle and using the partitioning engine again after incorrect loading, decontaminate the aspiration needle.
- If you inadvertently loaded a partitioning fluid bottle after incorrect loading without decontaminating the aspiration needle, do not use the partitioning engine. Immediately unload the partitioning fluid bottle again and dispose of it according to local regulations.
- Decontaminate the aspiration needle following the decontamination procedure.

Decontaminating the aspiration needle of the partitioning engine (479)

Unpartitioned nanowell plate lanes

Even if a nanowell plate lane contains a reaction mixture, the nanowell plate lane may remain unpartitioned on the partitioning engine. Processing nanowell plates with unpartitioned nanowell plate lanes that contain reaction mixtures on the analyzer may contaminate the analyzer, which may cause incorrect results.

- Before unloading a partitioned nanowell plate from the partitioning engine, always check the partitioning status of the nanowell plate lanes by means of the color of the partitioning indicators.
- If a partitioning indicator of a nanowell plate lane that contains a reaction mixture remains gray, discard the nanowell plate according to local regulations.
- Do not load nanowell plates with unpartitioned nanowell plate lanes that contain reaction mixtures on the analyzer.

About the Plate Setup panel (85)

Leakage of sample material from nanowell plates

Pipetted and partitioned nanowell plates do not have a physical barrier against leakage of the reaction mixtures from the nanowell plates. Leakage of the reaction mixtures from the nanowell plates may contaminate the laboratory, which may cause incorrect, invalid, or delayed results.

- After unloading the nanowell plates from the analyzer, immediately place them in a resealable plastic bag that you keep sealed.
- Dispose of the plastic bag that contains the nanowell plates according to local regulations.

Delayed processing of partitioned nanowell plates

Delayed processing of partitioned nanowell plates on the analyzer may cause degradation of biological material and/or invalidation of the nanowell plates, which may cause incorrect, invalid, or delayed results.

- Only pipette and partition nanowell plates if you can directly run them on the analyzer afterwards.
- Ensure that you start the run directly after loading the analyzer.
- For diagnostic runs, observe that there may be a time limit configured in the analysis packages between partitioning and processing of a nanowell plate. If the time limit is exceeded, the nanowell plate is invalidated and cannot be processed anymore.

Incorrect run type

Starting a development run on nanowell plates that are designated for a diagnostic run, may cause invalid or delayed results.

- As an administrator, assign the appropriate user roles to the user accounts.

User management (545)

Missing measurements

Missing measurements (e.g., because of incomplete loading of the analyzer or invalidated nanowell plate lanes) that are needed for result calculation may cause invalid or delayed results.

- Ensure that you load all nanowell plates of a sample setup on the analyzer (except invalid nanowell plates) to enable result calculation.
- Take extra care to avoid wrongly invalidating a nanowell plate lane that is required for result calculation.
- If you must invalidate a nanowell plate lane or if the sample setup contains invalid nanowell plates that cannot be processed on the analyzer, consider the implications for result calculation (e.g., missing measurements from nanowell plate lanes that contain controls, are part of merged lanes, or contain reaction mixtures for a different test).

Invalidated controls

If you invalidate a nanowell plate lane that contains a control, the system automatically invalidates all final results of the sample setup for the affected targets, which may cause delayed results.

- Take extra care to avoid wrongly invalidating a nanowell plate lane that contains a control.
- If you must invalidate a nanowell plate lane that contains a control, consider the implications for the final results of the sample setup.

Not supported characters in sample IDs

The system uses CP-1252 (code page 1252) to encode and decode ASTM messages.

If you connect the system to an LIS via the ASTM protocol, characters outside of code page 1252 (e.g., Unicode characters) are not supported in the transmissions to the LIS. Using unsupported characters in sample IDs may cause incorrect transmission of the sample IDs to the LIS, which may cause invalid or delayed results.

- If you use Unicode characters in your sample IDs, connect the system to an LIS via HL7 protocol.
- If you connect the system to an LIS via ASTM protocol, only use characters in the range of 0x21 (exclamation mark "!") to 0x7D (closing curly bracket "}") of the CP-1252 character encoding for sample IDs.

Incorrect assignment of partitioning engine to analyzer

An analyzer only processes nanowell plates that were partitioned on an assigned partitioning engine. If the partitioning engine you used to partition the nanowell plates is not assigned to the analyzer you want to process the nanowell plates on, the information from the partitioning engine may be lost, which may cause invalid or delayed results.

- Ensure that the partitioning engine is assigned to the analyzer.
- Pay extra attention to the assignment of the partitioning engines to the analyzers in a multiple instrument configuration (multiple partitioning engines and multiple analyzers).

Partitioning engine connection (596)

Weak passwords

Weak passwords may allow unauthorized access to the system, data manipulation or loss, or unauthorized access to personal information, which may cause incorrect, invalid, or delayed results.

- Use strong passwords.
- Do not share passwords.
- Do not write down passwords.
- Do not share user accounts.
- As an administrator, ensure that the global password policy configured in the analyzer software enforces safe password handling.

Password settings (599)

Compromised data security

Unprotected IT infrastructure and unrestricted physical access to the system and attached infrastructure may allow for infection with malicious software, manipulation of system components, or misuse of the system. Infection with malicious software, manipulation, or misuse may cause incorrect, invalid, or delayed results, or unauthorized access to personal information.

- Ensure that attached networks are secure and monitored for security breaches. Customers are responsible for the security of their local network, especially in protecting it against malicious software and attacks. This protection might include measures, such as a firewall, to separate the system from uncontrolled networks as well as measures that ensure that the connected network is free of malicious code.
- The Roche-provided firewall is mandatory and part of the system.
- Ensure that other computers and services on the network are properly secured and protected against malicious software and unauthorized access.
- Restrict physical access to the system and all attached IT infrastructure (computer, cables, network equipment, etc.).
- If parts of your network, which the system uses to exchange data, are connected by WLAN, secure the WLAN.
- Ensure that any external storage devices (such as USB flash drives) connected to the system are free of malicious software.

Unprotected export files

Insecure transfer or storage of backup files and archive files may allow for data manipulation, which may cause incorrect, invalid, or delayed results.

- Ensure that backup files and archive files are transferred securely, are stored in a secure location, and are protected from any unauthorized access and disaster.
- Ensure that any external storage devices (such as USB flash drives) that contain backup files and archive files are protected against unauthorized access.

Incorrect handling of master reagents

Incorrect handling of master reagents may lead to incorrect results.

- Adhere to the storage conditions defined in the Instructions for Use for the reagents and controls. The system does not allow the use of expired master reagents.
- Do not use master reagents that have been dropped on the floor or compromised in any other way.
- Do not manipulate supplies in any way not specified in the user documentation, Instructions for Use, or labels.

Waste handling

Environmental harm

The system generates waste. Improper disposal may contaminate the environment.

- Dispose of waste according to local regulations.

Notices

In this section

Delay

Incorrect loading of the partitioning engine

The partitioning fluid bottles and the liquid waste bottles are indistinguishable by their overall appearance. Loading a liquid waste bottle in the position of the partitioning fluid bottle may contaminate the partitioning engine, which may cause a time delay.

- Store partitioning fluid bottles and liquid waste bottles in a way to allow for proper distinction.
- Mark all waste bottles with a permanent marker as waste bottles. Mark empty or expired partitioning fluid bottles as waste bottles immediately after unloading them from the partitioning engine.
- Dispose of liquid waste bottles according to local regulations directly after unloading them from the partitioning engine.
- If you inadvertently loaded a liquid waste bottle in the position of the partitioning fluid bottle, immediately unload it again.
- Before loading a partitioning fluid bottle and using the partitioning engine again after incorrect loading, decontaminate the aspiration needle.
- If you inadvertently loaded a partitioning fluid bottle after incorrect loading without decontaminating the aspiration needle, do not use the partitioning engine. Immediately unload the partitioning fluid bottle again and dispose of it according to local regulations.
- Decontaminate the aspiration needle following the decontamination procedure.

Decontaminating the aspiration needle of the partitioning engine (479)

Loss of supplies

Incorrect loading of the partitioning engine

The partitioning fluid bottles and the liquid waste bottles are indistinguishable by their overall appearance. Loading a partitioning fluid bottle in the position of the liquid waste bottle contaminates the partitioning fluid and the partitioning fluid bottle.

- Store partitioning fluid bottles and liquid waste bottles in a way to allow for proper distinction.
- Mark all waste bottles with a permanent marker as waste bottles. Mark empty or expired partitioning fluid bottles as waste bottles immediately after unloading them from the partitioning engine.
- If you inadvertently loaded a partitioning fluid bottle in the position of the liquid waste bottle, immediately unload it again.
- Do not use the partitioning fluid bottle anymore. Instead, treat the contaminated partitioning fluid bottle as waste and dispose of it according to local regulations.

Unauthorized access to personal information

Compromised data security

Unrestricted physical access to the system and attached infrastructure, and unprotected IT infrastructure may allow for infection with malicious software, manipulation of system components, or misuse of the system. Infection with malicious software, manipulation, or misuse may cause incorrect, invalid, or delayed results, or unauthorized access to personal information.

- Do not install and/or execute any other software on the analyzer.
- Restrict physical access to the analyzer and all attached IT infrastructure (computer, cables, network equipment, etc.).
- Ensure that attached networks are secure and monitored for security breaches. Customers are responsible for the security of their local network, especially in protecting it against malicious software and attacks. This protection might include measures, such as a firewall, to separate the system from uncontrolled networks as well as measures that ensure that the connected network is free of malicious code.
- The Roche-provided firewall is mandatory and part of the system.
- Ensure other computers and services on the network are properly secured and protected against malicious software and unauthorized access.
- If parts of your network, which the system uses to exchange data, are connected by WLAN, secure the WLAN.
- Ensure that any external storage devices (such as USB flash drives) connected to the analyzer are free of malicious software.

Unprotected export files

Insecure transfer or storage of backup files and archive files may allow data manipulation, which may cause unauthorized access to personal information.

- Ensure that backup files and archive files are transferred securely, are stored in a secure location, and are protected from any unauthorized access and disaster.

Damage to the instruments

Circuit breakers and fuses

Improper use may result in damage to the system.

- If a circuit breaker trips or a fuse blows, contact your Roche Service representative.

Mechanical stress

Shock, vibration, or pressure can damage the system.

- Keep sources of vibration away from the instruments.
- Do not place objects on top of the instruments.

Safety labels on the system

In this section

About safety labels on the system

The system has warning labels to draw your attention to areas of potential hazard. The following list explains the meanings of the labels at the locations where you find the labels.

The safety labels on the system comply with the following standards: ANSI Z535, IEC 61010-2-101, IEC 61010-1, IEC 60417, or ISO 15223-1.

Only Roche Service representatives may replace damaged labels. For replacement labels, contact your Roche Service representative.

List of safety labels on the system

General warning

Potential hazards located near this label may lead to death or serious injury.

Refer to the user documentation for instructions on safe operation.

Moving parts

There is a risk of hand injuries from moving parts near this label.

Keep hands away from moving parts.

No heavy load

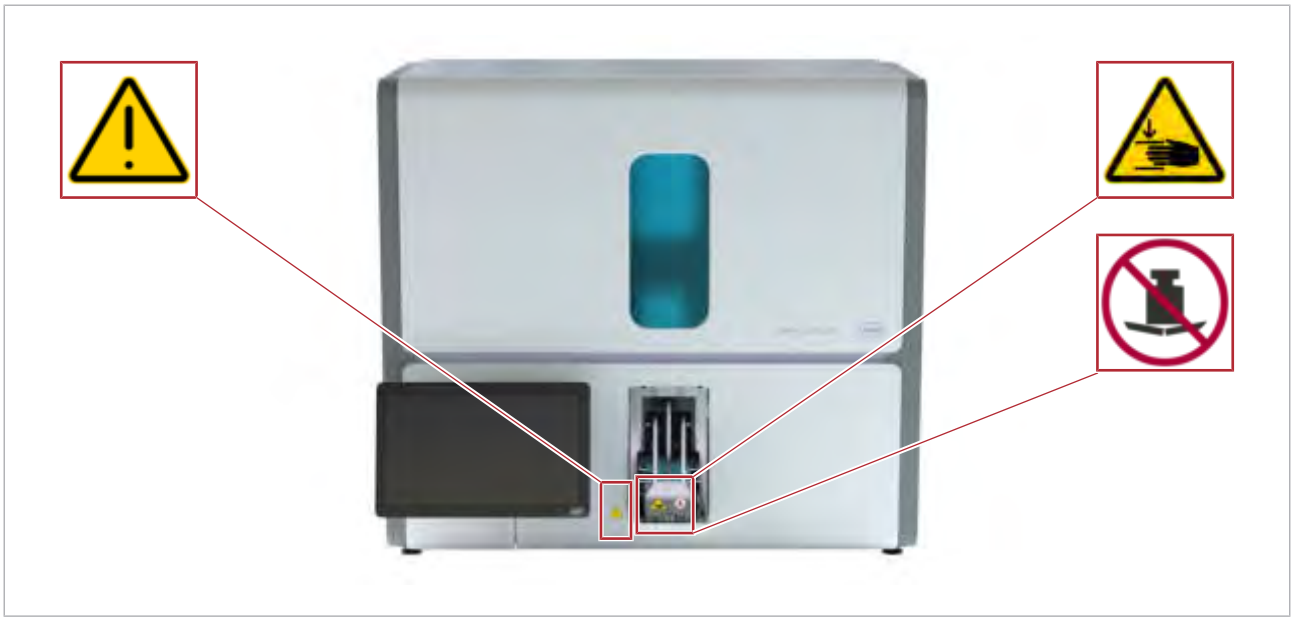
There is a risk of instrument damage near this label.

Do not place heavy objects on the instrument part.

Location of safety labels on the partitioning engine

Safety labels on the partitioning engine (front view with open nanowell plate drawer)

Location of safety labels on the analyzer



Safety labels on the analyzer (front view with open nanowell plate stack drawer)

Safety labels on the analyzer (side view)

Safety information for disposal

Disposal

- Dispose of the system according to local regulations. For more information, contact your Roche Service representative.

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User Assistance

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Using the User Assistance

In this chapter 2

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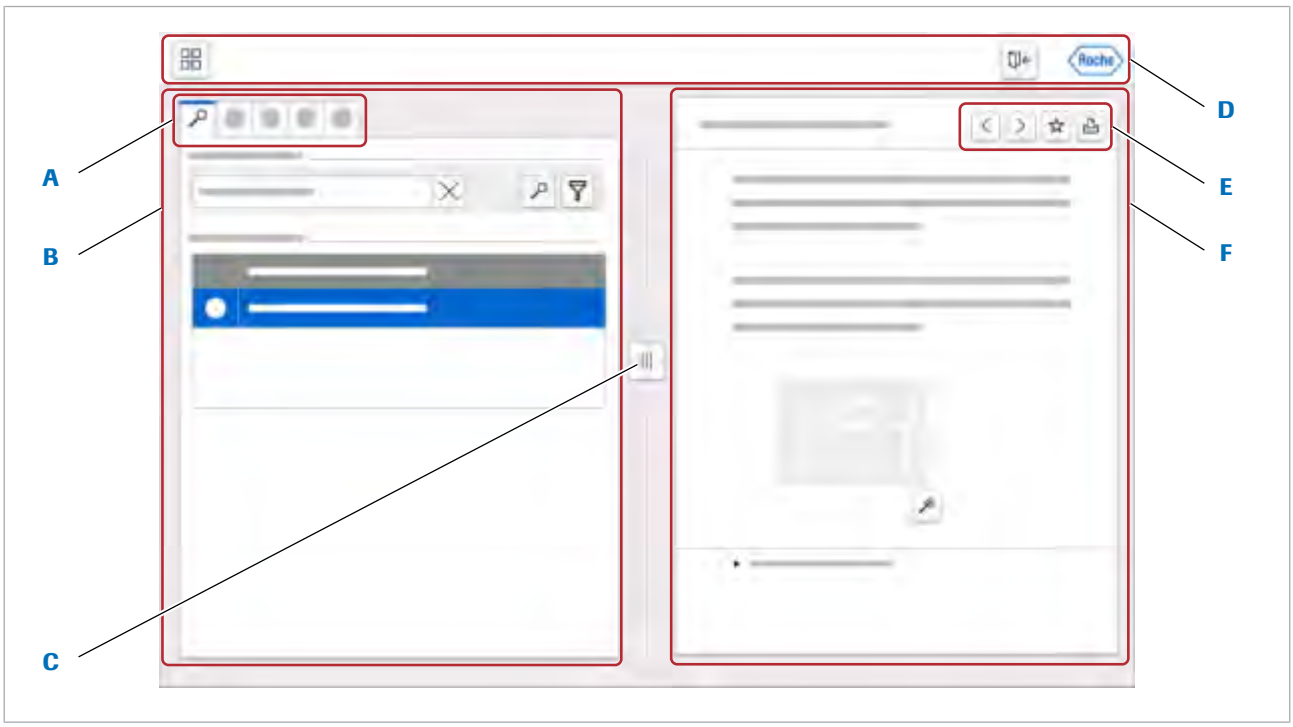
About the User Assistance

The User Assistance supports you in your daily work. It is available in different formats (e.g., online, offline,...). The functionalities provided by the user interface are similar across all formats.

The User Assistance window is divided into a main panel and a detail panel.



A Tabs for selective information access (tabs available depend on configuration)
B Main panel
C Panel splitter
D Global information area
E Buttons for navigation and other functions
F Detail panel

Overview of the User Assistance window

Tabs in the main panel

Home

To view the description of the available tabs. From here, you can access each tab directly.

Context-sensitive help

To view context-related topics when you access the User Assistance directly from your system's user interface.

Search in this publication

To search for information in the whole User Assistance.

Table of contents

To get an overview of the User Assistance publication.

Recently viewed

To get a list of the most recent topics that you have viewed.

Favorites

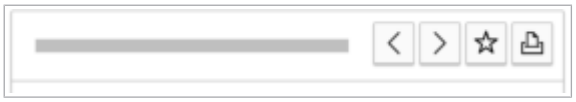
To store your frequently used topics for direct access at any time.

Overview of User Assistance functions

Enlarging images

You can enlarge an image by choosing the button beside it. The image is displayed in a callout in which you can further zoom in using the zoom slider.

Browsing history



You can use the < and > navigation buttons to go backwards and forwards in your browsing history.

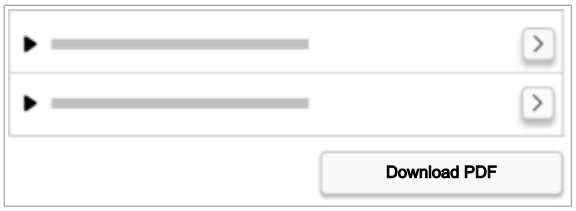
Related topics

At the end of some topics, there is a list of links to other topics that contain related information. You can go back to the original topic using the < button.

Viewing descriptions of terms

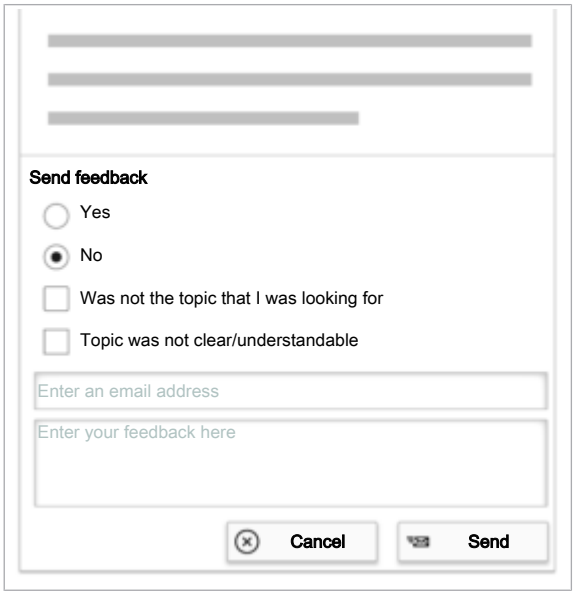
The ⓘ button in text indicates that you can view information about the term to the button's left. When you choose the ⓘ button, a callout is displayed containing a description of the term.

Downloading a PDF



You can download the publication to your computer in PDF format using the **Download PDF** button.

Giving feedback



In the User Assistance online, at the bottom of each topic, you can give feedback on that topic. We use your feedback to improve the next update of our publications.

Accessing the User Assistance from the software

If you need support while you are using the software, you can access the User Assistance directly within the software.

Some features are not available in the User Assistance integrated in the software.

To access the User Assistance from the analyzer software and the web application

1 In the global information area of the analyzer software or the web application, choose the ? button.
   ➔ The User Assistance window is displayed with the 🔑 tab selected. If available, topics related to the active panel of the software are listed.
2 If the topic you need is not listed, choose another tab to find it.

To access the User Assistance from the development software

1 In the **Navigation** area of the development software, choose **File** > ••• > **Help** > **User Assistance**.
   ➔ The User Assistance window is displayed with the 🔑 tab selected. If available, topics related to the active tab of the software are listed.
2 If the topic you need is not listed, choose another tab to find it.

Accessing the User Assistance online

When accessing the User Assistance online, the latest content is always available.

If you have no internet access, contact your Roche representative for a standalone version of the User Assistance.

- ☐ PC, tablet, or smartphone (iOS or Android)
- ☐ Connection to internet
- ☐ Internet browser (Safari or Chrome)

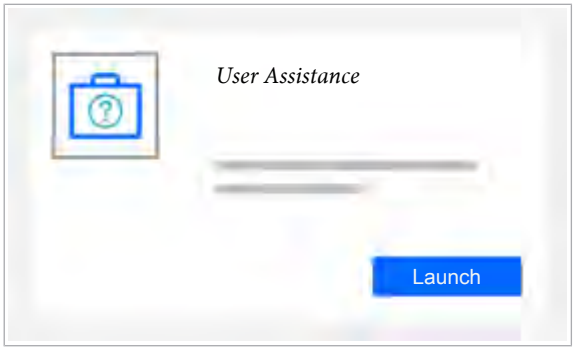
- ☐ Access to the Roche DiaLog portal provided by your Roche representative

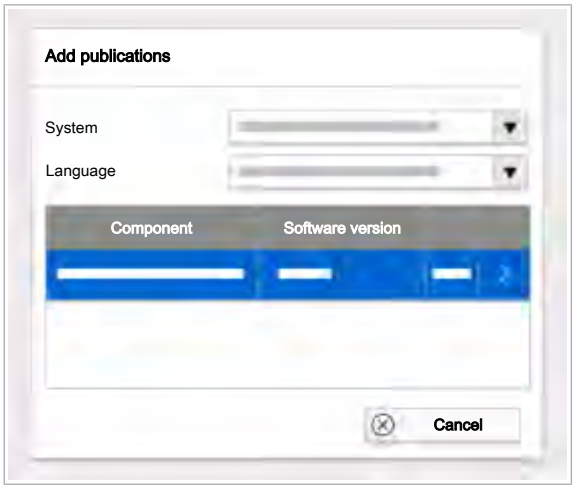
To use the User Assistance online

1 In the browser, enter the link to the Roche DiaLog portal (*dialog.roche.com*).

2 Choose the **Log on** button and enter your Roche DiaLog user name and password.

3 In the list of e-services, find the **User Assistance** card, and then choose the **Launch** button in the card.
➔ The User Assistance publication selector is displayed.





4 Use the filter settings to find the publication you want.

5 Select the publication that you want, and then choose the **Add publication** button, and then the **Add to list** button.

6 To access a User Assistance, choose the desired publication and then, on the detail panel, choose the **Open publication** button.

Accessing the User Assistance offline

You can use the standalone User Assistance offline on your PC. No internet connection is required.

To get the installer for the standalone User Assistance, contact your Roche representative.

- ☐ PC
- ☐ Installer for standalone User Assistance

To access the User Assistance offline

1. Copy the installer for the standalone User Assistance to your PC.
2. Double-click the installer file, and then follow the instructions in the installation wizard.
3. Once installed, start the User Assistance, by double-clicking the User Assistance icon on your desktop.

Searching in the User Assistance

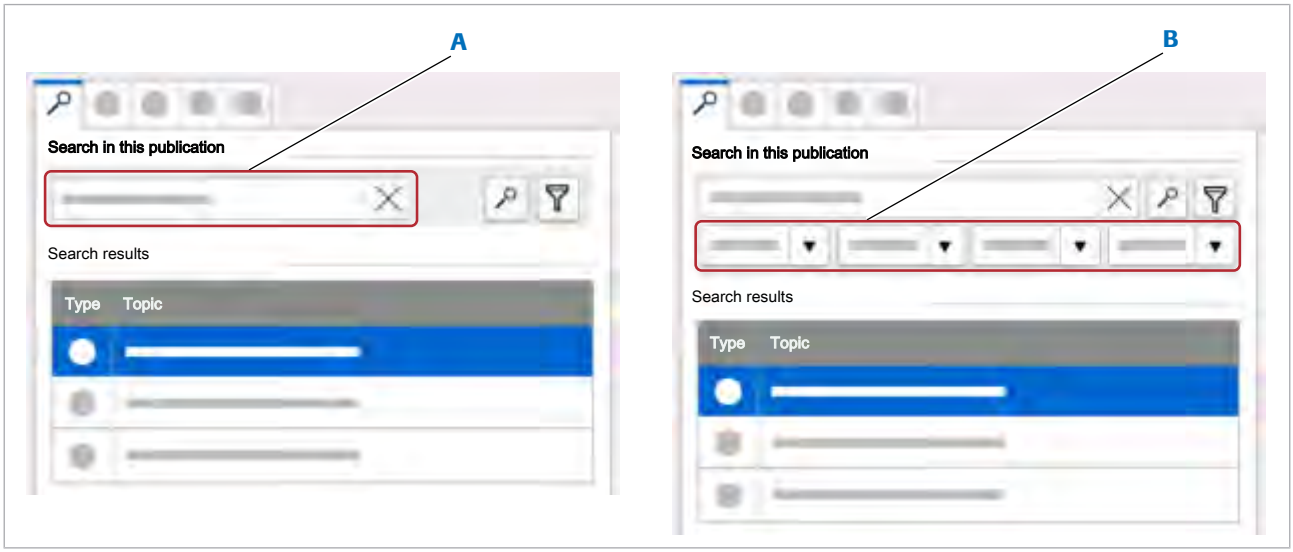
Use the search function in the User Assistance to find information directly.

Search options

There are 2 search options in the User Assistance:

- Text search: Searches the text entered in the search field.
- Faceted search: Limits the number of search results using filters.

You can combine both search options.



A Text search function

B Faceted search function

Search options

Search results

The **Search results** table lists the 20 topics with the highest ranking.

The term you searched for is highlighted. If you searched for a deprecated term, the preferred term is highlighted.

Topic types

The icon on the left of the search results shows you the topic type:

Description

Explains concepts and gives additional background information.

Procedure

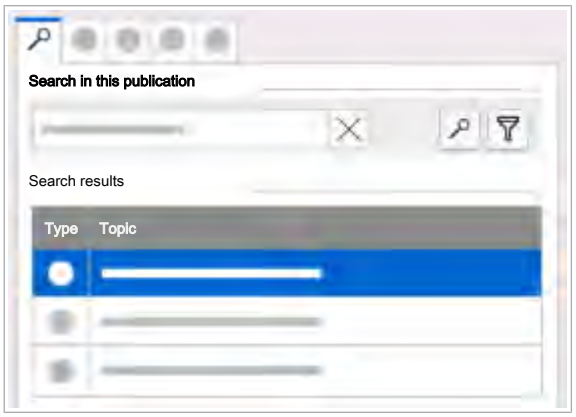
Explains how to perform a task step-by-step.

Reference

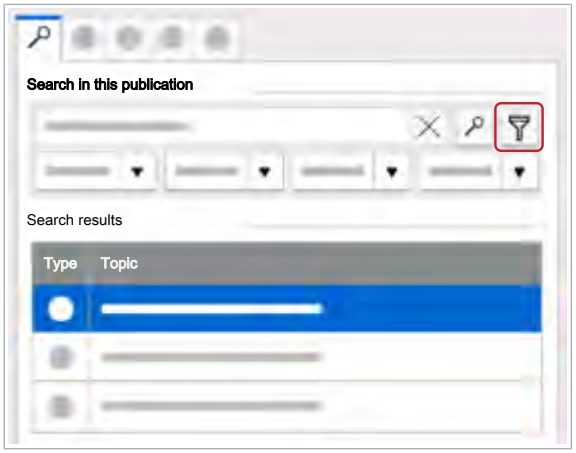
Provides reference information.

To perform a search in the User Assistance

1 In the User Assistance, choose the tab.



2 To perform a simple search, enter full or partial text entries, and then choose the button.



3 To perform a faceted search, choose the button.
➔ The filter drop-down lists are displayed.

4 From the drop-down lists, choose one or more search filters.

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System description

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Overview of the system

In this chapter 3

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Overview of the system

The system is a nucleic acid quantification system that uses digital PCR technology (dPCR).

The system partitions a sample into a large number of nanowells to allow for absolute quantification of a target nucleic acid sequence without a standard curve.

The system allows for a wide range of applications, e.g., in oncology by analyzing cell-free DNA, rare mutations, copy number variations, and gene expression, or in infectious disease diagnostics by detection and quantification of low viral loads.

The main features of the system are:

- Digital PCR technology (dPCR) for detection of low target concentrations
- 6 fluorescence channels for multichannel detection
- 3 analysis types (absolute quantification, CNV, indel)
- Workflows for diagnostic and development purposes
- Development software for detailed data analysis
- 5x concentrated DNA and RNA master reagents for higher sample fraction
- Partitioning of each sample into a large number of nanowells on a dedicated nanowell plate
- Merged lanes to emulate the partitioning of a larger sample volume into an even higher number of nanowells
- 3 types of nanowell plates (universal, high resolution, high sensitivity) for different applications
- Partitioning of up to 8 samples on 1 nanowell plate in the partitioning engine
- Processing of up to 96 samples on 12 nanowell plates on the analyzer

About the system components

The system consists of the following components:

- Nanowell plates:
  A nanowell plate holds up to 8 samples in 8 nanowell plate lanes and offers a large number of nanowells per nanowell plate lane for partitioning of the sample.
- Partitioning engine:
  The partitioning engine partitions the samples into the nanowells on the nanowell plates and seals the nanowells with partitioning fluid.
- Analyzer:
  The analyzer performs the thermal cycling and image acquisition.

- Software components:
  The software components (partitioning engine software, analyzer software, web application, and development software) control the instruments and/or allow you to plan, perform, and analyze your runs.

About merged lanes

Merged lanes emulate the partitioning of a larger sample volume into a higher number of nanowells. The system treats the nanowells of a set of merged lanes as if they belong to 1 nanowell plate lane. Merged lanes therefore facilitate detection of very low target concentrations.

Up to 8 nanowell plate lanes can be merged.

A set of merged lanes has the following characteristics:

- The same reaction mixture is pipetted into the merged lanes.
- The merged lanes are analyzed together. A set of merged lanes gets 1 final result.

Overview of the workflows

The system supports 2 distinct workflows (diagnostic workflow and development workflow) for different purposes.

About the diagnostic workflow

The diagnostic workflow is designed for diagnostic purposes.

In diagnostic workflows, you work with the following system components:

- Web application
- Partitioning engine
- Analyzer

As part of a diagnostic workflow, the nanowell plates are processed in a diagnostic run on the analyzer.

There are 2 types of diagnostic workflows:

- IVD workflow:
  - Developed and validated by Roche.
  - All supplies are provided by Roche.
- LDT workflow:
  - Developed by a laboratory via a development workflow.
  - Test validation is the responsibility of the laboratory.
  - Supplies are partly provided by Roche (e.g., master reagents, nanowell plates) and partly by the laboratory (e.g., primers and probes).

Depending on configuration, the raw data files from diagnostic workflows can be used in the development software.

Overview of diagnostic workflow (193)

About the development workflow

The development workflow is designed for research and development purposes.

In a development workflow, you work with the following system components:

- Development software
- Partitioning engine
- Analyzer

As part of a development workflow, the nanowell plates are processed in a development run on the analyzer.

The supplies for a development workflow are partly provided by Roche (e.g., master reagents, nanowell plates) and partly by the laboratory (e.g., primers and probes).

For development workflows, there are the following 2 options to plan the sample setup (i.e., the reaction mixtures and their distribution on the nanowell plates for the development run):

- Without unassigned sample setup:
  - You plan the sample setup outside of the development software.
  - You add the information of the sample setup to the run data in the development software after the development run is finished.
- With unassigned sample setup:
  - You plan the sample setup in the development software before starting the development run.
  - The information of the sample setup is assigned to the run data in the development software after the development run is finished.

Overview of development workflow without unassigned sample setup (194)

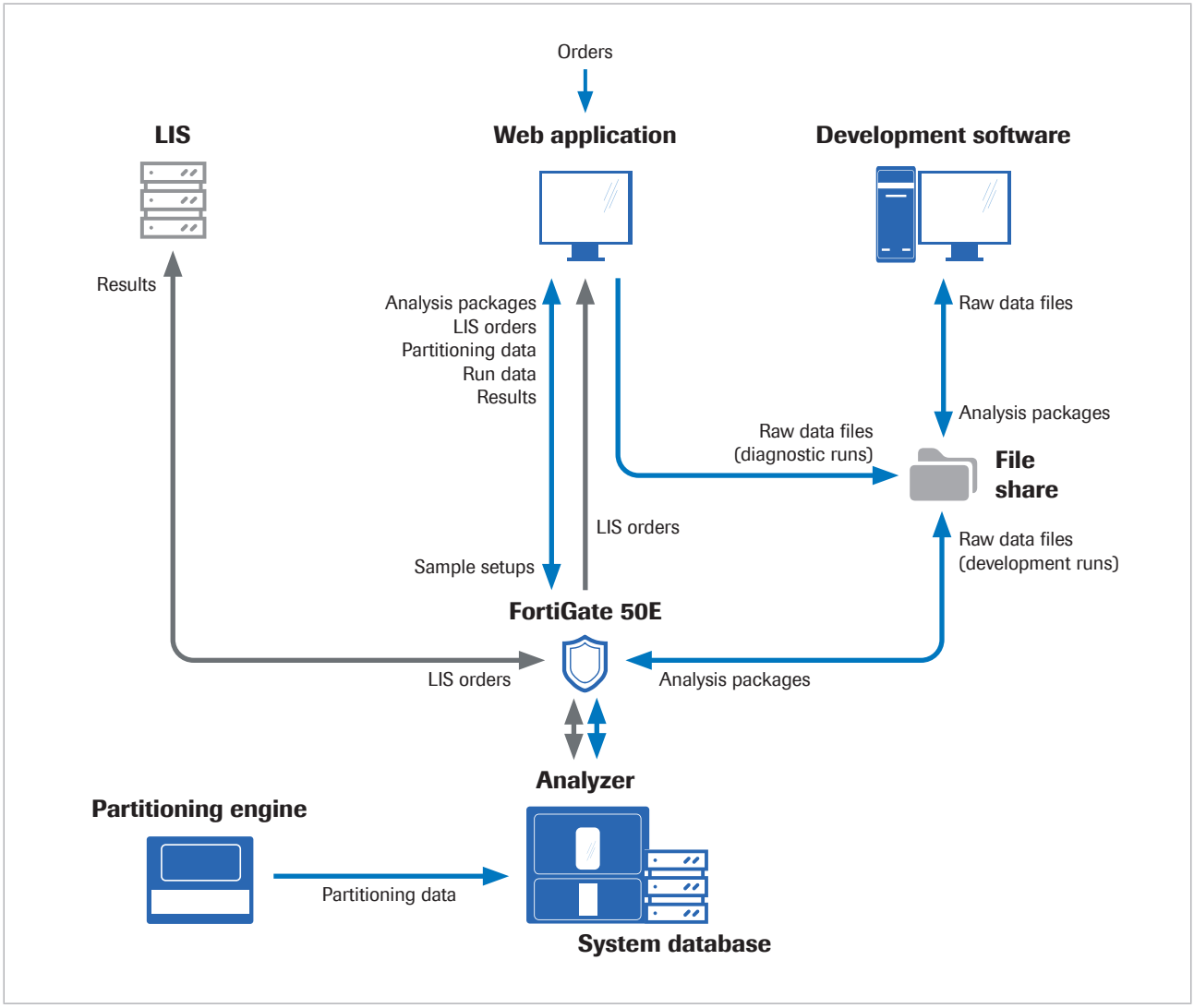
Overview of development workflow with unassigned sample setup (195)

Overview of the system architecture and the data flow

The following illustration gives an overview of the system architecture and the data flow.

The following applies:

- The database of the system is located on the analyzer.
- The data transfer between the system components takes place either via direct connection or via LAN.
- For diagnostic workflows, result calculation is done on the analyzer.
  For development workflows, result calculation is part of the analyses in the development software.



Overview of the system architecture and data flow

In diagnostic workflows, you work with the following system components:

- Web application

- Partitioning engine
- Analyzer

In a development workflow, you work with the following system components:

- Development software
- Partitioning engine
- Analyzer

Overview of the connections

You can connect the system to an LIS, to AVENIO Connect, and/or to an external device via EDI.

The system behavior depends on the type of connection.

About LIS connection

If the system is connected to an LIS, the following applies to the diagnostic workflow:

- The web application can receive the orders automatically from the LIS (LIS orders).
- The results are sent back from the web application to the LIS (manually or automatically).

An LIS connection does not influence the development workflow.

About LIS orders (170)

About AVENIO Connect

AVENIO Connect allows you to perform diagnostic AVENIO Connect runs on the analyzer as part of an integrated laboratory workflow.

Instead of the web application, the AVENIO Connect Software manages the samples through the diagnostic workflow. AVENIO Connect runs are hidden in the web application. The results are automatically sent to the AVENIO Connect Software and the raw data files are automatically exported to the configured location.

About EDI connections

A connection via EDI allows you to connect an external device (e.g., a handler for nanowell plates) and to access and control the analyzer remotely.

The following actions are possible on the analyzer via EDI connection:

- Log on:
  It depends on the EDI settings if a locally logged on user is logged off from the analyzer when an EDI user logs on.
- Log off:
  EDI users are not logged off automatically from the analyzer.
- Open nanowell plate stack drawer:
  An EDI user must be logged on and the analyzer must be in **Analyzer ready** status.
- Close nanowell plate stack drawer:
  An EDI user must be logged on and the analyzer must be in **Analyzer ready** status.

- Start development run:
  An EDI user must be logged on and the requested run profile must exist on the analyzer.
- Start diagnostic run:
  An EDI user must be logged on.
- Query analyzer status:
  Possible without EDI user logged on.
- Query workflow status:
  An EDI user must be logged on.

You cannot work locally on the analyzer if it is controlled remotely via EDI.

Overview of the instruments

In this chapter 4

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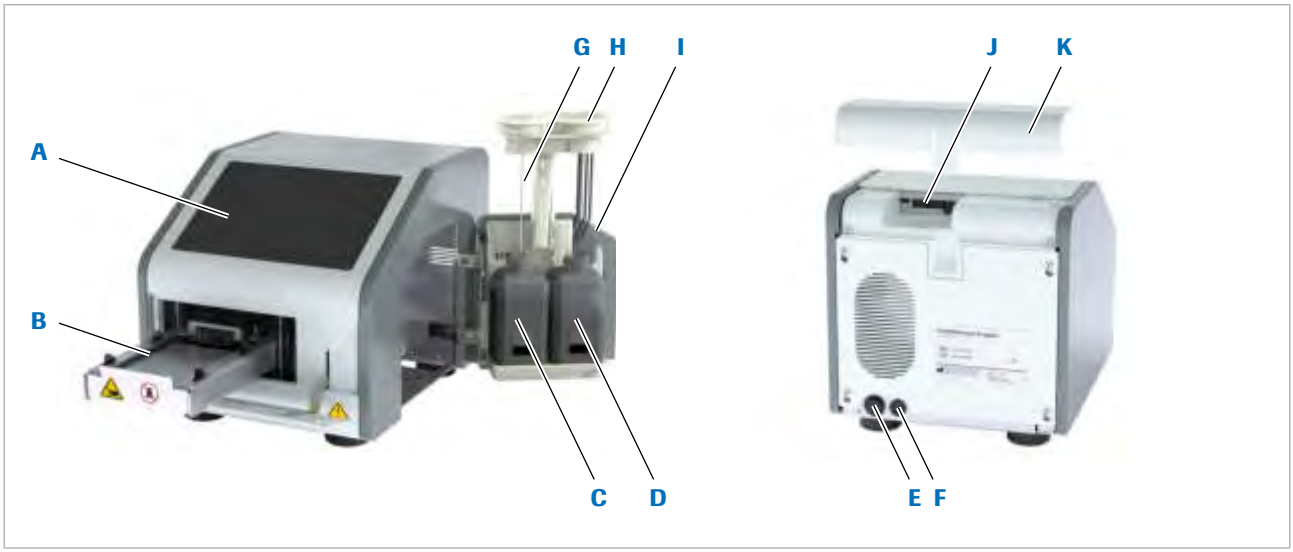
Overview of the partitioning engine

The partitioning engine partitions the samples into the nanowells on the nanowell plates and seals the nanowells with partitioning fluid.

The main features of the partitioning engine are:

- Partitioning of up to 8 samples on 1 nanowell plate
- Sealing the nanowells with partitioning fluid
- Checking the partitioning status of the nanowell plate lanes and flagging invalid nanowell plate lanes
- Connection to the analyzer via LAN



A Touch screen monitor
B Nanowell plate drawer
C Partitioning fluid bottle
D Liquid waste bottle
E Power switch
F Power inlet
G Aspiration needle
H Aspiration and dispensing arm
I Fluids door
J LAN port and USB ports
K Cover

Partitioning engine (front view and back view)

The partitioning engine is a standalone instrument suitable for multiroom configurations. The partitioning engine is touch screen operated.

Each partitioning engine is assigned to a specific analyzer. To run nanowell plates on an analyzer, they must be partitioned on an assigned partitioning engine.

Partitioning engine connection (596)

About the touch screen monitor

The touch screen monitor displays the user interface of the partitioning engine software and allows you to operate the partitioning engine.

Use your finger or a touch screen stylus on the touch screen monitor.

Overview of the partitioning engine software (83)

About the nanowell plate drawer

The nanowell plate drawer holds 1 nanowell plate during partitioning.

The design of the nanowell plate drawer and the beveled corner of the nanowell plate ensure the correct orientation of the nanowell plate in the nanowell plate drawer.

Do not try to close the nanowell plate drawer manually. Instead, follow the partitioning procedure for the partitioning engine.

Partitioning the nanowell plates (221)

About the fluids door

The fluids door is located on the right side of the partitioning engine. On the inside, the fluids door holds the aspiration and dispensing arm with the aspiration needle, the partitioning fluid bottle, and the liquid waste bottle.

To open the fluids door, push the front edge inside until the fluids door disengages. Then open the fluids door completely.

To close the fluids door, push the front edge inside until the fluids door engages with an audible click.

To replace the partitioning fluid bottle and the liquid waste bottle, the aspiration and dispensing arm can be moved up and down.

Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460)

About the power switch

The power switch is located at the back of the partitioning engine.

For routine shutdown of the partitioning engine, do not simply press the power switch. Instead, follow the shutdown procedure and only press the power switch when prompted to do so.

Only press the power switch outside of the shutdown procedure if immediate shutdown is required, e.g., in case of system failure or emergency shutdown.

- Starting up the partitioning engine (231)
- Shutting down the partitioning engine (437)
- Restarting an unresponsive partitioning engine (506)

About the power inlet

The power inlet is located at the back of the partitioning engine.

About the LAN port

The LAN port is located at the back of the partitioning engine. To access the LAN port, remove the cover.

About the USB ports

The partitioning engine has 2 USB ports to connect external storage devices, e.g., USB flash drives.

The USB ports are located at the back of the partitioning engine. To access to the USB ports, remove the cover.

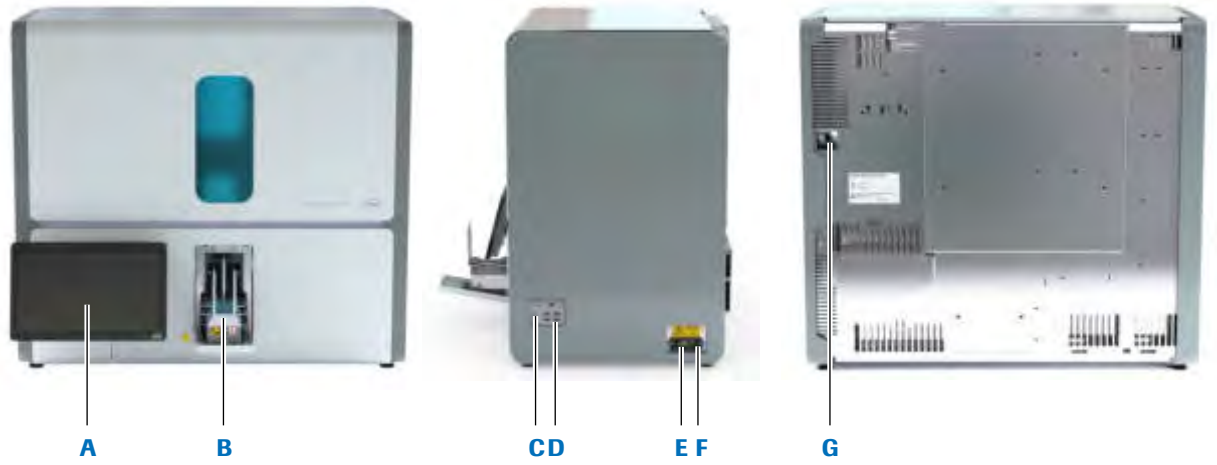
- Copying the logs from the partitioning engine to an external storage device (504)

Overview of the analyzer

The analyzer performs thermal cycling and image acquisition.

The main features of the analyzer are:

- Processing of up to 96 samples on 12 nanowell plates in 1 run
- 6 fluorescence channels for multichannel detection



A Touch screen monitor
B Nanowell plate stack drawer
C Power button
D USB ports
E Power switch
F Power inlet
G LAN port

Analyzer (front view and side view)

The analyzer is a standalone instrument suitable for multiroom configurations. The analyzer is touch screen operated.

About the touch screen monitor

The touch screen monitor displays the user interface of the analyzer software and allows you to operate the analyzer.

Use your finger or a touch screen stylus on the touch screen monitor. Optionally, an external keyboard and a mouse can be connected to the USB ports of the analyzer.

You can tilt the touch screen monitor up and down.

About the nanowell plate stack drawer

The nanowell plate stack drawer holds up to 12 nanowell plates during loading and unloading of the analyzer.

The design of the nanowell plate stack drawer and the beveled corners of the nanowell plates ensure the correct orientation of the nanowell plates in the nanowell plate stack drawer.

Do not try to close the nanowell plate stack drawer manually. Instead, follow the loading and unloading procedures for the analyzer.

Loading the analyzer (225)

Unloading the analyzer (227)

About the power button

The analyzer has a power button to turn the analyzer on and off during routine startup and shutdown.

The power button is located on the right side of the analyzer next to the USB ports.

For routine shutdown of the analyzer, do not simply press the power button. Instead, follow the shutdown procedure and only press the power button after the touch screen turns dark.

Only press the power button outside of the shutdown procedure if immediate shutdown is required, e.g., in case of system failure or emergency failure.

Starting up the analyzer (235)

Shutting down the analyzer (440)

Restarting an unresponsive analyzer (519)

About the USB ports

The analyzer has 4 USB ports to connect external devices (e.g., hand-held barcode reader, keyboard, and mouse) and/or external storage devices (e.g., USB flash drives).

The USB ports are located on the right side of the analyzer.

About the hand-held barcode readers (77)

About the mouse (78)

About the external keyboard (79)

About the power switch

The analyzer has a power switch to turn the power on and off.

The power switch is located on the right side of the analyzer.

Resolving an alarm of the analyzer (527)

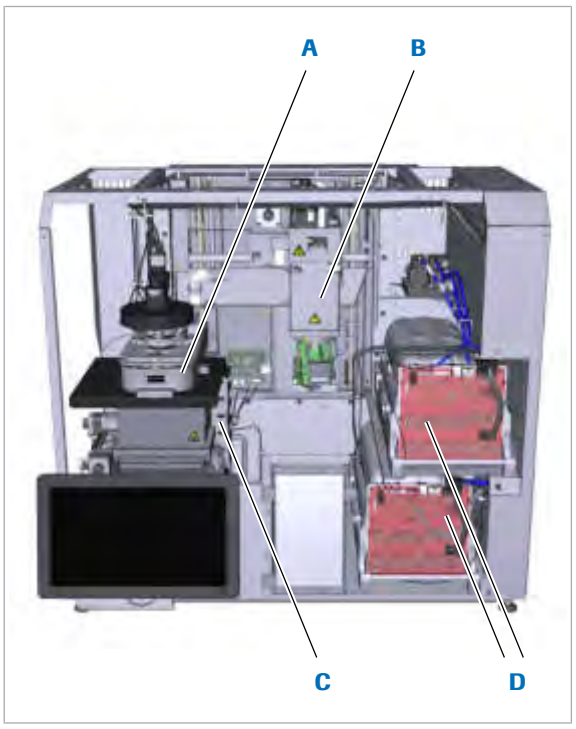
About the power inlet

The power inlet is located on the right side of the analyzer next to the power switch.

About the LAN port

The LAN port is located at the back of the analyzer.

About the components inside the analyzer



A Detection unit
B Nanowell plate handler
C Nanowell plate park position (behind the detection unit)
D Thermal cycler units

The **nanowell plate handler** transfers the nanowell plates between the nanowell plate stack drawer, the thermal cycler units, the nanowell plate park position, and the detection unit.

The pressurized **thermal cycler units** provide and control the temperature profiles for the thermal cycling. The analyzer has 2 thermal cycler units for 3 nanowell plates each.

The **detection unit** acquires and stores the fluorescence images of the nanowells in up to 6 channels.

After thermal cycling, nanowell plates are parked temporarily in the **nanowell plate park position**.

About the hand-held barcode readers

You can connect hand-held barcode readers to the analyzer, to the computer running the web application, and to the computer running the development software.

Instead of manually entering the IDs, e.g., sample IDs and nanowell plate IDs, use a hand-held barcode reader to scan the barcode labels.

Connect the hand-held barcode reader to a USB port on the right side of the analyzer.

Contact your local IT support for installation and configuration of the hand-held barcode readers.

About the USB ports (75)

Computer specifications (187)

About the mouse

You can connect a mouse to the analyzer.

Instead of using the touch screen, use the mouse to work with the analyzer software.

Connect the mouse to a USB port on the right side of the analyzer.

Contact your local IT support for installation and configuration of the mouse.

About the USB ports (75)

About the external keyboard

You can connect an external keyboard to the analyzer.

Instead of using the virtual keyboard in the analyzer software, use the external keyboard for data entry.

Connect the external keyboard to a USB port on the right side of the analyzer.

Contact your local IT support for installation and configuration of the external keyboard.

About the USB ports (75)

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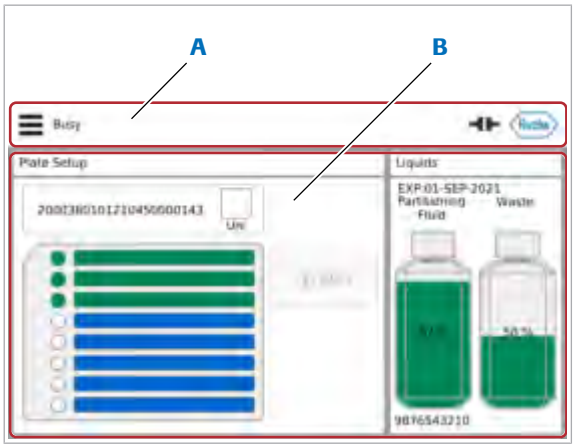
Overview of the software components

In this chapter 5

Overview of the partitioning engine software



A Global information area

B Work area

You access the partitioning engine software and operate the partitioning engine via the user interface.

The user interface of the partitioning engine software consists of the following elements:

- Global information area
- Work area

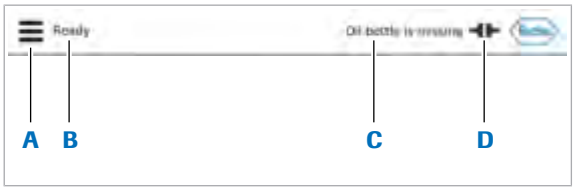
In this section

About the global information area of the partitioning engine software (83)

About the work area of the partitioning engine software (85)

About the global information area of the partitioning engine software

The global information area of the partitioning engine software provides functions and information that are always available.



A Menu button

B Status indicator

C Message

D Connection indicator

The global information area is always displayed and contains the following elements:

- Menu button
- Status indicator
- Messages
- Connection indicator

About the menu button

The ≡ button allows you to access the following functions and panels of the partitioning engine from a drop-down menu:

Initialize Instrument

Initializing the partitioning engine (505)

Prime Instrument

Priming the partitioning engine (232)

Copy Logs to USB

Copying the logs from the partitioning engine to an external storage device (504)

Event Viewer

Displaying the event viewer in the partitioning engine software (503)

Information

To display the system information in the partitioning engine software (452)

Shut Down Instrument

Shutting down the partitioning engine (437)

To display the drop-down menu and to hide it again, choose the ≡ button.

To perform a function or to access a panel, from the drop-down menu, choose the command.

About the status indicator

The partitioning engine status indicator displays the current status of the partitioning engine:

- **Ready**
- **Busy**
- **Warning**
- **Error**

About the messages

If certain events occur, a message is displayed.

For each message, a corresponding event is logged in the event viewer.

List of messages on the partitioning engine (499)

Displaying the event viewer in the partitioning engine software (503)

About the connection indicator

The connection indicator displays the status of the connection of the partitioning engine to the analyzer:

Connected

Disconnected

Do not partition nanowell plates if the partitioning engine is disconnected from the analyzer. The partitioning information will be lost and you will not be able to run the nanowell plates on the analyzer.

About the work area of the partitioning engine software

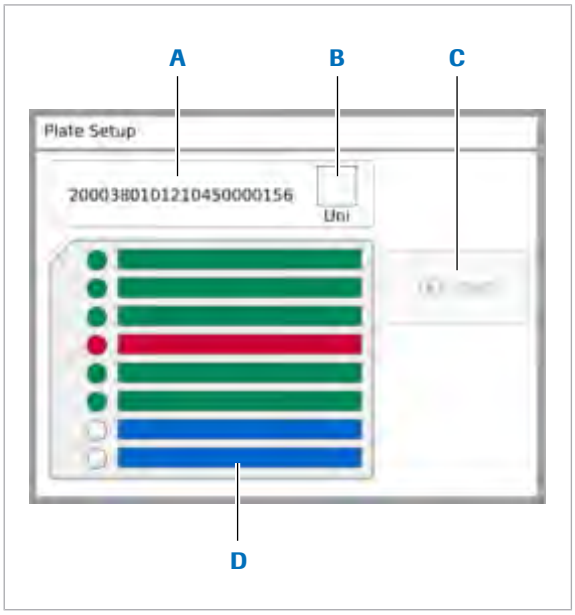
The work area is the center of your activities when working with the partitioning engine software. The work area displays the panels.

By default, the work area displays the **Plate Setup** panel and the **Liquids** panel.

To display the **Information** panel or the event viewer, choose the ≡ button. From the drop-down menu, choose the corresponding command.

About the menu button (83)

About the Plate Setup panel



A Nanowell plate ID
B Nanowell plate type
C Function button
D Partitioning indicator

The **Plate Setup** panel displays a visual representation of a nanowell plate and contains buttons to perform functions.

For a loaded nanowell plate, the following information is displayed:

- Nanowell plate ID
- Nanowell plate type with color-coding
- Partitioning indicators for nanowell plate lanes

The partitioning indicators are color-coded according to the partitioning status of the nanowell plate lanes before, during, and after partitioning:

Gray:
The nanowell plate lane is empty, is not yet partitioned, or was not partitioned.

Blue:
The nanowell plate lane is currently being partitioned.

Green:
The nanowell plate lane was partitioned successfully.

Red:
Partitioning of the nanowell plate lane failed. The nanowell plate lane is flagged and invalidated.

For invalid nanowell plate lanes, the following applies:

- The contained reaction mixture is flagged and invalidated:
  - For a sample, the final results will be invalid.
  - For a control, the final results of all associated targets or samples will be invalid.
- If all partitioned nanowell plate lanes of a nanowell plate are invalid, the whole nanowell plate is invalid. You cannot process invalid nanowell plates on the analyzer.

The function buttons on the **Plate Setup** panel allow you to perform the following functions:

Prime
Primes the partitioning engine.

Load
Opens the nanowell plate drawer.

Close
Closes the nanowell plate drawer.

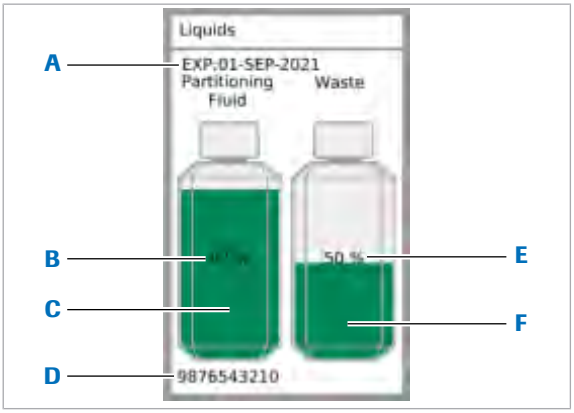
Start
Closes the nanowell plate drawer and starts partitioning.

The buttons change its symbol and label depending on the availability of the corresponding functions.

Priming the partitioning engine (232)

Partitioning the nanowell plates (221)

About the Liquids panel



A Expiry date of the partitioning fluid
B Fill percentage of partitioning fluid bottle
C Fill level and status of partitioning fluid bottle
D Lot number of partitioning fluid bottle
E Fill percentage of liquid waste bottle
F Fill level and fill status of liquid waste bottle

The **Liquids** panel displays the following information about the partitioning fluid bottle and the liquid waste bottle:

- Expiry date of the partitioning fluid
- Fill percentage
- Fill level
- Fill status
- Lot number of the partitioning fluid

The fill status is color-coded:

Green:
Sufficient bottle volume for normal operation.

Yellow:
Bottle needs to be exchanged soon.

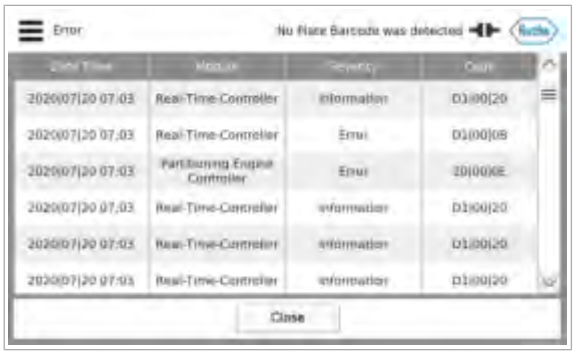
Red:
Bottle must be exchanged.
You cannot prime the partitioning engine or partition another nanowell plate unless you change the bottle.

For the partitioning fluid bottle, the fill percentage and fill level **fall** with each performed partitioning run. The fill status changes when the partitioning fluid bottle gets increasingly empty.

For the liquid waste bottle, the fill percentage and fill level **rise** with each performed priming. The fill status changes when the liquid waste bottle gets increasingly full.

Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460)

About the event viewer



The event viewer displays a list of the events with event severity and event code.

An event can have the following severity:

- **Information**
- **Warning**
- **Error**

If an error event occurs, a corresponding message is displayed in the global information area.

To display the event viewer, in the global information area, choose the ≡ button. From the drop-down menu, choose the **Event Viewer** command.

Displaying the event viewer in the partitioning engine software (503)

Copying the logs from the partitioning engine to an external storage device (504)

About the Information panel

The **Information** panel displays the following information about the partitioning engine:

- Software version
- System version
- Serial number
- Network address

To display the **Information** panel, in the global information area, choose the ≡ button. From the drop-down menu, choose the **Information** command.

From the **Information** panel, you can copy the license.

Displaying system information (452)

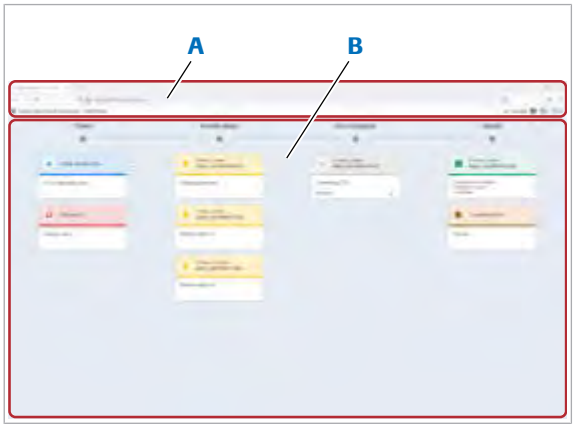
Overview of the web application

The web application is a dedicated application to plan and to start diagnostic workflows and to review the results.

The web application is the interface between the system and a connected LIS.

You access and operate the web application in a browser window.

Specifications for the web application (187)



A Global information area **B** Dashboard

The web application window consists of the following elements:

- Global information area
- Dashboard or screen

In this section

About the global information area of the web application

The global information area of the web application provides functions and information that are always available.

A Application version
B URL for analyzer connection
C Dashboard button
D Screen name
E Serial number of the connected analyzer
F LIS connection indicator
G Logon indicator
H User Assistance

The global information area is always displayed and contains the following elements:

- Application version
- URL for the connection to the analyzer
- Dashboard button
- Screen name
- Serial number of the connected analyzer
- LIS connection indicator
- Logon indicator
- User Assistance

About the dashboard button

To return to the dashboard from a screen, choose the button.

About the LIS connection indicator

The LIS connection indicator displays the status of the connection to the LIS:

Connected

Disconnected

If the system is not connected to an LIS, the LIS connection indicator is not displayed.

About the logon indicator

The logon indicator displays the currently logged on user.

To log off from the web application, choose the logon indicator.

In the web application, you can only change your password upon request. You can change your password at any time only in the analyzer software.

Logging off from the web application (438)

Change password (237)

To change my password at logon in the web application (238)

About the User Assistance

To display the User Assistance, choose the ? button.

The User Assistance is context-sensitive and displays information about the screen you are currently using.

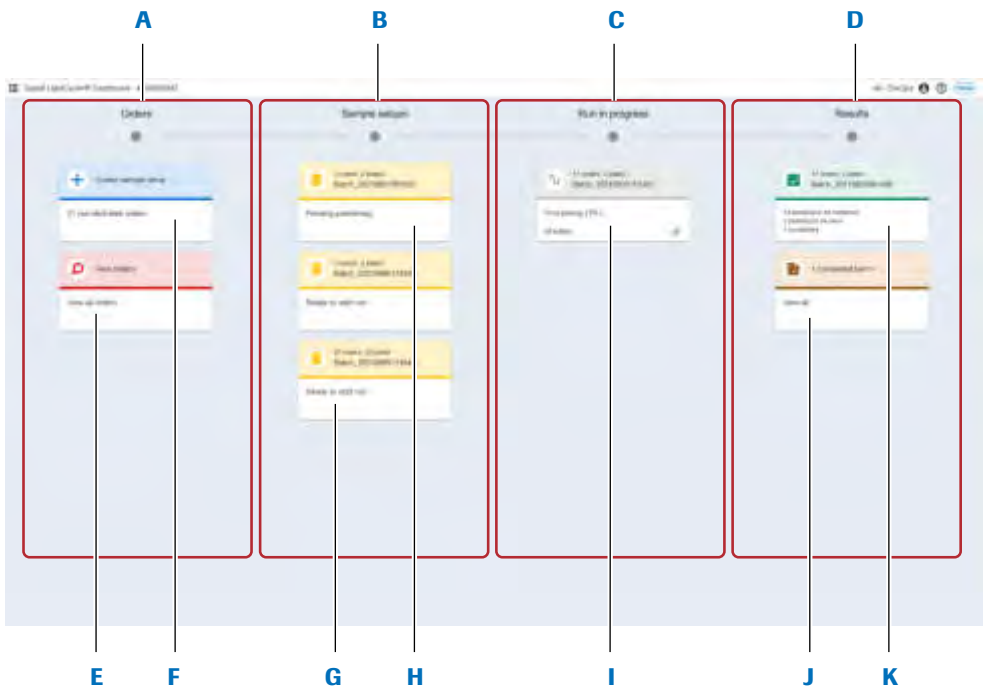
About the User Assistance (47)

About the dashboard of the web application

When you log on to the web application, the dashboard is displayed.

The dashboard consists of the following elements:

- Columns
- Tiles



A **Orders** column
B **Sample setups** column
C **Run in progress** column
D **Results** column

E **View orders** tile
F **Create sample setup** tile (displays the number of not allocated orders)

G Batch tile for batch in **Ready to start run** status
H Batch tile for batch in **Pending partitioning** status
I Batch tile for batch in **Processing** status
J **Completed batches** tile (displays the number of completed batches)
K Batch tile for batch after run finished

Columns and tiles on the dashboard of the web application

To display a screen with further information, choose a tile on the dashboard.

About the columns on the dashboard

The columns on the dashboard display the tiles and are ordered according to the consecutive steps in a diagnostic workflow:

- **Orders** column:
  Displays the **Create sample setup** tile and the **View orders** tile for accessing orders.
- **Sample setups** column:
  Displays a batch tile per confirmed but unprocessed sample setup (i.e., the sample IDs and their distribution on the nanowell plates for a run).
- **Run in progress** column:
  Displays the batch tile of the sample setup that is currently run on the analyzer. If there is currently no diagnostic run on the analyzer, the **Run in progress** column is empty.

- **Results** column:
  Displays a batch tile per processed but not completed batch, and the **Completed batches** tile if there are completed batches on the system.

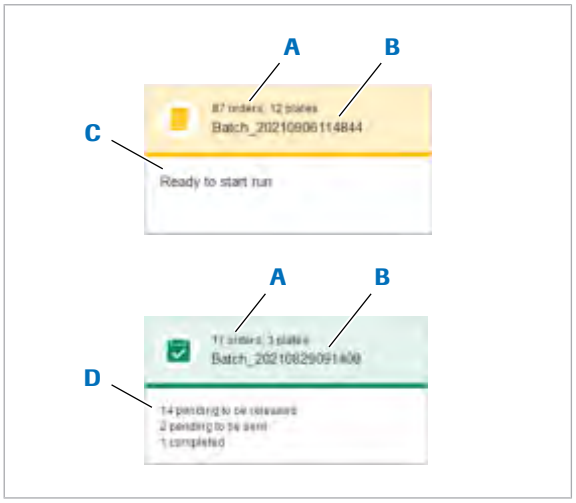
A batch is processed if the run on the analyzer is finished.

A batch is completed if all results are complete, i.e., released and sent.

The batch tiles are ordered consecutively in the **Sample setups** column and the **Results** column with the newest batch at the top.

About the batch tiles (93)

About the batch tiles



A Number of orders and nanowell plates

B Batch name

C Batch status

D Result status

A batch consists of the orders that are allocated to 1 confirmed sample setup. A batch is processed in 1 diagnostic run on the analyzer.

In the web application, a batch and its sample setup are represented by a batch tile. Each batch has its own batch tile.

When a sample setup is confirmed, a corresponding batch tile is automatically created in the **Sample setups** column on the dashboard. If a sample setup is deleted again, the corresponding batch tile is deleted as well.

While the batch is processed, its status and the status of its orders change and the batch tile moves through the corresponding columns on the dashboard.

A batch tile displays the following information:

- The number of orders and the number of nanowell plates that comprise the batch.
- The unique batch name.
  By default, a batch is named:
  "Batch_YYYYMMDDhhmmss"
  with the date and time the batch (i.e., the sample setup) was created.
  The batch name is used as the run name on the analyzer.
- The number of flags (if applicable).
- For unprocessed batches, the batch status:
  - **Incomplete setup**
  - **Pending partitioning**
  - **Ready to start run**
  - **Ready to start run (loaded)**

  - **Processing ({percent}%)** (with "{percent}" replaced by the percentage of the run that has already elapsed)
- For processed but not completed batches, the number of results with the result status (with "{count}" replaced by the applicable number):
  - **{count} pending to be released**
  - **{count} pending to be sent**
  - **{count} completed**

The **{count} completed** result status on the batch tile summarizes the results that are in **Send queued** status or **Sent** status on the **Samples** tab on the **Results of** screen.

About the result status in the web application (102)

About the columns on the dashboard (92)

List of naming placeholders (154)

About the screens in the web application

The screens of the web application display detailed information on orders, batches, and results, and offer corresponding functions.

To display a screen, choose a tile on the dashboard.

To return to the dashboard from a screen, in the global information area, choose the button.

The following screens are available:

- **Orders**
- **Edit orders**
- **Sample setup**
- **Results of**
- **Completed batches**

About the icons for analysis packages

On the screens of the web application, analysis packages can be marked with the following icons:

Analysis package provided by Roche.

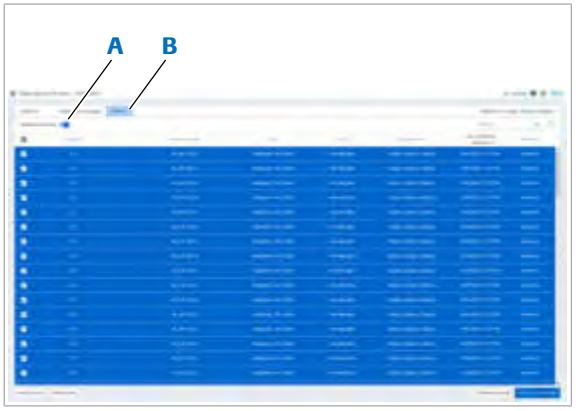
Analysis package is in **In validation** status in the analyzer software.

About statuses of analysis packages (580)

In this section

About the Orders screen

If assignment mode is enabled, the **Orders** screen lists the orders that are not allocated. If assignment mode is disabled, the **Orders** screen lists all orders.



A Toggle button to enable and disable assignment mode

B **Refresh** button to update screen

To toggle between the assignment mode enabled and disabled, on the **Orders** screen, choose the **Assignment mode** toggle button.

On the **Orders** screen, a row summarizes all orders that belong to the same sample ID, are for tests from the same analysis package, and are in the same status.

If the information on the **Orders** screen has changed, a **Refresh** button is displayed. To update the screen, choose the **Refresh** button.

About orders (169)

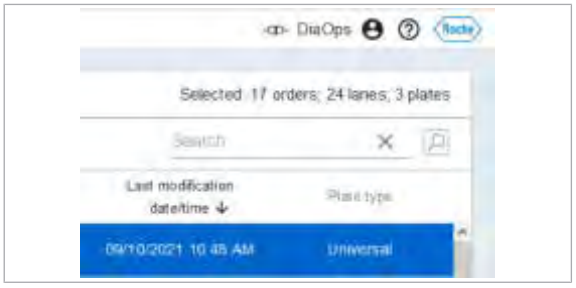
Navigating to the Orders screen

To display the **Orders** screen, on the dashboard, do one of the following:

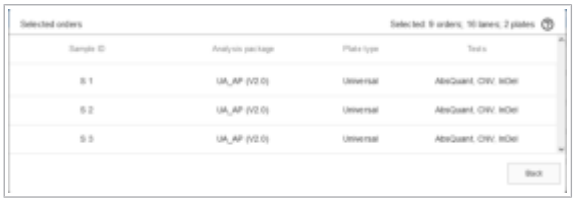
- To display the **Orders** screen in assignment mode, choose the **Create sample setup** tile.
- To display the **Orders** screen with assignment mode disabled, choose the **View orders** tile.

About the Orders screen in assignment mode

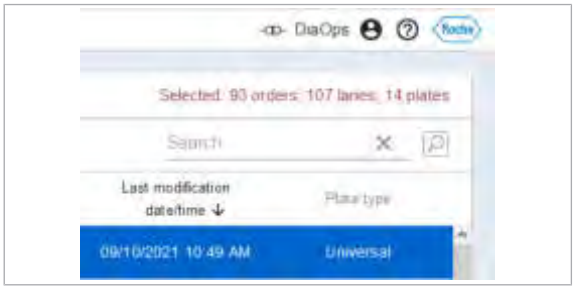
The **Orders** screen in assignment mode lists the orders that are not allocated (an order is not allocated if it is not assigned to a sample setup).



If you choose rows on the **Orders** screen in assignment mode, the number of orders, needed nanowell plate lanes, and needed nanowell plates is calculated and displayed at the top right of the table.



Alternatively, to display the same information in the **Selected orders** dialog box, choose the **Selection overview** button.



If you choose too many rows for 12 nanowell plates, the number of orders, needed nanowell plate lanes, and needed nanowell plates is displayed in red. You cannot assign this selection to a sample setup.

The web application automatically includes the controls in the number of needed nanowell plate lanes and needed nanowell plates. Therefore, these numbers may be higher than the number of chosen orders suggests.

About the Orders screen with assignment mode disabled

If assignment mode is disabled, the **Orders** screen lists all orders and their status, except orders belonging to completed batches that are listed on the **Completed batches** screen.

Except for not allocated orders and orders in **In process** status, the order status in the **Status** column is a link to the screen where the order is currently listed. For example, if you choose an **Allocated** link, the **Sample setup** screen for the sample setup that includes the order is displayed.

About the Edit orders screen

The **Edit orders** screen displays sample IDs and analysis packages to create orders manually and to delete orders (except LIS orders).

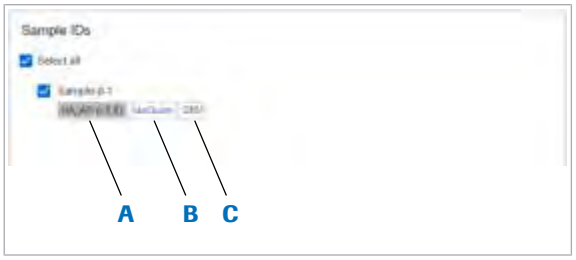
A **Add sample ID** card
B **Sample IDs** card
C **Analysis package and test** card

The **Edit orders** screen comprises the **Add sample ID** card, the **Sample IDs** card, and the **Analysis package and test** card.

To display the **Edit orders** screen, on the **Orders** screen in assignment mode, choose the **Add/edit order** button.

If orders are selected on the **Orders** screen, they are displayed on the **Edit orders** screen.

If no orders are selected on the **Orders** screen, only the available analysis packages are displayed on the **Edit orders** screen.



A Analysis package
B Test of LIS order
C Test of order

On the **Edit orders** screen, on the **Sample IDs** card, the entries are color-coded:

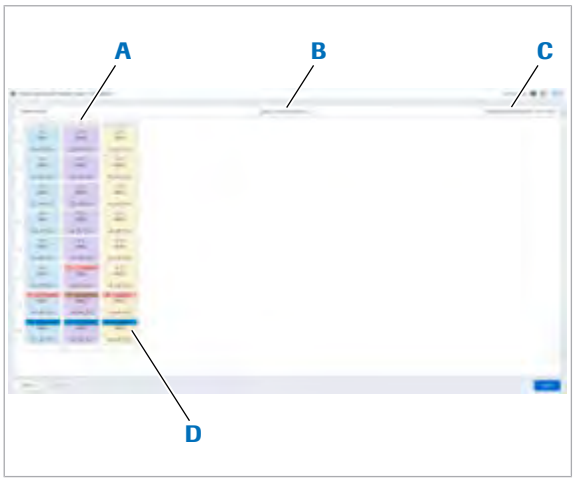
- The analysis package is displayed in black font with a gray background.
- The tests of LIS orders are displayed in blue font.
- The tests of all other orders are displayed in black font.

On the **Edit orders** screen, an entry summarizes all orders that belong to the same sample ID, are for tests from the same analysis package, and are in the same status.

Ordering in the web application (250)

About the Sample setup screen

The **Sample setup** screen displays the sample setup in plate view, i.e., the compiled nanowell plates for a diagnostic run.



A Column for 1 nanowell plate

B Batch name

C Estimated run duration

D Tile for 1 nanowell plate lane

The **Sample setup** screen displays the following information:

- Batch name (used as name of the diagnostic run on the analyzer)
- Estimated run duration on the analyzer
- Sample setup in plate view:
  - 1 column per nanowell plate with column header and column footer
  - 1 tile per nanowell plate lane

On the **Sample setup** screen, to deselect all tiles, press Esc.

About sample setups in plate view (150)

Navigating to the Sample setup screen

To display the **Sample setup** screen, do one of the following:

- Assign orders to a sample setup, i.e., on the **Orders** screen in assignment mode, choose the orders and choose the **Assign to sample setup** button.
- In the **Sample setups** column on the dashboard, choose a batch tile.
- On the **Orders** screen with assignment mode disabled, in the **Status** column, choose an **Allocated** link.

About the column headers on the Sample setup screen

In the web application, the column headers are color-coded according to the status of the nanowell plate:

Gray:
Unpartitioned nanowell plate.

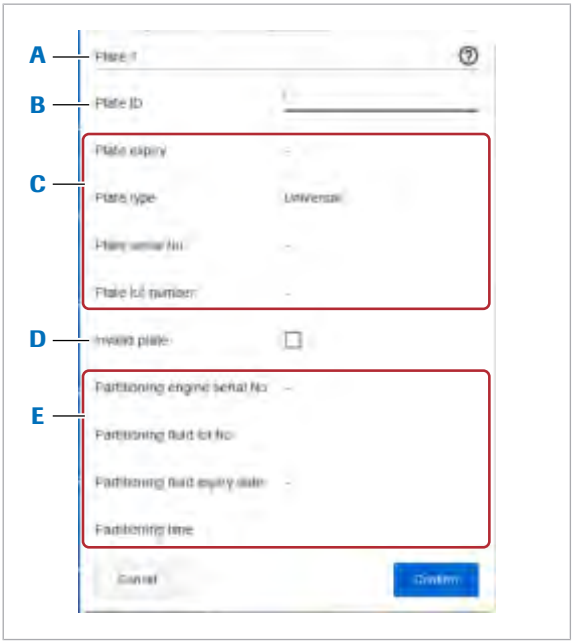
Blue:
Unpartitioned nanowell plate, column selected.

Green:
Nanowell plate partitioned successfully.

Red:
Nanowell plate information incomplete, e.g., missing nanowell plate ID.
To display a callout with additional information, mouse over the column header.

Invalidated nanowell plates are grayed out, regardless of the status of the nanowell plate.

About the Plate: combo box



A Position of nanowell plate in sample setup
B Field for nanowell plate ID
C Nanowell plate information
D Check box to invalidate nanowell plate
E Partitioning information

The **Plate:** combo box displays the currently available information about the nanowell plate:

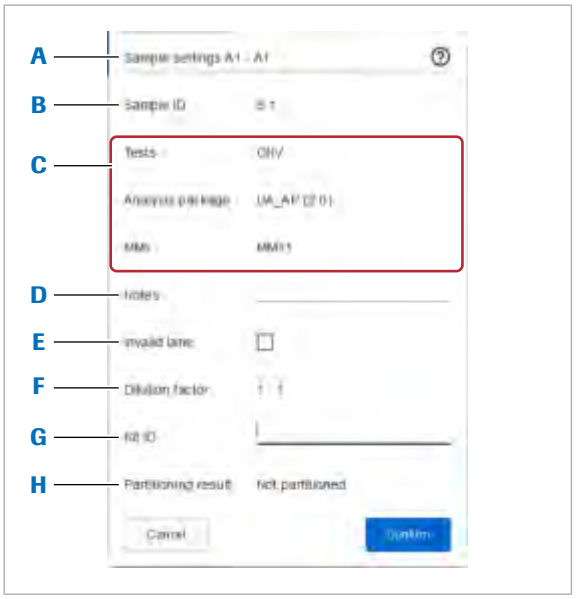
- Position of the nanowell plate in the sample setup
- Nanowell plate ID
- Nanowell plate information
- Invalidation status of nanowell plate
- Partitioning information

You cannot enter the nanowell plate ID of a nanowell plate that is expired, has the wrong type, is already part of a sample setup, and/or is already partitioned.

To display the **Plate:** combo box, on the **Sample setup** screen, choose a column header twice.

About the positions of nanowell plate lanes in sample setups (153)

About the Sample settings: combo box



- **A** Position of nanowell plate lane in sample setup
- **B** Sample ID
- **C** Analysis package information
- **D** Field for notes
- **E** Check box to invalidate nanowell plate lane
- **F** Dilution factor
- **G** Field for kit ID
- **H** Partitioning flags

The **Sample settings:** combo box displays the currently available information about the nanowell plate lane:

- Position of the nanowell plate lane in the sample setup
- Sample ID
- Analysis package information
- Notes
- Invalidation status of nanowell plate lane
- Dilution factor
- Kit ID
- Partitioning flags

If you choose several nanowell plate lanes, **Multiple** is displayed in some fields, e.g., for the sample ID.

To display the **Sample settings:** combo box, on the **Sample setup** screen, choose a tile twice.

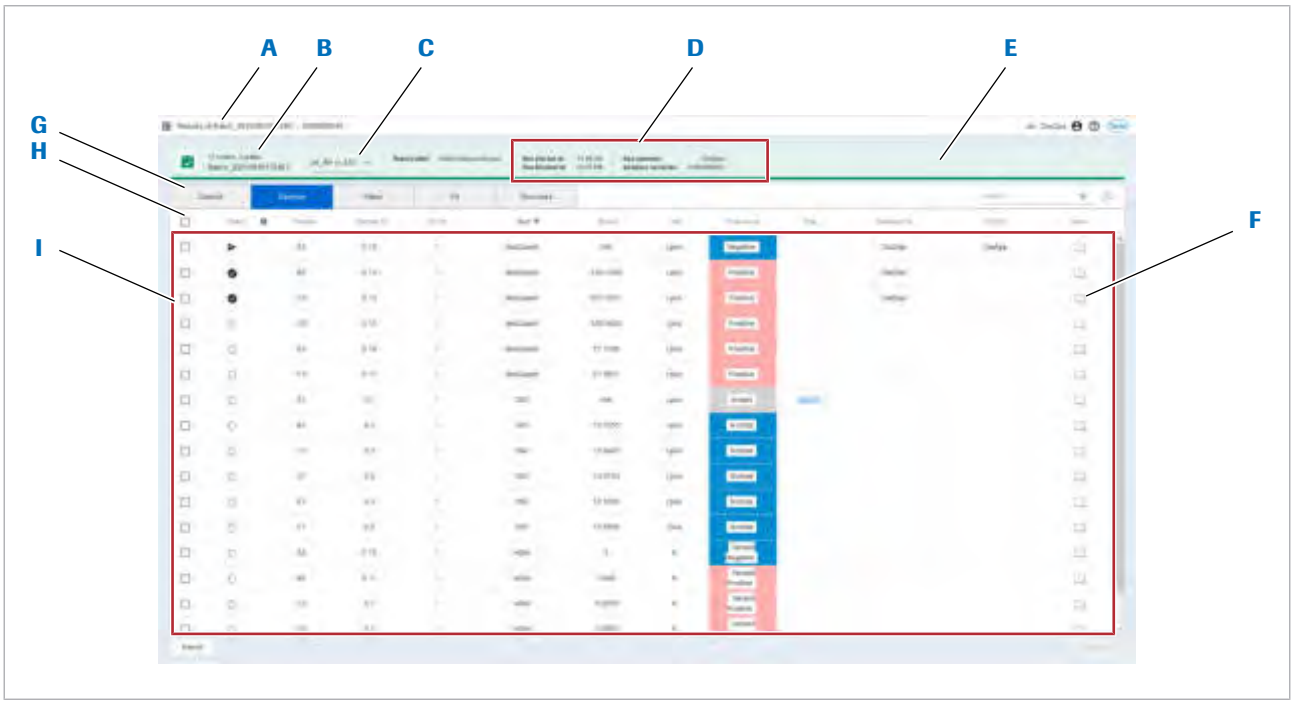
About the positions of nanowell plate lanes in sample setups (153)

About the Results of screen

The **Results of** screen displays the results for a processed batch after the diagnostic run on the analyzer is finished.

The **Samples** tab on the **Results of** screen displays 1 row per processed order.

The screen name is appended with the batch name, e.g., "Results of Batch_YYYYMMDDhhmmss".



A Screen name and run name
B Details of sample setup
C Drop-down list for analysis packages
D Run details
E Color-coded screen header
F Notes indicator
G Row with tabs
H Row with columns headers
I Results table

Results of screen

On the **Results of** screen, the results are ordered as follows:

1. By analysis package:
   To access the results for a specific analysis package, choose the analysis package from the drop-down list.
2. By tabs:
   To access results and run information, choose a tab:
   - **Controls**
     Lists results for controls (1 row only for a set of merged lanes).
   - **Samples**
     Lists results for samples (1 row only for a set of merged lanes).
   - **Plates**
     Lists the used nanowell plates.
   - **Kits**
     Lists the used IVD kits if the information was added to the sample setup.
   - **Run notes**
     Lists run notes if they were added to the sample setup.

3. By columns:
   The information is ordered in columns. You can sort by columns.

To reach the result that you want to access, navigate through this hierarchy or use the search function.

About header colors

The header on the **Results of** screen has the same color as the tiles in the **Results** column on the dashboard:

Light-green:

- There are results that are not released and/or sent yet.
- The batch is processed, but not completed.
- There is a corresponding batch tile in the **Results** column on the dashboard.

Light-brown:

- All results are released and sent.
- The batch is completed.
- There is no corresponding batch tile in the **Results** column on the dashboard anymore. The batch is listed on the **Completed batches** screen.

About the result status in the web application

In the web application, results for samples can be in the following statuses:

Pending release

Pending send

Send queued

Sent

Results for orders with analysis packages in **In validation** status have no status icon.

The result status applies to samples only.

The following applies:

- Results are **incomplete** if they are in **Pending release** status or **Pending send** status.
- Results are **complete** if one of the following applies:
  - The results are in **Send queued** status or **Sent** status.
  - The results are for orders with analysis packages in **In validation** status. You cannot release or send such results, and they have no status icon.

The **{count} completed** result status on the batch tile summarizes the results that are in **Send queued** status or **Sent** status on the **Samples** tab on the **Results of** screen.

About the batch tiles (93)

On the **Results of** screen in the web application, the result status for samples is displayed in the **Status** column on the **Samples** tab.

To display a callout with the status legend, in the **Status** column header on the **Samples** tab, choose the icon.

About final results (173)

Releasing results manually in the web application (265)

Sending results manually in the web application (267)

Sending results again in the web application (538)

Navigating to the Results of screen

To display the **Results of** screen for a batch, do one of the following:

- For batches with at least 1 result that is incomplete: In the **Results** column on the dashboard, choose the batch tile.
- For batches with complete results only: In the **Results** column on the dashboard, choose the **Completed batches** tile. On the **Completed batches** screen, choose the batch and choose the **View** button.

Results are complete if they are released and sent, or if they are for orders with analysis packages in **In validation** status.

About the result status in the web application (102)

About final results

Final results are displayed on the **Results of** screen as follows:

- Final quantitative results are displayed in the **Result** column (with the corresponding unit in the **Unit** column).
- Final qualitative results are displayed in the **Final result** column.

The final qualitative results of samples are color-coded, i.e., the result names are underlaid with the corresponding color.

About final results (173)

About color-coding of final results for samples (149)

About the notes indicator

The notes indicator is displayed in the **Notes** column on the **Controls** tab and the **Samples** tab.

The notes indicator indicates if a sample or control has notes:

No notes.

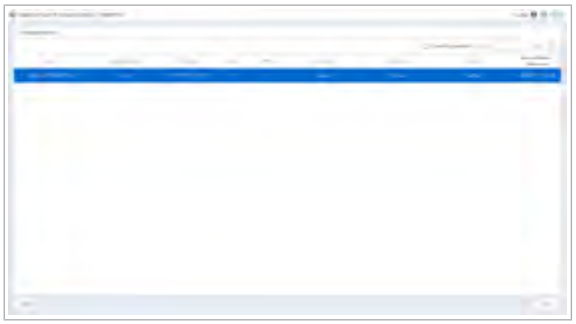
There are notes.

To add, edit, or delete notes, choose the notes indicator.

Viewing, adding, editing, and deleting result notes (263)

About the Completed batches screen

The **Completed batches** screen lists all batches on the system that have complete results only.



If all results of a batch are complete, i.e., released and sent, the batch is completed.

A batch is immediately listed on the **Completed batches** screen after the diagnostic run is finished if one of the following applies:

- The system is configured to release and send results automatically.
- All orders of the batch were for analysis packages in **In validation** status.

To display the **Completed batches** screen, in the **Results** column on the dashboard, choose the **Completed batches** tile.

To display the **Results of** screen of a completed batch, on the **Completed batches** screen, choose the batch and choose the **View** button. The screen header of the **Results of** screen is color-coded.

About header colors (102)

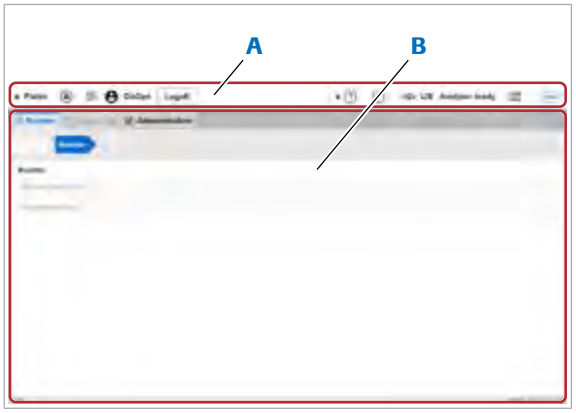
Searching on the Completed batches screen

To search for runs by batch information, enter the search term in the **Search** field.

To search for runs by sample IDs that were processed in the run, select the **Search by sample ID** check box and enter the sample ID in the **Search** field.

Overview of the analyzer software

You access the analyzer software and operate the analyzer via the user interface.



A Global information area **B** Work area

The user interface of the analyzer software consists of the following elements:

- Global information area
- Work area

In this section

About the global information area of the analyzer software

The global information area of the analyzer software provides functions and information that are always available.

A **Plates** button
B Button to open and close the nanowell plate stack drawer
C Message indicator
D Logon indicator
E **Log on** button or **Log off** button
F User Assistance
G Shutdown button
H Connection indicator
I Analyzer status indicator
J Screenshot button

Global information area of the analyzer software

The global information area is always displayed and contains the following elements:

- **Plates** button
- Button to open and close the nanowell plate stack drawer
- Message indicator
- Logon indicator
- **Log on** button / **Log off** button (depending on logon status)
- Shutdown button
- User Assistance
- Connection indicators
- Analyzer status indicator
- Screenshot button

About the Plates button

To display the **Plates** panel and to hide it again, choose the **Plates** button.

You do not need to be logged on to display the **Plates** panel.

About the Plates panel (112)

About the button to open and close the nanowell plate stack drawer

To open or close the nanowell plate stack drawer, choose the button.

If you open the nanowell plate stack drawer, the **Plates** panel is displayed automatically.

Whenever you close the nanowell plate stack drawer, the analyzer attempts to read the barcode labels of loaded nanowell plates and refreshes the **Plates** panel.

You can only open and close the drawer if the analyzer is in **Analyzer ready** status.

You do not need to be logged on to open or close the nanowell plate stack drawer.

Loading the analyzer (225)

Unloading the analyzer (227)

About the message indicator

To display the messages panel and to hide it again, choose the message indicator.

The message indicator is color-coded if a user is logged on to the analyzer software. If no user is currently logged on, the message indicator is unavailable.

The color of the message indicator corresponds to the unconfirmed message with the highest severity:

Red:
There is at least 1 unconfirmed error message.

Orange:
There is at least 1 unconfirmed warning message.

White:
There are only confirmed error and/or warning messages, and/or there are only information messages.

The color of the message indicator is updated immediately when a corresponding event occurs or when you confirm messages.

About the messages panel (121)

Messages in the analyzer software (509)

About the logon indicator

The logon indicator displays the full name of the currently logged on user.

User management (545)

About the Log on button and the Log off button

To log on to the analyzer, choose the **Log on** button.

To log off from the analyzer, choose the **Log off** button.

Starting up the analyzer (235)

Logging on to the analyzer software (236)

Logging off from the analyzer software (439)

Shutting down the analyzer (440)

About the User Assistance

To display the User Assistance and to hide it again, choose the ? button.

The User Assistance is context-sensitive and displays information about the panel you are currently using.

About the User Assistance (47)

About the shutdown button

To shut down the analyzer and the analyzer software, choose the ⏻ button.

The ⏻ button is only available if the nanowell plate stack drawer is closed and the analyzer is in **Analyzer not initialized** status, **Analyzer ready** status, or **Analyzer paused** status.

Shutting down the analyzer (440)

About the connection indicators

If the system is connected to an LIS and/or to AVENIO Connect, a corresponding connection indicator displays the status and type of the connection.

The connection indicator displays the connection status:

- Connection is configured.
- Last communication was successful, i.e., the connection is working.

- Connection is configured.
- Last communication was unsuccessful, i.e., the connection is not working.

The connection indicator displays the connection type next to the connection status:

- **LIS**
- **AVENIO Connect**

The connection indicators for an LIS connection and an AVENIO Connect connection are displayed separately.

If a connection is not configured, the corresponding connection indicator is not displayed.

Overview of the connections (67)

Connection settings (569)

About the analyzer status indicator

The analyzer status indicator displays the current status of the analyzer:

- **Analyzer not initialized**
- **Analyzer initializing**
- **Analyzer ready**
- **Analyzer processing**
- **Archiving**

- **Backup**
- **Analyzer paused**
- **Error**
- **Analyzer connected**
- **Analyzer disconnected**
- **Analyzer performing maintenance**
- **Analyzer offline**
- **Analyzer starting up**
- **Analyzer pre-initialized**
- **Analyzer shutting down**
- **Software starting up**

If the analyzer status changes, the analyzer status indicator is updated immediately.

If the analyzer status changes to **Error** status, the message indicator will turn red and a corresponding error message will be displayed in the messages panel.

About the message indicator (108)

About the messages panel (121)

About the screenshot button

To take a screenshot of the currently displayed panel, choose the button.

The button is also available on messages callouts.

The screenshots are saved automatically on the analyzer and listed on the **Manage screenshots** panel. You can export and delete the screenshots.

The screenshots are also included in custom problem reports.

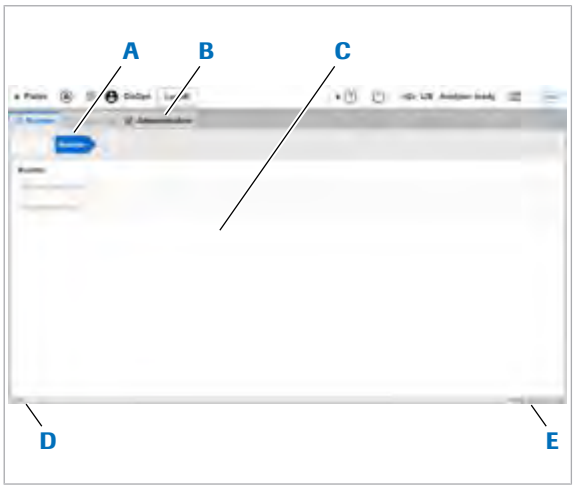
Managing screenshots in the analyzer software (447)

About the message callouts (510)

Problem reports on the analyzer (512)

About the work area of the analyzer software

The work area is the center of your activities when working with the analyzer software.



A Navigation bar
B Tabs
C Panel
D Software version
E Date and time

The work area contains the following elements:

- Tabs
- Navigation bar with back button, forward button, and breadcrumb
- Panel
- Software version
- Date and time

About the tabs

A tab groups related tasks, e.g., all administration tasks. It depends on your user role which tasks you can access from the tabs.

The work area contains the following tabs:

- **Routine**
- **Monitoring** (only available during a run)
- **Administration**

Each tab has the navigation bar at the top and displays the panels.

About the panels in the analyzer software (112)

About the navigation bar

The navigation bar contains the following navigation elements:

- Back button < and forward button >:
  - While navigating through the work area, each location is stored automatically in a browse history.
  - To browse the history, choose the < button and the > button.
- Breadcrumb:
  - The path from the tab to the current location is displayed as a breadcrumb.
  - The first element in the breadcrumb is the tab.

- The blue element in the breadcrumb is the current location.
- Choose an element of the breadcrumb to go back to that location.

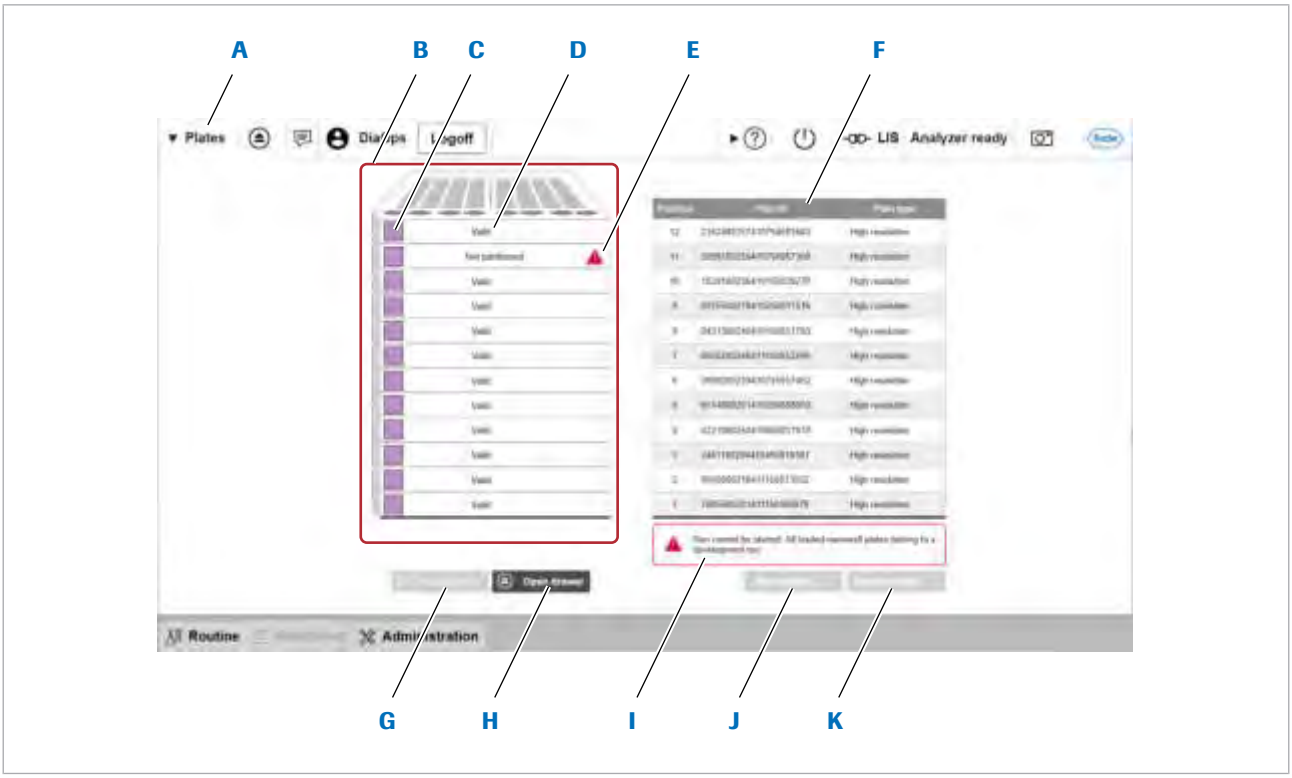
About the panels in the analyzer software

A panel in the analyzer software is an organizational unit within a tab and groups information and related software functions.

In this section

About the Plates panel

The **Plates** panel displays the loading status of the analyzer and the plate status of the loaded nanowell plates.



A **Plates** button
B Nanowell plate stack
C Color-coding of nanowell plate type
D Status of loaded nanowell plate
E Error indicator for nanowell plate
F Table of nanowell plates with position, nanowell plate ID, and nanowell plate type
G **Manual entry** button
H **Open drawer** button / **Close drawer** button
I Error indicator and error description for run prerequisites
J **Run profile** button for development runs
K **Sample setup** button for diagnostic runs

Plates panel

To display and to hide the **Plates** panel, in the global information area of the analyzer software, choose the **Plates** button.

When you open the nanowell plate stack drawer, the **Plates** panel is displayed automatically in the analyzer software.

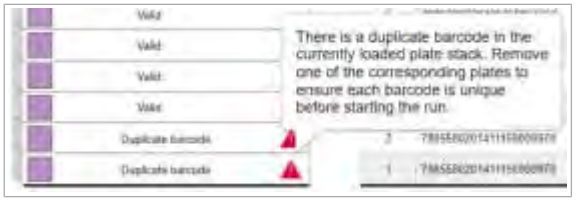
To read the barcode labels of the loaded nanowell plates again and refresh the **Plates** panel, open and close the nanowell plate stack drawer.

After closing the nanowell plate stack drawer, the analyzer reads the barcode labels of the loaded nanowell plates and performs a series of consecutive checks. For example, for flags sent from the partitioning engine.

About the nanowell plate status

Depending on the outcome of the checks, a loaded nanowell plate can be in the following statuses:

- **Barcode scan failed**
- **Invalid barcode**
- **Duplicate barcode**
- **Expired**
- **Results already exist**
- **Not partitioned**
- **Valid**



For each plate that is not in **Valid** status, an error indicator is displayed. To display a callout with additional information, choose the error indicator.

You can only start the run if all nanowell plate loading errors are resolved so that all loaded nanowell plates are in **Valid** status, and if the other prerequisites for the run are met.

Nanowell plate loading errors on the analyzer (520)

About run prerequisites

If any of the run prerequisites are not met, an error indicator and error description are displayed below the table of nanowell plates.

About run prerequisites (172)

About the Manual entry button

The **Manual entry** button is only available if the following applies:

- A nanowell plate ID could not be read by the analyzer.
- The nanowell plate is in **Barcode scan failed** status.
- The nanowell plate stack drawer is closed.

Resolving a nanowell plate ID reading error (521)

About the Open drawer button and the Close drawer button

The **Open drawer** button or **Close drawer** button is only available if the analyzer is in **Analyzer ready** status.

About the Run profile button

The **Run profile** button is only available if the prerequisites for a development run are met.

Prerequisites for a development run (172)

About the Sample setup button

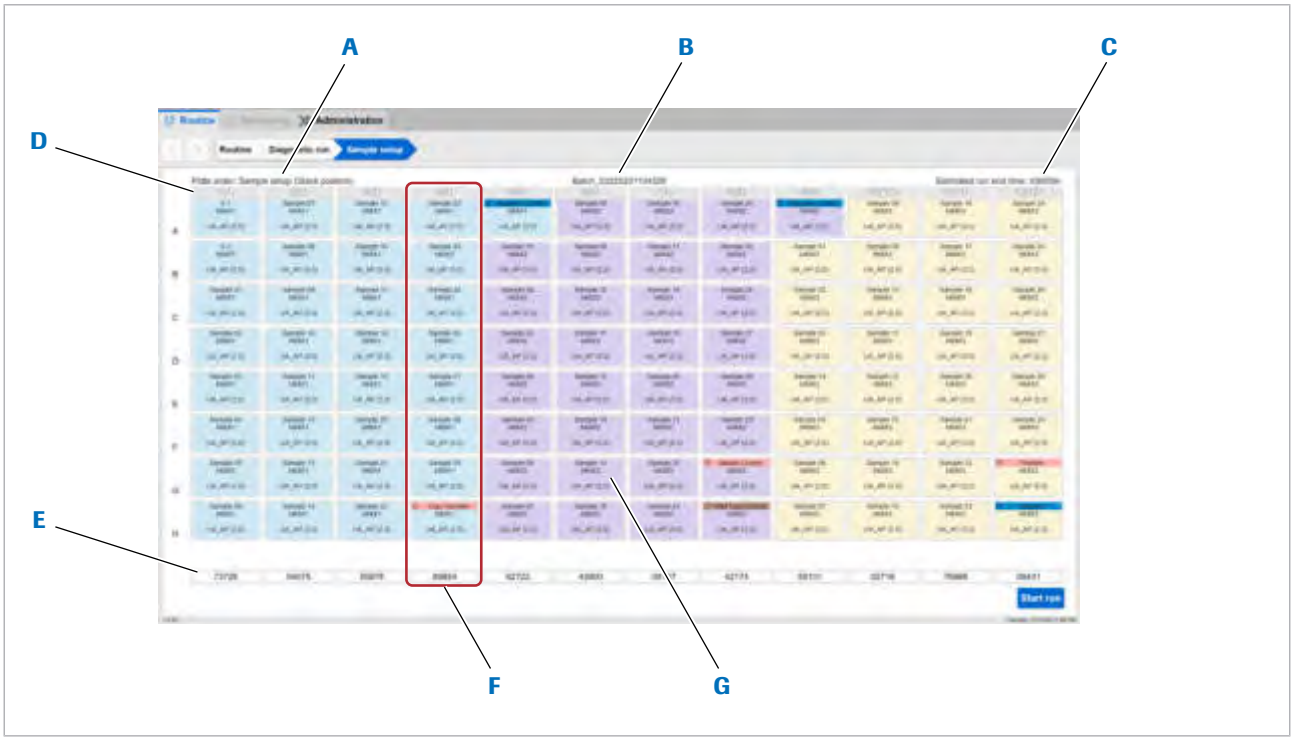
The **Sample setup** button is only available if the prerequisites for a diagnostic run are met.

Prerequisites for a diagnostic run (172)

About the Sample setup panel

The **Sample setup** panel displays the sample setup for a diagnostic run that was received from the web application.

The **Sample setup** panel is read-only.



A Legend for nanowell plate order
B Batch name / run name
C Estimated end time
D Column header
E Column footer
F Column for 1 nanowell plate
G Tile for 1 nanowell plate lane

Sample setup panel

The **Sample setup** panel in the analyzer software displays the same information as the **Sample setup** screen in the web application:

- Batch name as defined in the web application (used as name of the diagnostic run on the analyzer)
- Estimated end time
- Sample setup in plate view:
  - 1 column per nanowell plate with column header and column footer
  - 1 tile per nanowell plate lane, i.e., reaction mixture

Invalidated nanowell plate lanes or nanowell plates are grayed out.

The nanowell plates on the **Sample setup** panel are displayed in the same order as in the sample setup in the web application, not in the actual loading order on the analyzer. This is to facilitate the verification of the loaded sample setup against the sample setup report from the web application.

The **Sample setup** panel is displayed automatically after loading the analyzer if the prerequisites for a diagnostic run are met.

If you left the **Sample setup** panel, to navigate back to it, do one of the following:

- On the **Plates** panel, choose the **Sample setup** button.
- Choose **Routine > Diagnostic run > Sample setup**.

If the analyzer is in **Analyzer ready** status, the **Start run** button is available on the **Sample setup** panel.

About run prerequisites (172)

About sample setups in plate view (150)

About the Sample setup screen (97)

About the column headers on the Sample setup panel

In the analyzer software, the column header displays the positions of the nanowell plate in the sample setup and in the nanowell plate stack, e.g., "1(1)":

- The first number is the position of the nanowell plate in the sample setup (as displayed in the column header on the **Sample setup** screen in the web application).
- The second number in brackets is the position of the nanowell plate in the stack as currently loaded on the analyzer.

The corresponding legend
Plate order: Sample setup (Stack position)
for the displayed nanowell plate positions is displayed at the top left of the **Sample setup** panel.

The positions of the nanowell plates in the stack are numbered from bottom to top:

- Nanowell plate 1 is at the bottom of the stack
- Nanowell plate 12 is at the top of the stack

If the denoted positions of a nanowell plate do not match, the numbers in the column header differ.

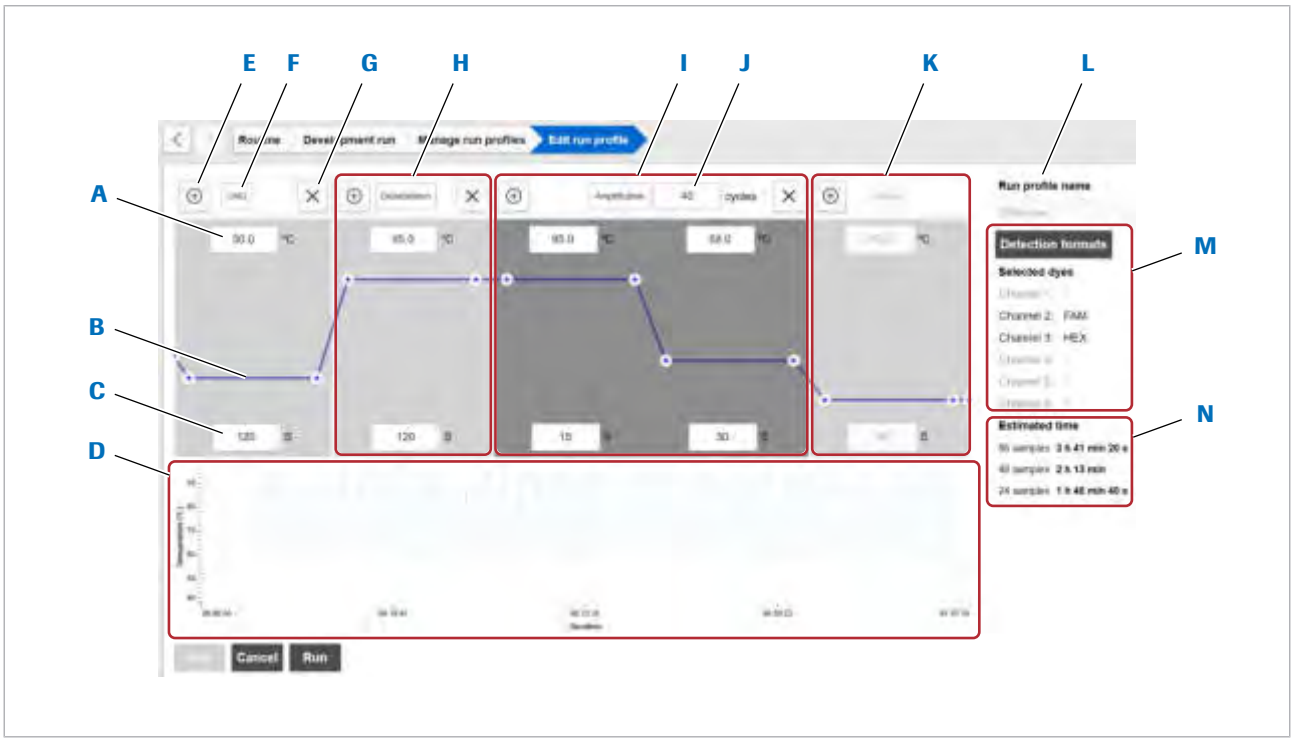
If a nanowell plate was invalidated by the partitioning engine or in the web application, and is not loaded on the analyzer, a hyphen is displayed in the brackets instead of the position of the nanowell plate in the stack. (The column for the nanowell plate is still displayed on the **Sample setup** panel.)

About the positions of nanowell plate lanes in sample setups (153)

About the Edit run profile panel

For development runs, the **Edit run profile** panel displays a visual representation of a run profile and allows you to edit unlocked run profiles.

You cannot edit locked run profiles on the **Edit run profile** panel.



A Temperature of the step [in °C]
B Temperature curve
C Duration of the step [in seconds]
D Temperature chart of the run
E Add program button
F Name of the program
G Delete program button
H Incubation program
I Amplification program
J Number of PCR cycles
K Mandatory cooling program
L Run profile name
M Detection formats
N Estimated run duration depending on number of samples

Edit run profile panel

Each run profile is a progression of the following programs:

- Incubation programs
- Amplification programs
- Cooling program

Editing run profiles on the Edit run profile panel in the analyzer software (303)

About incubation programs

A run profile can contain up to 5 incubation programs.

An incubation program has a temperature and the duration for which the temperature is kept after it is reached.

The default values for an incubation program are as follows:

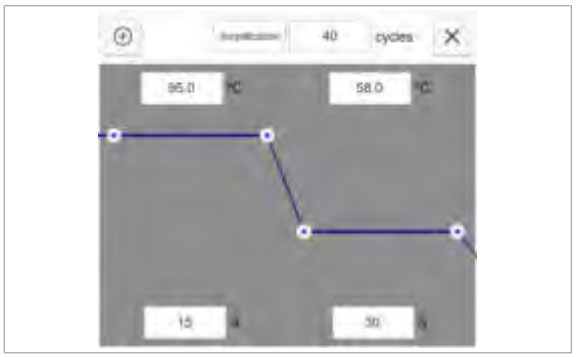
- Name: **Incubation**
- Temperature: 95 °C

- Duration: 120 s

About amplification programs

A run profile can contain up to 5 amplification programs.

An amplification program can contain 2 or 3 steps.



A **2-step amplification program** is a sequence of 2 steps with different temperatures and durations, and the number of PCR cycles that the analyzer repeats the sequence.

The default values for a 2-step amplification program are as follows:

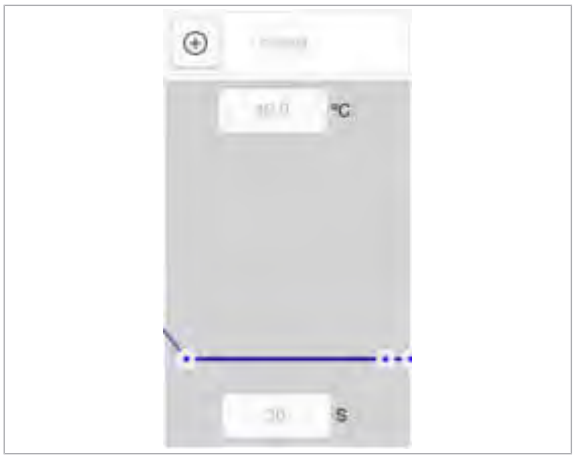
- Name: **Amplification**
- Number of PCR cycles: 40
- Step 1:
  - Temperature: 95 °C
  - Duration: 10 s
- Step 2:
  - Temperature: 60 °C
  - Duration: 20 s

A **3-step amplification program** is a sequence of 3 steps with different temperatures and durations, and the number of PCR cycles that the analyzer repeats the sequence.

The default values for a 3-step amplification program are as follows:

- Name: **Amplification**
- Number of PCR cycles: 40
- Step 1:
  - Temperature: 95 °C
  - Duration: 10 s
- Step 2:
  - Temperature: 60 °C
  - Duration: 15 s
- Step 3:
  - Temperature: 72 °C
  - Duration: 15 s

About the cooling program



Each run profile contains a mandatory cooling program at the end that cannot be edited or deleted.

The values for the cooling program are as follows:

- Name: **Cooling**
- Temperature: 40 °C
- Duration: 30 s

About the detection formats

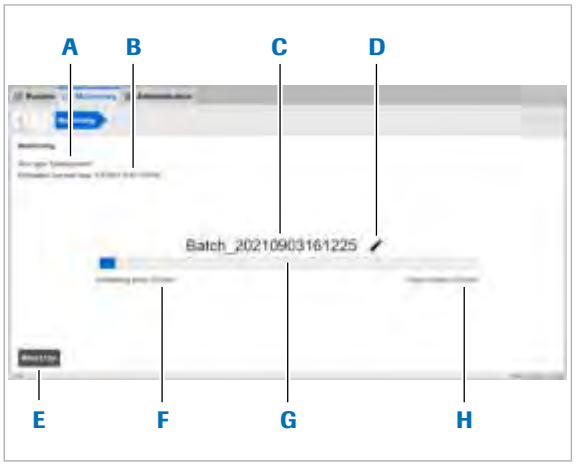
The detection formats define the channels, the dye per channel, and the integration time for the detection of fluorescence by the analyzer.

The following applies:

- Enable the channels for all dyes that are contained in any of the master mix reagents used in the development run.
- Disable the channels for dyes that are not contained in any of the master mix reagents used in the development run. Disabling empty channels shortens the run time, reduces the size of the raw data file, and enhances the performance of the development software.
- You cannot use different dyes that are detected in the same channel in 1 development run.

About the Monitoring panel

During a run on the analyzer, the **Monitoring** panel displays run-specific information and a progress indicator.



A Run type
B Estimated end time
C Run name
D Button to edit run name and to add run notes
E **Abort run** button
F Estimated remaining run duration
G Progress indicator
H Estimated run duration

The **Monitoring** panel is displayed automatically after a run is started on the analyzer.

The ✎ button to edit the run name and/or to add run notes is only displayed during a development run.

The progress indicator on the **Monitoring** panel is color-coded:

Blue:
Run is processing.

Green:
Run is completed.

Red:
Run is aborted.

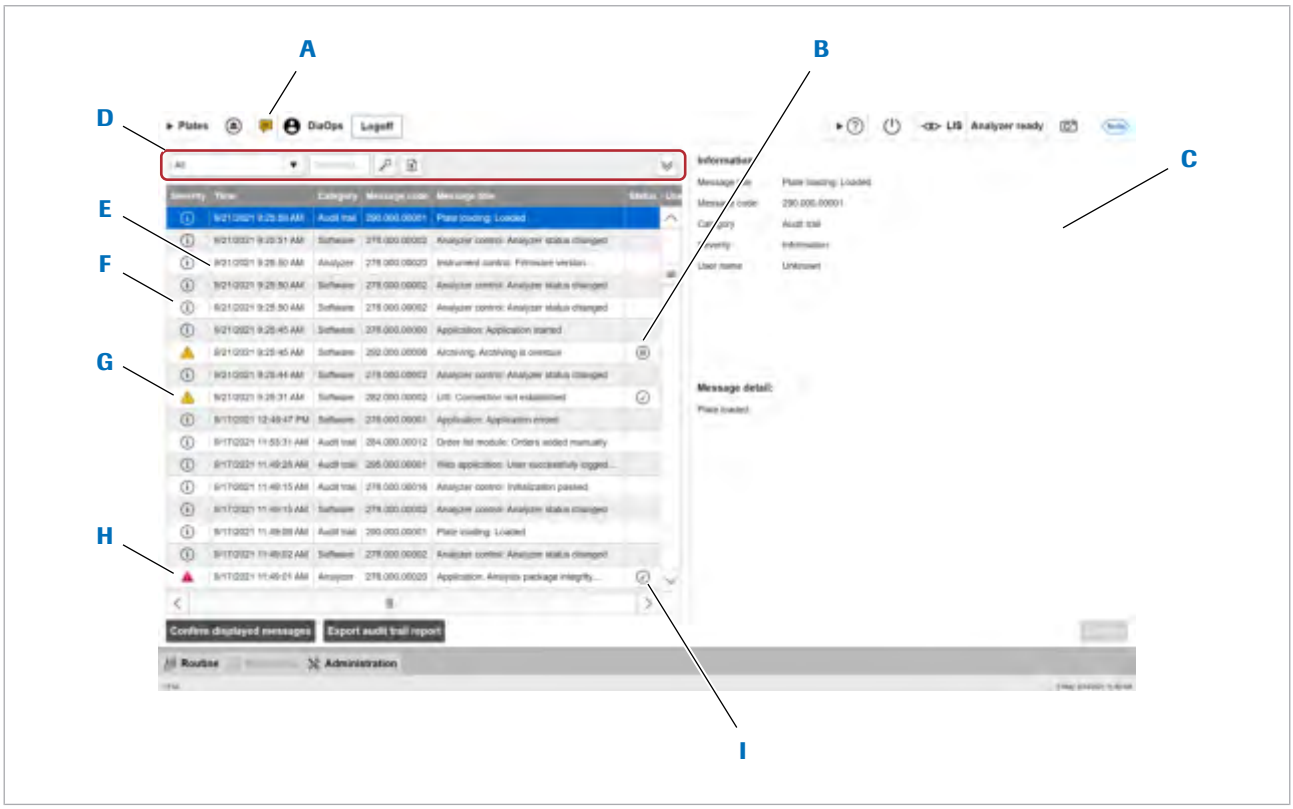
About the messages panel

By default, the messages panel displays the unconfirmed messages. If there are no unconfirmed messages, the messages panel displays all messages.

You can also display the audit trails on the messages panel because the system displays audit trails as information messages.

To display and to hide the messages panel, in the global information area of the analyzer software, choose the message indicator.

To display the details of a message, choose the message.



A Message indicator
B Icon indicating unconfirmed message
C Detail panel
D Sort, filter, configure columns, and export
E Messages table
F Icon indicating information message
G Icon indicating warning message
H Icon indicating error message
I Icon indicating confirmed message

Messages panel

Audit trails in the analyzer software (449)
Messages in the analyzer software (509)

About the severity icons

An icon in the **Severity** column of the messages table indicates the severity of the messages:

Red:
Error message

Yellow:
Warning message

Information message

The color-coding of the icons match the color-coding of the message indicator in the global information area.

About the message indicator (108)

About the status icons

An icon in the **Status** column of the messages table indicates the status of messages that need confirmation:

Unconfirmed message

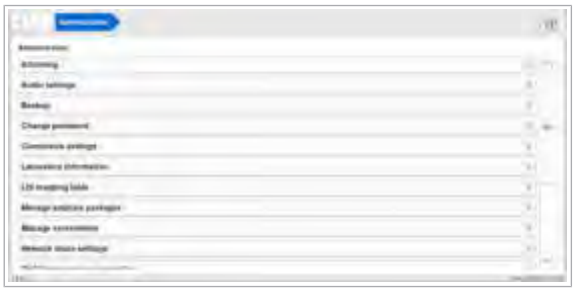
Confirmed message

If there is no icon displayed in the **Status** column, the message does not need confirmation.

Displaying and confirming messages in the analyzer software (511)

About the Administration panel

The **Administration** panel displays the task buttons to perform administrator tasks.

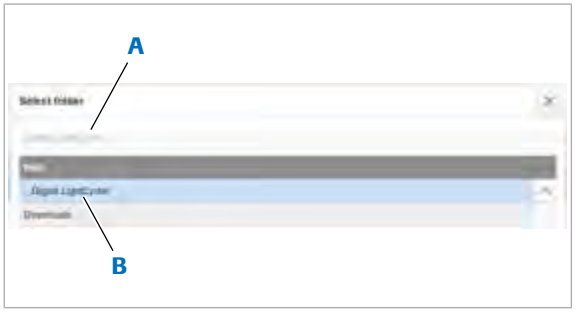


You need administrator user role to perform most administrator tasks on the **Administration** panel. However, you can change your password, manage screenshots, and handle problem reports with any user role on the **Administration** panel.

About the file and folder browsers

Whenever you choose a folder to export or save a file, a folder browser is displayed in a dialog box in the analyzer software. Whenever you choose a file for import from a folder, a file browser complements the folder browser.

About the folder browsers



A Current path **B** First entry

The folder browsers allow you to navigate the folder trees to choose a folder.

For folder browsers, the following rules apply:

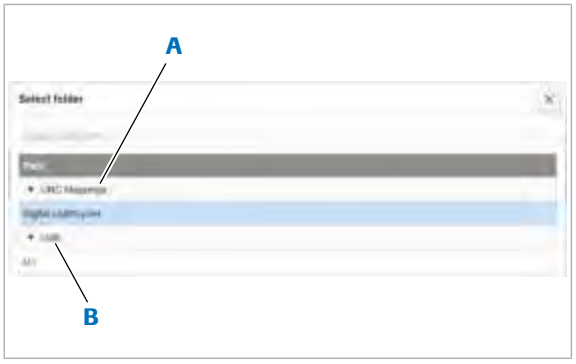
- To go down a level in the folder tree, double-click an entry.
- To go up a level in the folder tree, do one of the following (depending on availability):
  - Double-click the first entry (starting with "..").
  - Choose the < button.
- The current path is displayed in a field.

- The last selected folder is retained:
  The folder you selected the last time for a function is preselected the next time the folder browser is displayed for the same function.
- If you create a folder, the folder name can consist of 1 to 30 characters. The name must not contain the following characters:
  ? * < > / \ : " | ’

Do not create folders in network shares in a folder browser. Instead, create all necessary folders and subfolders in the network and include them in the UNC path for the network share.

Network share settings (591)

About the top level of the folder browser



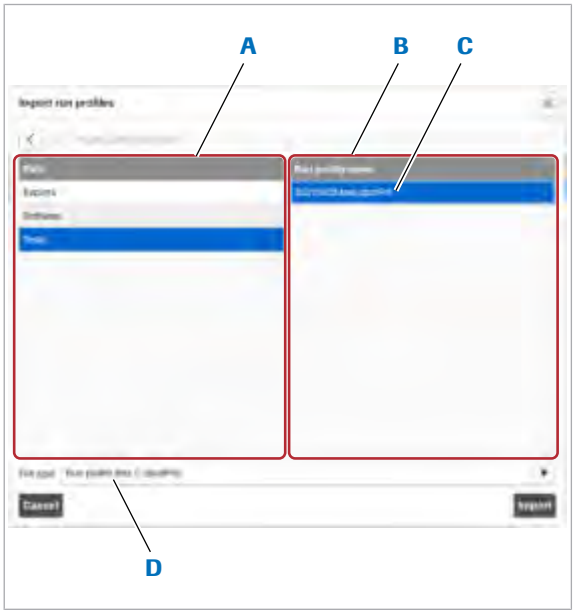
A Network shares
B External storage devices

On the top level of the folder browser, the following groups are displayed:

- **UNC Mappings**:
  Lists all network shares configured on the analyzer.
- **USB**:
  Lists all external storage devices currently connected to the analyzer.

To go down in the folder tree, double-click an entry in a group.

About the file browsers



A Folder browser
B File browser
C File for import
D Importable file types

The file browsers allow you to choose a file for import after you navigated to a folder in the folder browser.

For file browsers, the following rules apply:

- The file types that can be imported are displayed in a drop-down list.
- The file browser lists the importable files that are located in the folder that is currently selected in the folder browser.

About the virtual keyboard

Use the virtual keyboard for data entry.

Whenever input is required, the virtual keyboard is displayed automatically.

To toggle between the alphanumeric and the numeric keyboard, choose the **123** button or the **Text** button, respectively.

To hide the virtual keyboard, choose the ✕ button.

The layout of the virtual keyboard depends on the active language package in the analyzer software.

User Assistance and language settings (607)

Overview of the development software

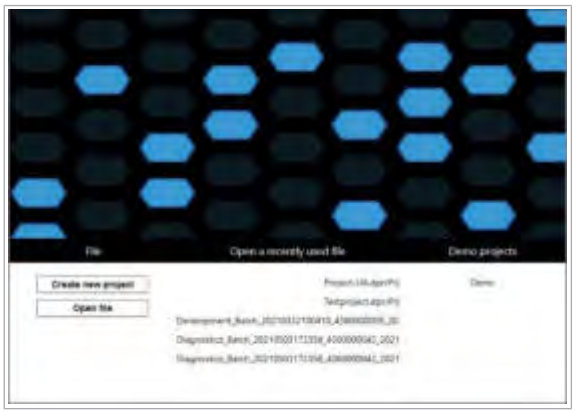
The development software is a dedicated software to plan development runs, to analyze development runs and diagnostic runs, and to create analysis packages.

A project in the development software can contain up to 50 analyses, allowing for an iterative approach.

In the development software, the language of the user interface and the User Assistance is determined by the Windows language settings.

The development software can be installed on a standalone computer or on a server.

Computer specifications (187)



After starting the development software, the start page is displayed.

On the start page, you can do the following:

- Create a project.
- Open a file.

A Header
B **Navigation** area
C Work area

After performing an action on the start page, the project page of the development software is displayed.

The project page consists of the following elements:

- Header with file or project name
- **Navigation** area
- Work area

The active or selected element is highlighted in blue.

Projects in the development software (294)

In this section

About the Navigation area of the development software

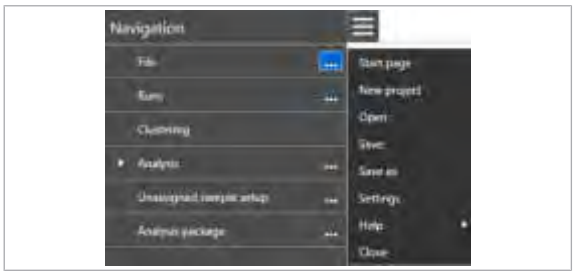
The **Navigation** area of the development software provides menus and commands that are always available.

The **Navigation** area contains the following menus:

- **File**
- **Runs**
- **Clustering**
- **Analysis**
- **Unassigned sample setup**
- **Analysis package**

To hide the **Navigation** area, choose the button at the top left of the work area. To display the **Navigation** area again, choose the button at the top left of the work area.

About the menu commands



To display the menu commands, choose the button next to the menu name. The availability of commands depends on the status of the project.

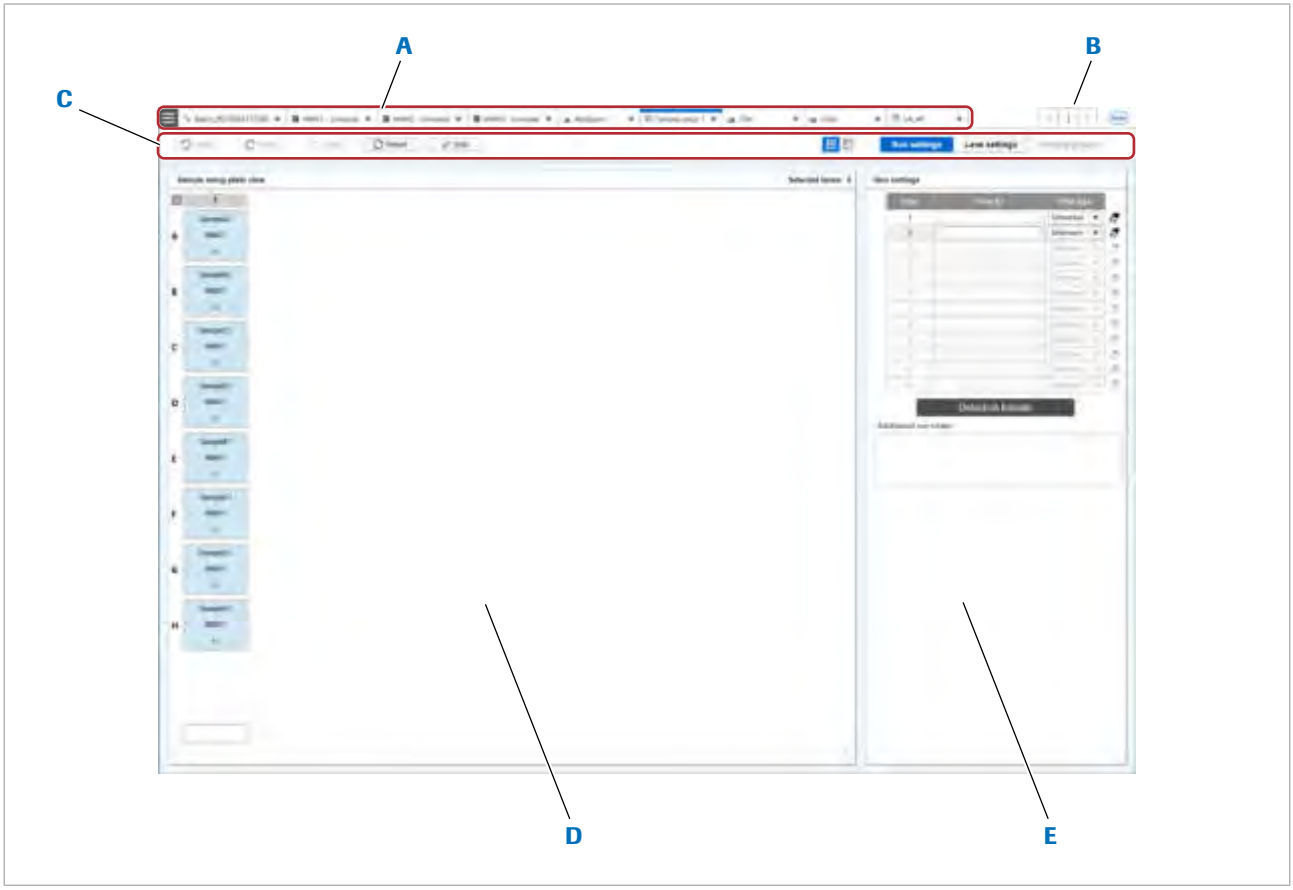
About the work area of the development software

The work area of the development software displays all data and functions that belong to 1 project.

The work area contains the following elements:

- Tabs

- Tab navigation buttons
- Buttons
- Cards



A Tabs
B Tab navigation buttons
C Buttons
D **Sample setup plate view** card
E **Run settings** card

Work area of the development software

In the work area, several tabs of the same sort can be displayed (e.g., several clustering tabs).

You can arrange the tabs in the work area:

- To close a tab, choose its ✕ button.
  To display the tab in the work area again, choose its entry from the corresponding menu in the **Navigation** area.
- To display the **Start page** tab, choose **File** > ••• > **Start page**.
- To change the order of the tabs, drag and drop the tabs horizontally.
- To detach a tab, i.e., to display the tab in a separate window, drag and drop the tab vertically.
  To reattach the tab, i.e., to display it in the work area again, close the window and reopen the tab from the **Navigation** area.

About the tab navigation buttons

Use the tab navigation buttons to access the tabs:

- To scroll the tabs to the right or left, choose the ◀ button or the ▶ button, respectively.
- To navigate to a certain tab, choose the ⋮ button. From the drop-down list, choose the tab.
- To close all tabs, choose ⋮ > **Close all tabs**.

The ◀ button and the ▶ button are only available if not all tabs are visible.

Tabs in the development software

In the development software, the tabs are displayed in the work area and display the buttons and cards.

In this section

About the tabs in the development software

In the development software, a tab groups information and related software functions that belong to a step of a development workflow.

It depends on the tab which buttons and cards are displayed.

All tabs belong to the same project. To save changes on a tab, you must save the project.

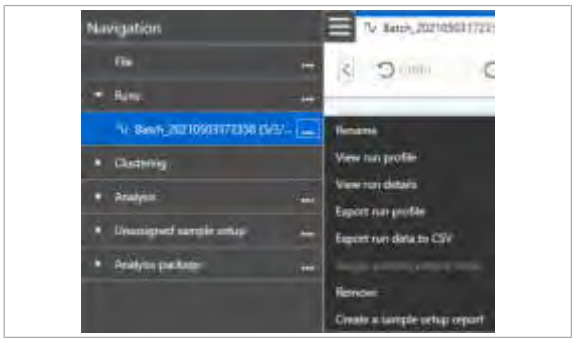
Tabs are listed in the corresponding menu in the **Navigation** area.

If the data on a tab needs to be recalculated, the tab name and the tab entry in the **Navigation** area are displayed in italics.

To trigger the recalculation, choose the tab entry from the **Navigation** area. If several tabs require recalculation, choose the tab entries in the sequence of a development

workflow, i.e., choose the affected tab entries from top to bottom in the **Navigation** area. This is because later steps in the workflow (e.g., an analysis) may be affected by the recalculation of an earlier step (e.g., a clustering).

About the tab commands

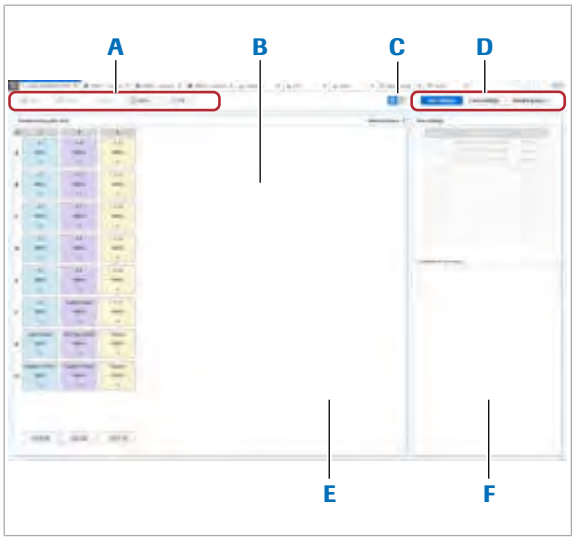


To display the tab commands, in the **Navigation** area, choose the ••• button next to the tab entry in the corresponding menu. The availability of commands depends on the status of your project.

There are no tab commands for clustering tabs.

About the run tabs

A run tab displays the sample setup **after** a run, i.e., after you imported the raw data file of a development run or diagnostic run into the development software.



- **A** Buttons for editing
- **B** Sample setup in plate view
- **C** Buttons for plate and table view
- **D** Buttons for run settings, lane settings, and sample groups
- **E** **Sample setup plate view** card
- **F** **Run settings** card

By default, the run tabs are named "RunName (DD.MM.YYYY hh:mm:ss)" with the date and time when the run was started on the analyzer.

You can rename the run tabs via the tab commands.

In the **Navigation** area, the run tabs are listed in the **Runs** menu. The run tabs are ordered by run date, with the oldest run at the top.

You can display the sample setup on the run tab either in plate view or in table view.

To display the **Run settings** card, the **Lane settings** card, or the **Sample groups** card, choose the corresponding button.

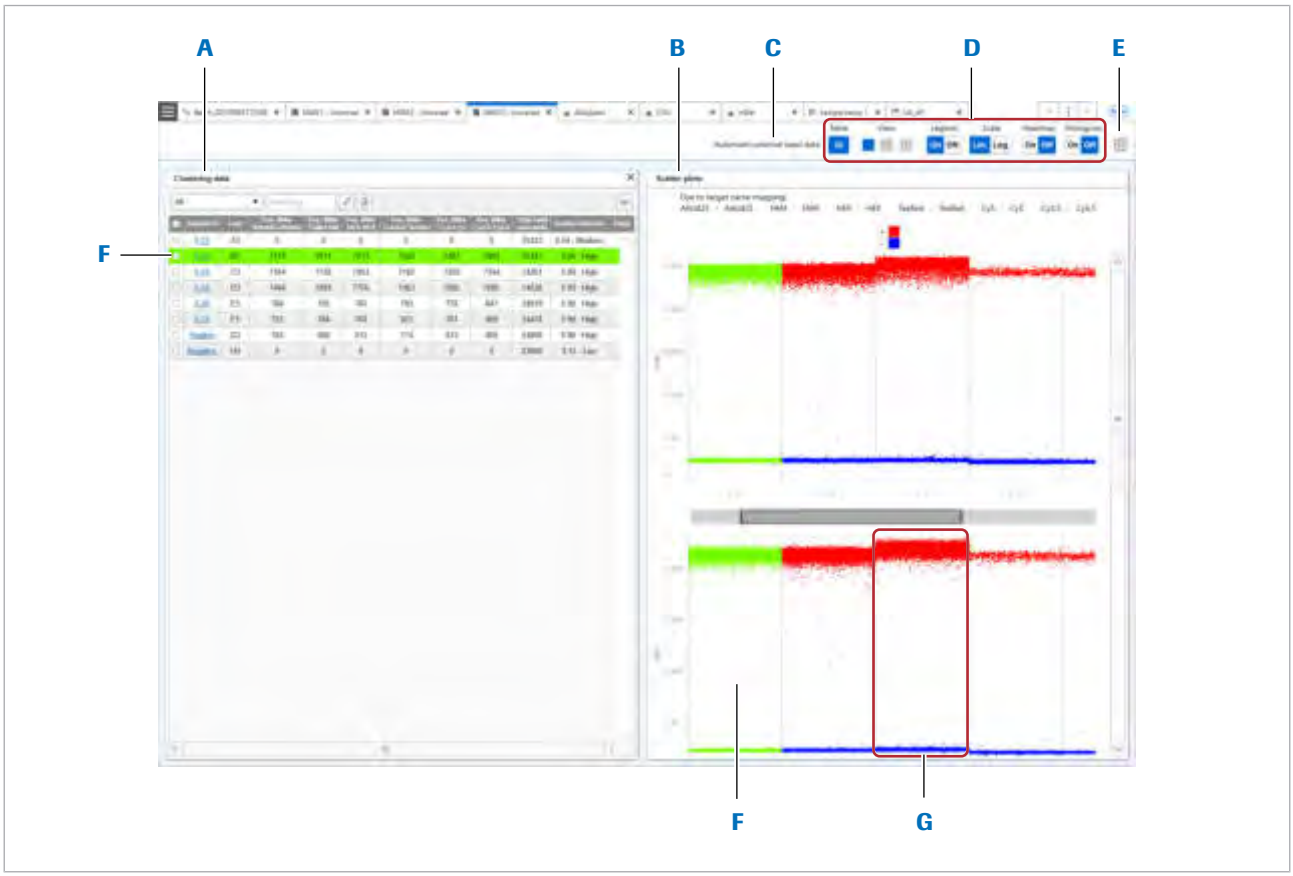
Merged nanowell plate lanes are still processed separately. Therefore, each merged lane is listed individually on a run tab.

- Sample setups in plate view (150)
- List of naming placeholders (154)
- Plate view and table view in the development software (138)

Runs in the development software (309)

About the clustering tabs

A clustering tab displays the clustering for one combination of master mix reagent and nanowell plate type across all runs of a project.



A **Clustering data** card
B **Scatter plots** card
C Clustering method indicator
D Buttons for display options
E Button to display the **Settings** combo box
F Highlighted sample
G Scatter plot from 1 nanowell plate lane

Clustering tab in the development software

The clustering tabs are named "MMx - PlateType".

In the **Navigation** area, the clustering tabs are listed in the **Clustering** menu. The clustering tabs are listed in the order they were added to the project, with the oldest clustering at the top.

There are no menu commands for the **Clustering** menu and no tab commands for the clustering tabs.

Merged lanes are listed individually on a clustering tab and their scatter plots are displayed separately.

List of naming placeholders (154)

Clustering in the development software (338)

About the clustering data table

The clustering data table on the **Clustering data** card displays the samples included in the clustering.

When you mouse over an entry in the clustering data table, the entry and the corresponding scatter points in the scatter plots are highlighted in green.

List of columns on the Clustering data card (339)

About the scatter plots

The scatter plots on the **Scatter plots** card display the fluorescence intensity of each nanowell as separate scatter points. The scatter plot for each nanowell plate lane is displayed separately in a rectangular area.

The axes of the scatter plots depend on the selected scatter plot type (1D, 2D, or 3D).

The buttons above the scatter plots allow you to adjust the display of the scatter plots.

Changing the display options for the scatter plots in the development software (341)

About the clustering method indicator

The clustering method indicator displays the currently applied clustering method.

For the **Manual** clustering method, the **Threshold** button, the **Lasso** button, and the **Spider** button are displayed below the clustering method indicator.

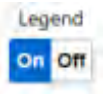
About the display options

To adjust the display, choose the buttons above the scatter plots:

The **Table** button displays or hides the **Clustering data** card.

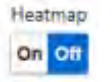
Alternatively, choose the ✕ button at the top right of the **Clustering data** card.

The **View** buttons display the scatter plots for the different channels in 1, 2, or 3 columns.



The **Legend** buttons display or hide the dye to target name mapping and a legend for the color-coding of the scatter plots.

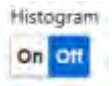
The **Scale** buttons display a linear or a logarithmic scale for the fluorescence axes.



The **Heatmap** buttons display or hide the scatter plots as heatmaps.

The heatmaps are color-coded according to the density of the scatter points:

- green = low density
- red = high density



The **Histogram** buttons display or hide vertical histograms of the scatter points to the left of the corresponding scatter plots.

The histogram displays the intensity distribution of the fluorescence of the scatter plots:

- x-axis = intensity
- y-axis = number of scatter points

The active option is highlighted in blue. Any change in the display applies to all scatter plots.

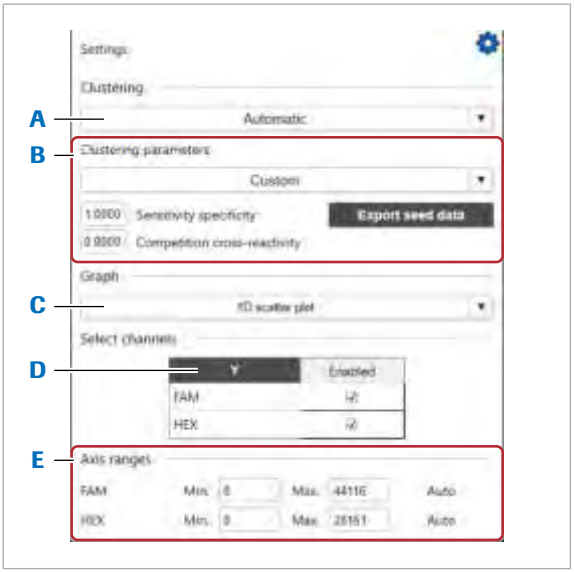
Changing the display options for the scatter plots in the development software (341)

About the button for the clustering settings

To display the **Settings** combo box for the clustering settings, choose the ⚙ button.

Adjusting the clustering in the development software (342)

About the Settings combo box



A Clustering method
B Clustering parameters
C Scatter plot type
D Channels
E Axis ranges

The **Settings** combo box displays the current clustering settings and allows you to change them:

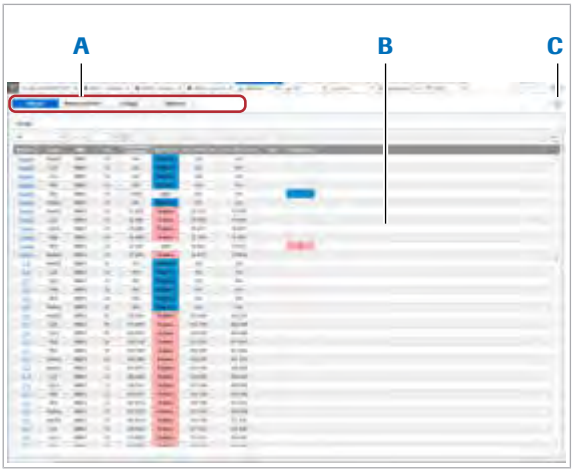
- Clustering method
- Clustering parameters
- Scatter plot type
- Channels displayed in the scatter plots
- Axis ranges for the scatter plots

The availability of the clustering parameters depends on the selected clustering method.

List of clustering settings in the development software (342)

About the analysis tabs

An analysis tab displays the analysis results ordered on separate panels.



A Buttons for panels
B **Results** panel
C Button for analysis settings

By default, the analysis tabs are named "AbsQuant", "CNV", or "InDel" as the analyses and numbered consecutively.

You can rename analysis tabs via the tab commands.

By default, each project contains an **Abs Quant – All** analysis and the corresponding analysis tab that cannot be renamed or deleted.

In the **Navigation** area, the analysis tabs are listed in the **Analysis** menu. The analysis tabs are ordered alphanumerically.

Analyses in the development software (358)

About the panels

The results on an analysis tab are displayed on the following panels:

- **Results**
- **Result overview**

- **Linkage** (for absolute quantification analysis only)
- **Statistics**

To display a panel, choose the corresponding button.

The panels only display results for samples that are included in the analysis.

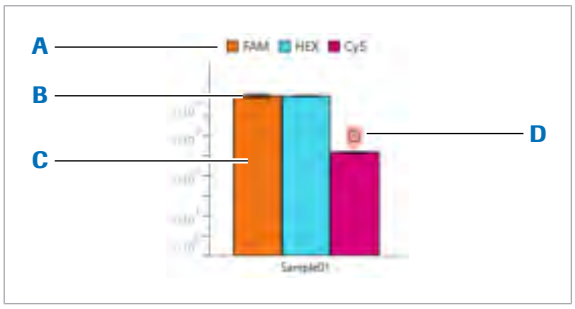
Merged lanes are analyzed together. Therefore, a set of merged lanes has 1 entry on an analysis tab.

The sample ID in the **Sample ID** columns on the panels is a link to the run tab of the run in which the sample was processed. To display the run tab with the sample selected, choose the link.

Do not choose the link to highlight a row in a table on the panels. Choose anywhere else in the row instead.

About the bar charts

On the **Result overview** panel on an analysis tab, you can display the final quantitative results as bar charts.



A Legend
B Error bars
C Bar for target
D Indicator for positive control

For each sample or control that is included in the analysis, a separate bar chart is displayed.

Each bar chart displays 1 bar per target if there is a valid final result for the target and the value is inside the range for displaying quantitative results (if configured).

Each bar includes error bars for the 95% confidence interval.

For negative or invalid final results, and for results that are only displayed qualitatively, no bar is displayed.

A legend is displayed above the bar charts on the **Graph** card.

Bars that represent a control are marked with the icon and the color for controls.

To adjust the display of the bar charts, use the field and buttons above the bar charts. The active option is highlighted in blue.

Any change in the display applies to all bar charts.

About color-coding of controls (148)

Displaying the bar charts (400)

About the button for the analysis settings

To display the **Settings** combo box for the analysis settings, choose the ⚙ button.

Analyses in the development software (358)

About the Settings combo box

The **Settings** combo box displays the current analysis settings and allows you to change them. The analysis settings are ordered on the following tabs:

- **Sample selection**
- **Analysis setup**
- **Controls**
- **Internal controls**
- **Target limits**

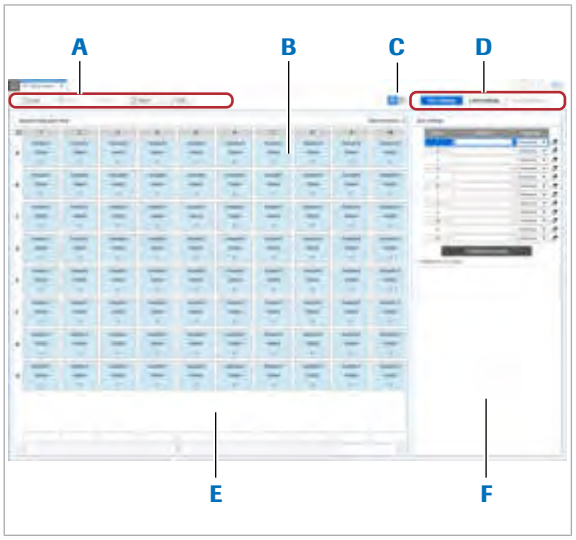
The availability of the tabs depends on the analysis type.

The availability of settings on a tab depends on the current settings on the other tabs.

Analyses in the development software (358)

About the sample setup tabs

A sample setup tab displays an unassigned sample setup **before** a development run, i.e., a sample setup that is used to plan a development run and is not yet assigned to the raw data of a development run.



A Buttons for editing
B Unassigned sample setup in plate view
C Buttons for plate and table view
D Buttons for run settings and lane settings
E **Sample setup plate view** card
F **Run settings** card

By default, the sample setup tabs are named "Sample Setup" and numbered consecutively.

You can rename sample setup tabs via the tab commands.

In the **Navigation** area, the sample setup tabs are listed in the **Unassigned sample setup** menu.

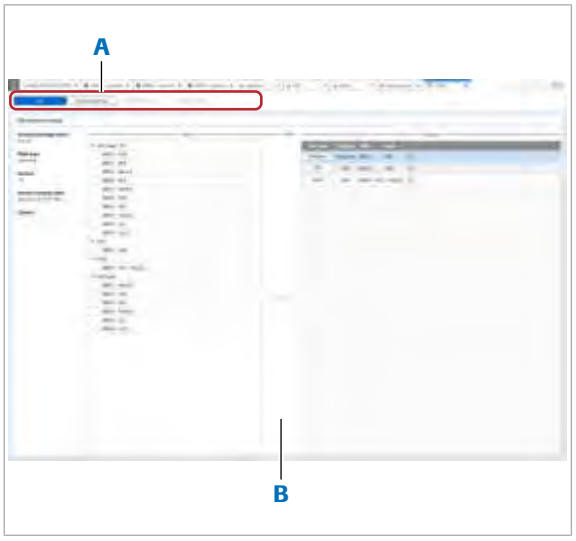
You can display the unassigned sample setup on the sample setup tab either in plate view or in table view.

To display the **Run settings** card or the **Lane settings** card, choose the corresponding button.

Sample setups in plate view (150)
Plate view and table view in the development software (138)
Unassigned sample setups in the development software (402)

About the analysis package tabs

An analysis package tab displays the current settings for an analysis package on separate panels and allows them to be edited.



A Breadcrumb **B** Panel

When you create an analysis package, you must name the analysis package. By default, the name is appended with the version number.

You cannot rename an analysis package later.

In the **Navigation** area, the analysis package tabs are listed in the **Analysis package** menu. The analysis package tabs are ordered alphanumerically.

If you change an analysis package, you must update the version of the analysis package before you can export it.

If you must update the version, an * is added to the tab entry in the **Navigation** area.

Analysis packages in the development software (412)

About the breadcrumb

At the top of the panels, an analysis package tab always displays the breadcrumb for the steps that you must perform in the given order to create an analysis package:

- **Edit**
- **General settings**
- **Test definition**
- **MMx settings**

To display the panel for a step, choose a button from the breadcrumb.

Plate view and table view in the development software

In the development software, you can toggle between plate view and table view on run tabs and sample setup tabs.

In this section

About plate view and table view

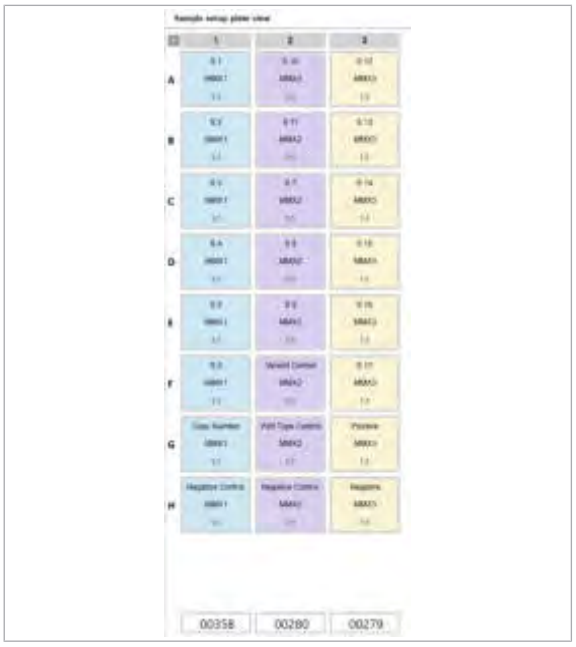
In the development software, a sample setup on a run tab or on a sample setup tab can be displayed in plate view or in table view.

To toggle between plate view and table view, choose the button or the button, respectively.

You can copy and paste lane settings between sample setups of the same project in the same view.

Editing lane settings via copy and paste in the development software (335)

About plate view



By default, the development software displays all sample setups in plate view.

In plate view, 1 column per nanowell plate and 1 tile per nanowell plate lane is displayed.

To perform an action on a selected tile, choose the tile.

To select several tiles, press Shift or Ctrl while choosing tiles.

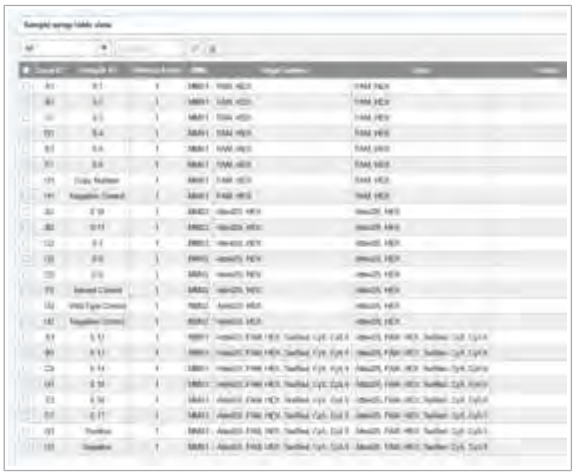
To select all tiles, choose the button at the top left of the plate view.

If available, the column footer displays the last 5 digits of the nanowell plate ID.

By default, the tiles are color-coded according to master mix reagents.

Configuring plate view (139)

About table view



In table view, a table with 1 row per nanowell plate lane is displayed.

In table view, you can configure the visible columns, search for table entries, and filter the table.

Configuring table columns (142)

Working with tables (142)

About the positions of nanowell plate lanes in sample setups (153)

Configuring plate view

You can configure the display of lane settings and the color-coding of the tiles in plate view independently for each sample setup.

The currently displayed lane settings are listed in the **Lane legend** group box on the **Lane settings** card.

About configuring table view

In table view, you can configure which columns are displayed.

Configuring table columns (142)

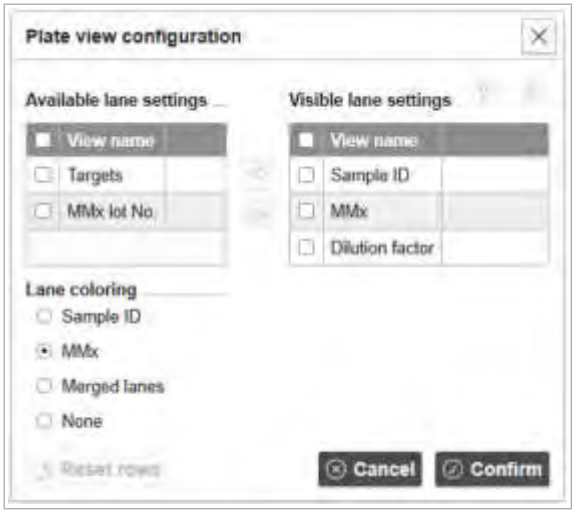
☐ Sample setup tab or run tab in plate view

To configure plate view

1 In the development software, in the **Navigation** area, choose a run from the **Runs** menu or an unassigned sample setup from the **Unassigned sample setup** menu.

2 If the sample setup is displayed in table view, choose the button.

3 On top of the tab, choose the **Edit** button.
➔ The **Plate view configuration** combo box is displayed.



4 To adjust the visibility of the lane settings on the tiles, do the following:
- To hide a lane setting, choose the lane setting from the **Visible lane settings** table and choose the ⇦ button.
- To display a lane setting, choose the lane setting from the **Available lane settings** table and choose the ⇨ button.

ⓘ A maximum of 3 lane settings can be displayed. You must hide a lane setting before you can display another.

5 To adjust the order of the visible lane settings, do the following:
- To move a lane setting up, choose the lane setting from the **Visible lane settings** table and choose the ⇧ button.
- To move a lane setting down, choose the lane setting from the **Visible lane settings** table and choose the ⇩ button.

6 To change the color-coding of the tiles, choose an option from the **Lane coloring** list:
- **Sample ID**
- **MMx**
- **Merged lanes**
- **None**

ⓘ If you choose the **None** option, all tiles are displayed with the same color (dark gray).

7 To reset the tiles to the default layout of lane settings, choose the **Reset rows** button.

ⓘ The reset does not apply to the project coloring options.

8 Choose the **Confirm** button.

➔ The plate view is updated.

Common software functions

In this section

Working with tables

The analyzer software, the web application, and the development software offer similar functions for data in tables.

In this section

Configuring table columns

You can configure which columns are visible in tables and in which order the columns are displayed.

You can configure the table columns in the analyzer software and in the development software.

You cannot hide columns that are marked with an ⓘ icon.

To place table columns via drag and drop

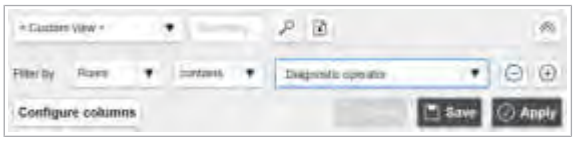
1 Navigate to a table.

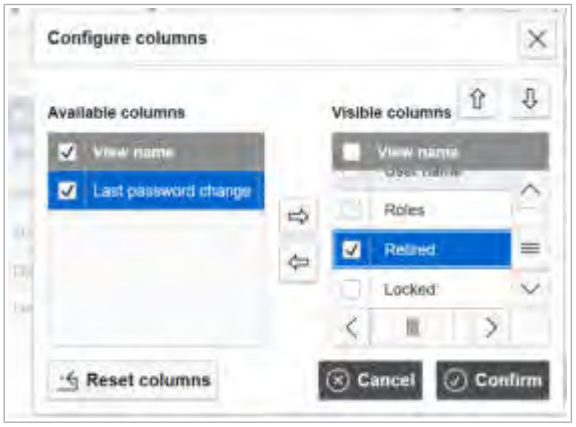
2 To adjust the order of the columns, do the following:
- Choose a column header.
- Drag and drop the column to its new location.

To configure table columns

1 Navigate to a table.

2 At the top right of the table, choose the ⌄⌄ button.





3 Choose the **Configure columns** button.
➔ The **Configure columns** callout is displayed.

4 Adjust the visibility of the table columns:
- To display a column, choose the column from the **Available columns** table and choose the ⇨ button.
- To hide a column, choose the column from the **Visible columns** table and choose the ⇦ button.

ⓘ You cannot hide columns that are marked with an ⓘ icon.

5 Adjust the order of the visible columns:
- To move a column to the left in the table, choose the column from the **Visible columns** table and choose the ⇧ button.
- To move a column to the right in the table, choose the column from the **Visible columns** table and choose the ⇩ button.

6 To reset the table to the default layout, choose the **Reset columns** button.

7 Choose the **Confirm** button.

Sorting, searching, and filtering tables

To find entries in a table, you can sort, search, and filter tables.

In the analyzer software, the web application, and the development software, you can sort and search tables.

In the analyzer software and the development software, you can additionally filter tables.

About sorting

Each table has its own default sort column and sort order (ascending or descending).

You can custom sort tables by its columns.

About searching

Searching is the fastest way to display only the entries in a table that contain a search term.

The search term is not case-sensitive.

Depending on the table, the search term is applied to some or all columns that are visible in the table. Hidden columns are not searched.

If a search produces no matches, consider if the search term is only contained in not searchable or hidden columns.

You cannot search and filter a table simultaneously. Searching a table disables any previously applied filter.

About filtering

Filter a table to reduce the number of entries.

There are 2 types of filters:

- Default filters:
  - The analyzer software and the development software include predefined default filters for each table.
  - For each table, at least the **All** default filter is available.
  - Default filters are available from the filter drop-down list above the table.
- Custom filters:
  - Custom filters are user-defined.
  - You can combine several filter criteria to a custom filter.
  - If you combine several filter criteria for the same column, they are combined by a logical OR operator.
  - If you combine several filter criteria for different columns, they are combined by a logical AND operator.
  - You can apply, save, and delete custom filters.
  - A saved custom filter is added to the filter drop-down list and can be applied like a default filter.

You cannot search and filter a table simultaneously. Filtering a table disables any previously applied search.

To sort a table

1 Navigate to a table.

2 To sort the table by a column in ascending or descending order, choose the column header.

➔ To indicate the custom sorting, **< Custom view >** is displayed in the filter drop-down list.

3 To toggle between ascending and descending sort order, choose the column header again.

To search a table

1 Navigate to a table.

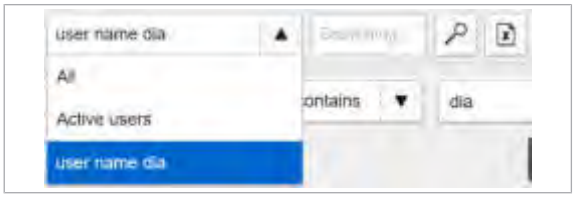
2 To display the table entries that contain a search term, do the following:
- In the field at the top of the table, enter your search term.
- Choose the 🔍 button.

ⓘ If there are no matches, the search term may be contained in not searchable or hidden columns only.

3 To display all table entries again, do the following:
- Clear the field.
- Choose the 🔍 button.
- Alternatively, from the filter drop-down list, choose the **All** default filter.

To filter a table

1 Navigate to the table.



2 To display the table entries that fulfill the filter criteria, from the filter drop-down list, choose the filter.

ⓘ You can apply the default filters or the saved custom filters.

3 To display all table entries again, from the filter drop-down list, choose the **All** default filter.

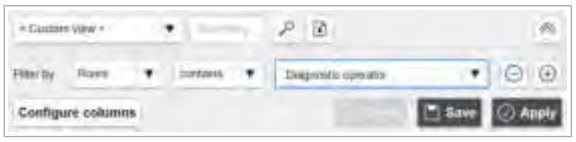
To define a custom filter

1 Navigate to a table.

2 To start with an empty custom filter, from the filter drop-down list, choose the **All** option.

ⓘ If you choose another filter from the filter drop-down list, the corresponding filter criteria are already entered in the custom filter.

3 At the top right of the table, choose the ⌄⌄ button.



4 In the **Filter by** row, define the filter criterion:
- From the first drop-down list, choose the column.
- From the second drop-down list, choose the logical condition.
- Depending on table column, from the third drop-down list, choose the value. Alternatively, in the field, enter the value.

5 To combine filter criteria, do the following:
- To add a criterion, choose the ⊕ button.
- To remove a criterion, choose the ⊖ button.

ⓘ Filter criteria for the same column are combined by a logical OR operator. Filter criteria for different columns are combined by a logical AND operator.

6 To filter the table and to test the custom filter, choose the **Apply** button.

ⓘ If you apply a custom filter only, the filter will be lost when you navigate to a different location in the software. To keep a custom filter permanently, you must save it.

7 To save the custom filter, do the following:
- Choose the **Save** button.
- Choose the **Save view as** field and enter a name for the filter.
- Choose the **Save** button.

➔ The custom filter is added to the filter drop-down list of the table.

To delete a custom filter

1 Navigate to a table.

2 From the filter drop-down list, choose the custom filter.

3 At the top right of the table, choose the ⌄ button.

4 Choose the **Delete** button.

ⓘ You cannot delete a default filter.

➔ The custom filter is deleted from the filter drop-down list.

Exporting tables as Excel files

In the analyzer software and the development software, you can export tables as an XLSX file.

The XLSX file contains the data of the table that is visible at the time of the export. If you filter a table or hide columns, the content of the export file will change accordingly.

In the analyzer software, you can export the XLSX file to a network share or external storage device. You cannot save the XLSX file on the analyzer.

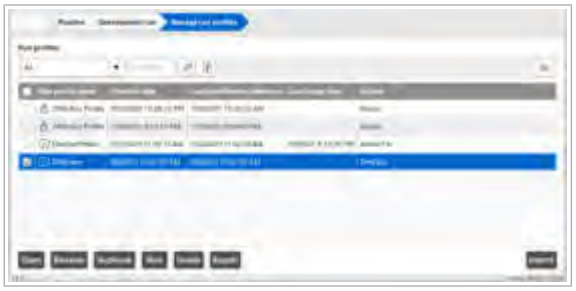
It depends on the applications installed on the computer running the development software if the XLSX file is displayed directly or if you are asked to save it.

By default, the XLSX file is named *exportYYYYMMDD-hhmmss.xlsx* with the date and time of the export.

List of naming placeholders (154)

☐ Optionally, external storage device, e.g., USB flash drive

☐ In the analyzer software:
Access to the panel that displays the table (depending on user role)



To export a table as Excel file in the analyzer software

1 Optionally, to export to an external storage device, connect the external storage device to the analyzer.

2 In the analyzer software, navigate to the table.

3 At the top of the table, choose the button.
➔ The **Export to Excel** dialog box is displayed.

4 Optionally, enter a different file name.

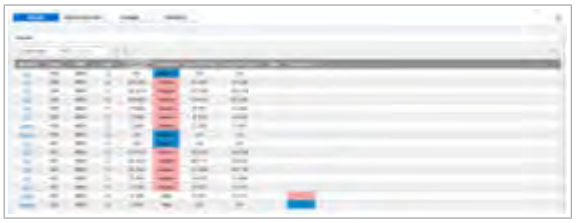
5 To change the export path, choose the button.
➔ The **Select folder** dialog box is displayed.

6 In the folder browser, navigate to a folder.

7 Choose the **Confirm** button.

8 In the **Export to Excel** dialog box, choose the **Export to Excel** button.
➔ The table entries are exported as an XLSX file to the folder.

9 Optionally, disconnect the external storage device.



To export a table as Excel file in the development software

1 Optionally, to export to an external storage device, connect the external storage device to the computer running the development software.

2 In the development software, navigate to the table.

3 At the top of the table, choose the button.
➔ If an application for XLSX files is installed on the computer, the XLSX file is displayed directly. You can then save the file from the application.
➔ If no application for XLSX files is installed on the computer, you are asked to save the file.

4 If the **Export** dialog box is displayed, do the following:
- Navigate to a folder.
- Optionally, enter a different file name.
- Choose the **Save** button.

➔ The table entries are exported as an XLSX file.

5 Optionally, disconnect the external storage device.

Color-coding

The software components of the system share a common color-coding concept.

If your color vision is impaired, refer to the texts and/or icons in the software components to obtain the same information.

In this section

About color-coding of nanowell plates

The nanowell plates are color-coded according to nanowell plate types.

The web application, the partitioning engine software, the analyzer software, and the development software adopt the color-coding of the nanowell plate types from the labels of the nanowell plates:

White:
Universal nanowell plate

Violet:
High resolution nanowell plate

Light-blue:
High sensitivity nanowell plate

Example:
Column footers in sample setups in plate view

Sample setups in plate view (150)

About color-coding of controls

In the software components of the system, controls are color-coded and have an icon according to the control type.

The web application, the analyzer software, and the development software use the following color-coding and icons for controls:

Blue:
Negative control

Pink:
Positive control for absolute quantification analysis

Copy number control for CNV analysis

Variant control for indel analysis

Brown:
Wild type control for indel analysis

Orange:
Internal control for absolute quantification analysis

Example:
Tile header for controls in sample setups in plate view

Sample setups in plate view (150)

About color-coding of final results for samples

In the software components of the system, final results of samples are color-coded.

When a final result is displayed in the web application or the development software, the result names are underlaid with the corresponding color.

For diagnostic workflows, the result names for valid final results, e.g., "Positive" and "Negative", are configurable in the analysis packages.

About final results (173)

Color-coding for absolute quantification analysis

The web application and the development software use the following color-coding for final results of an absolute quantification analysis:

Pink:
Positive

Blue:
Negative

Gray:
Invalid

Color-coding for CNV analysis

The web application and the development software use the following color-coding for final results of a CNV analysis:

Pink:
Low

Blue:
Normal

Dark pink:
High

Gray:
Invalid

Color-coding for indel analysis

The web application and the development software use the following color-coding for final results of an indel analysis:

Pink:
Variant positive

Blue:
Variant negative

Gray:
Invalid

Sample setups in plate view

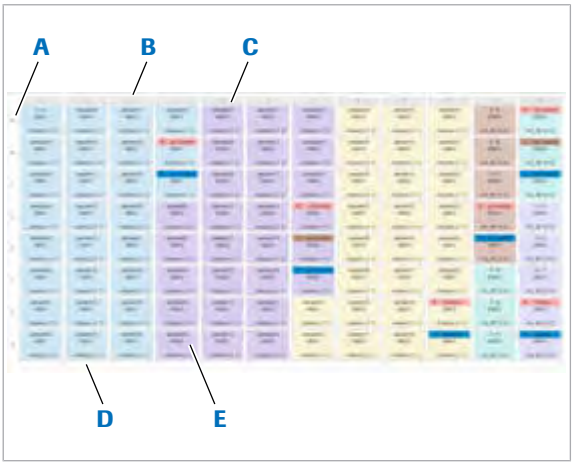
The web application, the analyzer software, and the development software display sample setups in plate view.

In the development software, you can also display the sample setups in table view.

In this section

About sample setups in plate view

A sample setup in plate view is a visual representation of the compiled nanowell plates for 1 run, and the positions of the samples and controls on the nanowell plates.



A Nanowell plate lane letters (A to H)

B Column for nanowell plate

C Column header

D Column footer

E Tile for nanowell plate lane

A sample setup in plate view consists of the following elements:

- Letters (A to H) on the left denoting the position of the nanowell plate lane
- 1 column per nanowell plate with column header and column footer
- 1 tile per nanowell plate lane, i.e., reaction mixture

A sample setup in plate view can contain up to 12 columns for the 12 nanowell plates that can be processed in 1 run on the analyzer.

Each column contains 8 tiles for the 8 nanowell plate lanes on a nanowell plate.

Sample setups in plate view are displayed in the following locations in the software components:

- On the **Sample setup** screen in the web application.
- On the **Sample setup** panel in the analyzer software.
- On the sample setup tabs and on the run tabs in the development software.

About the Sample setup screen (97)

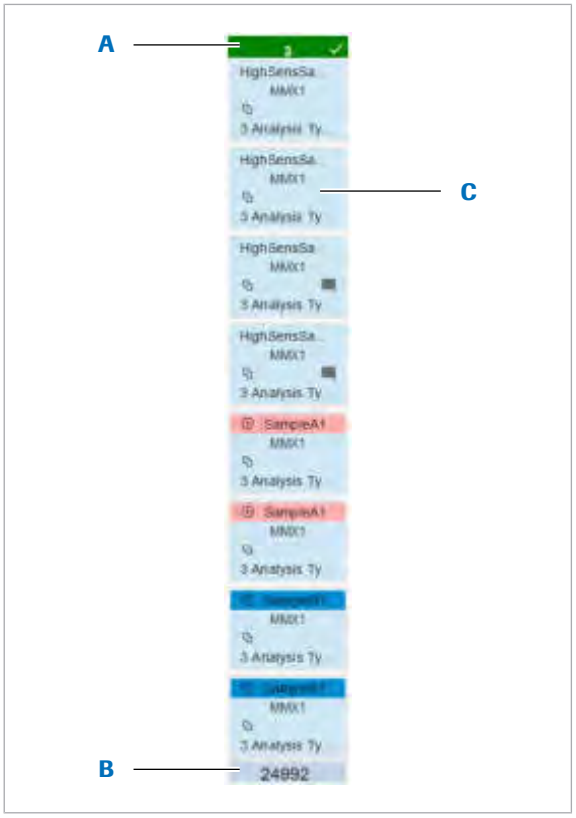
About the Sample setup panel (115)

About the run tabs (130)

About the sample setup tabs (136)

About the columns of sample setups

Each column in a sample setup represents a nanowell plate that is part of the sample setup.



A Column header
B Column footer
C Tile for nanowell plate lane

Each column has a column header and a column footer.

The column header displays the position of the nanowell plate in the sample setup (1 to 12). In the analyzer software, the column header additionally displays the position of the nanowell plate in the stack in the nanowell plate stack drawer, e.g., 1(1).

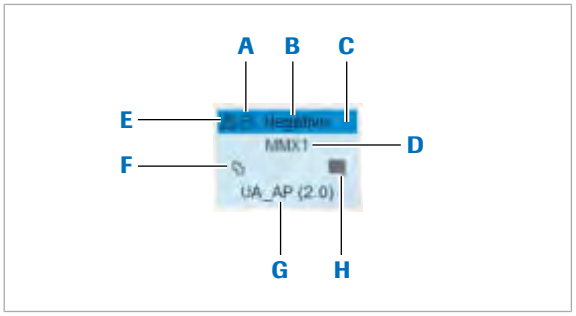
If available, the column footer displays the last 5 digits of the nanowell plate ID and is color-coded according to nanowell plate type.

In the web application and the analyzer software, the columns for invalidated nanowell plates are grayed out.

Color-coding (148)

About the tiles of sample setups

Each column in a sample setup contains 8 tiles. Each tile represents a nanowell plate lane, i.e., 1 reaction mixture that contains a sample or a control.



A Icon for control type
B Sample ID
C Header for control
D Master mix reagent
E Indicator for partitioning flag
F Icon for merged lanes
G Analysis package
H Icon for notes

In the web application and the analyzer software, a tile displays the following information (if applicable):

- Sample ID
- Tile header for controls with icon and color for control type
- Master mix reagent
- Analysis package
- Icon for merged lanes
- Icon for notes belonging to the nanowell plate lane
- Indicator for partitioning flags
  To display a callout with additional information, mouse over the indicator.

Additionally, the following applies in the web application and the analyzer software:

- The tiles are color-coded according to master mix reagent: All nanowell plate lanes that contain the same master mix reagent have the same color.

- If there are master mix reagents with the same name from different analysis packages, they are considered and colored differently.
- The tiles for unused nanowell plate lanes are white and empty.
- The tiles for invalidated nanowell plate lanes are grayed out.

About color-coding of controls (148)

In the development software, you can configure which information is displayed on a tile and how the tiles are colored.

Configuring plate view (139)

About the positions of nanowell plate lanes in sample setups

The positions of the 96 nanowell plate lanes in a sample setup are denoted as A1 to H12 in the web application, the analyzer software, and the development software.

A Position A1 **B** Position H12

The letters A to H label the 8 nanowell plate lanes on a nanowell plate. If you place a nanowell plate in front of you with the barcode label facing to the left, lane A is at the top of the nanowell plate.

The numbers 1 to 12 identify the positions of the nanowell plates in a sample setup from left to right.

When combined, the nanowell plate lanes in a sample setup are denoted in a grid-like fashion:

- Nanowell plate lane A1 is at the top left of the sample setup.
- Nanowell plate lane H12 is at the bottom right of the sample setup.

When stacking the nanowell plates, the left-to-right numbering of the nanowell plates in the sample setup translates to a bottom-to-top numbering in the stack:

- Nanowell plate 1 is at the bottom of the stack.
- Nanowell plate 12 is at the top of the stack.

The position of a set of merged lanes in a sample setup is denoted by the lowest position of the included nanowell plate lanes.
Example:
If the nanowell plate lanes A1, B1, and C1 are merged, the position of the set of merged lanes is denoted as

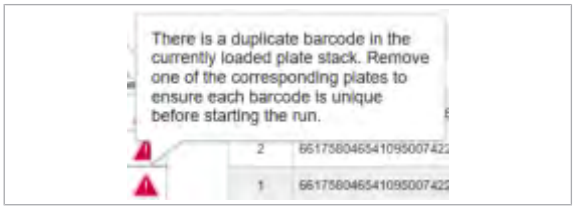
"A1".
The position is also used as name for the set of merged lanes.

The positions of the nanowell plate lanes and sets of merged lanes are derived from plate view. However, the same denominations are used whenever the position is displayed, e.g., in table view.

About callouts

A callout is a context-specific element that provides additional information. A callout always points to the software element it belongs to.

In the analyzer software and the development software, if the content of a field is missing or invalid, the field is marked with a red border. To display a callout with additional information, select the field.



In the web application, the analyzer software, and the development software, an error indicator is displayed whenever an error occurs. To display a callout with additional information, mouse over or choose the error indicator.

List of naming placeholders

The descriptions of names in this publication use the following placeholders:

- YYYY = Year
- MM = Month
- DD = Day
- hh = Hours
- mm = Minutes
- ss = Seconds
- SN = Serial number of the analyzer
- BatchName = Name of the batch as given on the **Sample setup** screen in the web application (used as the run name on the analyzer)
- RunName = Name of the run on the analyzer
- PlateType = Type of nanowell plate (i.e., "Uni", "HiRes", or "HiSens")

- RunType = Type of the run, i.e., "Diagnostic" or "Development"
- MMx = Name of the master mix reagent
- TypeOfReport = Type of problem report (i.e., "Basic", "Advanced", "Extended", or "Complete")

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Overview of the supplies

In this chapter 6

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Consumables

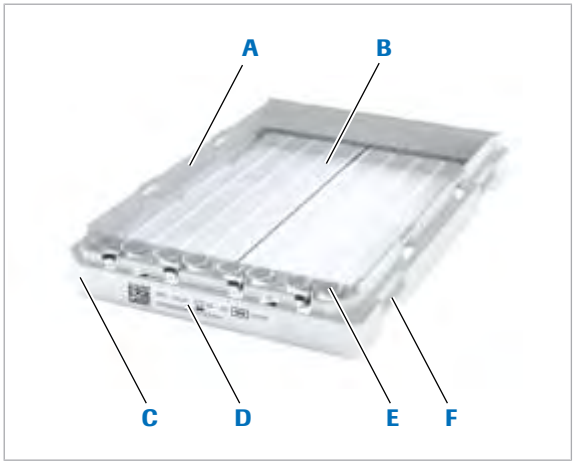
Consumables are for single use only. Do not reuse consumables.

Dispose of consumables according to local regulations.

In this section

Nanowell plates

Nanowell plates hold the reaction mixtures.



A Nanowell plate frame
B Nanowell plate lanes
C Beveled corner
D Label with barcode
E Inlet port for lane H
F Alignment notch

All nanowell plates have the following common characteristics:

- Nanowell plate frame with alignment notches and beveled corner for correct stacking and orientation in the partitioning engine and the analyzer
  For handling, touch the long sides of the nanowell plate frame only.
- 8 nanowell plate lanes with inlet ports for pipetting of the reaction mixtures
  Do not touch the nanowell plate lanes or inlet ports.
- Labels A to H for nanowell plate lanes
  If the beveled corner of the nanowell plate is at the top left, lane A is at the top of the nanowell plate.
- Color-coded nanowell plate label including the following information:
  - Nanowell plate type
  - Nanowell plate ID
  - Expiry date
    Expired nanowell plates cannot be used.

Nanowell plates are available in 3 different types (universal, high sensitivity, high resolution) that differ in the number of nanowells per nanowell plate lane and the input volume.

For the input volumes of the reaction mixtures per nanowell plate lane, refer to the Instructions for Use of the nanowell plates.

To facilitate the target detection for samples with a low concentration of target molecules, the software components allow merged lanes to emulate nanowell plate lanes with an even higher number of nanowells.

About color-coding of nanowell plates (148)

About merged lanes (62)

Universal nanowell plates

Universal nanowell plates have white labels.

High resolution nanowell plates

High resolution nanowell plates have violet labels.

High resolution nanowell plates have a higher number of nanowells per nanowell plate lane and therefore allow for very accurate quantification of target concentrations.

High sensitivity nanowell plates

High sensitivity nanowell plates have light-blue labels.

High sensitivity nanowell plates allow for a higher input volume per nanowell plate lane and therefore detection of very low target concentrations.

Liquid waste bottles

The liquid waste bottle holds the liquid waste in the partitioning engine.

The fill status of the liquid waste bottle is displayed in the **Liquids** panel in the partitioning engine software.

Empty liquid waste bottles are delivered together with the partitioning engine. They are marked as liquid waste bottle on the RFID tag.

When a liquid waste bottle is full, discard it together with the liquid waste. Do not empty and reuse a liquid waste bottle. Instead, use empty or expired partitioning fluid bottles as liquid waste bottles.

- About the Liquids panel (87)
- Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460)

Reagents and controls

Reagents and controls enable the processing of samples, the detection of targets, and the monitoring of the process.

Dispose of reagents and controls according to local regulations.

In this section

IVD kits

For IVD workflows, the Roche-provided IVD kits contain the mandatory master mix reagents (with primers and probes) and controls.

The IVD kits have a barcode label with the kit ID. You must enter the kit ID in the sample setup in the web application.

The IVD kits have an expiry date. You cannot use expired IVD kits.

For details about preparing the reaction mixtures, refer to the Instructions for Use of the IVD kit.

Master reagents

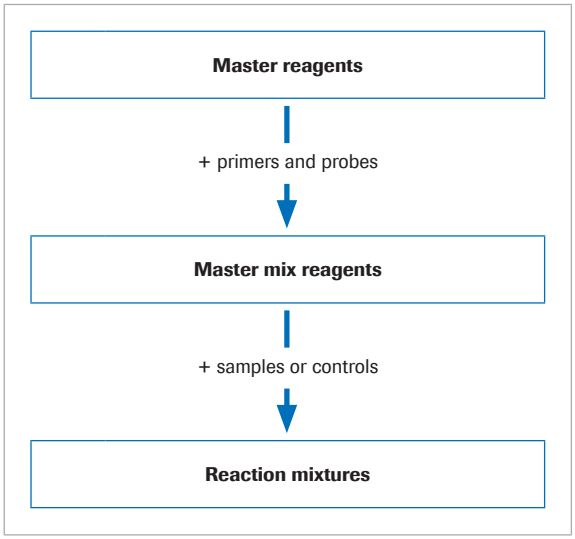
For LDT workflows and development workflows, the Roche-provided master reagents are the required bases for the reaction mixtures.

A DNA master reagent and an RNA master reagent are available for DNA and RNA applications, respectively.

The master reagents have a barcode label with the master reagent ID. You can enter the master reagent ID in the sample setup in the web application and the development software.

The master reagents have an expiry date. Do not use expired master reagents.

About preparation



To prepare the master mix reagents, add the primers and probes to the master reagents.

To prepare the reaction mixtures, add the samples or controls to the master mix reagents.

For details about preparing the master mix reagents and reaction mixtures, refer to the Instructions for Use of the master reagents.

The stability of the reaction mixtures between partitioning of a nanowell plate and processing it on the analyzer has been tested for 90 minutes.

Partitioning fluid

The partitioning engine uses the partitioning fluid to partition the reaction mixtures into the nanowells and to seal the nanowell plates.

The partitioning fluid is provided in the partitioning fluid bottle that is loaded into the partitioning engine.

The fill status of the partitioning fluid bottle is displayed in the **Liquids** panel in the partitioning engine software.

The partitioning fluid bottle has an RFID tag with the partitioning fluid ID.

The partitioning fluid has an expiry date and an onboard stability (60 days).

The partitioning engine monitors the loaded partitioning fluid for the expiry date and for the onboard stability. You must exchange the partitioning fluid when the expiry date or the onboard stability is exceeded (whichever happens first). You cannot use expired partitioning fluid on the partitioning engine.

The date when the partitioning fluid will expire is displayed on the **Liquids** panel in the partitioning engine software.

Keep empty or expired partitioning fluid bottles as liquid waste bottles. The system marks empty and expired partitioning fluid bottles as liquid waste bottles on the RFID tag.

About the Liquids panel (87)

Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460)

Primers, probes, and dyes

Primers, probes, and dyes enable target amplification and detection.

About primers

A pair of primers marks the start and the end of the target nucleic acid sequence to be amplified during the PCR.

For IVD workflows, the IVD kits contain the primers.

For LDT workflows and development workflows, you must provide your own primers.

For details about preparing the reaction mixtures, refer to the Instructions for Use of the IVD kits and the master reagents.

About probes

The probes enable the detection of the amplified target nucleic acid sequences. The probes contain the dyes that fluoresce if the target nucleic acid sequence is present.

For IVD workflows, the IVD kits contain the probes.

For LDT workflows and development workflows, you must provide your own probes.

For details about preparing the reaction mixtures, refer to the Instructions for Use of the IVD kits and the master reagents.

About dyes

The dyes are part of the probes. If the target nucleic acid sequence is present, the dyes fluoresce and can be detected by the system.

For IVD workflows, the IVD kits contain probes with system-compatible dyes.

For LDT workflows and development workflows, ensure that your probes contain system-compatible dyes only.

The following table lists the dyes that can be used with the system:

Channel	Dyes
Channel 1	▪ Atto425 ▪ Coumarin ▪ Cyan500
Channel 2	▪ FAM
Channel 3	▪ HEX ▪ VIC
Channel 4	▪ TexRed ▪ LC610 ▪ CFR610
Channel 5	▪ Cy5 ▪ LC640 ▪ JA270
Channel 6	▪ Cy5.5

System-compatible dyes

You cannot use different dyes that are detected in the same channel in 1 development run.

Controls

Use controls to monitor the workflows, e.g., the reaction quality, the test and analyzer performance, for pipetting errors, and for cross-contamination.

The system invalidates the results for samples if the result of a corresponding control is invalid.

Depending on workflow, the following applies:

- IVD workflows:
  - Controls are mandatory.
  - Controls are part of the Roche-provided IVD kits.
- LDT workflows:
  - It depends on the settings in the analysis packages if the sample setup contains controls.
  - It is the responsibility of the issuers of the analysis packages to include controls.
  - You must prepare your own user-defined controls in advance.
- Development workflows:
  - It is your responsibility to add controls to the sample setup.
  - You must prepare your own user-defined controls in advance.

For details about preparing the reaction mixtures, refer to the Instructions for Use of the IVD kits and the master reagents.

About control types

The supported control types depend on analysis type:

- For absolute quantification analysis:
  - Internal controls
  - Negative controls
  - Positive controls
- For CNV analysis:
  - Negative controls
  - Copy number controls
- For indel analysis
  - Negative controls
  - Variant controls
  - Wild type controls

Internal controls are measured as a separate target and are therefore lane-specific:
If the internal control in a nanowell plate lane is invalid, the system automatically invalidates the final results for all targets that are tested in that nanowell plate lane.

All other controls are measured as a separate sample and are therefore target-specific:
If a control for a target is invalid, the system automatically invalidates the final results for that target for all samples of the run.

Overview of orders, run prerequisites, and results

In this chapter 7

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About orders

For diagnostic workflows, orders tell the system which tests to perform on which samples. There are no orders for development workflows.

An order is the distinct combination of 1 sample ID with 1 test.

If more than 1 test is assigned to the same sample ID, each combination of sample ID and test constitutes a separate order.

In a diagnostic workflow, each test belongs to an analysis package. Therefore, the system can deduce from the order the analysis package and the nanowell plate type that must be used.

Orders are exclusively managed in the web application.

The web application gets orders in the following ways:

- Automatically received from an LIS (LIS orders)
- Imported as an orders list
- Manually created in the web application

> The system can also receive orders from AVENIO Connect as part of an integrated laboratory workflow. However, AVENIO Connect orders are hidden in the web application and cannot be accessed.

The web application can manage orders from all sources simultaneously. Orders from all sources can be assigned to the same sample setup if the analysis packages of the tests specify the same run profile.

On some screens of the web application, 1 row summarizes all orders that belong to the same sample ID, are for tests from the same analysis package, and have the same status.

About the Orders screen (95)

Ordering in the web application (250)

About order status

On the **Orders** screen in the web application, orders can be in the following statuses:

- **Not allocated**
- **Allocated**
- **In process**
- **Executed**

- **Released**
- **Sent**

As soon as an order is in **Executed** status, a result exists for that order in the web application. An order is in **Released** status if the corresponding result is released. An order is in **Sent** status if the corresponding result is sent.

About the Orders screen (95)

About allocation of orders

Orders that are not yet assigned to a sample setup are called **not allocated orders**. You can edit and delete not allocated orders (except LIS orders).

Orders that are assigned to a sample setup are called **allocated orders**. You cannot assign allocated orders to a different sample setup. To edit an allocated order, you must either delete the sample setup (so that again the orders are not allocated) or you must create a new not allocated order.

When you assign orders to a sample setup, the web application applies the following logic:

- The orders that are summarized by 1 row on the **Orders** screen are always assigned to the same sample setup. You cannot assign the summarized orders to different sample setups.
- Only orders with the same run profile in the analysis packages can be processed in 1 diagnostic run and can be assigned to the same sample setup.
- You can only choose as many orders as can be processed in 1 diagnostic run, i.e., on 12 nanowell plates. The web application automatically includes and counts the required controls.

A **batch** consists of the orders that are allocated to 1 sample setup. A batch is processed in 1 diagnostic run on the analyzer.

Orders in the web application (250)

Sample setups in the web application (255)

About LIS orders

In the web application, the following rules apply to LIS orders:

- When there are 2 versions of the same analysis package on the system (1 version in **Enabled** status and 1 version in **In validation** status), always the enabled version of the analysis package is assigned to LIS orders.

- On the **Orders** screen, **LIS** is displayed in the **Requester name** column.
- On the **Sample IDs** card on the **Edit orders** screen, tests from LIS orders are displayed in blue font.
- You cannot delete LIS orders, i.e., you cannot deassign the test from an LIS order.
- You can add orders for sample IDs that are part of LIS orders. I.e., you can assign additional tests to a sample ID that was received as part of an LIS order (because assigning additional tests to a sample ID creates new orders and the LIS orders remain unchanged).
- You must send the results to the LIS (if not done automatically).

About run prerequisites

You can only start a diagnostic run or a development run on the analyzer if the corresponding run prerequisites are met.

You can use different types of nanowell plates together in 1 run. However, you cannot start a run if nanowell plates for a diagnostic run and nanowell plates for a development run are loaded together on the analyzer.

Prerequisites for a diagnostic run

You can only start a diagnostic run on the analyzer if the following prerequisites are met:

- Preventive maintenance of the analyzer is not overdue.
- The analyzer is in **Analyzer ready** status.
- The nanowell plate stack drawer is closed.
- You are logged on with diagnostic operator user role.
- All loaded nanowell plates are in **Valid** status.
- There is a matching sample setup in **Ready to start run** status in the web application:
  - All loaded nanowell plates belong to the same sample setup.
  - All nanowell plates of the sample setup except invalidated nanowell plates are loaded.
- The maximum allowed timespan between partitioning of the nanowell plates and starting the run on the analyzer has not elapsed.

About the analyzer status indicator (109)

About the nanowell plate status (114)

Sample setups in the web application (255)

Prerequisites for a development run

You can only start a development run on the analyzer if the following prerequisites are met:

- The analyzer is in **Analyzer ready** status.
- The nanowell plate stack drawer is closed.
- You are logged on with development operator user role.
- All loaded nanowell plates are in **Valid** status.
- None of the loaded nanowell plates belong to a diagnostic sample setup in the web application.

About the analyzer status indicator (109)

About the nanowell plate status (114)

About final results

Final results are the outcomes of your workflows.

The system displays final quantitative and final qualitative results.

The final results for samples consider the corresponding control results.

About final results for controls

A control can have the following final results for a target:

Analysis type	Possible final results for controls	
	Quantitative	Qualitative
Absolute quantification	▪ Target concentration [cp/µL] ▪ N/A	▪ Valid ▪ Invalid
CNV	▪ Copy number of the target of interest ▪ N/A	▪ Valid ▪ Invalid
Indel	▪ Percentage of variant sequence [%] ▪ N/A	▪ Valid ▪ Invalid

Possible final results for controls

About final results for samples

A sample can have the following final results for a target:

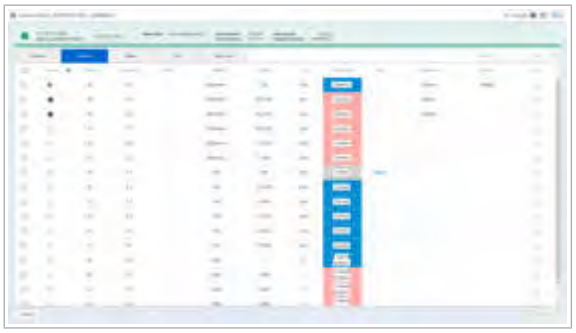
Analysis type	Possible final results for samples	
	Quantitative	Qualitative
Absolute quantification	▪ Target concentration [cp/µL] ▪ N/A	▪ Negative ▪ Positive ▪ Invalid
CNV	▪ Copy number of the target of interest ▪ N/A	▪ Low ▪ Normal ▪ High ▪ Invalid
Indel	▪ Percentage of variant sequence [%] ▪ N/A	▪ Variant negative ▪ Variant positive ▪ Invalid

Possible final results for samples

The final qualitative results for samples are color-coded, i.e., the result denominations are underlaid with the corresponding color.

About color-coding of final results for samples (149)

About results of diagnostics workflows



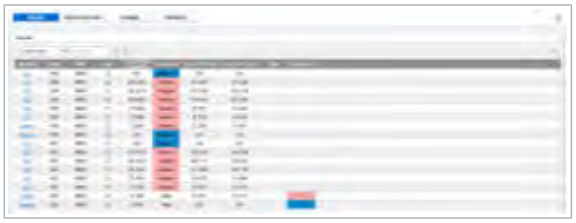
After an order is processed in a diagnostic workflow, the corresponding final results are calculated automatically and displayed on the **Results of** screen in the web application.

- If configured, the final quantitative results are displayed in the **Result** column (with the corresponding unit in the **Unit** column).
- The final qualitative results are displayed in the **Final result** column.

The denominations of the final (qualitative) results depend on the settings in the analysis package.

- About the Results of screen (100)
- Results in the web application (263)

About results of development workflows



In the development software, final results are determined by clustering and analyzing the raw data. Final results are displayed on the **Results** panel on the analysis tab.

You can configure the development software to display the initial results additionally.

- About the analysis tabs (134)
- Configuring table columns (142)
- Analyses in the development software (358)

Maintenance overview

In this chapter 8

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About maintenance

Maintenance ensures safe and reliable operation of the system.

Do not carry out any maintenance actions that are not described in this publication.

Automatic maintenance actions

You can schedule automatic archiving and automatic backups on the system.

- Scheduling automatic archiving (560)
- Scheduling automatic backups (566)

Manual maintenance actions

You must perform the following maintenance actions manually:

- Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460)
- Cleaning up not allocated orders (466)
- Performing manual archiving (467) (if automatic archiving is not configured or fails)
- Performing a manual backup (469) (if automatic backup is not configured or fails)
- Cleaning the partitioning engine (473)
- Cleaning the analyzer (476)

Decontamination

If the inside of the partitioning engine or the inside of the analyzer may be contaminated, contact your Roche Service representative.

If the nanowell plate drawer of the partitioning engine may be contaminated, decontaminate the nanowell plate drawer.

If the nanowell plate stack drawer of the analyzer may be contaminated, decontaminate the nanowell plate stack drawer.

If the aspiration needle of the partitioning engine may be contaminated, decontaminate the aspiration needle.

- Decontamination (478)

Preventive maintenance

Your Roche Service representative performs preventive maintenance.

About preventive maintenance (482)

Specifications

In this chapter 9

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System specifications

In this section

General specifications

In this section

General specifications of the system

The system has the following general specifications:

System	
Noise emission	< 60 db (A)

General specifications of the system

General specifications of the analyzer

The analyzer has the following general specifications:

Analyzer	
Throughput	Up to 3.5 hours for 1 to 6 nanowell plates
	Up to 5 hours for 7 to 12 nanowell plates

General specifications of the analyzer

General specifications of the partitioning engine

The partitioning engine has the following general specifications:

	Partitioning engine
Throughput	Up to 5 minutes for 1 nanowell plate
	Up to 60 minutes for 12 nanowell plates

General specifications of the partitioning engine

Electric power supply

In this section

Electric power supply for the analyzer

The electric power supply for the analyzer must fulfill the following requirements:

		International (Europe)	US / Canada
Voltage		100-240 V AC ± 10%	
Frequency		50-60 Hz	
Current		15-6.25 A	
Installation	Installation category	Installation Category II (IEC 61010-1)	
	Protection class	Protection Class I	

Electric power supply for the analyzer

Electric power supply for the partitioning engine

The electric power supply for the partitioning engine must fulfill the following requirements:

	International (Europe)	US / Canada
Voltage	24 V DC	
Current	4 A	

Electric power supply for the partitioning engine

The power supply (AC adapter) of the partitioning engine must fulfill the following requirements:

		International (Europe)	US / Canada
Input voltage		100-240 V AC ± 10%	
Input frequency		50-60 Hz	
Input current		1.6 A	
Output voltage		24 V DC	
Output current		5 A	
Installation	Installation category	Installation Category II (IEC 61010-1)	
	Protection class	Protection Class I	

Power supply (AC adapter) of the partitioning engine

Only use the power supply (AC adapter) that is delivered together with the partitioning engine.

Environmental conditions for the system

The location must comply with the following conditions:

		International (Europe)	US / Canada
Ambient temperature	During operation	15 to 30 °C	59 to 86 °F
	During storage	5 to 40 °C	41 to 104 °F
	During transportation	-20 to 60 °C	-4 to 140 °F
Ambient humidity	During operation	20 to 80% (non-condensing)	
	During storage	15 to 85% (non-condensing)	
	During transportation	10 to 90% (non-condensing)	
Altitude above sea level		Up to 2000 m	Up to 6561 ft
Pollution degree		2	

Environmental conditions

Never operate the system if one of the environmental conditions is not fulfilled.

Other environmental conditions

- Indoor use only
- Horizontal installation space
- Dust-free environment with adequate ventilation
- No direct sunlight
- No perceptible vibration
- No equipment generating electromagnetic waves in the near vicinity
- No machines discharging ultrahigh frequencies (e.g., electric discharger)

Dimensions and weight

In this section

Dimensions and weight of the analyzer

The analyzer has the following dimensions and weight:

	International (Europe)	US
Height	90 cm	35.4 in
Width	100 cm	39.4 in
Depth	60 cm (without monitor)	23.6 in
Weight	200 kg	440 lbs

Dimensions and weight of the analyzer

Dimensions and weight of the partitioning engine

The partitioning engine has the following dimensions and weight:

	International (Europe)	US
Height	25 cm	9.8 in
Width	25 cm	9.8 in
Depth	30 cm	11.8 in
Weight	11 kg	24 lbs

Dimensions and weight of the partitioning engine

Required space

In this section

Space required around the analyzer

Do not operate the analyzer if there is insufficient free space around it.

	International (Europe)	US
Front	30 cm	12 in
Back	0 cm	0 in
Left side	50 cm	20 in
Right side	30 cm	12 in
Top	50 cm	20 in

Space required around the analyzer

Space required around the partitioning engine

Do not operate the partitioning engine if there is insufficient free space around it.

	International (Europe)	US
Front	20 cm	8 in
Back	10 cm	4 in
Left side	0 cm	0 in
Right side	30 cm	12 in
Top	20 cm	8 in

Space required around the partitioning engine

Radio equipment specifications

The partitioning engine contains radio equipment:

	Partitioning engine
Frequency	13.56 MHz
Maximum radio-frequency power	< 500 mW
Number of RFID readers	1 (MUX 1 to 2)
Number of RFID antennas	2

Radio equipment specifications of the partitioning engine

Supported characters in ASTM messages

The system uses CP-1252 (code page 1252) to encode and decode ASTM messages. Characters outside of code page 1252 (e.g., Unicode characters) are not supported and are replaced by a "?" (question mark) in ASTM messages.

If you connect the system to an LIS via the ASTM protocol, only use characters in the range of 0x21 (exclamation mark "!") to 0x7D (closing curly bracket "}") of the CP-1252 character encoding for sample IDs.

List of available consumables and reagents

Below is a list of globally available consumables and reagents. For ordering information, contact your local sales representative.

Image of product	Product name
	Digital LightCycler® Universal Nanowell Plate
	Digital LightCycler® High Resolution Nanowell Plate
	Digital LightCycler® High Sensitivity Nanowell Plate
	Digital LightCycler® Partitioning Fluid
	Digital LightCycler® Waste Bottle
	Digital LightCycler® 5x DNA Master
	Digital LightCycler® 5x RNA Master

Available consumables and reagents

Computer specifications

In this section

Specifications for the development software

	Minimum	Recommended
Computer	Operating system: Windows 10	
	Intel i5 processor	Intel i7 processor or higher
	8 GB RAM	16 GB RAM or more
Monitor resolution	1366 × 768	1920 × 1080

Specifications for the development software

Specifications for the web application

	Specification
Browser	Firefox ESR 91.1.0
Monitor resolution	1920 × 1080

Specifications for the web application

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Operation

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Overview of routine tasks

In this chapter 10

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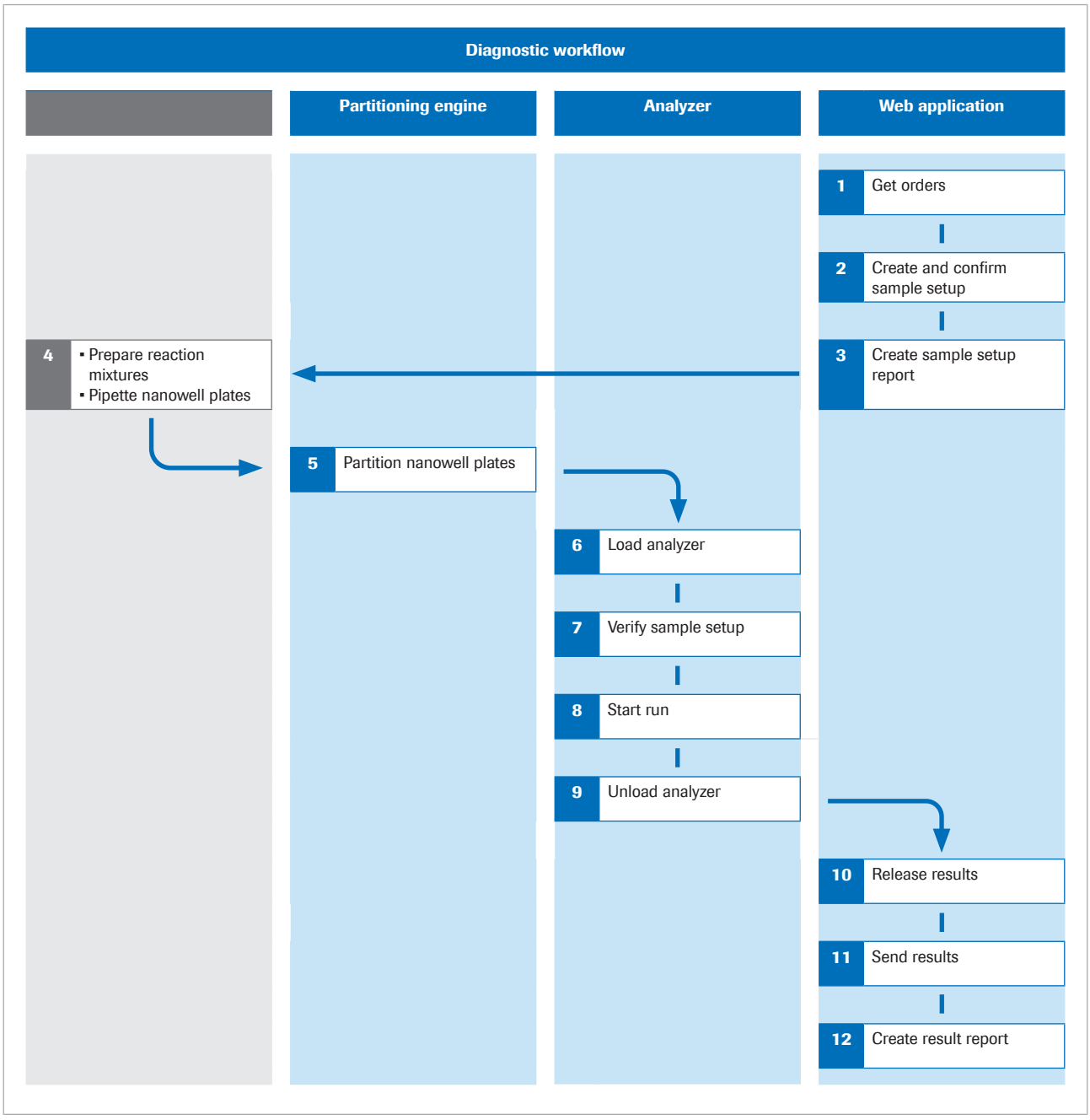
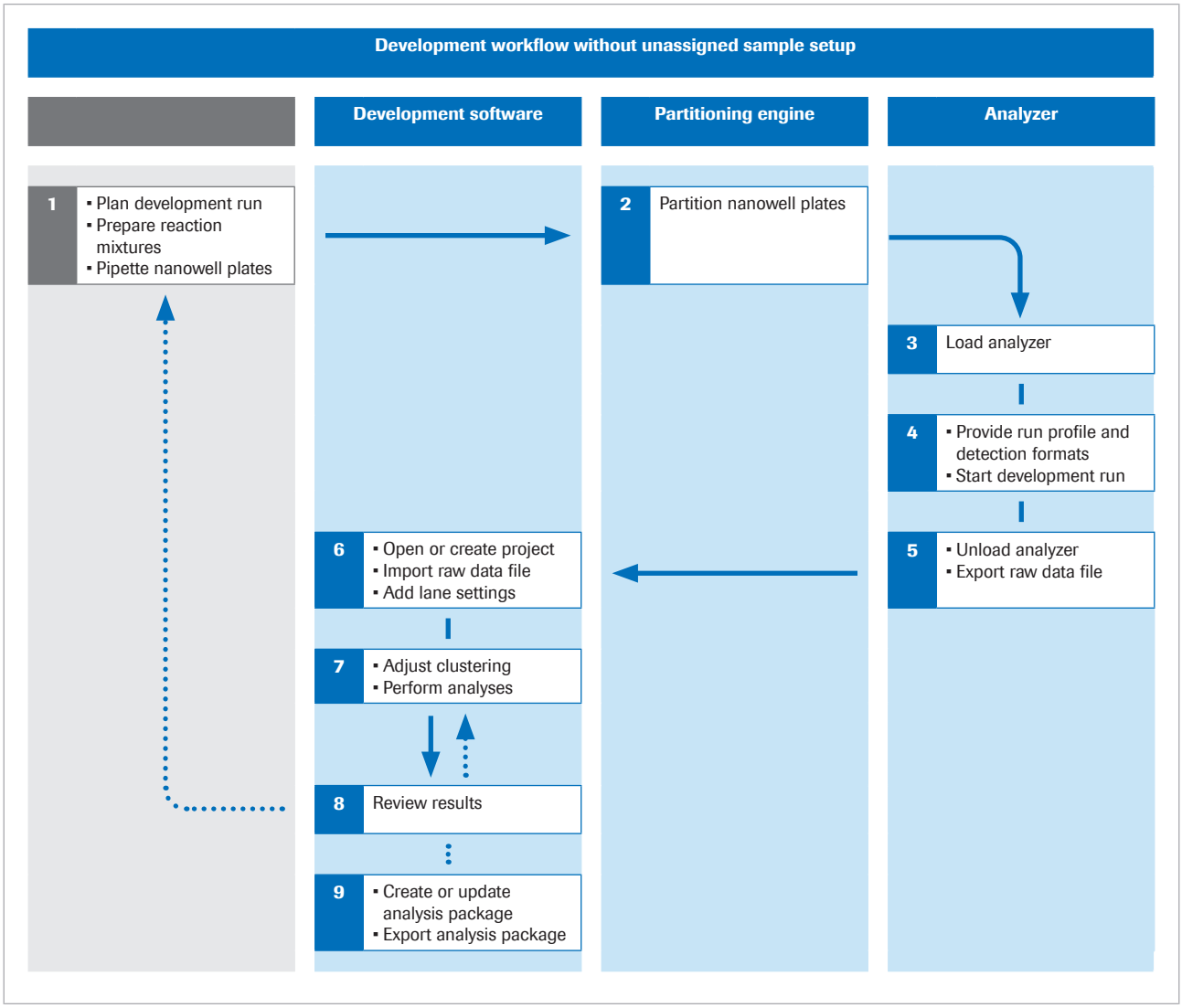
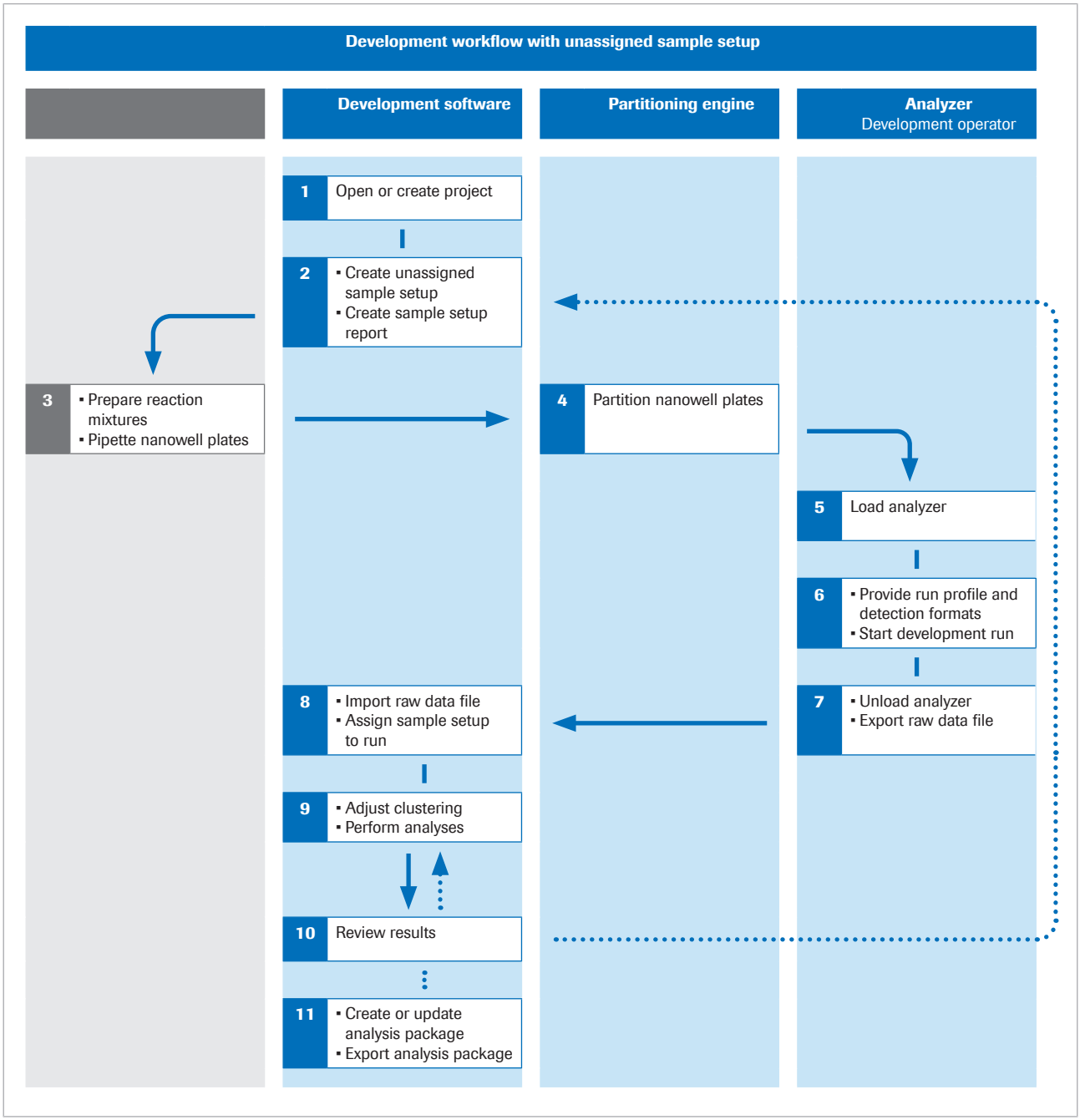
Overview of diagnostic workflow



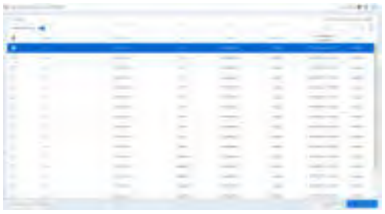
Overview of development workflow without unassigned sample setup



Overview of development workflow with unassigned sample setup



Diagnostic workflow (quick reference)

Step		Description
1	**Web application** If orders are not exclusively received from an LIS: Create and import the orders list and/or create the orders.	  To create and import an orders list, do the following: 1. Create a CSV file for the orders. 2. In the **Orders** column on the dashboard, choose the **View orders** tile. 3. On the **Orders** screen, choose the **Import order list** button. 4. Navigate to the orders list and choose the **Open** button. 5. In the dialog box, choose the **Confirm** button. To create the orders manually, do the following: 1. In the **Orders** column on the dashboard, choose the **Create sample setup** tile. 2. On the **Orders** screen in assignment mode, choose the **Add/edit order** button. 3. On the **Add sample ID** card on the **Edit orders** screen, choose the **Sample ID** field. Scan or enter the sample ID and choose the **Add** button. 4. On the **Sample IDs** card, select the sample ID. 5. On the **Analysis package and test** card, assign complete analysis packages, or expand the analysis packages and assign selected tests only. 6. Choose the **Save** button. Ordering in the web application (250)
2	**Web application** Create the sample setup.	 1. In the **Orders** column on the dashboard, choose the **Create sample setup** tile. 2. On the **Orders** screen in assignment mode, select the first row of orders for the sample setup. 3. Select the other rows of orders for the sample setup. 4. Choose the **Assign to sample setup** button. Creating sample setups in the web application (255)

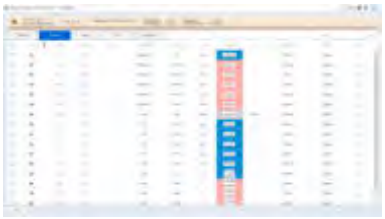
Diagnostic workflow (quick reference)

Step			Description
3	**Web application** Enter or scan the nanowell plate IDs.		On the **Sample setup** screen, do the following for each nanowell plate: 1. To display the **Plate:** combo box, choose the column header twice. 2. In the **Plate ID** field, scan or enter the nanowell plate ID. 3. Choose the **Confirm** button.
4	**Web application** If required, enter or scan the kit IDs and/or enter sample notes.		If required, on the **Sample setup** screen, do the following for each nanowell plate lane: 1. To display the **Sample settings:** combo box, choose the tile twice. 2. Optionally, in the **Notes** field, enter sample notes. 3. If required, in the **Kit No.** field, scan or enter the kit ID. 4. Choose the **Confirm** button.
5	**Web application** Optionally, change the batch name and/or enter run notes.		1. On the **Sample setup** screen, choose the ✎ button. 2. In the **Run information** dialog box, change the batch name and/or enter run notes. 3. Choose the **Confirm** button.
6	**Web application** Confirm the sample setup.		1. On the **Sample setup** screen, choose the **Confirm** button.
7	**Web application** Create the sample setup report.		1. In the **Sample setups** column on the dashboard, choose the batch tile. 2. On the **Sample setup** screen, choose the **Generate report** button. 3. Choose to open or to save the file, and choose the **Confirm** button. If required, navigate to a folder and choose the **Save** button. 4. On the **Sample setup** screen, choose the **Confirm** button. 5. Print the sample setup report as a guide for pipetting. Creating sample setup reports in the web application (259)

Diagnostic workflow (quick reference)

Step			Description
8	Prepare the reaction mixtures.		1. Prepare the reaction mixtures. 2. Refer to the sample setup report to identify the nanowell plates and to allocate the reaction mixtures to the nanowell plate lanes. For details about preparing the reaction mixtures and pipetting, refer to the Instructions for Use of the reagents and controls.
9	**Partitioning engine** Pipette and partition the nanowell plates.	 	1. Pipette the reaction mixtures into the inlet ports of the first nanowell plate. 2. Choose the **Load** button. 3. Place the nanowell plate in the nanowell plate drawer. 4. Choose the **Start** button. 5. When the nanowell plate drawer opens, check that all nanowell plate lanes that contain reaction mixtures are partitioned. 6. Remove the nanowell plate. 7. Place the nanowell plate on a flat and clean surface. 8. Pipette and partition the other nanowell plates. 9. Stack the partitioned nanowell plates. Partitioning the nanowell plates (221)
10	**Analyzer** Load the analyzer.		1. In the global information area, choose the ⏏ button. 2. Place the nanowell plate stack in the nanowell plate stack drawer. 3. Choose the ⏏ button. Loading the analyzer (225)
11	**Analyzer** Verify the sample setup and start the run.		1. On the **Sample setup** panel, verify the displayed sample setup against the sample setup report. 2. Choose the **Start run** button.
12	**Web application** Optionally, enter run notes.		1. In the **Run in progress** column on the dashboard, choose the ✎ button on the batch tile. 2. Enter the run notes. 3. Choose the **Confirm** button. Entering run information for a diagnostic run in the web application (261)

Diagnostic workflow (quick reference)

Step		Description
13	**Analyzer** Unload the analyzer. 	1. When the run is finished, in the global information area, choose the ⏏ button. 2. Remove the nanowell plate stack from the nanowell plate stack drawer. 3. Choose the ⏏ button. 4. Dispose of the nanowell plates according to local regulations. Unloading the analyzer (227)
14	**Web application** If required, release and/or send the results. 	If the analyzer is not configured for automatic release of results, release the results: 1. In the **Results** column on the dashboard, choose the batch tile. 2. On the **Results of** screen, review the results. 3. Choose the **Samples** column. 4. Choose the results from the list and choose the **Release** button. 5. In the **Confirmation** dialog box, enter your password and choose the **Release** button. Releasing results manually in the web application (265) If the analyzer is not configured for automatic sending of results, with diagnostic approver user role, send the results: 1. In the **Results** column on the dashboard, choose the batch tile. 2. On the **Results of** screen, choose the released results from the list and choose the **Send** button. 3. In the **Confirmation** dialog box, enter your password and choose the **Send** button. Sending results manually in the web application (267)
15	**Web application** Optionally, create the result report. 	1. In the **Results** column on the dashboard, choose the **Completed batches** tile. 2. Choose the batch from the list and choose the **View** button. 3. On the **Results of** screen, choose the **Report** button. Creating result reports in the web application (268)

Diagnostic workflow (quick reference)

Related topics

- Performing a diagnostic workflow (243)

Development workflow without unassigned sample setup (quick reference)

The following table provides you with a quick reference of how to perform a development workflow **without** unassigned sample setup.

For a quick reference for a development workflow with unassigned sample setup, refer to Development workflow with unassigned sample setup (quick reference) (208).

Step			Description
1	Prepare the reaction mixtures.		1. Prepare the reaction mixtures. For details about preparing the reaction mixtures and pipetting, refer to the Instructions for Use of the reagents and controls.
2	**Partitioning engine** Pipette and partition the nanowell plates.		1. Pipette the reaction mixtures into the inlet ports of the first nanowell plate. 2. Choose the **Load** button. 3. Place the nanowell plate in the nanowell plate drawer. 4. Choose the **Start** button. 5. When the nanowell plate drawer opens, check that all nanowell plate lanes that contain reaction mixtures are partitioned. 6. Remove the nanowell plate. 7. Place the nanowell plate on a flat and clean surface. 8. Pipette and partition the other nanowell plates. 9. Stack the partitioned nanowell plates. Partitioning the nanowell plates (221)
3	**Analyzer** Load the analyzer.		1. In the global information area, choose the ⏏ button. 2. Place the nanowell plate stack in the nanowell plate stack drawer. 3. Choose the ⏏ button. Loading the analyzer (225)
4	**Analyzer** Verify the nanowell plates and the sample setup.		1. On the **Plates** panel, verify that all nanowell plates have status **Valid**. 2. Verify the displayed nanowell plates against the planned sample setup. 3. Choose the **Run profile** button.

Development workflow without unassigned sample setup (quick reference)

Step			Description
5	**Analyzer** Optionally, duplicate or import a run profile.		To duplicate a run profile, do the following: 1. On the **Manage run profiles** panel, choose a run profile. 2. Choose the **Duplicate** button. 3. In the **Edit run profile name** dialog box, enter a name for the run profile. 4. Choose the **Save** button. To import a run profile, do the following: 1. On the **Manage run profiles** panel, choose the **Import** button. 2. In the folder browser in the **Import run profiles** dialog box, navigate to the folder. 3. In the file browser, choose the run profile. 4. Choose the **Import** button. Working with run profiles on the Manage run profiles panel in the analyzer software (299)
6	**Analyzer** Edit the run profile.		1. On the **Manage run profiles** panel, choose an unlocked run profile. 2. Choose the **Open** button. 3. Optionally, on the **Edit run profile** panel, edit the programs. 4. Choose the **Detection formats** button. 5. In the **Detection format** combo box, disable the channels for dyes that are not contained in any of the master mix reagents. For each enabled channel, choose the dye from the drop-down list. Optionally, edit the integration time. Choose the **Save** button. 6. Choose the **Save** button. Editing run profiles on the Edit run profile panel in the analyzer software (303)
7	**Analyzer** Start the run.	 	To start the run on the **Manage run profiles** panel, do the following: 1. Choose the run profile 2. Choose the **Run** button. To start the run on the **Edit run profile** panel: 1. Choose the **Run** button.

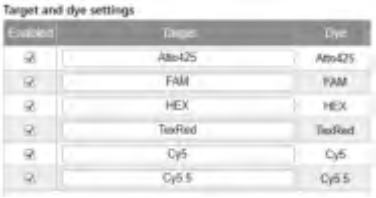
Development workflow without unassigned sample setup (quick reference)

Step			Description
8	**Analyzer** Optionally, change the run name and/or enter run notes.		1. In the middle of the **Monitoring** panel, next to the run name, choose the ✎ button. 2. In the dialog box, in the **Run name** field, enter a new run name. 3. In the **Edit notes** field, enter run notes. 4. Choose the **Confirm** button. ▸ Entering run information for a development run in the analyzer software (307)
9	**Analyzer** Unload the analyzer.		1. When the run is finished, in the global information area, choose the ⏏ button. 2. Remove the nanowell plate stack from the nanowell plate stack drawer. 3. Choose the ⏏ button. 4. Dispose of the nanowell plates according to local regulations. ▸ Unloading the analyzer (227)
10	**Analyzer** If required, export the raw data file.		If the analyzer is not configured for automatic export, export the raw data file of the development run: 1. Optionally, to export to an external storage device, connect the external storage device to the analyzer. 2. Choose **Routine > Development run > Development results**. 3. Choose the run and choose the **Export** button. 4. Navigate to a folder and choose the **Export** button 5. Optionally, disconnect the external storage device. ▸ Managing raw data files of development runs in the analyzer software (312)

Development workflow without unassigned sample setup (quick reference)

Step		Description
11	**Development software** Create a project or open a project.	 To **open** a project: 1. On the **Start page** tab, choose the **Open file** button. 2. Navigate to the *dpcrPrj* file and choose the **Open** button. To **create** a project: 1. If you exported the raw data file to an external storage device, connect the external storage device to the computer running the development software. 2. In the Windows Explorer, double-click the raw data file of the development run. 3. To save the project, choose **File >** ••• **> Save as**. Navigate to a folder, enter a project name, and choose the **Save** button. 4. Optionally, disconnect the external storage device. Working with projects in the development software (295)
12	**Development software** If required, import the raw data file of the development run.	If you **opened** a project, import the raw data file of the development run: 1. If you exported the raw data file to an external storage device, connect the external storage device to the computer running the development software. 2. From the **Navigation** area, choose **Runs >** ••• **> Import**. 3. Navigate to the raw data file and choose the **Open** button. 4. Save the project. 5. Optionally, disconnect the external storage device. Working with raw data files and runs in the development software (317)
13	**Development software** Optionally, enter run notes.	1. Optionally, in the **Additional run notes:** field, enter run notes. 2. Save the project.

Development workflow without unassigned sample setup (quick reference)

Step			Description
14	**Development software** Add the lane settings.		1. On the run tab, choose the **Lane settings** button. 2. Choose one or several tiles (in plate view) or rows (in table view). 3. On the **Lane settings** card, choose the **Sample ID** field. Scan or enter the sample ID. If required, press Enter. 4. Optionally, edit the dilution factor for the sample. 5. In the **MMx** field, enter the name of the master mix reagent. 6. Optionally, enter the ID, the expiry date, and/or the lot number of the master reagent or the master mix reagent. 7. Optionally, enter notes and/or sample preparation notes. 8. Save the project. Adding and editing lane settings of a run in the development software (325)
15	**Development software** Edit the target and dye settings.		For each master mix reagent, do the following: 1. Choose a tile (in plate view) or a row (in table view). 2. In the **Target and dye settings** table, disable the dyes that are not contained in the master mix reagent. 3. Optionally, rename the targets. 4. Save the project.
16	**Development software** Optionally, enter notes.		1. Choose one or several tiles (in plate view) or rows (in table view). 2. Choose the **Edit notes** button or the **Edit sample preparation notes** button. 3. In the dialog box, enter the notes. 4. Choose the **Save** button. 5. Save the project.

Development workflow without unassigned sample setup (quick reference)

Step		Description
17	**Development software** Optionally, work with sample groups.		1. On the run tab, choose the **Sample groups** button. 2. Add and/or edit sample groups. 3. Save the project. Working with sample groups in the development software (328)
18	**Development software** Check and adjust the clustering.		1. Choose the clustering from the **Clustering** menu. 2. Choose the ⚙ button. 3. In the **Settings** combo box, adjust the clustering settings. 4. Choose the ⚙ button. 5. If required, adjust the thresholds. Choose the **Calculate** button. 6. Save the project. Adjusting the clustering in the development software (342)

Development workflow without unassigned sample setup (quick reference)

Step		Description
19	**Development software** Perform the analyses.	 To **add** an analysis, do the following: 1. From the **Navigation** area, choose **Analysis** > ••• Choose the analysis type. 2. In the **Settings** combo box, choose the samples and choose the **Update analysis** button. 3. Optionally, add and/or edit sample groups. 4. On the other tabs in the **Settings** combo box, enter the settings required for the analysis type. 5. Choose the ⚙ button. 6. Save the project. To **edit** an analysis, do the following: 1. Choose the analysis from the **Analysis** menu. 2. Choose the ⚙ button. 3. In the **Settings** combo box, edit the analysis settings. 4. Choose the ⚙ button. 5. Save the project. Analyses in the development software (358)

Development workflow without unassigned sample setup (quick reference)

Step		Description
20	**Development software** Optionally, create or update an analysis package. 	To **create** an analysis package: 1. From the **Navigation** area, choose **Analysis package** > ••• > **Create analysis package**. 2. In the **Create analysis package** dialog box, enter a name for the analysis package and the type of nanowell plate. Choose the **Confirm** button. 3. On the panels of the analysis package tab, enter the required information. 4. Choose the analysis package from the **Analysis package** menu. 5. Choose ••• > **Update version**. 6. In the **Increment version number** dialog box, choose the version number and choose the **Update** button. 7. Save the project. To **update** an analysis package: 1. Choose the analysis package from the **Analysis package** menu. 2. On the panels of the analysis package tab, edit the information. 3. Choose the analysis package from the **Analysis package** menu. 4. Choose ••• > **Update version**. 5. In the **Increment version number** dialog box, choose the version number and choose the **Update** button. 6. Save the project. Working with analysis packages (429)
21	**Development software** Optionally, export the analysis package.	1. Choose the analysis package from the **Analysis package** menu. 2. Choose ••• > **Export**. 3. Navigate to a folder that is accessible from the analyzer and choose the **Save** button. Working with analysis packages (429)

Development workflow without unassigned sample setup (quick reference)

Related topics

- Performing a development workflow without unassigned sample setup (275)

Development workflow with unassigned sample setup (quick reference)

The following table provides you with a quick reference of how to perform a development workflow **with** unassigned sample setup.

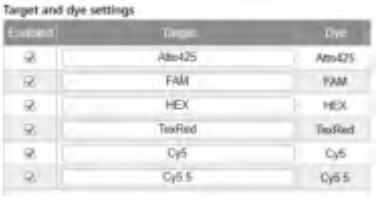
For a quick reference for a development workflow without unassigned sample setup, refer to Development workflow without unassigned sample setup (quick reference) (200).

Step		Description
1	**Development software** Create a project or open a project.	 To **open** a project: 1. On the **Start page** tab, choose the **Open file** button. 2. Navigate to the *dpcrPrj* file and choose the **Open** button. To **create** a project: 1. On the **Start page** tab, choose the **Create new project** button. 2. To save the project, choose **File > ••• > Save as**. Navigate to a folder, enter a project name, and choose the **Save** button. Working with projects in the development software (295)
2	**Development software** If required, create an unassigned sample setup.	If you **opened** a project, add an unassigned sample setup to the project: 1. In the **Navigation** area, choose **Unassigned sample setup > ••• > Create new**. 2. Save the project. If you **created** a project, an unassigned sample setup is added automatically. Working with unassigned sample setups in the development software (405)

Development workflow with unassigned sample setup (quick reference)

Step		Description
3	**Development software** Add the nanowell plates.	1. On the sample setup tab, from the **Plate type** drop-down list, choose the nanowell plate type. 2. Optionally, scan or enter the nanowell plate ID. If required, press Enter. 3. Save the project. Adding run settings and lane settings to unassigned sample setups in the development software (406)
4	**Development software** Set the detection formats.	1. Choose the **Detection formats** button. 2. Disable the channels for dyes that are not contained in any of the master mix reagents. 3. For each enabled channel, choose the dye from the drop-down list. 4. To edit the integration times, choose the **Advanced Settings** check box and edit the values in the **Integration time (ms)** fields. 5. Choose the **Save** button. 6. Save the project. Adding run settings and lane settings to unassigned sample setups in the development software (406)
5	**Development software** Optionally, enter run notes.	1. Optionally, in the **Additional run notes:** field, enter run notes. 2. Save the project.

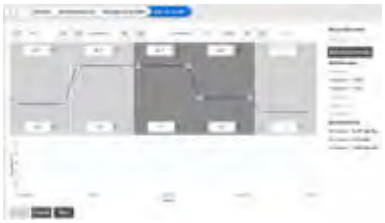
Development workflow with unassigned sample setup (quick reference)

Step			Description
6	**Development software** Add the lane settings.		1. On the sample setup tab, choose the **Lane settings** button. 2. Choose one or several tiles (in plate view) or rows (in table view). 3. On the **Lane settings** card, choose the **Sample ID** field. Scan or enter the sample ID. If required, press Enter. 4. Optionally, edit the dilution factor for the sample. 5. In the **MMx** field, enter the name of the master mix reagent. 6. Optionally, enter the ID, the expiry date, and/or the lot number of the master reagent or the master mix reagent. 7. Optionally, enter notes and/or sample preparation notes. 8. Save the project. Adding run settings and lane settings to unassigned sample setups in the development software (406)
7	**Development software** Edit the target and dye settings.		For each master mix reagent, do the following: 1. Choose a tile (in plate view) or a row (in table view). 2. In the **Target and dye settings** table, disable the dyes that are not contained in the master mix reagent. 3. Optionally, rename the targets. 4. Save the project.
8	**Development software** Optionally, enter notes.		1. Choose one or several tiles (in plate view) or rows (in table view). 2. Choose the **Edit notes** button or the **Edit sample preparation notes** button. 3. In the dialog box, enter the notes. 4. Choose the **Save** button. 5. Save the project.
9	**Development software** Create a sample setup report.		1. In the **Navigation** area, from the unassigned sample setup in the **Unassigned sample setup** menu, choose ••• **> Create a sample setup report**. 2. Navigate to a folder. Enter a name for the sample setup report and choose the **Save** button. Creating a sample setup report of an unassigned sample setup in the development software (410)

Development workflow with unassigned sample setup (quick reference)

Step		Description
10	Prepare the reaction mixtures.	1. Prepare the reaction mixtures. 2. Refer to the sample setup report to identify the nanowell plates and to allocate the reaction mixtures to the nanowell plate lanes. For details about preparing the reaction mixtures and pipetting, refer to the Instructions for Use of the reagents and controls.
11	**Partitioning engine** Pipette and partition the nanowell plates.	  1. Pipette the reaction mixtures into the inlet ports of the first nanowell plate. 2. Choose the **Load** button. 3. Place the nanowell plate in the nanowell plate drawer. 4. Choose the **Start** button. 5. When the nanowell plate drawer opens, check that all nanowell plate lanes that contain reaction mixtures are partitioned. 6. Remove the nanowell plate. 7. Place the nanowell plate on a flat and clean surface. 8. Pipette and partition the other nanowell plates. 9. Stack the partitioned nanowell plates. Partitioning the nanowell plates (221)
12	**Analyzer** Load the analyzer.	 1. In the global information area, choose the ⏏ button. 2. Place the nanowell plate stack in the nanowell plate stack drawer. 3. Choose the ⏏ button. Loading the analyzer (225)
13	**Analyzer** Verify the nanowell plates and the sample setup.	 1. On the **Plates** panel, verify that all nanowell plates are in **Valid** status. 2. Verify the displayed nanowell plates against the sample setup report. 3. Choose the **Run profile** button.

Development workflow with unassigned sample setup (quick reference)

Step		Description
14	**Analyzer** Optionally, duplicate or import a run profile. 	To duplicate a run profile, do the following: 1. On the **Manage run profiles** panel, choose a run profile. 2. Choose the **Duplicate** button. 3. In the **Edit run profile name** dialog box, enter a name for the run profile. 4. Choose the **Save** button. To import a run profile, do the following: 1. On the **Manage run profiles** panel, choose the **Import** button. 2. In the folder browser in the **Import run profiles** dialog box, navigate to the folder. 3. In the file browser, choose the run profile. 4. Choose the **Import** button. Working with run profiles on the Manage run profiles panel in the analyzer software (299)
15	**Analyzer** Edit the run profile. 	1. On the **Manage run profiles** panel, choose an unlocked run profile. 2. Choose the **Open** button. 3. Optionally, on the **Edit run profile** panel, edit the programs. 4. Choose the **Detection formats** button. 5. In the **Detection format** combo box, disable the channels for dyes that are not contained in any of the master mix reagents. For each enabled channel, choose the dye from the drop-down list. Optionally, edit the integration time. Choose the **Save** button. 6. Choose the **Save** button. Editing run profiles on the Edit run profile panel in the analyzer software (303)
16	**Analyzer** Start the run.  	To start the run on the **Manage run profiles** panel, do the following: 1. Choose the run profile 2. Choose the **Run** button. To start the run on the **Edit run profile** panel: 1. Choose the **Run** button.

Development workflow with unassigned sample setup (quick reference)

Step		Description
17	**Analyzer** Optionally, change the run name and/or enter run notes.		1. In the middle of the **Monitoring** panel, next to the run name, choose the ✎ button. 2. In the dialog box, in the **Run name** field, enter a new run name. 3. In the **Edit notes** field, enter run notes. 4. Choose the **Confirm** button. ▸ Entering run information for a development run in the analyzer software (307)
18	**Analyzer** Unload the analyzer.		1. When the run is finished, in the global information area, choose the ⏏ button. 2. Remove the nanowell plate stack from the nanowell plate stack drawer. 3. Choose the ⏏ button. 4. Dispose of the nanowell plates according to local regulations. ▸ Unloading the analyzer (227)
19	**Analyzer** If required, export the raw data file.		If the analyzer is not configured for automatic export, export the raw data file of the development run: 1. Optionally, to export to an external storage device, connect the external storage device to the analyzer. 2. Choose **Routine > Development run > Development results**. 3. Choose the run and choose the **Export** button. 4. Navigate to a folder and choose the **Export** button 5. Optionally, disconnect the external storage device. ▸ Managing raw data files of development runs in the analyzer software (312)

▸ Development workflow with unassigned sample setup (quick reference)

Step		Description
20	**Development software** Import the raw data file of the development run.	1. If the raw data file was exported to an external storage device, connect the external storage device to the computer running the development software. 2. From the **Navigation** area, choose **Runs >** ••• **> Import**. 3. Navigate to the raw data file and choose the **Open** button. 4. If a match is found, to confirm the assignment of the unassigned sample setup to the run, choose the **Confirm** button. 5. Save the project. 6. Optionally, disconnect the external storage device. ▸ Working with raw data files and runs in the development software (317)
21	**Development software** If required, assign the unassigned sample setup to the run.	If the unassigned sample setup was not assigned to the run automatically, assign it manually: 1. Choose the run from the **Runs** menu. 2. Choose ••• **> Assign existing sample setup**. 3. Choose the unassigned sample setup and choose the **Confirm** button. 4. Save the project. ▸ Assigning partially matching unassigned sample setups to development runs in the development software (321)
22	**Development software** Optionally, edit the lane settings.	 1. On the run tab, choose the **Lane settings** button. 2. Choose one or several tiles (in plate view) or rows (in table view). 3. Edit the sample IDs, the dilution factor, the master mix reagent, and/or the additional information for the master mix reagent or master reagent. 4. Edit the target and dye settings. 5. Add notes. 6. Save the project. ▸ Adding and editing lane settings of a run in the development software (325)

Development workflow with unassigned sample setup (quick reference)

Step		Description
23	**Development software** Optionally, work with sample groups.	 	1. On the run tab, choose the **Sample groups** button. 2. Add and/or edit sample groups. 3. Save the project. Working with sample groups in the development software (328)
24	**Development software** Check and adjust the clustering.	 	1. Choose the clustering from the **Clustering** menu. 2. Choose the ⚙ button. 3. In the **Settings** combo box, adjust the clustering settings. 4. Choose the ⚙ button. 5. If required, adjust the thresholds. Choose the **Calculate** button. 6. Save the project. Adjusting the clustering in the development software (342)

Development workflow with unassigned sample setup (quick reference)

Step		Description
25	**Development software** Perform the analyses.	 To **add** an analysis, do the following: 1. From the **Navigation** area, choose **Analysis** > ••• Choose the analysis type. 2. In the **Settings** combo box, choose the samples and choose the **Update analysis** button. 3. Optionally, add and/or edit sample groups. 4. On the other tabs in the **Settings** combo box, enter the settings required for the analysis type. 5. Choose the ⚙ button. 6. Save the project. To **edit** an analysis, do the following: 1. Choose the analysis from the **Analysis** menu. 2. Choose the ⚙ button. 3. In the **Settings** combo box, edit the analysis settings. 4. Choose the ⚙ button. 5. Save the project. Analyses in the development software (358)

Development workflow with unassigned sample setup (quick reference)

Step		Description
26	**Development software** Optionally, create or update an analysis package.	 To **create** an analysis package: 1. From the **Navigation** area, choose **Analysis package** > ••• > **Create analysis package**. 2. In the **Create analysis package** dialog box, enter a name for the analysis package and the type of nanowell plate. Choose the **Confirm** button. 3. On the panels of the analysis package tab, enter the required information. 4. Choose the analysis package from the **Analysis package** menu. 5. Choose ••• > **Update version**. 6. In the **Increment version number** dialog box, choose the version number and choose the **Update** button. 7. Save the project. To **update** an analysis package: 1. Choose the analysis package from the **Analysis package** menu. 2. On the panels of the analysis package tab, edit the information. 3. Choose the analysis package from the **Analysis package** menu. 4. Choose ••• > **Update version**. 5. In the **Increment version number** dialog box, choose the version number and choose the **Update** button. 6. Save the project. Working with analysis packages (429)
27	**Development software** Optionally, export the analysis package.	1. Choose the analysis package from the **Analysis package** menu. 2. Choose ••• > **Export**. 3. Navigate to a folder that is accessible from the analyzer and choose the **Save** button. Working with analysis packages (429)

Development workflow with unassigned sample setup (quick reference)

Related topics

- Performing a development workflow with unassigned sample setup (283)

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Frequently performed tasks

In this chapter 11

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Partitioning the nanowell plates

You must partition the pipetted nanowell plates in the partitioning engine before you can process them on the analyzer.

The stability of the reaction mixtures between partitioning of a nanowell plate and processing it on the analyzer has been tested for 90 minutes.

The design of the drawer of the partitioning engine and the beveled corner of the nanowell plates ensure the correct orientation of the nanowell plate in the drawer.

⚠ CAUTION!

Moving drawer

The nanowell plate drawer of the partitioning engine opens and closes during operation. An opening drawer may strike you. A closing drawer may pinch your fingers.

- Keep away from the nanowell plate drawer during operation.
- Do not try to close the nanowell plate drawer manually by pushing against it.
- Leave sufficient free space around the partitioning engine to allow for unobstructed movement of the nanowell plate drawer.

⚠ CAUTION!

Improper handling of nanowell plates

Scratches, finger prints, dust, or other artifacts on the nanowell plate lanes compromise the image integrity, which may cause incorrect, invalid, or delayed results.

- Do not leave the nanowell plates in the open for any length of time.
- Do not touch the nanowell plate lanes.
- Handle the nanowell plates by the long sides of their nanowell plate frames only.
- Wear lab gloves when handling the nanowell plates. Regularly change the lab gloves.

About partitioning information

Directly after partitioning, the partitioning engine sends the following information to the analyzer it is assigned to (if the connection is working):

- Nanowell plate ID
- Timestamp
- Serial number of the partitioning engine

- Information about the partitioning fluid
- Invalid nanowell plate lanes
- Partitioning flags

Without this information, the validation of the nanowell plate fails during loading on the analyzer and the nanowell plate cannot be processed.

In a diagnostic workflow, the information is also sent to the web application.

In a development workflow, the analyzer includes the information in the raw data file of the run.

About invalid nanowell plate lanes

The partitioning engine flags invalid nanowell plate lanes.

If an invalid nanowell plate lane contains a sample, the final results for all targets will be invalid.

If an invalid nanowell plate lane contains a control, the final results for all associated targets or samples will be invalid.

If all partitioned nanowell plate lanes of a nanowell plate are invalid, the whole nanowell plate is invalid. Do not load invalid nanowell plates on the analyzer. You cannot start a run on the analyzer while invalid nanowell plates are loaded.

For a development run, consider pipetting new nanowell plates to replace invalid ones.

For a diagnostic run, you cannot replace invalid nanowell plates.

Dispose of pipetted nanowell plates according to local regulations.

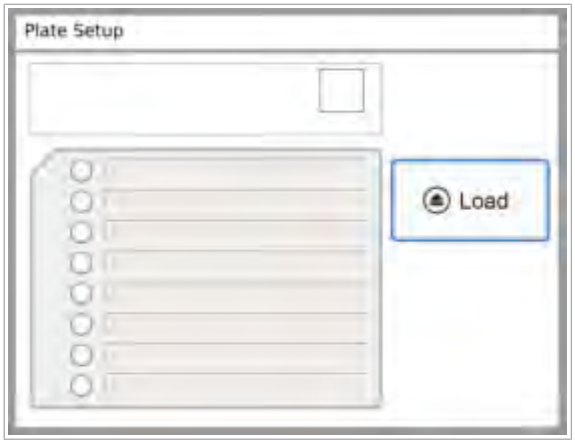
- ☐ Pipetted nanowell plates
- ☐ For diagnostic workflow:
  Sample setup report from the web application
- ☐ For development workflow:
  Sample setup report from the development software (if available) or other planning of development run

- ☐ Partitioning engine started, initialized, and primed

- Starting up the partitioning engine (231)
- Initializing the partitioning engine (505)
- Priming the partitioning engine (232)

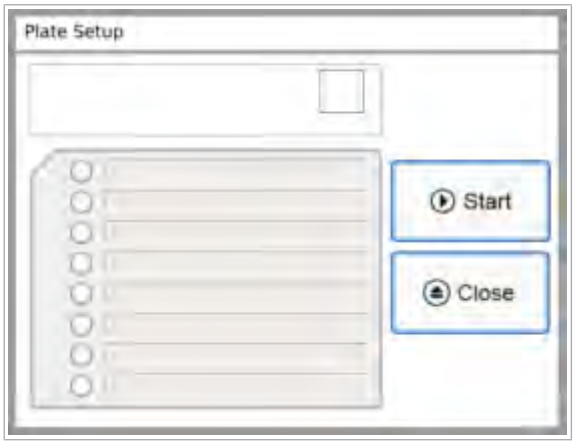
To partition a nanowell plate

1 Ensure that the connection indicator in the global information area indicates that the partitioning engine is connected to the analyzer.



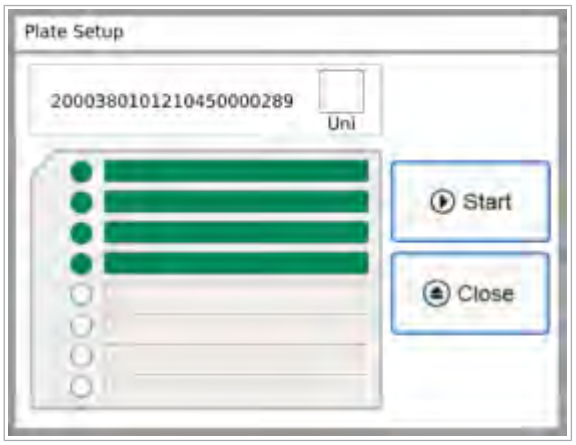
2 On the **Plate Setup** panel, choose the **Load** button.
➔ The nanowell plate drawer opens.

3 Place a pipetted nanowell plate in the nanowell plate drawer with the beveled corner at the back right.



4 Choose the **Start** button.
ⓘ Do not try to close the nanowell plate drawer manually by pushing against it.
➔ The nanowell plate drawer closes.
➔ The nanowell plate ID and type are displayed on the **Plate Setup** panel.
➔ The nanowell plate is partitioned.
➔ The partitioning indicators display the partitioning status of the nanowell plate lanes.

5 Wait until partitioning of the nanowell plate is finished and the nanowell plate drawer opens.



6 Check the partitioning status of the nanowell plate lanes by means of the color of the partitioning indicators:

- Check that the partitioning indicators for all nanowell plate lanes that contain reaction mixtures are green or red.
- If partitioning indicators of nanowell plate lanes that contain reaction mixtures remain gray, discard the nanowell plate according to local regulations.

ⓘ The partitioning indicators of nanowell plate lanes that do not contain reaction mixtures will always remain gray. You do not need to consider such nanowell plate lanes.

7 Remove the nanowell plate from the nanowell plate drawer.

8 Choose the **Close** button.

➔ The nanowell plate drawer closes.

9 Do the following with the nanowell plates for a run:

- Place the first partitioned nanowell plate on a flat and clean surface.
- Stack the partitioned nanowell plates on top of each other.

Loading the analyzer

You must load the partitioned nanowell plates on the analyzer.

The stability of the reaction mixtures between partitioning of a nanowell plate and processing it on the analyzer has been tested for 90 minutes.

For diagnostic runs, do not load nanowell plates on the analyzer that you invalidated in the web application. You cannot start the diagnostic run while invalidated nanowell plates are loaded.

⚠ CAUTION!

Moving drawer

The nanowell plate stack drawer of the analyzer opens and closes during operation. An opening drawer may strike you. A closing drawer may pinch your fingers.

- Keep away from the nanowell plate stack drawer during operation.
- Do not try to close the nanowell plate stack drawer manually by pushing against it.
- Leave sufficient free space around the analyzer to allow for unobstructed movement of the nanowell plate stack drawer.

☐ Partitioned nanowell plates

☐ Analyzer in **Analyzer ready** status

To load the analyzer

1 In the analyzer software, choose the ⏏ button.
➔ The nanowell plate stack drawer opens.

2 CAUTION! Risk of incorrect, invalid, or delayed results.
Do not load nanowell plates with unpartitioned nanowell plate lanes that contain reaction mixtures. Avoid scratches, finger prints, dust, or other artifacts on the nanowell plate lanes.

Place the nanowell plate stack in the nanowell plate stack drawer with the barcode labels facing to the front of the analyzer.

ⓘ For diagnostic runs, do not load invalid nanowell plates on the analyzer.

3 To close the nanowell plate stack drawer, choose the ⏏ button.

ⓘ Do not try to close the nanowell plate stack drawer manually by pushing against it.

4 Wait until the automatic scanning of the barcode labels of the nanowell plates is finished.

➔ The nanowell plates are displayed on the **Plates** panel.

Unloading the analyzer

Unload the analyzer when a run is finished.

Always unload the analyzer before you shut down the analyzer.

⚠ CAUTION!

Moving drawer

The nanowell plate stack drawer of the analyzer opens and closes during operation. An opening drawer may strike you. A closing drawer may pinch your fingers.

- Keep away from the nanowell plate stack drawer during operation.
- Do not try to close the nanowell plate stack drawer manually by pushing against it.
- Leave sufficient free space around the analyzer to allow for unobstructed movement of the nanowell plate stack drawer.

- ☐ Run finished (completed or aborted)
- ☐ **Awaiting plate removal** displayed on **Monitoring** panel
- ☐ Analyzer in **Analyzer ready** status

To unload the analyzer

1. When the run is finished, in the global information area of the analyzer software, choose the ⏏ button.
   → The nanowell plate stack drawer opens.
2. Remove the nanowell plate stack from the nanowell plate stack drawer.
3. To close the nanowell plate stack drawer, choose the ⏏ button.
4. CAUTION! Risk of contamination of the laboratory. Do not leave nanowell plates in the open for any length of time.

   Pack the used nanowell plates in a resealable plastic bag.
5. Dispose of the plastic bag containing the used nanowell plates according to local regulations.

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Before routine operation

In this chapter 12

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Starting up the partitioning engine

You must start up the partitioning engine before use.

5 minutes

To start up the partitioning engine

1. At the back of the partitioning engine, press the power switch.
2. Wait until the partitioning engine is initialized and primed and is in **Ready** status.
3. Ensure that the connection indicator in the global information area indicates that the partitioning engine is connected to the analyzer.

Priming the partitioning engine

You can prime the partitioning engine when required or on demand.

Priming flushes the fluid system inside the partitioning engine with partitioning fluid to ensure it is free of air bubbles.

The partitioning engine primes automatically directly after startup.

The partitioning engine requires priming after 24 hours without activity or after shutdown.

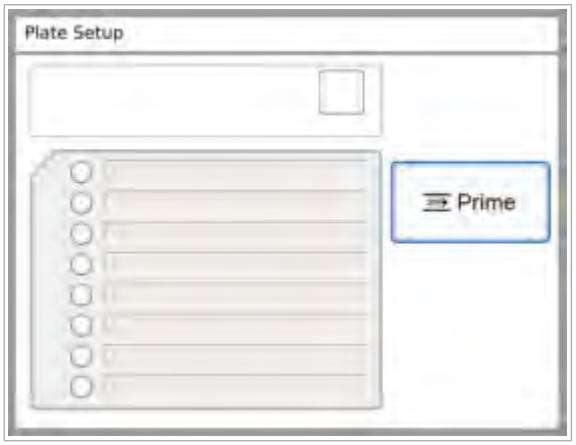
When priming is required, the **Prime** button is available on the **Plate Setup** panel.

Overview of the partitioning engine software (83)

At least when required, i.e., when the **Prime** button is available

- ☐ To prime when required:
  Prime button available on the **Plate Setup** panel
- ☐ To prime on demand:
  Partitioning engine in **Ready** status

To prime the partitioning engine



1 To prime the partitioning engine when required, on the **Plate Setup** panel, choose the **Prime** button.

2 To prime the partitioning engine on demand, in the global information area, choose ≡ > **Prime Instrument**.

3 Wait until priming is complete and the partitioning engine is in **Ready** status.

Logging on to the web application

You must log on to the web application before use.

To log on to the web application, you need diagnostic operator user role or diagnostic approver user role.

User accounts are managed in the analyzer software. You log on to the web application with the same user account that you use in the analyzer software.

- ☐ User name and password
- ☐ Diagnostic operator user role or diagnostic approver user role

To log on to the web application

1 In the Firefox browser, in the **Logon** dialog box, enter your user name and password.

   ⓘ Use the same user account as for the analyzer software.

2 Choose the **Logon** button.

   ➔ The dashboard of the web application is displayed.

Starting up the analyzer

You must start up the analyzer and log on before use.

During startup, the analyzer transfers all loaded nanowell plates to the nanowell plate stack drawer and displays the Plates panel. In this case, you must unload the analyzer before further use.

Unloading the analyzer (227)

10 minutes

☐ User name and password

To start up the analyzer

1 On the right side of the analyzer, press the power button.

2 Wait until the analyzer is initialized and is in **Analyzer ready** status.

3 In the global information area, choose the **Logon** button.

4 In the **Logon** dialog box, enter your user name and password.

5 Choose the **Confirm** button.
➔ The **Routine** panel is displayed.

Logging on to the analyzer software

If you logged off from the analyzer software or if you were logged off automatically, you must log on again before you can use the analyzer.

☐ User name and password

To log on to the analyzer software

1 In the global information area of the analyzer software, choose the **Logon** button.

2 In the **Logon** dialog box, enter your user name and password.

3 Choose the **Confirm** button.
➔ The **Routine** panel is displayed.

Change password

In the **Change password** dialog box, you change your password.

All users, regardless of their user roles, can change their own passwords.

The new password applies to the analyzer software and the web application.

⚠ CAUTION!

Weak passwords

Weak passwords may allow unauthorized access to the system, data manipulation or loss, or unauthorized access to personal information, which may cause incorrect, invalid, or delayed results.

- Use strong passwords.
- Do not share passwords.
- Do not write down passwords.
- Do not share user accounts.

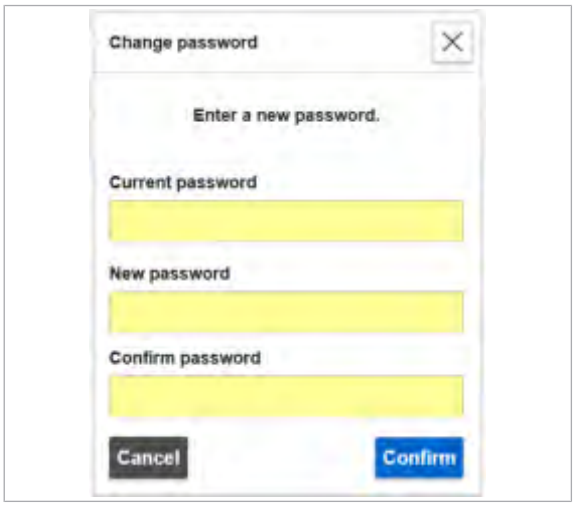
You can change your password at any time. Alternatively, the analyzer software or the web application may prompt you at logon to change your password (depending on which software component you log on to first).

The new password must conform to the global password policy configured in **Administration > Password settings**. Passwords are case-sensitive.

- Optional:
  Anytime
- Mandatory:
  When prompted at logon by the analyzer software or the web application

To change my password in the analyzer software

1 In the analyzer software, choose **Administration > Change password**.
➔ The **Change password** dialog box is displayed.



2 Enter your current password. Enter the new password twice.

ⓘ Passwords are case-sensitive.

3 Choose the **Confirm** button.

➔ The new password applies to the analyzer software and the web application.

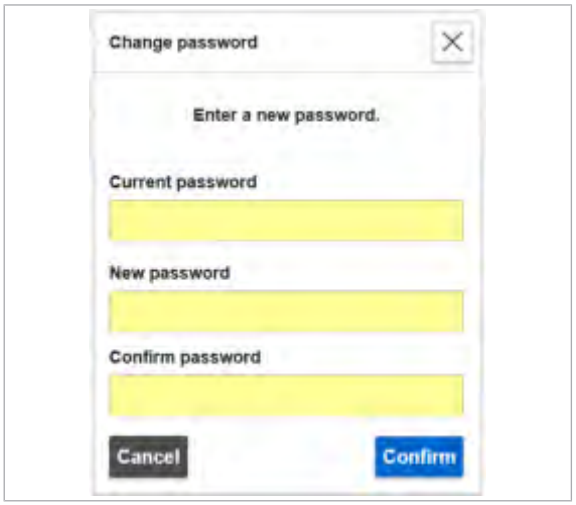
To change my password at logon in the analyzer software

1 In the global information area of the analyzer software, choose the **Logon** button.

2 In the **Logon** dialog box, enter your user name and password.

3 Choose the **Logon** button.

➔ The **Change password** dialog box is displayed.



4 Enter your current password. Enter your new password twice.

ⓘ Passwords are case-sensitive.

5 Choose the **Confirm** button.

➔ The new password applies to the analyzer software and the web application.

To change my password at logon in the web application

1 In your Firefox browser, enter the URL of the analyzer you want to connect to.

2 In the **Logon** dialog box, enter your user name and password.

ⓘ Use the same user account as for the analyzer software.

3 Choose the **Logon** button.

➔ The **Change password** dialog box is displayed.

4 Enter your new password twice.

ⓘ Passwords are case-sensitive.

5 Choose the **Confirm** button.

➔ The new password applies to the analyzer software and the web application.

Starting the development software

You must start the development software before use.

On the start page of the development software, the last 5 projects or raw data files that you worked with are listed in the **Open a recently used file** list. The project or file that you worked with last is listed at the top.

When you open a raw data file from the start page, a new project for that file is created automatically.

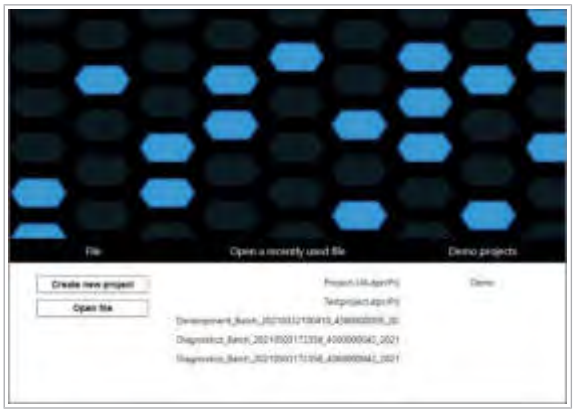
Projects in the development software (294)

To start the development software

1 To start the development software, double-click the icon on the desktop.

   Alternatively, start the development software from the Windows menu.

   ➔ The start page of the development software is displayed.



2 On the start page, do one of the following:

- To create a project, choose the **Create new project** button.
- To open a project or raw data file, choose the **Open file** button. Navigate to the project or file and choose the **Open** button.
- To open a project or raw data file that you recently worked with, choose the entry from the **Open a recently used file** list.
- To open the demonstration project, choose it from the **Demo projects** list.

   When you open a raw data file, a new project for that file is created automatically.

   ➔ The project page of the development software is displayed.

Routine operation of diagnostic workflow

In this chapter 13

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Performing a diagnostic workflow

Perform a diagnostic workflow for diagnostic purposes.

In diagnostic workflows, you work with the following system components:

- Web application
- Partitioning engine
- Analyzer

For diagnostic workflows, you need diagnostic operator user role, except for sending results you need diagnostic approver user role.

Before you can perform a diagnostic workflow, a user with administrator user role must import and enable suitable analysis packages in the analyzer software that include the tests and the nanowell plate types you want to use for your diagnostic workflow.

The procedure below gives an overview of the steps you must perform in a diagnostic workflow. For more details, refer to the individual procedures that are referenced in the steps.

⚠ CAUTION!

Delayed processing of partitioned nanowell plates

Delayed processing of partitioned nanowell plates on the analyzer may cause degradation of biological material and/or invalidation of the nanowell plates, which may cause incorrect, invalid, or delayed results.

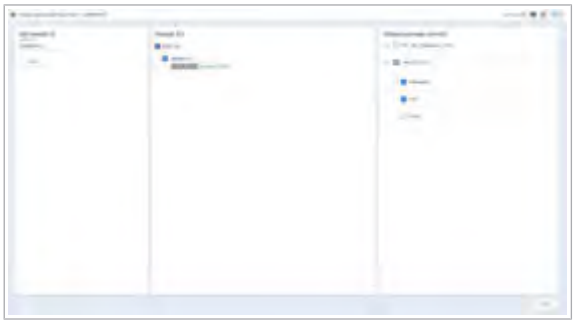
- Only pipette and partition nanowell plates if you can directly run them on the analyzer afterwards
- Ensure that you start the run directly after loading the analyzer.
- Observe that there may be a time limit configured in the analysis packages between partitioning and processing of a nanowell plate. If the time limit is exceeded, the nanowell plate is invalidated and cannot be processed anymore.

☐ Nanowell plates (plate types matching the analysis packages assigned in the orders)

- ☐ Diagnostic operator user role
- ☐ To send results manually:
  Diagnostic approver user role
- ☐ Analysis packages imported and enabled in analyzer software

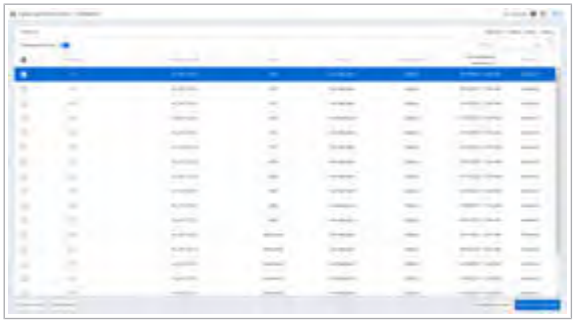
To perform a diagnostic workflow

1 If orders are not exclusively received from an LIS, in the web application, create and import an orders list as described in Ordering in the web application (250):
   - Create a CSV file for the orders.
   - In the **Orders** column on the dashboard, choose the **View orders** tile.
   - On the **Orders** screen in assignment mode, choose the **Import order list** button.
   - Navigate to the orders list and choose the **Open** button.
   - In the dialog box, choose the **Confirm** button.



2 Alternatively, in the web application, create orders manually as described in Ordering in the web application (250):
   - In the **Orders** column on the dashboard, choose the **Create sample setup** tile.
   - On the **Orders** screen in assignment mode, choose the **Add/edit order** button.
   - On the **Add sample ID** card on the **Edit orders** screen, choose the **Sample ID** field. Scan or enter the sample ID and choose the **Add** button.
   - On the **Sample IDs** card, select the sample ID.
   - On the **Analysis package and test** card, assign complete analysis packages, or expand the analysis packages and assign selected tests only.
   - Choose the **Save** button.

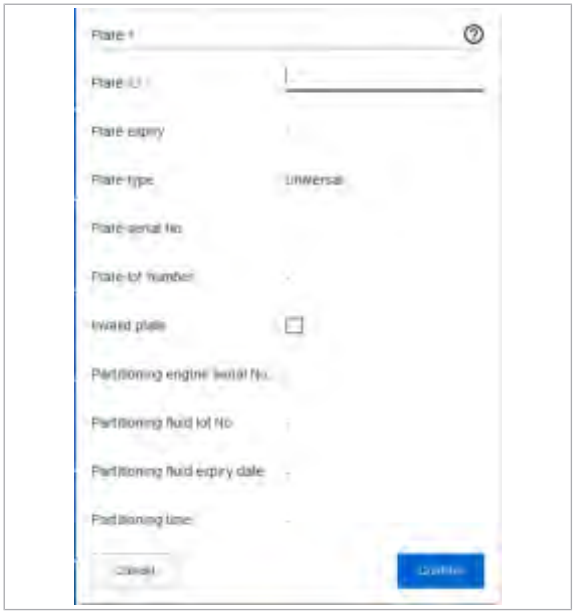
   ⓘ The web application can manage orders from all sources simultaneously.



3 In the web application, create a sample setup as described in Creating sample setups in the web application (255):
   - In the **Orders** column on the dashboard, choose the **Create sample setup** tile.
   - On the **Orders** screen in assignment mode, select the first row of orders for the sample setup.
   - Select the other rows of orders for the sample setup.
   - Choose the **Assign to sample setup** button.

   ➔ On the **Sample setup** screen, the unconfirmed sample setup is displayed in plate view.

➔ The column footers are color-coded according to nanowell plate type.



4 On the **Sample setup** screen, for each nanowell plate, assign the nanowell plate IDs:

- To display the **Plate:** combo box, choose the column header twice.
- In the **Plate ID** field, scan or enter the nanowell plate ID.
- Choose the **Confirm** button.

➔ The column footers display the last 5 digits of the nanowell plate IDs.

5 If required, on the **Sample setup** screen, for each nanowell plate lane, do the following:

- To display the **Sample settings:** combo box, choose the tile twice.
- Optionally, in the **Notes** field, enter sample notes.
- If required, in the **Kit No.** field, scan or enter the IVD kit ID.
- Choose the **Confirm** button.

ⓘ For IVD workflows, ensure that the IVD kits match the tests in the orders.
For LDT workflows, the **Kit No.** field is a free text field, e.g., to track the master mix reagents.

6 Optionally, on the **Sample setup** screen, change the batch name and/or enter run notes as described in Entering run information for a diagnostic run in the web application (261):

- In the top center of the screen, choose the ✎ button.
- In the **Run information** dialog box, change the batch name and/or enter run notes.
- Choose the **Confirm** button.

7 On the **Sample setup** screen, choose the **Confirm** button.

ⓘ Ensure that you confirm the sample setup. Otherwise the sample setup is lost when you leave the **Sample setup** screen.

➔ The sample setup is confirmed.

➔ In the **Sample setups** column on the dashboard, the batch tile of the sample setup is displayed in **Pending partitioning** status.

8 In the web application, create a sample setup report as described in Creating sample setup reports in the web application (259):

- In the **Sample setups** column on the dashboard, choose the batch tile.
- On the **Sample setup** screen, choose the **Generate report** button.
- Open or save the sample setup report.
- On the **Sample setup** screen, choose the **Confirm** button.

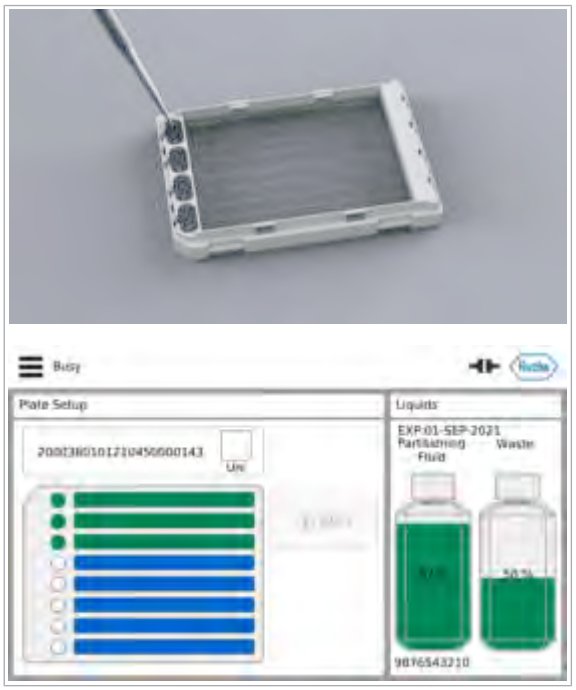
ⓘ Use the sample setup report as a guide for pipetting and for verification of the sample setup in the analyzer software.

9 Prepare the reaction mixtures.

ⓘ For details about preparing the reaction mixtures and pipetting, refer to the Instructions for Use of the reagents and controls.

10 Refer to the sample setup report to identify the nanowell plates and to allocate the reaction mixtures to the nanowell plate lanes.

ⓘ Ensure that you use the correct nanowell plates.



11 CAUTION! Risk of incorrect results.
Take care to avoid pipetting errors. If a pipetting error may have occurred, invalidate the affected nanowell plate lane in the web application.

Pipette and partition the nanowell plates on the partitioning engine as described in Partitioning the nanowell plates (221):

- Pipette the reaction mixtures into the inlet ports of the first nanowell plate.
- Choose the **Load** button.
- Place the nanowell plate in the nanowell plate drawer.
- Choose the **Start** button.
- When the nanowell plate drawer opens, check that all nanowell plate lanes that contain reaction mixtures are partitioned.
- Remove the nanowell plate.
- Place the nanowell plate on a flat and clean surface.
- Pipette and partition the other nanowell plates.
- Stack the partitioned nanowell plates.

ⓘ The stability of the reaction mixtures between partitioning of a nanowell plate and processing it on the analyzer has been tested for 90 minutes.

➔ In the web application, in the **Sample setups** column on the dashboard, the batch tile of the sample setup is displayed in **Ready to start run** status.

12 CAUTION! Risk of incorrect, invalid, or delayed results.
Do not load nanowell plates with unpartitioned nanowell plate lanes that contain reaction mixtures. Avoid scratches, finger prints, dust, or other artifacts on the nanowell plate lanes.

Load the analyzer as described in Loading the analyzer (225):

- In the global information area, choose the ⏏ button.
- Place the nanowell plate stack in the drawer.
- Choose the ⏏ button.

ⓘ Do not load invalid nanowell plates on the analyzer.

➔ In the analyzer software, the **Sample setup** panel is displayed.

13 Verify the displayed sample setup against the sample setup report from the web application.

14 To start the run, choose the **Start run** button.

➔ In the analyzer software, the **Monitoring** panel is displayed.

➔ In the web application, in the **Run in progress** column on the dashboard, the batch tile is displayed in **Processing** status.

➔ The expected run duration is displayed in the analyzer software and in the web application.

15 Optionally, in the web application, enter run notes as described in Entering run information for a diagnostic run in the web application (261):

- In the **Run in progress** column on the dashboard, choose the ✎ button on the batch tile.
- Enter run notes.
- Choose the **Confirm** button.

16 CAUTION! Risk of contamination of the laboratory. Pack the used nanowell plates in a resealable plastic bag.

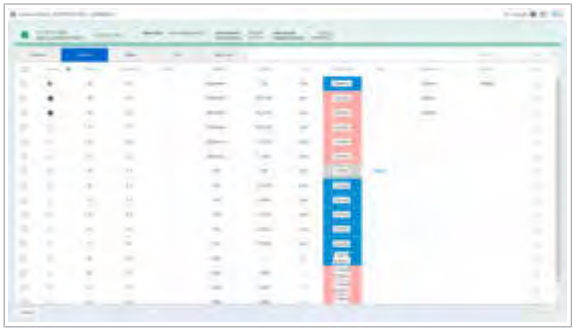
When the run is finished, unload the analyzer as described in Unloading the analyzer (227):

- In the global information area, choose the ⏏ button.
- Remove the nanowell plate stack from the drawer.
- Choose the ⏏ button.

ⓘ Dispose of the nanowell plates according to local regulations.

➔ In the web application, if results must be manually released and/or sent, the batch tile is displayed in the **Results** column on the dashboard.

➔ In the web application, if results are automatically released and sent, the batch is automatically listed on the **Completed batches** screen. On the dashboard, no separate batch tile is displayed anymore.



17 If required, release the results in the web application as described in Releasing results manually in the web application (265):

- In the **Results** column on the dashboard, choose the batch tile.
- On the **Results of** screen, navigate to the results.
- Review the results and the corresponding run information.

- Select the results from the list and choose the **Release** button.
- In the **Confirmation** dialog box, enter your password and choose the **Release** button.

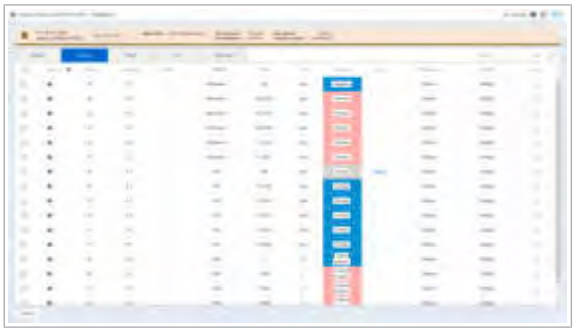
➔ The results are released.

18 If required, a user with diagnostic approver user role must send the results in the web application as described in Sending results manually in the web application (267):

- In the **Results** column on the dashboard, choose the batch tile.
- On the **Results of** screen, select the released results and choose the **Send** button.
- In the **Confirmation** dialog box, enter your password and choose the **Send** button.

➔ The results are sent.

➔ If all results are released and sent, the batch is listed on the **Completed batches** screen. On the dashboard, no separate batch tile is displayed anymore.



19 Optionally, in the web application, create a result report as described in Creating result reports in the web application (268):

- In the **Results** column on the dashboard, choose the **Completed batches** tile.
- Choose the batch from the list and choose the **View** button.
- On the **Results of** screen, choose the **Report** button.

ⓘ Alternatively, you can create a result report before you release and/or send the results.

Related topics

- Diagnostic workflow (quick reference) (196)
- Partitioning the nanowell plates (221)
- Loading the analyzer (225)
- Unloading the analyzer (227)
- Orders in the web application (250)
- Sample setups in the web application (255)
- Entering run information for a diagnostic run in the web application (261)
- Results in the web application (263)

Orders in the web application

For diagnostic workflows, orders tell the system which tests to perform on which samples.

In this section

Ordering in the web application

If orders are not exclusively received from an LIS, you must import an orders list and/or create orders manually in the web application.

About orders lists

To import an orders list, the file must conform to the following specifications:

- CSV file
- Separator: comma
- Header row with following content:
  - "SampleID"
  - "AssayName" (the test name)
  - "AnalysisPackageName"
  - "AnalysisPackageVersion"
- 1 separate row per order (i.e., per combination of sample ID and test, regardless of analysis package)
- The sample ID can consist of 1 to 25 characters
- The test name can consist of 1 to 30 characters

Importing an orders list fails in the following cases:

- If any row in the orders list is incomplete or contains errors, e.g., spelling errors in the names of tests or analysis packages.
- If there is a problem with the referenced analysis packages:
  - A referenced analysis package does not exist on the system or is in **Disabled** status.
  - The version of a referenced analysis package does not match the version of the analysis package on the system.
  - An ordered test is not contained in the referenced analysis package.

- If the orders list contains duplicate orders.
- If there is already a not allocated order in the web application that matches an order in the orders list.

If the import fails for 1 order of the orders list, no order is imported from the orders list.

☐ Suitable analysis package in **Enabled** status (or in **In validation** status)

☐ To import orders list:
CSV file with required content

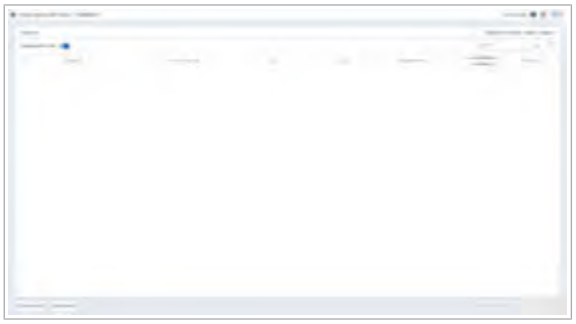
☐ Diagnostic operator user role

To import an orders list into the web application

1 Create a CSV file for the orders. Save the file in a folder that is accessible from the web application.

2 In the web application, in the **Orders** column on the dashboard, choose the **View all orders** tile.

➔ The **Orders** screen is displayed with assignment mode disabled.



3 Choose the **Import order list** button.

4 Navigate to the orders list and choose the **Open** button.

5 In the dialog box, choose the **Confirm** button.

ⓘ If the import fails for 1 order from the orders list, the import fails for all orders. No orders are imported.

➔ 1 order is created for each distinct combination of sample ID and test.

➔ The orders are displayed as summarized entries on the **Orders** screen.

➔ On the dashboard, the **Create sample setup** tile lists the number of not allocated orders.

To create orders manually in the web application

1 In the web application, in the **Orders** column on the dashboard, choose the **Create sample setup** tile.

➔ The **Orders** screen in assignment mode is displayed.

2 Choose the **Add/edit order** button.
➔ The **Edit orders** screen is displayed.

3 To add the sample IDs, do the following:
- On the **Add sample ID** card, choose the **Sample ID** field.
- Scan or enter the sample ID.
- Choose the **Add** button.

ⓘ The sample ID can consist of 1 to 25 characters. Do not press Enter after entering the sample ID. The Enter key does not work.

➔ The sample ID is added to the **Sample IDs** card.
➔ If there are already not allocated orders for the same sample ID, all already assigned tests and analysis packages are displayed on the **Sample IDs** card. Tests of LIS orders are displayed in blue font.

4 To assign the tests to the samples IDs, do the following:
- On the **Sample IDs** card, select the sample ID.
- On the **Analysis package and test** card, assign complete analysis packages, i.e., all tests of the analysis packages. Alternatively, expand the analysis packages and assign selected tests only (if possible).

ⓘ You can assign the same tests to multiple sample IDs at the same time. Alternatively, you can assign the tests individually to each sample ID.

5 Choose the **Save** button.
➔ 1 order is created for each distinct combination of sample ID and test.
➔ The orders are displayed as summarized entries on the **Orders** screen.
➔ On the dashboard, the **Create sample setup** tile lists the number of not allocated orders.

Editing not allocated orders in the web application

In the web application, you can edit not allocated orders except LIS order, i.e., orders that are not yet assigned to a sample setup.

You edit orders by assigning and/or deassigning tests from sample IDs.

Because an order is the combination of a sample ID and a single test, editing orders results in the following:

- If you assign an additional test to a sample ID, you **create** an additional order for the same sample ID.
- If you deassign a test from a sample ID, you **delete** the order.

For LIS orders, the following applies:

- You cannot delete LIS orders in the web application. To delete LIS orders, contact your LIS administrator.
- You can assign additional tests to sample IDs that were received with an LIS order (because assigning additional tests creates new orders and the LIS orders remain unchanged).

To edit already allocated orders, you must delete the sample setup in the web application so that the orders are not allocated again.

Deleting sample setups in the web application (445)

- ☐ Not allocated, editable orders in the web application
- ☐ Diagnostic operator user role

To edit not allocated orders

1 In the web application, in the **Orders** column on the dashboard, choose the **Create sample setup** tile.
   ➔ The **Orders** screen in assignment mode is displayed.
   ➔ The table lists all not allocated orders.

2 From the table, select the row of orders that you want to edit.
   ⓘ A row can summarize several orders.

3 Choose the **Add/edit order** button.
   ➔ The **Edit orders** screen is displayed.
   ➔ The sample IDs and their assigned tests are displayed on the **Sample IDs** card.
   Tests of LIS orders are displayed in blue font.

4 To create additional orders for a sample ID, assign additional tests to the sample ID:
   - On the **Sample IDs** card, select the check box of the sample ID and clear the check boxes of all other sample IDs.

- On the **Analysis package and test** card, assign complete analysis packages, i.e., all tests of the analysis packages. Alternatively, expand the analysis packages and assign selected tests only (if possible).

ⓘ You can create orders for sample IDs that were received as part of an LIS order.

5 To delete orders for a sample ID, deassign tests from that sample ID:

- On the **Sample IDs** card, select the check box of the sample ID and clear the check boxes of all other sample IDs.
- On the **Analysis package and test** card, deassign complete analysis packages, i.e., all tests of the analysis packages. Alternatively, expand the analysis packages and deassign selected tests only (if possible).

ⓘ You cannot delete LIS orders.

6 Choose the **Save** button.

➔ The orders are added to and/or deleted from the rows on the **Orders** screen.

➔ If all orders for a sample ID were deleted, there is no row for that sample ID on the **Orders** screen anymore.

➔ On the dashboard, the **Create sample setup** tile lists the number of not allocated orders.

Related topics

- Sample setups in the web application (255)
- Results in the web application (263)

Sample setups in the web application

A sample setup in the web application comprises the orders that are processed together in a diagnostic run on the analyzer.

In this section

Creating sample setups in the web application

To determine which orders are processed in 1 diagnostic run on the analyzer, you must create a sample setup in the web application.

You create a sample setup by assigning orders and nanowell plates to the sample setup. The web application automatically includes the required controls in the sample setup.

The orders that are allocated to a confirmed sample setup comprise 1 batch, are in **Allocated** status, and are processed in 1 diagnostic run on the analyzer.

When a sample setup is confirmed, a corresponding batch tile is automatically created in the **Sample setups** column on the dashboard. If a sample setup is deleted again, the corresponding batch tile is deleted as well.

By default, a sample setup and its batch tile are named "Batch_YYMMDDhhmmss"
with the date and time the sample setup was created.

The name of the sample setup is later used as the run name on the analyzer.

You can combine different analysis packages and different nanowell plate types in 1 sample setup if the analysis packages use the same run profile.

You can only start a diagnostic run on the analyzer if a sample setup exists for the loaded nanowell plates.

About the batch tiles (93)

List of naming placeholders (154)

Prerequisites for a diagnostic run (172)

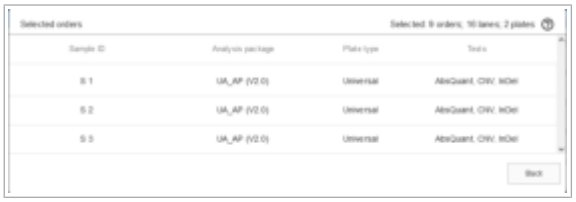
- ☐ Orders in the web application (received from LIS, imported as orders list, and/or added manually)
- ☐ Diagnostic operator user role

To create a sample setup in the web application

1 In the web application, in the **Orders** column on the dashboard, choose the **Create sample setup** tile.
   ➔ The **Orders** screen in assignment mode is displayed.
   ➔ The table lists all not allocated orders.

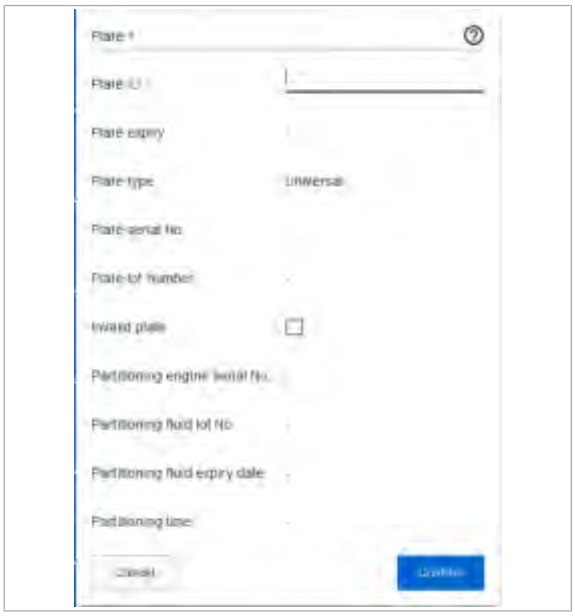
2 From the table, select a row of orders that you want to assign to the sample setup.
   ➔ The table is filtered automatically for orders that can be processed in the same diagnostic run.

3 Select the other rows of orders that you want to assign to the sample setup.
   ⓘ You can only choose as many orders as can be processed on 12 nanowell plates. The web application automatically counts the required controls.



4 Optionally, for an overview of the selected orders, do the following:
   - To display the **Selected orders** dialog box, choose the **Selection overview** button at the bottom right of the table.
   - To return to the **Orders** screen, choose the **Back** button.

5 Choose the **Assign to sample setup** button.
   ➔ The unconfirmed sample setup is created and displayed in plate view on the **Sample setup** screen.
   ➔ The web application automatically includes the required controls in the sample setup.



6 CAUTION! Risk of compromised image integrity. Avoid scratches, finger prints, dust, or other artifacts on the nanowell plate lanes.

For each nanowell plate of the sample setup, do the following:

- To display the **Plate:** combo box, choose the column header twice.
- In the **Plate ID** field, scan or enter the nanowell plate ID.
- Choose the **Confirm** button.

ⓘ You cannot enter a nanowell plate ID of a nanowell plate that is expired, has the wrong type, is already part of a sample setup, and/or is already partitioned.

7 Optionally, for each nanowell plate lane, do the following:

- To display the **Sample settings:** combo box, choose the tile twice.
- In the **Notes** field, enter sample notes.
- If required, in the **Kit No.** field, scan or enter the kit ID.
- Choose the **Confirm** button.

ⓘ For IVD workflows, it is mandatory to enter the kit IDs. For LDT workflows, the **Kit No.** field is a free-text field, e.g., for the ID of your master mix reagent.
You can select several tiles and enter the same sample settings for all of them.

8 Optionally, to change the batch name and/or enter run notes, do the following:

- In the top center of the **Sample setup** screen, choose the ✎ button.
- In the **Run information** dialog box, change the batch name and/or enter run notes.
- Choose the **Confirm** button.

ⓘ The batch name can consist of 1 to 25 characters. The batch name must not contain the following characters:
? * < > / \ : " | '

9 On the **Sample setup** screen, choose the **Confirm** button.

ⓘ You cannot generate a sample setup report before the sample setup is confirmed.

➔ The sample setup is confirmed.

➔ The dashboard is displayed.

➔ A batch tile in **Pending partitioning** status is created and displayed in the **Sample setups** column.

➔ The assigned orders are in **Allocated** status.

Editing sample setups in the web application

You can edit sample setups in the web application.

The editing options depend on the status of the sample setup.

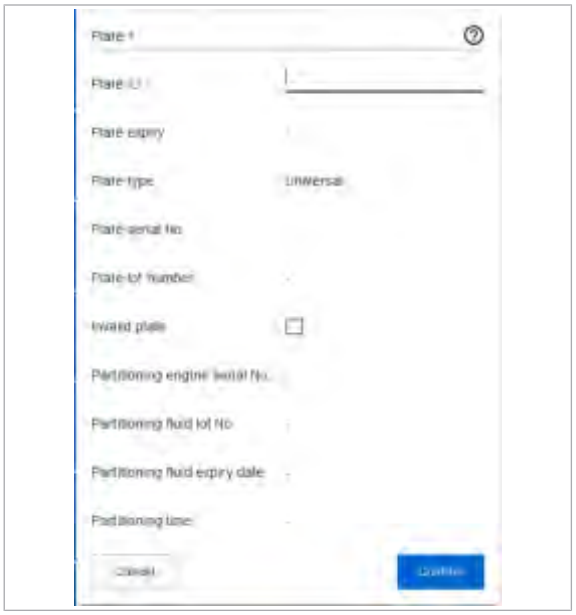
☐ Sample setup in the web application

☐ Diagnostic operator user role

To edit a sample setup in the web application

1 In the web application, in the **Sample setups** column on the dashboard, choose the batch tile.

➔ The **Sample setup** screen is displayed.



2 To edit the plate settings for a nanowell plate, do the following:

- To display the **Plate:** combo box, choose the column header twice.
- Edit the plate settings.
- Choose the **Confirm** button.

ⓘ You cannot change the nanowell plate ID if the nanowell plate is already partitioned.

3 To edit the sample settings for a nanowell plate lane, do the following:

- To display the **Sample settings:** combo box, choose the tile twice.
- Edit the sample settings.
- Choose the **Confirm** button.

ⓘ You can select several tiles and enter the same sample settings for all of them.

4 To change the batch name and/or enter run notes, do the following:

- In the top center of the **Sample setup** screen, choose the ✎ button.
- In the **Run information** dialog box, change the batch name and/or enter run notes.
- Choose the **Confirm** button.

ⓘ The batch name can consist of 1 to 25 characters. The batch name must not contain the following characters:
? * < > / \ : " | ’
You cannot enter run notes later during the run on the analyzer.

5 On the **Sample setup** screen, choose the **Confirm** button.

➔ The changes to the sample setup are confirmed.

➔ The dashboard is displayed.

Creating sample setup reports in the web application

Create a sample setup report in the web application as a guide for pipetting and for verification of the sample setup in the analyzer software.

A sample setup report is a PDF that contains the following information:

- Run notes
- Nanowell plates
- Samples that are invalid and/or have sample notes

- Plate view of the sample setup as on the **Sample setup** screen (plus the dilution)

By default, sample setup reports are named *Diagnostic Sample Setup Report - BatchName.pdf*

List of naming placeholders (154)

About the Sample setup screen (97)

☐ Sample setup in the web application
☐ Optionally, external storage device, e.g., USB flash drive

☐ Diagnostic operator user role

To create a sample setup report

1 Optionally, to save the sample setup report to an external storage device, connect the external storage device to the computer running the web application.

2 In the web application, in the **Sample setups** column on the dashboard, choose a batch tile.
➔ The **Sample setup** screen is displayed.

3 Choose the **Generate report** button.
➔ A dialog box is displayed.

4 Select to open or save the report. Choose the **OK** button.
ⓘ The available options and details depend on your browser and computer configuration.

5 On the **Sample setup** screen, choose the **Confirm** button.

6 Print the sample setup report as a guide for pipetting and for verification of the sample setup in the analyzer software.

7 Optionally, disconnect the external storage device.

Related topics

- Orders in the web application (250)
- Results in the web application (263)

Entering run information for a diagnostic run in the web application

Before and during a diagnostic run, you can enter run information in the web application.

Run information comprises the following:

- Run name:
  The name of the sample setup that is used as run name on the analyzer.
  The run name can consist of 1 to 25 characters.
  The run name must not contain the following characters:
  ? * < > / \ : " | ’
- Run notes:
  Additional information that is listed on the **Run notes** tab on the **Results of** screen.

The allowed actions depend on the status of the diagnostic run:

- Before you start the diagnostic run on the analyzer (i.e., batch tile in the **Sample setups** column in the web application), you can add run notes and change the batch name on the **Sample setup** screen in the web application.
- During the diagnostic run (i.e., batch tile in the **Run in progress** column in the web application), you can only enter run notes. You cannot change the run name anymore.
- When the diagnostic run is finished, you can only view run information. If you need to enter additional information, you must add notes to individual results.

Viewing, adding, editing, and deleting result notes (263)

☐ Diagnostic operator user role

To enter run information before the diagnostic run is started

1 In the web application, in the **Sample setups** column on the dashboard, choose a batch tile.
➔ The **Sample setup** screen is displayed.

2 In the top center of the **Sample setup** screen, choose the ✎ button.
➔ The **Run information** dialog box is displayed.

3 Change the run name and/or enter run notes.
ⓘ The run name can consist of 1 to 25 characters. The run name must not contain the following characters:
? * < > / \ : " | '

4 Choose the **Confirm** button.

To add run notes in the web application during the diagnostic run

1 In the web application, in the **Run in progress** column on the dashboard, choose the ✎ button on the batch tile.
➔ The **Run information** dialog box is displayed.

2 Enter run notes.
ⓘ You cannot change the run name after the run was started on the analyzer.

3 Choose the **Confirm** button.

Results in the web application

Results are the outcome of your diagnostic workflows.

It depends on the configuration of your system if you must release and/or send results manually to the LIS.

In this section

Viewing, adding, editing, and deleting result notes

You can view, add, edit, or delete result notes.

You can only add, edit, or delete result notes before a result is sent.

You can view result notes with any user role that allows access to the web application.

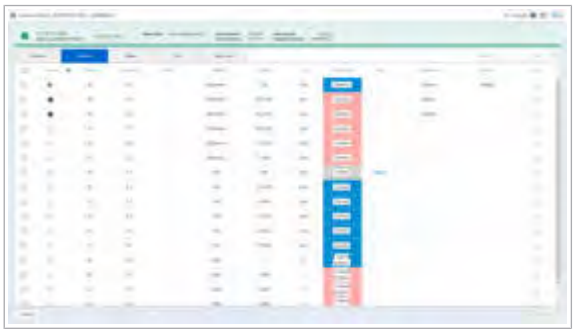
To add, edit, or delete result notes, you need diagnostic operator user role.

☐ To add, edit, or delete result notes:
Diagnostic operator user role

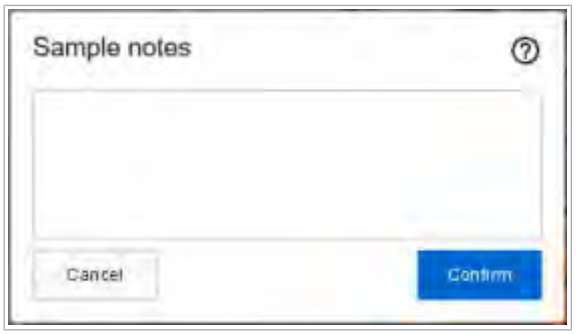
To view result notes

1 In the web application, in the **Results** column on the dashboard, choose a batch tile.
➔ The **Results of** screen is displayed.

2 Alternatively, for completed batches, choose the **Completed batches** tile. Choose the batch and choose the **View** button.
➔ The **Results of** screen is displayed.



3 Choose the **Controls** tab or the **Samples** tab.



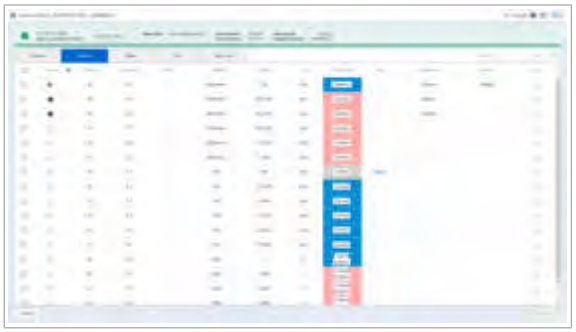
4 In the **Notes** column, choose the ■ indicator of the result.
➔ The **Sample notes** dialog box is displayed.

5 To close the **Sample notes** dialog box again, choose the **Cancel** button.

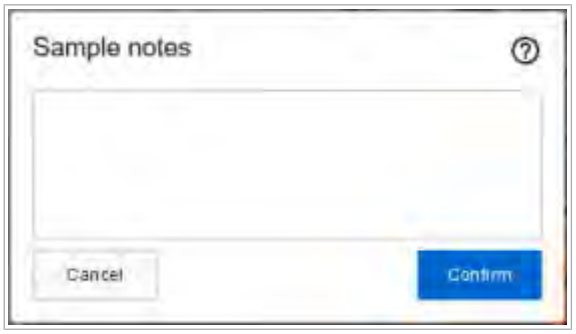
ⓘ Only choose the **Confirm** button if you are logged on with diagnostic operator user role.

To add result notes

1 In the web application, in the **Results** column on the dashboard, choose a batch tile.
➔ The **Results of** screen is displayed.



2 Choose the **Controls** tab or the **Samples** tab.

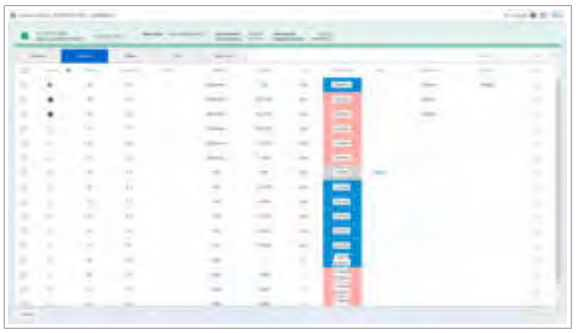


3 In the **Notes** column, choose the □ indicator or ■ indicator of the result.
➔ The **Sample notes** dialog box is displayed.

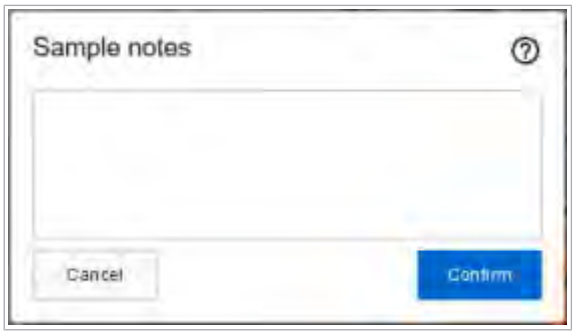
4 Enter your result notes and choose the **Confirm** button.

To edit result notes

1 In the web application, in the **Results** column on the dashboard, choose a batch tile.
➔ The **Results of** screen is displayed.



2 Choose the **Controls** tab or the **Samples** tab.

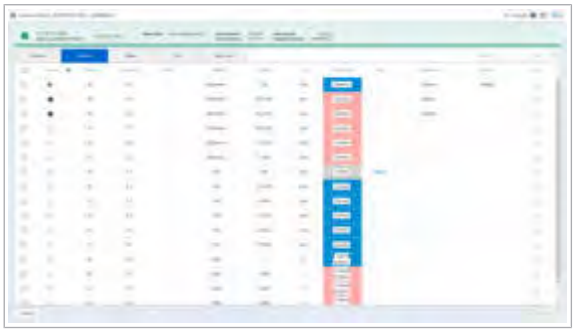


3 In the **Notes** column, choose the ■ indicator of the result.
➔ The **Sample notes** dialog box is displayed.

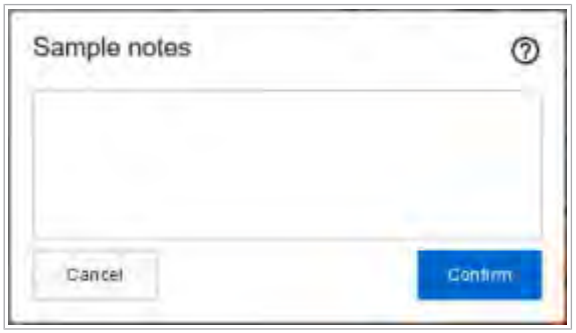
4 Edit the result notes and choose the **Confirm** button.

To delete result notes

1 In the web application, in the **Results** column on the dashboard, choose a batch tile.
➔ The **Results of** screen is displayed.



2 Choose the **Controls** tab or the **Samples** tab.



3 In the **Notes** column, choose the ■ indicator of the result.
➔ The **Sample notes** dialog box is displayed.

4 Delete the result notes and choose the **Confirm** button.

Releasing results manually in the web application

If results are not released automatically, you must release the results manually in the web application.

To release results manually, you need diagnostic operator user role.

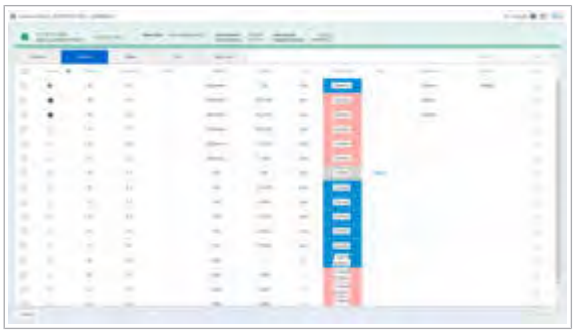
To complete the batch, the results must be sent additionally.

Results for orders with analysis packages in **In validation** status are complete immediately after the diagnostic run finishes. You cannot release such results or send them to the LIS.

- ☐ Results in **Pending release** status available in the web application
- ☐ Diagnostic operator user role

To release results manually in the web application

1 In the web application, in the **Results** column on the dashboard, choose a batch tile that lists results in **{count} pending to be released** status.
   ➔ The **Results of** screen is displayed.



2 Navigate to the results in **Pending release** status that you want to release:
   - From the drop-down list, choose the analysis package.
   - Choose the **Samples** tab.
   - Alternatively, use the search function.

   ⓘ Results in **Pending release** status are marked with an icon in the **Status** column.

3 Select 1 or several results in **Pending release** status.
   ⓘ You can release several results at the same time.

4 To release the result, choose the **Release** button.
   ➔ The **Confirmation** dialog box is displayed.

5 Enter your password and choose the **Release** button.
   ➔ The result status changes to **Pending send**, marked with an icon in the **Status** column.
   ➔ Your user name is added to the **Released by** column.

Sending results manually in the web application

If results are not sent automatically, you must send the results manually to the LIS.

You can only send results that are already released, either automatically or manually by a user with diagnostic operator user role (depending on system configuration).

To send results, you need diagnostic approver user role.

If the system is not connected to an LIS, sending results still changes the result status from **Pending send** to **Send queued** or **Sent**, and completes the batch.

Results for orders with analysis packages in **In validation** status are complete immediately after the diagnostic run finishes. You cannot release such results or send them to the LIS.

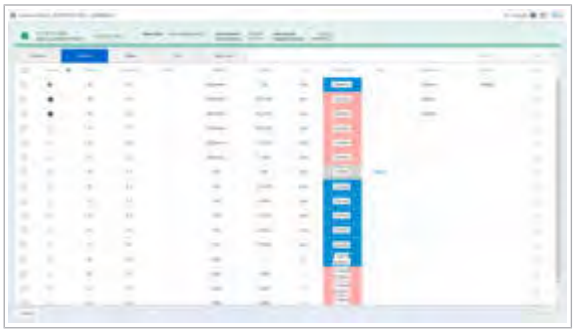
It depends on the system configuration if the control results are sent to the LIS.

Diagnostic results settings (604)

- ☐ Results in **Pending send** status available in the web application
- ☐ Diagnostic approver user role

To send results manually in the web application

1. In the web application, in the **Results** column on the dashboard, choose a batch tile that lists results in **{count} pending to be sent** status.
   ➔ The **Results of** screen is displayed.



2. Navigate to the results in **Pending send** status that you want to send:
   - From the drop-down list, choose the analysis package.
   - Choose the **Samples** tab.
   - Alternatively, use the search function.

   ⓘ Results in **Pending send** status are marked with the ✓ icon in the **Status** column.
3. Select 1 or several results in **Pending send** status.

   ⓘ You can send several results at the same time. If you choose results that are not released yet, the **Send** button is unavailable.

4 To send the results, choose the **Send** button.
➔ The **Confirmation** dialog box is displayed.

5 Enter your password and choose the **Send** button.
➔ The result status changes to **Send queued** or **Sent**, respectively, marked with an icon or an icon in the **Status** column (depending on LIS connection status).
➔ Your user name is added to the **Send by** column.
➔ If all results of the batch are in **Send queued** status or **Sent** status, the batch is complete, the header color of the **Results of** screen changes to light-brown, the batch tile is deleted from the **Results** column on the dashboard, and the batch is listed on the **Completed batches** tile.

Creating result reports in the web application

You can create result reports on the **Results of** screen.

A result report is a PDF that contains the same information as the **Results of** screen.

By default, a result report is named *Diagnostic Result Report - BatchName.pdf*

You can create result reports independent from the result status.

About the Results of screen (100)
About the Completed batches screen (104)
List of naming placeholders (154)

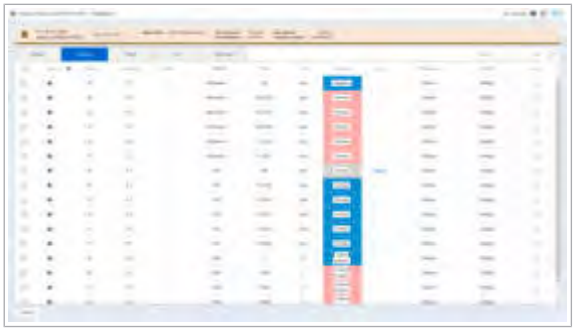
☐ Optionally, external storage device, e.g., USB flash drive

☐ Diagnostic operator user role or diagnostic approver user role

To create a result report in the web application

1 Optionally, to save the result report to an external storage device, connect the external storage device to the computer running the web application.

2 In the web application, in the **Results** column on the dashboard, do one of the following:
- Choose a batch tile.



- For completed batches, choose the **{count} completed batches** tile. Choose a batch and choose the **View** button.

➔ The **Results of** screen of the batch is displayed.

3 Choose the **Report** button.

➔ A dialog box is displayed.

4 Select to open or save the report. Choose the **OK** button.

ⓘ The available options and details depend on your browser and computer configuration.

5 Optionally, disconnect the external storage device.

Related topics

- Orders in the web application (250)
- Sample setups in the web application (255)

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Routine operation of development workflow

In this chapter 14

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Performing a development workflow without unassigned sample setup

In a development workflow without unassigned sample setup, you plan the sample setup outside of the development software. After the development run, you import the raw data file of the run into the development software and then add the sample setup information to the run.

In a development workflow, you work with the following system components:

- Development software
- Partitioning engine
- Analyzer

For a development workflow, you need development operator user role on the analyzer.

The procedure below gives an overview of the steps you must perform in a development workflow. For more details, refer to the individual procedures that are referenced in the steps.

⚠ CAUTION!

Delayed processing of partitioned nanowell plates

Delayed processing of partitioned nanowell plates on the analyzer may cause degradation of biological material, which may cause incorrect, invalid, or delayed results.

- ▸ Only pipette and partition nanowell plates if you can directly run them on the analyzer afterwards.
- ▸ Ensure that you start the run directly after loading the analyzer.

Overview of development workflow without unassigned sample setup (194)

Development workflow without unassigned sample setup (quick reference) (200)

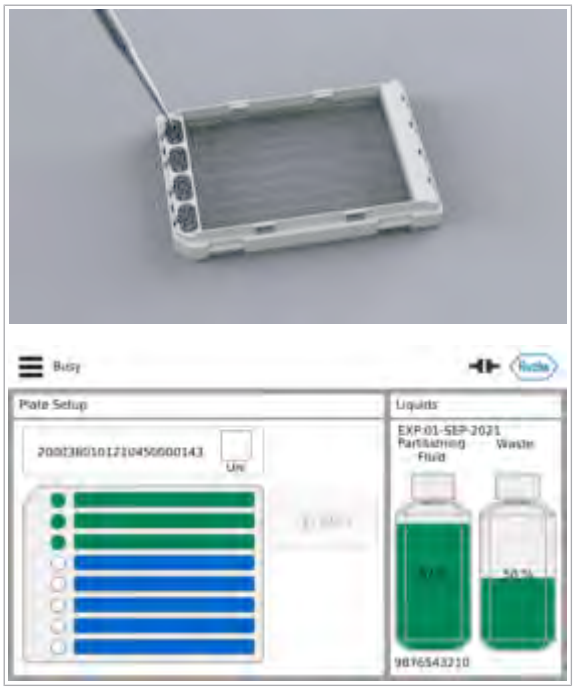
- ☐ Nanowell plates
- ☐ Optionally, external storage device, e.g., USB flash drive

- ☐ Development operator user role in the analyzer software

To perform a development workflow without unassigned sample setup

1 Prepare the reaction mixtures.

ⓘ For details about preparing the reaction mixtures and pipetting, refer to the Instructions for Use of the reagents and controls.



2 CAUTION! Risk of incorrect results.
Take care to avoid pipetting errors. If a pipetting error may have occurred, take note of the affected nanowell plate lane to exclude it from analysis.

Pipette and partition the nanowell plates on the partitioning engine as described in Partitioning the nanowell plates (221):

- Pipette the reaction mixtures into the inlet ports of the first nanowell plate.
- Choose the **Load** button.
- Place the nanowell plate in the drawer.
- Choose the **Start** button.
- When the nanowell plate drawer opens, check that all nanowell plate lanes that contain reaction mixtures are partitioned.
- Remove the nanowell plate.
- Place the nanowell plate on a flat and clean surface.
- Pipette and partition the other nanowell plates.
- Stack the partitioned nanowell plates.

ⓘ The stability of the reaction mixtures between partitioning of a nanowell plate and processing it on the analyzer has been tested for 90 minutes.

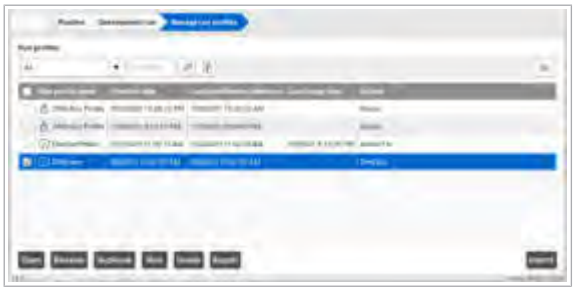
3 CAUTION! Risk of incorrect, invalid, or delayed results.
Do not load nanowell plates with unpartitioned nanowell plate lanes that contain reaction mixtures. Avoid scratches, finger prints, dust, or other artifacts on the nanowell plate lanes.

Load the analyzer as described in Loading the analyzer (225):

- In the global information area, choose the ⏏ button.
- Place the nanowell plate stack in the drawer.
- Choose the ⏏ button.

ⓘ Do not load invalid nanowell plates on the analyzer. You cannot start the run while invalid nanowell plates are loaded.

➔ In the analyzer software, the **Plates** panel is displayed.



4 In the analyzer software, on the **Plates** panel, do the following:
- Verify that all nanowell plates have status **Valid**.
- Verify the displayed nanowell plates against the planned sample setup.

5 Choose the **Run profile** button.
➔ The **Manage run profiles** panel is displayed.

6 Optionally, on the **Manage run profiles** panel, duplicate or import a run profile as described in Working with run profiles on the Manage run profiles panel in the analyzer software (299):
- To **duplicate** a run profile, choose a run profile and choose the **Duplicate** button. Enter a name for the run profile and choose the **Save** button.
- To **import** a run profile, choose the **Import** button. Navigate to the folder. Choose the run profile and choose the **Import** button.

7 Edit an unlocked run profile as described in Editing run profiles on the Edit run profile panel in the analyzer software (303):
- On the **Manage run profiles** panel, choose the run profile and choose the **Open** button.
- Optionally, on the **Edit run profile** panel, edit the programs.
- Choose the **Detection formats** button.
- In the **Detection format** combo box, disable the channels for dyes that are not contained in any of the master mix reagents. For each enabled channel, choose the dye from the drop-down list. Optionally, edit the integration time. Choose the **Save** button.
- Choose the **Save** button.

ⓘ Ensure that you disable empty channels.

8 To start the run, do one of the following:
- On the **Manage run profiles** panel, choose the run profile. Choose the **Run** button.
- On the **Edit run profile** panel, choose the **Run** button.

➔ The **Monitoring** panel is displayed.

9 Optionally, change the name of the development run and/or add run notes as described in Entering run information for a development run in the analyzer software (307):

- On the **Monitoring** panel, next to the run name, choose the ✎ button.
- In the dialog box, in the **Run name** field, enter a new run name.
- In the **Edit notes** field, enter run notes.
- Choose the **Confirm** button.

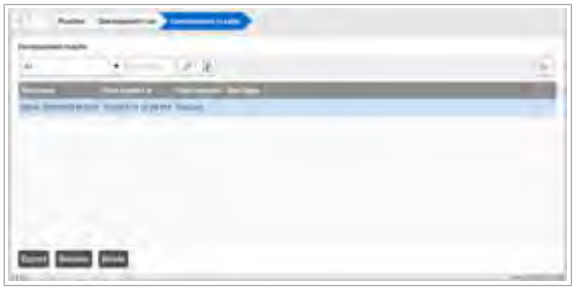
ⓘ You can also change the run name on the **Development results** panel after the run is finished.

10 CAUTION! Risk of contamination of the laboratory. Pack the used nanowell plates in a resealable plastic bag.

When the run is finished, unload the analyzer as described in Unloading the analyzer (227):

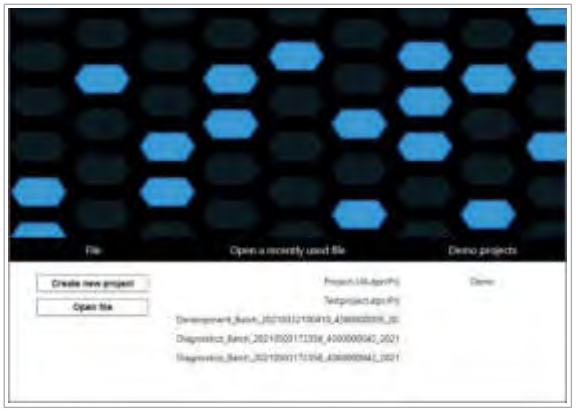
- In the global information area, choose the ⏏ button.
- Remove the nanowell plate stack from the drawer.
- Choose the ⏏ button.

ⓘ Dispose of the nanowell plates according to local regulations.



11 If the analyzer is not configured for automatic export, export the raw data file of the development run as described in Managing raw data files of development runs in the analyzer software (312):

- Optionally, to export to an external storage device, connect the external storage device to the analyzer.
- Choose **Routine > Development run > Development results**.
- Choose the run and choose the **Export** button.
- Navigate to a folder and choose the **Export** button.
- Optionally, disconnect the external storage device.



12 In the development software, open a project as described in Working with projects in the development software (295):

- On the **Start page** tab, choose the **Open file** button.
- Navigate to the *dpcrPrj* file of the project and choose the **Open** button.

13 Alternatively, in the development software, create a project as described in Working with projects in the development software (295):

- If the raw data file was exported to an external storage device, connect the external storage device to the computer running the development software.
- In the Windows Explorer, double-click the raw data file of the development run.
- Save the project as described in To save a project in the development software (296).
- Optionally, disconnect the external storage device.

➔ The run tab is displayed.

14 If you **opened** a project in the development software, import the raw data file of the development run as described in Working with raw data files and runs in the development software (317):

- If the raw data file was exported to an external storage device, connect the external storage device to the computer running the development software.
- From the **Navigation** area, choose **Runs** > ••• > **Import**.
- Navigate to the raw data file and choose the **Open** button.
- Save the project.
- Optionally, disconnect the external storage device.

➔ The run tab is displayed.

15 Optionally, in the **Additional run notes:** field on the **Run settings** card, enter run notes. Save the project.

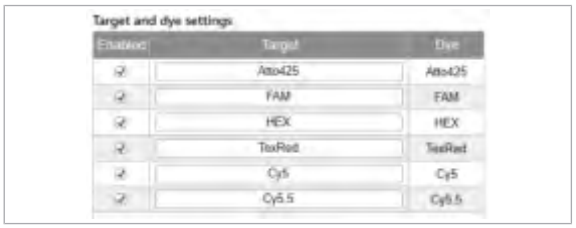
16 On the run tab, choose the **Lane settings** button.

➔ The **Lane settings** card is displayed.

17 Add the lane settings as described in Adding run settings and lane settings to unassigned sample setups in the development software (406):

- On the sample setup tab, choose one or several tiles (in plate view) or rows (in table view).
- On the **Lane settings** card, choose the **Sample ID** field. Scan or enter the sample ID. If required, press Enter.
- Optionally, edit the dilution factor.
- In the **MMx** field, enter the name of the master mix reagent or choose a master mix reagent from the drop-down list.
- Optionally, enter the ID, the expiry date, and the lot number of the master reagent or the master mix reagent.
- Save the project.

ⓘ If you enter the same lane settings for multiple tiles or rows, the nanowell plate lanes are automatically merged.



18 For each master mix reagent, in the **Target and dye settings** table, do the following:

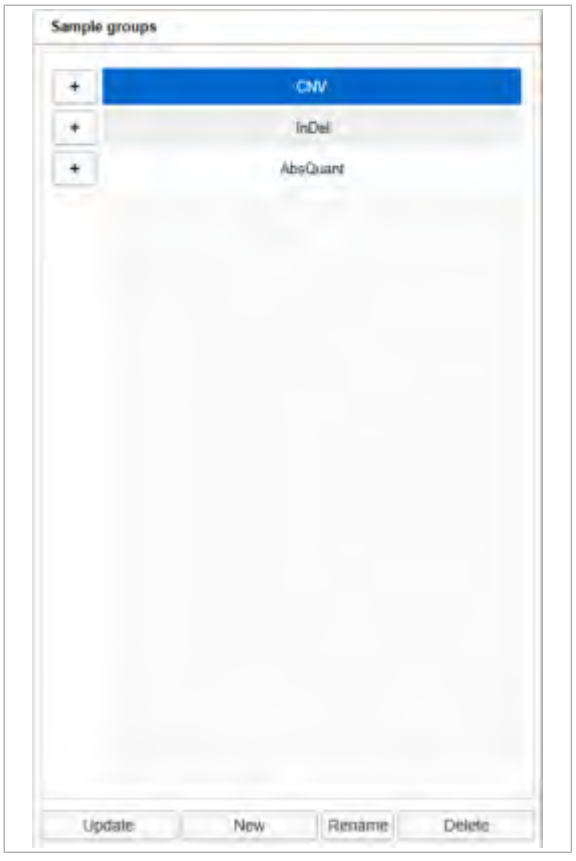
- Choose a tile (in plate view) or a row (in table view).
- Disable the dyes that are not contained in the master mix reagent.
- Optionally, rename the targets.
- Save the project.

ⓘ A change applies to all tiles that use the same master mix reagent.

19 Optionally, add notes and/or sample preparation notes:

- Choose one or several tiles (in plate view) or rows (in table view).
- Choose the **Edit notes** button or the **Edit sample preparation notes** button.
- In the dialog box, enter the notes.
- Choose the **Save** button.
- Save the project.

ⓘ The notes or sample preparation notes apply to all selected tiles.



20 Optionally, work with sample groups for statistical purposes as described in Working with sample groups in the development software (328):

- Choose the **Sample groups** button.
- Add and/or edit the sample groups.
- Save the project.

21 Check and adjust the clustering, as described in Adjusting the clustering in the development software (342):

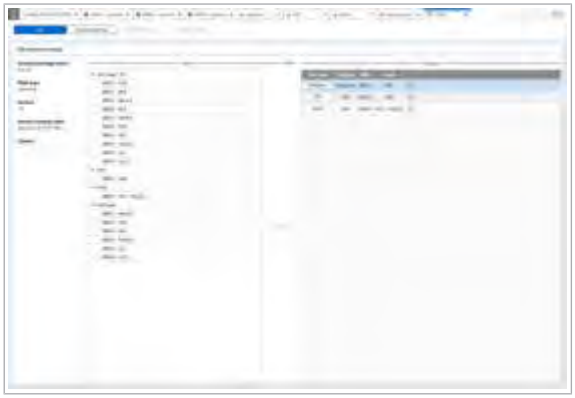
- From the **Clustering** menu, choose the clustering.
- Choose the ⚙ button.
- In the **Settings** combo box, adjust the clustering settings.
- Choose the ⚙ button.
- If required, adjust the thresholds in the scatter plots. Choose the **Calculate** button.
- Save the project.

22 Add analyses as described in Analyses in the development software (358):

- From the **Navigation** area, choose **Analysis >** ••• . Choose the analysis type.
- In the **Settings** combo box, choose the samples and choose the **Update analysis** button.
- Optionally, add and/or edit sample groups.
- On the other tabs in the **Settings** combo box, enter the settings required for the analysis type.
- Choose the ⚙ button.
- Save the project.

23 Alternatively, edit analyses as described in Analyses in the development software (358):

- From the **Analysis** menu, choose the analysis.
- Choose the ⚙ button.
- In the **Settings** combo box, edit the analysis settings.
- Choose the ⚙ button.
- Save the project.



24 Optionally, create an analysis package as described in Working with analysis packages (429):

- From the **Navigation** area, choose **Analysis package >** ••• **> Create analysis package**.
- In the **Create analysis package** dialog box, enter a name for the analysis package and the type of nanowell plate. Choose the **Confirm** button.
- On the panels of the analysis package tab, enter the required information.
- From the **Analysis package** menu, choose the analysis package.
- Choose ••• **> Update version**.
- In the **Increment version number** dialog box, choose the version number and choose the **Update** button.

- Save the project.

25 Optionally, update an analysis package as described in Working with analysis packages (429):

- From the **Analysis package** menu, choose the analysis package.
- On the panels of the analysis package tab, edit the information.
- From the **Analysis package** menu, choose the analysis package.
- Choose ••• **> Update version**.
- In the **Increment version number** dialog box, choose the version number and choose the **Update** button.
- Save the project.

26 Optionally, export the analysis package as described in Working with analysis packages (429):

- From the **Analysis package** menu, choose the analysis package.
- Choose ••• **> Export**.
- Navigate to a folder that is accessible from the analyzer and choose the **Save** button.

27 Save the project.

Related topics

- Development workflow without unassigned sample setup (quick reference) (200)
- Partitioning the nanowell plates (221)
- Loading the analyzer (225)
- Unloading the analyzer (227)
- Projects in the development software (294)
- Run profiles in the analyzer software (298)
- Entering run information for a development run in the analyzer software (307)
- Runs in the development software (309)
- Editing lane settings via copy and paste in the development software (335)
- Clustering in the development software (338)
- Analyses in the development software (358)
- Analysis packages in the development software (412)

Performing a development workflow with unassigned sample setup

In a development workflow with unassigned sample setup, you plan the sample setup in the development software. After the development run, you import the raw data file of the run into the development software and then assign the sample setup information to the run.

In a development workflow, you work with the following system components:

- Development software
- Partitioning engine
- Analyzer

For a development workflow, you need development operator user role on the analyzer.

The procedure below gives an overview of the steps you must perform in a development workflow. For more details, refer to the individual procedures that are referenced in the steps.

⚠ CAUTION!

Delayed processing of partitioned nanowell plates

Delayed processing of partitioned nanowell plates on the analyzer may cause degradation of biological material, which may cause incorrect, invalid, or delayed results.

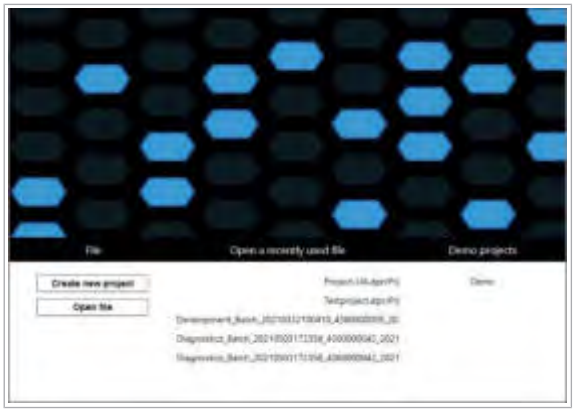
- ▸ Only pipette and partition nanowell plates if you can directly run them on the analyzer afterwards.
- ▸ Ensure that you start the run directly after loading the analyzer.

Overview of development workflow with unassigned sample setup (195)

Development workflow with unassigned sample setup (quick reference) (208)

- ☐ Nanowell plates
- ☐ Optionally, external storage device, e.g., USB flash drive

- ☐ Development operator user role in the analyzer software



To perform a development workflow with unassigned sample setup

1 In the development software, open a project as described in Working with projects in the development software (295):
   - On the **Start page** tab, choose the **Open file** button.
   - Navigate to the *dpcrPrj* file of the project and choose the **Open** button.

2 Alternatively, in the development software, create a project as described in Working with projects in the development software (295):
   - On the **Start page** tab, choose the **Create new project** button.
   - Save the project under a new name as described in To save a project in the development software (296).
   - ➔ An unassigned sample setup is automatically added to the project.
   - ➔ The sample setup tab of the unassigned sample setup is displayed.

3 If you **opened** a project, add an unassigned sample setup to the project as described in Working with unassigned sample setups in the development software (405):
   - In the **Navigation** area, choose **Unassigned sample setup > ••• > Create new**.
   - Save the project.
   - ➔ The sample setup tab of the unassigned sample setup is displayed.

4 On the **Run settings** card on the sample setup tab, add the nanowell plates to the unassigned sample setup as described in Adding run settings and lane settings to unassigned sample setups in the development software (406):
   - From the **Plate type** drop-down list, choose the nanowell plate type.
   - Optionally, choose the **Plate ID** field. Scan or enter the nanowell plate ID. If required, press Enter.
   - Save the project.

ⓘ You can use different types of nanowell plates in 1 development run.
The unassigned sample setup can later be assigned to the run only if the nanowell plate types and IDs in the unassigned sample setup and in the actual development run match.
The unassigned sample setup can only be assigned automatically if it contains the nanowell plate IDs.

5 On the **Run settings** card, set the detection formats for the development run:

- Choose the **Detection formats** button.
- In the **Detection format** combo box, disable the channels for dyes that are not contained in any of the master mix reagents used in the development run.
- For each enabled channel, choose the dye from the drop-down list.
- To edit the integration times, choose the **Advanced Settings** check box. In the **Integration time (ms)** fields, edit the values.
- Choose the **Save** button.
- Save the project.

ⓘ Ensure that you disable empty channels.
Only the enabled dyes can be assigned in the lane settings.
The unassigned sample setup can later be assigned to the run only if the detection formats in the unassigned sample setup and in the actual development run match.

6 Optionally, in the **Additional run notes:** field, enter run notes. Save the project.

7 On the sample setup tab, choose the **Lane settings** button.

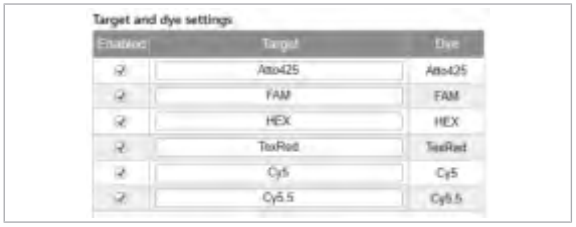
➔ The **Lane settings** card is displayed.

8 Add the lane settings as described in Adding run settings and lane settings to unassigned sample setups in the development software (406):

- On the sample setup tab, choose one or several tiles (in plate view) or rows (in table view).
- On the **Lane settings** card, choose the **Sample ID** field. Scan or enter the sample ID. If required, press Enter.
- Optionally, edit the dilution factor.
- In the **MMx** field, enter the name of the master mix reagent or choose a master mix reagent from the drop-down list.
- Optionally, enter the ID, the expiry date, and the lot number of the master reagent or the master mix reagent.

- Save the project.

ⓘ If you enter the same lane settings for multiple tiles or rows, the nanowell plate lanes are automatically merged.



9 For each master mix reagent, in the **Target and dye settings** table, do the following:

- Choose a tile (in plate view) or a row (in table view).
- Disable the dyes that are not contained in the master mix reagent.
- Optionally, rename the targets.
- Save the project.

ⓘ A change applies to all tiles that use the same master mix reagent.

10 Optionally, add notes and/or sample preparation notes:

- Choose one or several tiles (in plate view) or rows (in table view).
- Choose the **Edit notes** button or the **Edit sample preparation notes** button.
- In the dialog box, enter the notes.
- Choose the **Save** button.
- Save the project.

ⓘ The notes or sample preparation notes apply to all selected tiles.

11 From the unassigned sample setup, create a sample setup report as described in Creating a sample setup report of an unassigned sample setup in the development software (410):

- In the **Navigation** area, from the unassigned sample setup in the **Unassigned sample setup** menu, choose ••• **> Create a sample setup report**.
- Navigate to a folder. Enter a name for the report and choose the **Save** button.

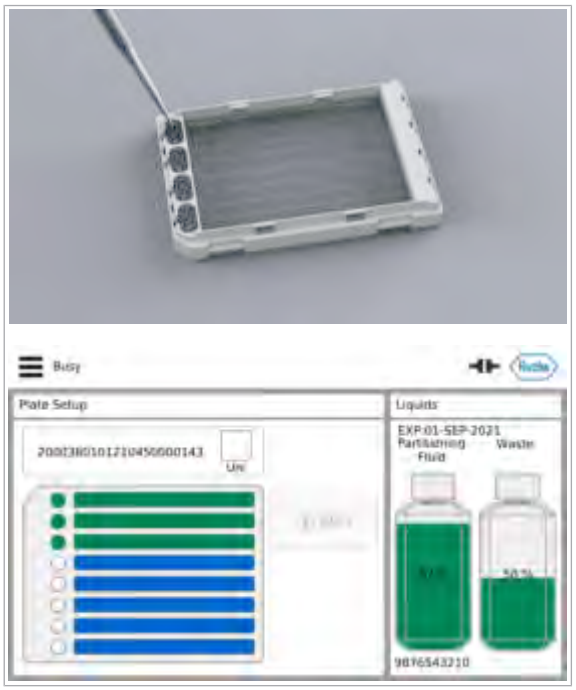
ⓘ Use the sample setup report as a guide for pipetting.

12 Prepare the reaction mixtures.

ⓘ For details about preparing the reaction mixtures and pipetting, refer to the Instructions for Use of the reagents and controls.

13 Refer to the sample setup report to identify the nanowell plates and to allocate the reaction mixtures to the nanowell plate lanes.

ⓘ Ensure that you use the correct nanowell plates.



14 CAUTION! Risk of incorrect results.
Take care to avoid pipetting errors. If a pipetting error may have occurred, take note of the affected nanowell plate lane to exclude it from analysis.

Pipette and partition the nanowell plates on the partitioning engine as described in Partitioning the nanowell plates (221):

- Pipette the reaction mixtures into the inlet ports of the first nanowell plate.
- Choose the **Load** button.
- Place the nanowell plate in the drawer.
- Choose the **Start** button.
- When the nanowell plate drawer opens, check that all nanowell plate lanes that contain reaction mixtures are partitioned.
- Remove the nanowell plate.
- Place the nanowell plate on a flat and clean surface.
- Pipette and partition the other nanowell plates.
- Stack the partitioned nanowell plates.

ⓘ The stability of the reaction mixtures between partitioning of a nanowell plate and processing it on the analyzer has been tested for 90 minutes.

15 CAUTION! Risk of incorrect, invalid, or delayed results.
Do not load nanowell plates with unpartitioned nanowell plate lanes that contain reaction mixtures. Avoid scratches, finger prints, dust, or other artifacts on the nanowell plate lanes.

Load the analyzer as described in Loading the analyzer (225):

- In the global information area, choose the ⏏ button.
- Place the nanowell plate stack in the drawer.
- Choose the ⏏ button.

ⓘ Do not load invalid nanowell plates on the analyzer. You cannot start the run while invalid nanowell plates are loaded.

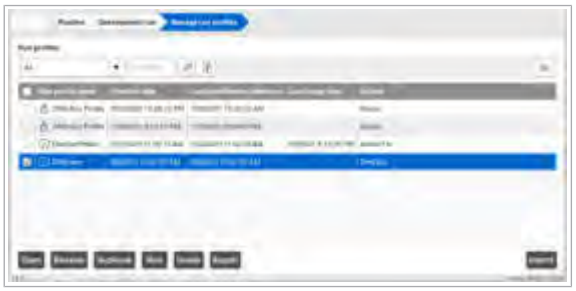
➔ In the analyzer software, the **Plates** panel is displayed.

16 In the analyzer software, on the **Plates** panel, do the following:

- Verify that all nanowell plates are in **Valid** status.
- Verify the displayed nanowell plates against the sample setup report from the development software.

17 Choose the **Run profile** button.

➔ The **Manage run profiles** panel is displayed.



18 Optionally, on the **Manage run profiles** panel, duplicate or import a run profile as described in Working with run profiles on the Manage run profiles panel in the analyzer software (299):

- To **duplicate** a run profile, choose a run profile and choose the **Duplicate** button. Enter a name for the run profile and choose the **Save** button.
- To **import** a run profile, choose the **Import** button. Navigate to the folder. Choose the run profile and choose the **Import** button.

19 Edit an unlocked run profile as described in Editing run profiles on the Edit run profile panel in the analyzer software (303):

- On the **Manage run profiles** panel, choose the run profile and choose the **Open** button.
- Optionally, on the **Edit run profile** panel, edit the programs.
- Choose the **Detection formats** button.
- In the **Detection format** combo box, disable the channels for dyes that are not contained in any of the master mix reagents. For each enabled channel, choose the dye from the drop-down list. Optionally, edit the integration time. Choose the **Save** button.
- Choose the **Save** button.

ⓘ Ensure that you disable empty channels.

20 To start the run, do one of the following:

- On the **Manage run profiles** panel, choose the run profile. Choose the **Run** button.
- On the **Edit run profile** panel, choose the **Run** button.

➔ The **Monitoring** panel is displayed.

21 Optionally, change the name of the development run and/or add run notes as described in Entering run information for a development run in the analyzer software (307):

- On the **Monitoring** panel, next to the run name, choose the ✎ button.
- In the dialog box, in the **Run name** field, enter a new run name.
- In the **Edit notes** field, enter run notes.
- Choose the **Confirm** button.

ⓘ You can also change the run name on the **Development results** panel after the run is finished.

22 CAUTION! Risk of contamination of the laboratory. Pack the used nanowell plates in a resealable plastic bag.

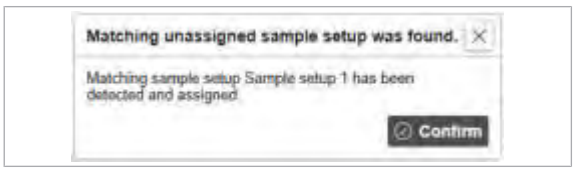
When the run is finished, unload the analyzer as described in Unloading the analyzer (227):

- In the global information area, choose the ⏏ button.
- Remove the nanowell plate stack from the drawer.
- Choose the ⏏ button.

ⓘ Dispose of the nanowell plates according to local regulations.

23 If the analyzer is not configured for automatic export, export the raw data file of the development run as described in Managing raw data files of development runs in the analyzer software (312):

- Optionally, to export to an external storage device, connect the external storage device to the analyzer.
- Choose **Routine > Development run > Development results**.
- Choose the run and choose the **Export** button.
- Navigate to a folder and choose the **Export** button.
- Optionally, disconnect the external storage device.



24 In the development software, import the raw data file of the development run into the project as described in Working with raw data files and runs in the development software (317):

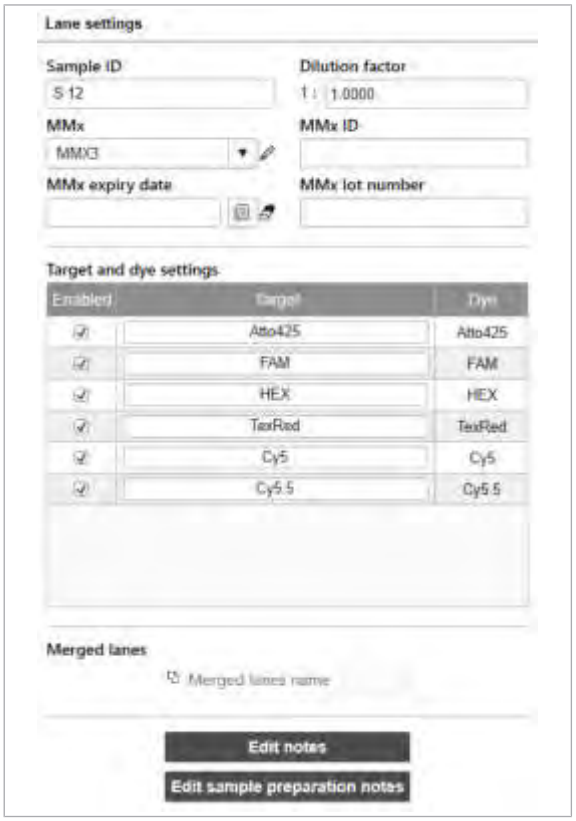
- If the raw data file was exported to an external storage device, connect the external storage device to the computer running the development software.
- From the **Navigation** area, choose **Runs** > ••• > **Import**.
- Navigate to the raw data file and choose the **Open** button.
- To confirm the automatic assignment of the unassigned sample setup to the run if a match is found, in the **Matching unassigned sample setup was found.** dialog box, choose the **Confirm** button.
- Save the project.
- Optionally, disconnect the external storage device.

➔ The run tab is displayed.

25 If required, assign a partially matching unassigned sample setup to the run as described in Assigning partially matching unassigned sample setups to development runs in the development software (321):

- From the **Runs** menu, choose the run.
- Choose ••• **> Assign existing sample setup**.
- Choose the unassigned sample setup and choose the **Confirm** button.
- Save the project.

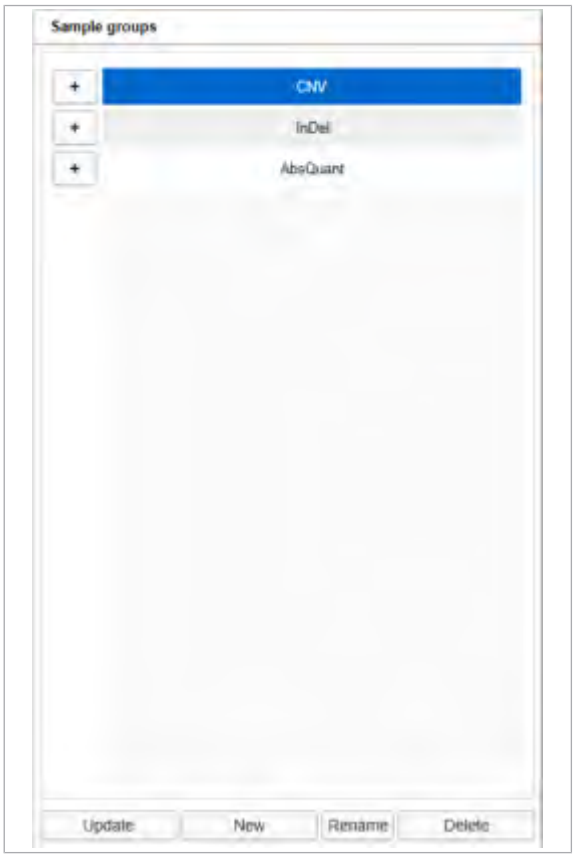
ⓘ If no unassigned sample setup can be assigned, you must add the lane settings directly to the run.



26 Optionally, edit the lane settings of the run as described in Adding and editing lane settings of a run in the development software (325):

- On the run tab, choose the **Lane settings** button.
- Choose one or several tiles (in plate view) or rows (in table view).
- Edit the sample IDs, the dilution factor, the master mix reagent, and/or the additional information for the master mix reagent or master reagent.
- Edit the target and dye settings.
- Save the project.

ⓘ If you enter the same lane settings for multiple tiles or rows, the nanowell plate lanes are automatically merged.



27 Optionally, work with sample groups for statistical purposes as described in Working with sample groups in the development software (328):

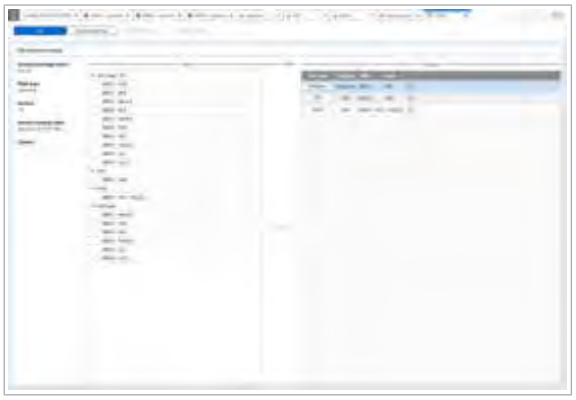
- Choose the **Sample groups** button.
- Add and/or edit the sample groups.
- Save the project.

28 Check and adjust the clustering, as described in Adjusting the clustering in the development software (342):

- From the **Clustering** menu, choose the clustering.
- Choose the ⚙ button.
- In the **Settings** combo box, adjust the clustering settings.
- Choose the ⚙ button.
- If required, adjust the thresholds in the scatter plots. Choose the **Calculate** button.
- Save the project.

29 Add analyses as described in Analyses in the development software (358):

- From the **Navigation** area, choose **Analysis >** ••• . Choose the analysis type.
- In the **Settings** combo box, choose the samples and choose the **Update analysis** button.
- Optionally, add and/or edit sample groups.
- On the other tabs in the **Settings** combo box, enter the settings required for the analysis type.
- Choose the ⚙ button.
- Save the project.



30 Alternatively, edit analyses as described in Analyses in the development software (358):

- From the **Analysis** menu, choose the analysis.
- Choose the ⚙ button.
- In the **Settings** combo box, edit the analysis settings.
- Choose the ⚙ button.
- Save the project.

31 Optionally, create an analysis package as described in Working with analysis packages (429):

- From the **Navigation** area, choose **Analysis package > ••• > Create analysis package**.
- In the **Create analysis package** dialog box, enter a name for the analysis package and the type of nanowell plate. Choose the **Confirm** button.
- On the panels of the analysis package tab, enter the required information.
- From the **Analysis package** menu, choose the analysis package.
- Choose ••• **> Update version**.
- In the **Increment version number** dialog box, choose the version number and choose the **Update** button.
- Save the project.

32 Optionally, update an analysis package as described in Working with analysis packages (429):

- From the **Analysis package** menu, choose the analysis package.
- On the panels of the analysis package tab, edit the information.
- From the **Analysis package** menu, choose the analysis package.
- Choose ••• **> Update version**.
- In the **Increment version number** dialog box, choose the version number and choose the **Update** button.
- Save the project.

33 Optionally, export the analysis package as described in Working with analysis packages (429):

- From the **Analysis package** menu, choose the analysis package.
- Choose ••• **> Export**.
- Navigate to a folder that is accessible from the analyzer and choose the **Save** button.

34 Save the project.

Related topics

- Development workflow with unassigned sample setup (quick reference) (208)
- Partitioning the nanowell plates (221)
- Loading the analyzer (225)
- Unloading the analyzer (227)
- Projects in the development software (294)
- Run profiles in the analyzer software (298)
- Entering run information for a development run in the analyzer software (307)
- Runs in the development software (309)
- Editing lane settings via copy and paste in the development software (335)
- Clustering in the development software (338)
- Analyses in the development software (358)
- Unassigned sample setups in the development software (402)
- Analysis packages in the development software (412)

Projects in the development software

In the development software, a project comprises associated data, for example, data belonging to the same research topic.

In this section

About projects in the development software

In the development software, a project is the container for all data that is collected in 1 or several development workflows. For example, a project can be used to collect and analyze the data belonging to the development of a test or to a research topic.

A project can contain the following data, corresponding to the steps of a development workflow:

- Runs (raw data files)
- Clustering
- Analyses
- Unassigned sample setups
- Analysis packages

You must save the project to save associated data. You cannot save any data separately.

A project in the development software can contain and process up to 672 samples and 50 analyses.

Some settings apply across the whole project. For example, if you change the name of a master mix reagent, the master mix reagent is renamed everywhere in the project.

The master mix reagents across a project must be unambiguous in regard to name and detection formats. A project cannot contain master mix reagents with the same name but different detection formats.

A project is always opened in its own instance of the development software. You cannot open 2 projects in the same software instance.

By default, projects are named "Project" and numbered consecutively.

A project has a *.dpcrPrj* file extension.

Working with projects in the development software

You can create, open, save, and close a project.

Always save your projects before closing.

To create a project in the development software

1 In the development software, do one of the following:
   - On the **Start page** tab, choose the **Create new project** button.
   - In the **Navigation** area, choose **File >** ••• **> New project**.

   ➔ For each project, a separate instance of the development software is opened.

   ➔ A new unassigned sample setup with 1 universal nanowell plate is added to the project automatically.

2 To save the project, choose **File >** ••• **> Save as**.

3 Navigate to a folder, enter a project name, and choose the **Save** button.

To open a project in the development software

1 In the development software, do one of the following:
- On the **Start page** tab, choose the project from the list of recent items.
- On the **Start page** tab, choose the **Open file** button.
- In the **Navigation** area, choose **File >** ••• **> Open**.
- In the Windows Explorer, double-click the *dpcrPrj* file.

2 If required, navigate to a *dpcrPrj* file and choose the **Open** button.
➔ A separate instance of the development software may be opened.
➔ All tabs of the project are displayed that were displayed when you last saved the project.

To save a project in the development software

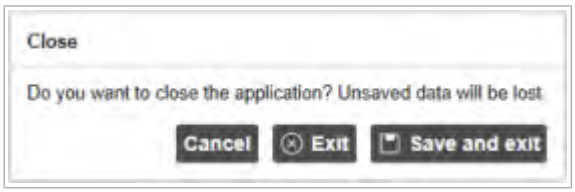
1 To save a new project, or to save a project under a different name or in a different folder, do the following:
- In the **Navigation** area, choose **File >** ••• **> Save as**.
- Navigate to a folder.
- Enter a name for the project.
- Choose the **Save** button.

2 To save an existing project with the same name and in the same folder, do one of the following:
- In the **Navigation** area, choose **File >** ••• **> Save**.
- Press Ctrl+S.

ⓘ You must save the project to save associated data. You cannot save any data separately.

To close a project in the development software

1 To close a project, do one of the following:
- In the **Navigation** area, choose **File** > ••• > **Close**.
- In the top right of the software window, choose the ✕ button.



2 In the **Close** dialog box, choose the **Exit** button.
➔ The project and the instance of the development software are closed.

Related topics

- Runs in the development software (309)
- Clustering in the development software (338)
- Analyses in the development software (358)
- Unassigned sample setups in the development software (402)
- Analysis packages in the development software (412)

Run profiles in the analyzer software

For development runs, run profiles contain the run parameters for the analyzer.

The run profiles are listed on the **Manage run profiles** panel.

You can edit the run profiles on the **Edit run profile** panel.

About the Edit run profile panel (117)

In this section

About run profiles in the analyzer software

For development runs, a run profile provides the run parameters for the analyzer.

A run profile contains the following run parameters:

- Temperatures
- Durations
- Number of cycles
- Detection formats

About the default run profiles

A default DNA run profile and a default RNA profile are contained in the analyzer software.

Default DNA run profile:

Detection formats	Program	Temperature	Duration	Number of cycles
Channel 2 / FAM	UNG	50 °C	120 s	1
Channel 3 / HEX	Denaturation	95 °C	120 s	1
	Amplification	Step 1: 95 °C	Step 1: 15 s	40
		Step 2: 58 °C	Step 2: 30 s	
	Cooling	40 °C	30 s	1

Default DNA run profile

Default RNA profile:

Detection formats	Program	Temperature	Duration	Number of cycles
Channel 2 / FAM	UNG	50 °C	120 s	1
Channel 3 / HEX	Denaturation	95 °C	20 s	1
	RT Step 1	55 °C	180 s	1
	RT Step 2	65 °C	720 s	1
	RT Inactivation	95 °C	15 s	1
	Amplification	Step 1: 95 °C	Step 1: 15 s	40
		Step 2: 58 °C	Step 2: 30 s	
	Cooling	40 °C	30 s	1

Default RNA run profile

About run profile status

A run profile can be locked or unlocked, which is indicated in the **Manage run profiles** panel by a symbol in the **Run profile name** column:

- Locked run profile
  - Cannot be renamed or deleted
  - Can be open and viewed but not edited
  - Duplicate as starting point for your own run profiles
- Unlocked run profile
  - All duplicated run profiles are unlocked
  - Can be renamed and deleted
  - Can be edited

You cannot change the status of a run profile.

Working with run profiles on the Manage run profiles panel in the analyzer software

On the **Manage run profiles** panel in the analyzer software, you can open, rename, duplicate, delete, export, and import run profiles and start a development run.

You cannot create a run profile. If you need a new run profile, you must duplicate an existing run profile and edit it.

Editing run profiles on the Edit run profile panel in the analyzer software (303)

You cannot rename or delete a locked run profile.

You can only rename a run profile in the analyzer software. Even if you change the file name of an exported run profile in the Windows Explorer, the name of the run profile itself will remain unchanged.

You can export run profiles to and import from a network share or external storage device.

You can only start a run from the **Manage run profiles** panel if the prerequisites for a development run are met.

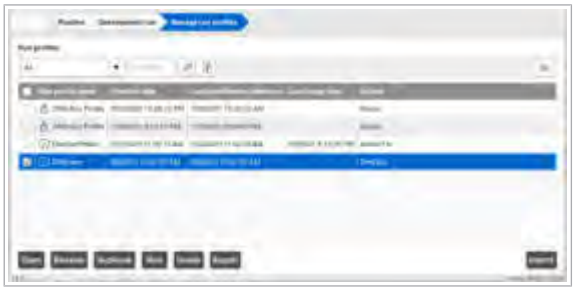
Prerequisites for a development run (172)

- ☐ To import a run profile:
  Run profile (*.dpcrPrfl* file) saved in network share or on external storage device
- ☐ To export a run profile:
  Optionally external storage device, e.g., USB flash drive

- ☐ Development operator user role

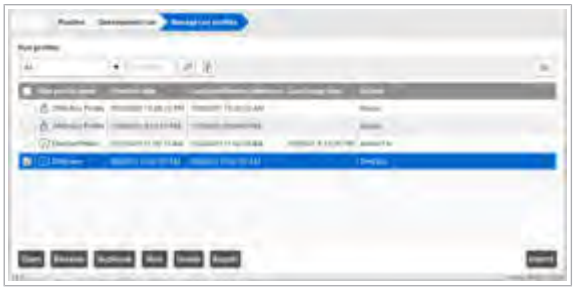
To open a run profile in the analyzer software

1. In the analyzer software, choose **Routine > Development run > Manage run profiles**.
   ➔ The **Manage run profiles** panel is displayed.
2. From the **Run profiles** table, choose a run profile.
3. Choose the **Open** button.
   ➔ The run profile is displayed on the **Edit run profile** panel.



To rename a run profile in the analyzer software

1. In the analyzer software, choose **Routine > Development run > Manage run profiles**.
   ➔ The **Manage run profiles** panel is displayed.
2. From the **Run profiles** table, choose a run profile.
   ⓘ You can only rename unlocked run profiles.
3. Choose the **Rename** button.



4 In the **Edit run profile name** dialog box, enter a new name for the run profile.

ⓘ The name can consist of 1 to 20 characters. The name must not contain the following characters:
? * < > / \ : " | '

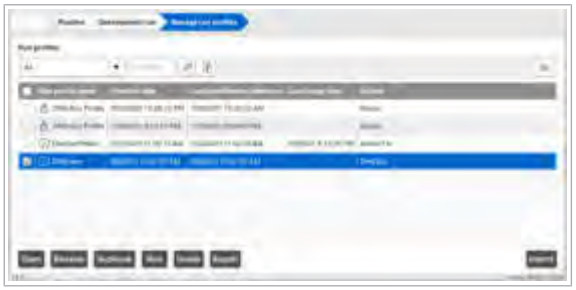
5 Choose the **Save** button.

➔ The run profile is displayed with the changed name in the **Run profiles** table.

To duplicate a run profile in the analyzer software

1 In the analyzer software, choose **Routine > Development run > Manage run profiles**.

➔ The **Manage run profiles** panel is displayed.



2 From the **Run profiles** table, choose a run profile.

3 Choose the **Duplicate** button.

4 In the **Edit run profile name** dialog box, enter a name for the new run profile.

ⓘ The name can consist of 1 to 20 characters.

5 Choose the **Save** button.

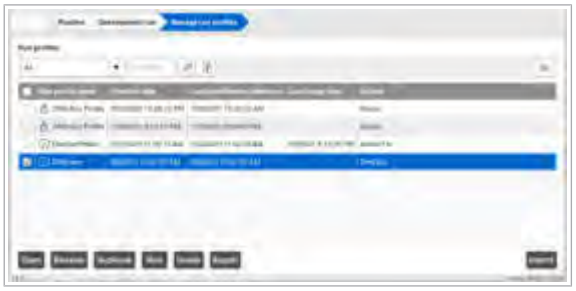
➔ The unlocked run profile is displayed in the **Run profiles** table.

➔ Your user name is added to the **Author** column.

To start a development run from the Manage run profiles panel in the analyzer software

1 In the analyzer software, choose **Routine > Development run > Manage run profiles**.

➔ The **Manage run profiles** panel is displayed.



2 From the **Run profiles** table, choose a run profile.

ⓘ You can only start a run if the analyzer is loaded and ready for a development run. Alternatively, you can open the run profile and start the run from the **Edit run profile** panel.

3 Choose the **Run** button.

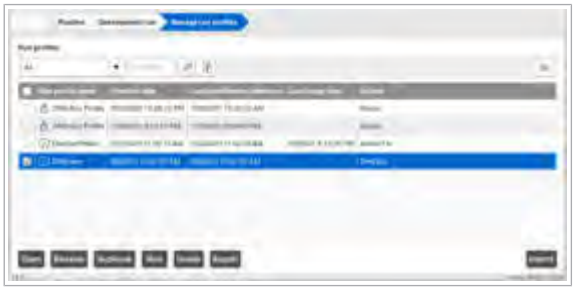
ⓘ You can only start the run if the prerequisites for a development run are met.

➔ The development run is started.

➔ The **Monitoring** panel is displayed.

To delete a run profile in the analyzer software

1 In the analyzer software, choose **Routine > Development run > Manage run profiles**.
➔ The **Manage run profiles** panel is displayed.



2 From the **Run profiles** table, choose a run profile.
ⓘ You can only delete unlocked run profiles. You can delete several run profiles simultaneously.

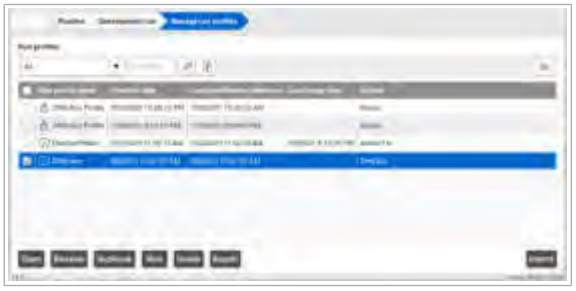
3 Choose the **Delete** button.

4 In the **Delete run profiles** dialog box, choose the **Confirm** button.
➔ The run profile is deleted from the **Run profiles** table.

To export a run profile in the analyzer software

1 Optionally, to export to an external storage device, connect the external storage device to the analyzer.

2 In the analyzer software, choose **Routine > Development run > Manage run profiles**.
➔ The **Manage run profiles** panel is displayed.



3 From the **Run profiles** table, choose a run profile.
ⓘ You can export several run profiles simultaneously.

4 Choose the **Export** button.

5 In the folder browser, navigate to a folder.

6 Choose the **Export** button.

7 Optionally, if a run profile with the same name already exists in the folder, to overwrite the existing run profile, choose the **Confirm** button.
➔ The run profile is exported as *.dpcrPrfl* file to the folder.

8 Optionally, disconnect the external storage device.

To import a run profile in the analyzer software

1 Optionally, to import from an external storage device, connect the external storage device to the analyzer.

2 In the analyzer software, choose **Routine > Development run > Manage run profiles**.
➔ The **Manage run profiles** panel is displayed.

3 Choose the **Import** button.
➔ The **Import run profiles** dialog box is displayed.

4 In the folder browser, navigate to the folder of the run profile.

5 In the file browser, choose the run profile.
ⓘ You can import several run profiles simultaneously.

6 Choose the **Import** button.

7 Optionally, if a run profile with the same name already exists in the analyzer software, in the **Action denied** dialog box, do one of the following:
- To keep the existing run profile, choose the **Rename** button. A number is appended to the name of the imported run profile.
- To replace the existing run profile, choose the **Overwrite** button.

➔ The run profile is displayed in the **Run profiles** table.

8 Optionally, disconnect the external storage device.

Editing run profiles on the Edit run profile panel in the analyzer software

On the **Edit run profile** panel, you can add, edit, and delete programs from run profiles, edit the detection formats, and start a development run.

If you edit the run profile, the temperature chart of the run and the estimated run duration are updated immediately.

You cannot delete the mandatory cooling program at the end of a run.

You cannot edit locked run profiles.

It depends on the location in the run profile which programs you can add.

About the Edit run profile panel (117)

You can only start a run from the **Edit run profile** panel if all changes to the run profile are saved and if the prerequisites for a development run are met.

Prerequisites for a development run (172)

About the detection formats

The detection formats define the channels, the dye per channel, and the integration time for the detection of fluorescence by the analyzer.

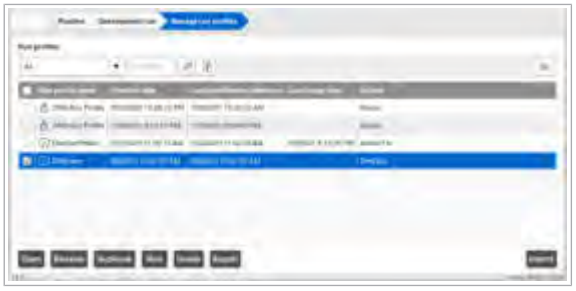
The following applies:

- Enable the channels for all dyes that are contained in any of the master mix reagents used in the development run.
- Disable the channels for dyes that are not contained in any of the master mix reagents used in the development run. Disabling empty channels shortens the run time, reduces the size of the raw data file, and enhances the performance of the development software.
- You cannot use different dyes that are detected in the same channel in 1 development run.

☐ Development operator user role

To edit a run profile in the analyzer software

1 In the analyzer software, choose **Routine > Development run > Manage run profiles**.
➔ The **Manage run profiles** panel is displayed.



2 Open an unlocked run profile:
- From the **Run profiles** table, choose the run profile.
- Choose the **Open** button.

➔ The run profile is displayed on the **Edit run profile** panel.

3 To edit a field value (i.e., program name, number of cycles, step temperature, or step duration), do the following:
- Choose the entry in the field.
- Enter the new value.
- Close the virtual keyboard.

4 Alternatively, to edit the step temperature, drag and drop the plateau segment of the temperature curve.

ⓘ You cannot edit the gradient of the temperature change.

5 To add a program, choose the + button. From the drop-down menu, choose the program.

ⓘ It depends on the location in the run profile which programs you can add.

➔ The new program is added to the left.

6 To delete a program, choose the × button.

ⓘ You cannot delete the cooling program at the end of the run profile.

7 Choose the **Detection formats** button.

➔ The **Detection format** combo box is displayed.

8 To edit the detection formats, do the following:

- To disable a channel, clear the **Enabled** check box.
- To enable a channel, select the **Enabled** check box.
- For each enabled channel, choose the dye from the **Dye** drop-down list.
- Optionally, to edit the integration time for a channel, select the **Advanced Settings** check box. Choose the **Integration time (ms)** field and enter the new value.
- Choose the **Save** button.

ⓘ Ensure that you disable empty channels.

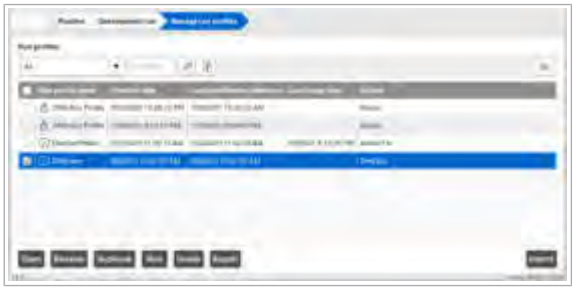
9 Choose the **Save** button.

10 On the **Edit run profile** panel, choose the **Save** button.

To start a development run from the Edit run profile panel in the analyzer software

1 In the analyzer software, choose **Routine > Development run > Manage run profiles**.

➔ The **Manage run profiles** panel is displayed.



2 Open a run profile:

- From the **Run profiles** table, choose the run profile.
- Choose the **Open** button.

➔ The run profile is displayed on the **Edit run profile** panel.

3 Choose the **Run** button.

ⓘ The **Run** button is only available if there are no unsaved changes in the run profile and if the prerequisites for a development run are met. Alternatively, you can start the development run from the **Manage run profiles** panel.

➔ The development run is started.

➔ The **Monitoring** panel is displayed.

Entering run information for a development run in the analyzer software

During a development run, you can enter run information on the **Monitoring** panel of the analyzer software.

Run information comprises the run name and run notes.

By default, a development run is named "Batch_YYYYMMDDhhmmss" with the date and time the development run was started on the analyzer.

The run name can consist of 1 to 25 characters.
The run name must not contain the following characters:
? * < > / \ : " | ’

Alternatively, you can rename the development run in the analyzer software after the run is finished or in the development software after import of the raw data file.

- List of naming placeholders (154)
- Managing raw data files of development runs in the analyzer software (312)
- Working with raw data files and runs in the development software (317)

- ☐ Development run processing on the analyzer
- ☐ **Monitoring** panel displayed in the analyzer software
- ☐ Development operator user role

To enter run information for a development run

1 On the **Monitoring** panel in the analyzer software, choose the ✎ button next to the run name.
   ➔ A dialog box is displayed.
   ➔ Previously added run notes are displayed with user name and timestamp.

2 Change the run name and/or enter run notes.

ⓘ The run name can consist of 1 to 25 characters. The run name must not contain the following characters:
? * < > / \ : " | '

3 Choose the **Confirm** button.

Runs in the development software

At the end of each run, a raw data file is generated that contains the run parameters and fluorescence values. You import the raw data files as runs into the development software for data analysis.

You can import the raw data files of up to 600 samples into the development software.

Merged nanowell plate lanes are still processed separately. Therefore, each merged lane is listed individually on a run tab.

In this section

About raw data files and runs

The raw data of a run consists of the run parameters and a list of the valid nanowells and their fluorescence values. The raw data is compiled into a single raw data file at the end of the run.

Raw data files can be exported:

- Automatically from the analyzer at the end of the run (if configured).
- Manually from the analyzer software (for development runs) or the web application (for diagnostic runs).

Raw data files are then imported as runs into the development software and are listed in the **Runs** menu. The raw data is the basis for clustering and analyses.

- Automatic export of raw data files (602)
- Managing raw data files of development runs in the analyzer software (312)
- Exporting raw data files of diagnostic runs from the web application (315)

Content of raw data files

A raw data file always contains the following information (regardless of run type):

- Run details:
  - Run name
  - Date and time the run was started and finished on the analyzer
  - User ID of the user that started the run on the analyzer
  - Serial number of the analyzer
  - Run flags
  - Partitioning information and flags
- Run profile on the analyzer:
  - Programs (temperatures, durations, number of cycles)
  - Detection formats
- Run settings:
  - Number of nanowell plates
  - Nanowell plate IDs and types
  - Run notes (optional)
- Fluorescence values for valid nanowells
  (The system may invalidate some nanowells, e.g., nanowells that cannot be imaged properly due to dust particles.)

For a **diagnostic run**, the raw data file contains the following additional information:

- Lane settings (editable in the development software):
  - Sample IDs
  - Merged lanes
  - Dilution factors
  - Master mix reagents
  - Target and dye settings
- Clustering settings (import optional)
- Analysis settings (import optional)

For a **development run**, the lane settings are not contained in the raw data file. The lane settings can either be assigned to the run from an unassigned sample setup or they can be added directly to the run.

- Working with raw data files and runs in the development software (317)
- Assigning partially matching unassigned sample setups to development runs in the development software (321)
- Adding and editing lane settings of a run in the development software (325)

About target and dye settings

The raw data file contains the detection formats of the run in the run settings, i.e., the channels, the dyes, and the integration time for the detection of fluorescence by the analyzer.

In the lane settings, in the **Target and dye settings** table, you define which subset of the detected dyes is contained in the individual master mix reagents and you map the targets to the dyes.

The following applies:

- Only dyes that are enabled in the run settings are available in the lane settings.
- You can only reuse a master mix reagent across a project if the runs or unassigned sample setups use the same detection formats.

If you enable or disable targets for a master mix reagent in the lane settings, any clustering for that master mix reagent is updated accordingly.

About merged lanes

Merged lanes emulate the partitioning of a larger sample volume into a higher number of nanowells. The system treats the nanowells of a set of merged lanes as if they belong to 1 nanowell plate lane. Merged lanes therefore facilitate detection of very low target concentrations.

Up to 8 nanowell plate lanes can be merged.

A set of merged lanes has the following characteristics:

- The same reaction mixture is pipetted into the merged lanes.
- The merged lanes are analyzed together. A set of merged lanes gets 1 final result.

In the development software, nanowell plate lanes with identical lane settings are merged automatically. Empty lane settings are considered as identical.

The position of a set of merged lanes in a sample setup is denoted by the lowest position of the included nanowell plate lanes.
Example:
If the nanowell plate lanes A1, B1, and C1 are merged, the position of the set of merged lanes is denoted as "A1".
The position is also used as name for the set of merged lanes.

About the positions of nanowell plate lanes in sample setups (153)

Naming of raw data files

Before export, raw data files are identified by the run name in the analyzer software and the web application.

By default, after export, a raw data file is named *RunType_RunName_SN_YYYYMMDDhhmmss.dpcrRaw* with the date and time the run was started on the analyzer.

A raw data file has a *.dpcrRaw* file extension.

If you change the name of a development run in the analyzer software before export, the run name is used as name of the export file.

After import into the development software, the raw data files are listed in the **Runs** menu as "RunName (DD/MM/YYYY hh:mm:ss)".

List of naming placeholders (154)

Managing raw data files of development runs in the analyzer software

For development runs, you can rename, export, and delete the raw data files in the analyzer software.

About renaming

Renaming the raw data file in the analyzer software changes the file name as well as the run name that is contained in the raw data file.

The name can consist of 1 to 20 characters.
The name must not contain the following characters:
? * < > / \ : " | ’

Do not change the file name in the Windows Explorer. Changing the file name does not change the run name.

Alternatively, you can change the run name in the development software after import of the raw data file.

Working with raw data files and runs in the development software (317)

About export

Even if automatic export of the raw data files is configured, manual export of the raw data files is always possible.

If no automatic export of the raw data files is configured or if automatic export fails, you must export the raw data files manually.

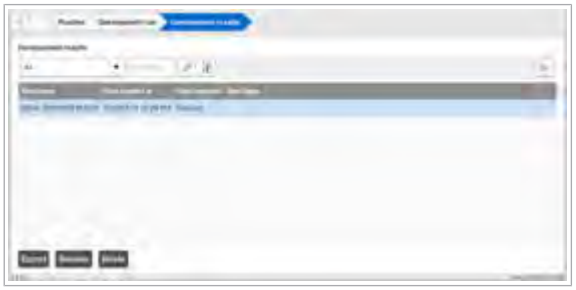
After export, you can open or import the raw data file in the development software.

Working with raw data files and runs in the development software (317)

- ☐ Optionally, external storage device, e.g., USB flash drive

- ☐ Raw data available in analyzer software (development run finished on the analyzer)
- ☐ Enough memory in the network share or on the external storage device
- ☐ Development operator user role

To rename the raw data of a development run in the analyzer software



1. In the analyzer software, choose **Routine > Development run > Development results**.
   ➔ The **Development results** panel is displayed.
2. Choose the run.
3. Choose the **Rename** button.
   ➔ The **Rename** dialog box is displayed.

4 Enter a new name for the run and choose the **Save** button.

ⓘ The name can consist of 1 to 20 characters. The name must not contain the following characters:
? * < > / \ : " | '

➔ The new name is displayed on the **Development results** panel.

To export the raw data of a development run manually from the analyzer software

1 Optionally, to export to an external storage device, connect the external storage device to the analyzer.

2 In the analyzer software, choose **Routine > Development run > Development results**.

➔ The **Development results** panel is displayed.

3 Choose the run.

4 Choose the **Export** button.

➔ The **Export** dialog box is displayed.

5 To change the export path, choose the ··· button.

➔ The **Select folder** dialog box is displayed.

6 In the folder browser, navigate to a folder.

7 Choose the **Confirm** button.

8 In the **Export** dialog box, choose the **Export** button.

➔ The results are exported as *dpcrRaw* file.

To delete the raw data of a development run in the analyzer software

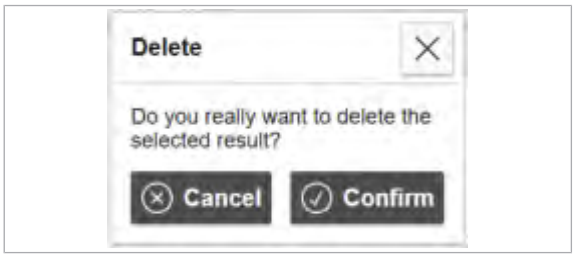
1 In the analyzer software, choose **Routine > Development run > Development results**.

➔ The **Development results** panel is displayed.

2 Choose the run.

3 Choose the **Delete** button.

➔ The **Delete** dialog box is displayed.



4 Choose the **Confirm** button.
➔ The run is deleted from the table on the **Development results** panel.

Exporting raw data files of diagnostic runs from the web application

For diagnostic runs, you can export the raw data files from the web application if the export conditions are met.

Even if automatic export of the raw data files is configured, manual export of the raw data files is always possible if the export conditions are met.

If no automatic export of the raw data files is configured or if automatic export fails, you must export the raw data files manually.

After export, you can open or import the raw data file in the development software.

Working with raw data files and runs in the development software (317)

About export conditions

For a diagnostic run, the export of the raw data file is only possible if the following conditions are met:

- All results of the diagnostic run must be complete, i.e., released and sent. The run must be listed on the **Completed batches** screen.
- The export of the raw data file must be enabled in the analysis packages used for the diagnostic run.

If a diagnostic run uses 2 or more analysis packages with different export settings, the most restrictive option is applied to the raw data file of that run.

Analysis packages in the development software (412)

About export options

There are the following export options depending on the browser and computer configuration:

- If you access the web application from the computer running the development software, you can export the raw data file and directly open it as a new project in the development software.

- Alternatively, you can export and save the raw data file for later import into the development software.

☐ Optionally, external storage device, e.g., USB flash drive

☐ Raw data ready for export in the web application (diagnostic run listed on the **Completed batches** screen)

☐ Export of raw data allowed in the analysis packages of the diagnostic run

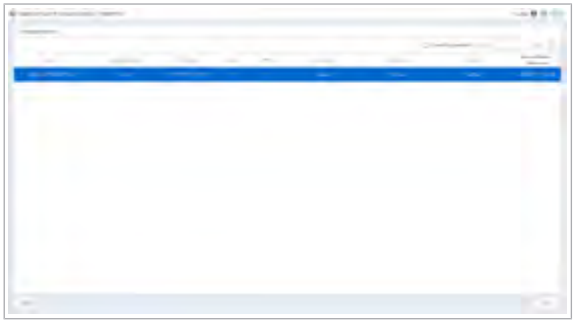
☐ Enough memory in the network share or on the external storage device

☐ Diagnostic operator user role or diagnostic approver user role

To export and open the raw data file of a diagnostic run from the web application

1 In the web application, in the **Results** column on the dashboard, choose the **{count} completed batches** tile.

➔ The **Completed batches** screen is displayed.



2 Choose the run and choose the **Export** button.

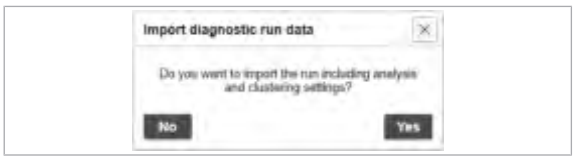
➔ A dialog box is displayed.

3 Select to open the raw data file and choose the **OK** button.

ⓘ The available options and details depend on your browser and computer configuration.
You can only open the raw data file if the development software is installed on the same computer.

➔ The development software is started.

➔ The **Import diagnostic run data** dialog box is displayed.



4 In the development software, do one of the following:

- To include the analysis and clustering settings in the import, choose the **Yes** button.
- To exclude the analysis and clustering settings from the import, choose the **No** button.

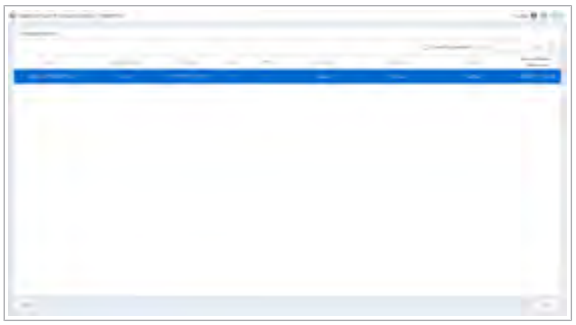
➔ The diagnostic run is imported into the development software and listed in the **Runs** menu.

To export and save the raw data file of a diagnostic run from the web application

1 Optionally, to export to an external storage device, connect the external storage device to the computer running the web application.

2 In the web application, in the **Results** column on the dashboard, choose the **{count} completed batches** tile.

➔ The **Completed batches** screen is displayed.



3 Choose the run and choose the **Export** button.

➔ A dialog box is displayed.

4 Select to save the raw data file and choose the **OK** button.

ⓘ The available options and details depend on your browser and computer configuration.

➔ The raw data file is exported and saved in the export location.

5 Optionally, disconnect the external storage device.

Working with raw data files and runs in the development software

You can open or import the exported raw data files in the development software. Then, you can rename the runs, view the run details and the run profiles, export the run profiles and the run data, delete the runs, or create sample setup reports.

About matching unassigned sample setups

During import of the raw data file of a development run, the development software checks the project for a matching unassigned sample setup:

- A **matching** unassigned sample setup is assigned automatically during import.
- A **partially matching** unassigned sample setup can be assigned manually after import.

The assignment transfers the lane settings from the unassigned sample setup to the development run.

An unassigned sample setup is **matching** if the following parameters match between the unassigned sample setup and the development run:

- Number of nanowell plates (different order is allowed)

- Nanowell plate IDs
- Detection formats

An unassigned sample setup is **partially matching**, if the following parameters match between the unassigned sample setup and the development run:

- Number of nanowell plates
- Nanowell plate types
- Order of the nanowell plates
- Detection formats

After an unassigned sample setup is assigned to a development run, the following applies:

- The unassigned sample setup is deleted from the **Unassigned sample setup** menu in the **Navigation** area.
- You cannot assign a different unassigned sample setup to the same development run. Instead, you must edit the lanes settings of the run directly.

Unassigned sample setups in the development software (402)

☐ Optionally, external storage device with exported raw data file, e.g., USB flash drive

☐ Raw data file exported and available in network share or on external storage device

To open the raw data file in the development software as a new project

1 Optionally, if the raw data file was exported to an external storage device, connect the external storage device to the computer running the development software.

2 Do one of the following:

- In the development software, on the **Start page** tab, choose the **Open file** button.
- In the development software, in the **Navigation** area, choose **File** > ▪▪▪ > **Open**.
- In the Windows Explorer, double-click the *dpcrRaw* file.

ⓘ The **Open** commands always open a new instance of the development software.

3 If required, navigate to the *dpcrRaw* file and choose the **Open** button.

➔ A project is created and displayed in a separate instance of the development software. By default, the project is named as the run.

➔ The run tab is displayed in the work area.

➔ In the **Navigation** area, the run is listed in the **Runs** menu.

➔ 1 default clustering per combination of master mix reagent and plate type is added to the project and listed in the **Clustering** menu.

4 Save the project.

To import the raw data file into a project in the development software

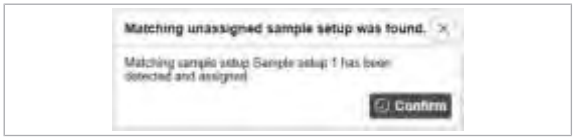
1 In the development software, open the project as described in Working with projects in the development software (295).

ⓘ You can import several runs into the same project.

2 In the **Navigation** area, choose **Runs >** ••• **> Import**.

ⓘ The **Import** command imports the raw data file into the same instance of the development software.

3 Navigate to the *dpcrRaw* file and choose the **Open** button.



4 If a matching unassigned sample setup is found, the **Matching unassigned sample setup was found.** dialog box is displayed. Choose the **Confirm** button.

➔ The run tab is displayed in the work area.

➔ In the **Navigation** area, the run is listed in the **Runs** menu.

➔ Any affected clustering is updated according to the rules for clustering.

5 If the project contains a partially matching unassigned sample setup, assign it manually as described in Assigning partially matching unassigned sample setups to development runs in the development software (321).

6 Save the project.

To rename a run in the development software

1 In the **Navigation** area, choose the run from the **Runs** menu. Choose ••• **> Rename**.

2 In the **Edit run name** dialog box, enter the new name.

3 Choose the **Save** button.

➔ The run tab is renamed.

➔ The run listed in the **Runs** menu is renamed.

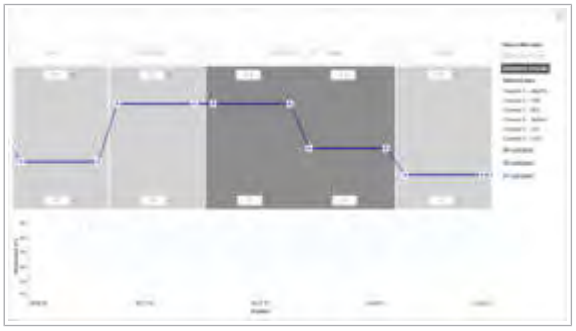
4 Save the project.

To view the run profile of a run in the development software

1 In the **Navigation** area, choose the run from the **Runs** menu. Choose ••• **> View run profile**.

➔ The run profile is displayed in the same format as on the **Edit run profile** panel in the analyzer software.

➔ The run profile is view only. You cannot edit the run profile.



2 To display the channel, dye, and integration time settings, choose the **Detection formats** button.

3 To close the **Detection format** combo box, choose the **Cancel** button.

4 To close the run profile, choose the ✕ button.

To view the run details of a run in the development software

1 In the **Navigation** area, choose the run from the **Runs** menu. Choose ••• **> View run details**.

➔ The **Run details** dialog box is displayed.

2 To close the run details, choose the **Close** button.

To export the run profile of a run from the development software

1 In the **Navigation** area, choose the run from the **Runs** menu. Choose ••• **> Export run profile**.

2 Navigate to a folder. Enter a name for the export file and choose the **Save** button.

➔ The run profile is exported as *dpcrPfrl* file.

To export the run data of a run to CSV from the development software

1 In the **Navigation** area, choose the run from the **Runs** menu. Choose ••• **> Export run data to CSV**.

2 Navigate to a folder and choose the **OK** button.

➔ A CSV file per nanowell plate lane is exported to the folder.

➔ The first row in the CSV files contains the column headers, i.e., the legend.

To delete a run from a project in the development software

1 In the **Navigation** area, choose the run from the **Runs** menu. Choose ••• **> Remove**.

2 In the **Warning** dialog box, choose the **Confirm** button.

ⓘ You cannot restore the run, but you can open or import the run again.

➔ The run is deleted from the project.

➔ The samples of the run are deleted from any affected clustering. An empty clustering is deleted from the project.

➔ The samples of the run are deleted from the analyses. Empty analyses are kept in the project.

➔ Any analysis package that was created based on the run is not affected, but kept unchanged in the project.

3 Save the project.

To create a sample setup report of a run in the development software

1 In the **Navigation** area, choose the run from the **Runs** menu. Choose ••• **> Create a sample setup report**.

2 Navigate to a folder. Enter a name for the report and choose the **Save** button.

ⓘ A printout of the sample setup report may be helpful when performing analysis.

➔ The sample setup report is saved as a PDF file.

Assigning partially matching unassigned sample setups to development runs in the development software

To transfer the lane settings from a partially matching unassigned sample setup to the corresponding imported development run, assign the unassigned sample setup to the run.

An unassigned sample setup is **partially matching**, if the following parameters match between the unassigned sample setup and the development run:

- Number of nanowell plates
- Nanowell plate types
- Order of the nanowell plates
- Detection formats

After an unassigned sample setup is assigned to a development run, the following applies:

- The unassigned sample setup is deleted from the **Unassigned sample setup** menu in the **Navigation** area.
- You cannot assign a different unassigned sample setup to the same development run. Instead, you must edit the lanes settings of the run directly.

Unassigned sample setups that are not at least partially matching cannot be assigned to an imported development run.

You cannot assign an unassigned sample setup to a diagnostic run.

Working with raw data files and runs in the development software (317)

- ☐ Development run imported into project
- ☐ Project contains partially matching unassigned sample setup

To assign a partially matching unassigned sample setup to a development run in the development software

1. In the development software, in the **Navigation** area, choose the run from the **Runs** menu.
2. Choose ••• **> Assign existing sample setup**.
   ➔ A list of partially matching unassigned sample setups is displayed as submenu.
3. Choose the sample setup.
4. Choose the **Confirm** button.
   ➔ The lane settings of the run are transferred from the unassigned sample setup to the run.
   ➔ The unassigned sample setup is deleted from the project.
   ➔ Any affected clustering is updated according to the rules for clustering.

5 Save the project.

List of columns on the Sample setup table view card

On run tabs and sample setup tabs, the columns on the **Sample setup table view** card (and the entries on the tiles on the **Sample setup plate view** card) display the lane settings as entered on the **Lane settings** card.

The entry in the **MMx ID** field on the **Lane settings** card is not displayed on the **Sample setup table view** card.

If you change a lane setting on the **Lane settings** card, the corresponding column on the **Sample setup table view** card (and the entry on the tile in plate view) is updated accordingly. If the update is delayed, close the tab and reopen it from the **Navigation** area.

In plate view, a combination of 3 selected lane settings can be displayed on the tiles.

- Configuring plate view (139)
- Adding and editing lane settings of a run in the development software (325)
- Adding run settings and lane settings to unassigned sample setups in the development software (406)

Lane ID column The position of the sample in the sample setup.

Sample ID column The ID of the sample as entered in the **Sample ID** field on the **Lane settings** card.

The sample ID can be displayed on the tiles in plate view.

Dilution factor column The dilution factor for the sample in the reaction mixture as entered in the **Dilution factor** field on the **Lane settings** card.

Example:
A dilution factor of 2 (i.e., a dilution of 1:2) means half of the reaction mixture consists of sample.

By default (dilution of 1:1), the development software calculates the quantitative results in relation to the volume of the reaction mixture.

If you enter a dilution factor, the development software automatically uses it as a multiplication factor to calculate the quantitative results in relation to the sample volume.

Precision = 4 decimal places

The dilution factor can be displayed on the tiles in plate view.

MMx column

The name of the master mix reagent as entered in the **MMx** field on the **Lane settings** card.

The name of the master mix reagent can be displayed on the tiles in plate view.

Target names column

The name of the targets as entered and enabled for the master mix reagent in the **Target and dye settings** table on the **Lane settings** card.

By default, the targets are named as the dyes.

The name of the targets can be displayed on the tiles in plate view.

Dyes column

The dyes that are enabled for the master mix reagent in the **Target and dye settings** table on the **Lane settings** card.

Notes column

The notes as entered via the **Edit notes** button on the **Lane settings** card.

Sample preparation notes column

The sample preparation notes as entered via the **Edit sample preparation notes** button on the **Lane settings** card.

Flags column

The flags associated with the sample.

MMx lot number column

Additional identifying information, e.g., the lot number of the master reagent or master mix reagent, as entered in the **MMx lot number** field on the **Lane settings** card.

MMx expiry date column

The expiry date, e.g., of the master reagent or the master mix reagent, as entered in the **MMx expiry date** field on the **Lane settings** card.

Merging column

Indicates if the nanowell plate lane belongs to a set of merged lanes.

For unmerged nanowell plate lanes, "None" is displayed.

For merged nanowell plate lanes, "Merged" is displayed.

Merged lanes name column

The name of the set of merged lanes that is derived from the lowest position of the merged lanes.

About the positions of nanowell plate lanes in sample setups (153)

Adding and editing lane settings of a run in the development software

After import of the raw data file into the development software, add and/or edit the lane settings to prepare for clustering.

If an unassigned sample setup was assigned to a development run or if the raw data originates from a diagnostic run, the lane settings will be prefilled but can be edited.

You can also copy and paste lane settings between unassigned sample setups and/or runs of the same project.

Editing lane settings via copy and paste in the development software (335)

About lane settings

Lane settings comprise the following information that applies to individual nanowell plate lanes, i.e., samples:

- Sample ID
- Dilution factor of sample
- Name of master mix reagent

- ID of master mix reagent or master reagent
- Expiry date of master mix reagent or master reagent
- Lot number of master mix reagent or master reagent
- Target and dye settings
- Notes and sample preparation notes

The following applies to lane settings:

- Changes to a master mix reagent, e.g., a name change or changed target and dye settings, are applied across the project wherever the same master mix reagent is used.
- If you enter the same lane settings for multiple nanowell plate lanes, the nanowell plate lanes are merged automatically.
- For merged lanes, empty lane settings are considered as identical.
- Changes to 1 merged lane are applied automatically to all other merged lanes of the same set.
- It is recommended to use the fields for the ID, expiry date, and lot number to track your own master mix reagents.

List of columns on the Sample setup table view card (323)

☐ Run imported into development software

To add and edit lane settings of a run in the development software

1 In the development software, in the **Navigation** area, choose the run from the **Runs** menu.

2 On the run tab, choose the **Lane settings** button.
➔ The **Lane settings** card is displayed.

3 Choose one or several tiles (in plate view) or rows (in table view).

4 To enter the sample ID for the selected tiles or rows, do the following:
- Choose the **Sample ID** field.
- Scan or enter the sample ID.
- If required, press Enter.

➔ The sample ID is displayed on the selected tiles or in the selected rows.

5 Optionally, to enter a dilution factor for the selected tiles or rows, do the following:
- Choose the **Dilution factor** field.
- Enter the dilution factor.
- Press Enter.

6 To add a new master mix reagent to the project and assign it to the selected tiles or rows, do the following:
- Choose the **MMx** field.
- Enter the name of the master mix reagent.
- Press Enter.

➔ The master mix reagent is displayed on the selected tiles or in the selected rows.

➔ By default, in plate view, all tiles with the same master mix reagent are displayed with the same color.

7 To assign a master mix reagent that exists in the project to the selected tiles or rows, do the following:
- Next to the **MMx** field, choose the ▾ button.
- From the drop-down list, choose the master mix reagent.

ⓘ You can only assign an existing master mix reagent if the dyes that are enabled in the run settings match.
If you assign an existing master mix reagent, the target and dye settings are taken over from the master mix reagent.

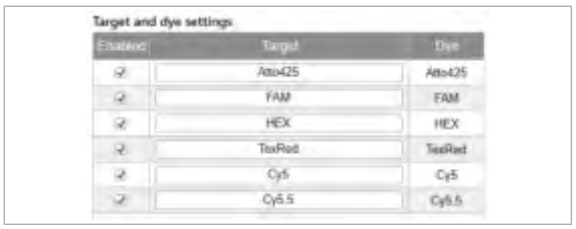
➔ The master mix reagent is displayed on the selected tiles or in the selected rows.

➔ By default, in plate view, all tiles with the same master mix reagent are displayed with the same color.

8 Optionally, to rename the assigned master mix reagent across the project, do the following:
- Next to the next to the **MMx** field, choose the ✎ button.
- In the **Edit MMx name** dialog box, enter a new name.
- Choose the **Save** button.

➔ The master mix reagent is renamed across the project.

9 Optionally, for the selected tiles or rows, choose the following fields and scan or enter the additional information for the master mix reagent or master reagent:
- **MMx ID**
- **MMx expiry date**
- **MMx lot number**



10 Optionally, in the **Target and dye settings** table, disable targets for the selected tiles or rows.

ⓘ Only the dyes for channels that were enabled in the run settings are displayed.
At least 1 target must be enabled for each master mix reagent.
Disabled targets are excluded from clustering and analysis later in the development workflow.
Ensure that you disable empty channels.

11 To map the targets to the dyes, rename the targets:

- Choose the **Target** field.
- Enter the name of the target.
- Press Enter.

ⓘ You can display the mappings on the clustering tabs later in the development workflow.

12 Optionally, add notes and/or sample preparation notes.

13 Repeat steps **3** to **12** for all other tiles or rows.

14 Optionally, to undo or redo changes, choose the buttons above the tiles (in plate view) or rows (in table view):

- To undo a change, choose the **Undo** button.
- To redo a change, choose the **Redo** button.
- To reset all lane settings to default values, choose the **Reset** button.

ⓘ The last 15 steps are retained and can be undone or redone, including a reset to default.

15 Save the project.

Working with sample groups in the development software

Sample groups allow you to perform statistics on selected samples.

Sample groups are effective across all runs and analyses of a project. Sample groups are displayed in the **Sample groups** cards on all run tabs and analysis tabs. Any action on a sample group is synchronized across all run tabs and analysis tabs of a project.

If you import a diagnostic run into the development software, a sample group per performed test is created automatically. All samples of the run that have orders for the corresponding test are added to the corresponding sample group.

Sample groups and merged lanes

If merged lanes belong to a sample group, always all lanes of the set of merged lanes belong to the sample group because the merged lanes contain the same sample.

If you add a merged lane to a sample group, all other merged lanes of the same set are added automatically to the sample group.

If you merge a lane that is part of a sample group, all other merged lanes of the same set are added automatically to the sample group.

To create a sample group in the development software

1 In the development software, to navigate to the **Sample groups** card from the **Navigation** area, do one of the following:

- Choose the run from the **Runs** menu. On the run tab, choose the **Sample groups** button.
- Choose the analysis from the **Analysis** menu. On the analysis tab, choose the ⚙ button. In the **Settings** combo box, choose the **Sample selection** tab.

2 Select the samples for the sample group.

ⓘ To add samples across runs and/or analyses, create the sample group from 1 run or analysis, and then update the sample group with the samples from the other runs and/or analyses.

3 On the **Sample groups** card, choose the **New** button.
   ➔ A sample group is created that contains the selected samples and is listed on the **Sample groups** card.
   ➔ Sample groups are numbered consecutively.

4 Save the project.

To add samples to a sample group in the development software

1 In the development software, to navigate to the **Sample groups** card from the **Navigation** area, do one of the following:
   - Choose the run from the **Runs** menu. On the run tab, choose the **Sample groups** button.
   - Choose the analysis from the **Analysis** menu. On the analysis tab, choose the ⚙ button. In the **Settings** combo box, choose the **Sample selection** tab.

2 Select the samples that you want to add to a sample group.

3 On the **Sample groups** card, choose the + button of the sample group you want to add the samples to.

➔ The new samples and the samples already belonging to the sample group are selected.

4 On the **Sample groups** card, choose the **Update** button.

ⓘ Without this step, the samples are not added to the sample group!

➔ The sample group contains both the old and the newly added samples.

5 Save the project.

To update a sample group in the development software

1 In the development software, to navigate to the **Sample groups** card from the **Navigation** area, do one of the following:

- Choose the run from the **Runs** menu. On the run tab, choose the **Sample groups** button.
- Choose the analysis from the **Analysis** menu. On the analysis tab, choose the ⚙ button. In the **Settings** combo box, choose the **Sample selection** tab.

2 On the **Sample groups** card, choose the sample group.
   ➔ The samples belonging to the sample group are selected.

3 Press and hold Ctrl. Select and/or deselect samples for the sample group.
   ⓘ Pressing Ctrl keeps the selected samples. If you just select a sample without pressing Ctrl, all other samples are deselected.

4 On the **Sample groups** card, choose the **Update** button.
   ⓘ Instead of updating a sample group, consider deleting it and creating a new one.
   ➔ The selected samples are added to the sample group.
   ➔ The deselected samples are removed from the sample group.

5 Save the project.

To rename a sample group in the development software

1 In the development software, to navigate to the **Sample groups** card from the **Navigation** area, do one of the following:
   - Choose the run from the **Runs** menu. On the run tab, choose the **Sample groups** button.
   - Choose the analysis from the **Analysis** menu. On the analysis tab, choose the ⚙ button. In the **Settings** combo box, choose the **Sample selection** tab.

2 On the **Sample groups** card, choose the sample group.

3 Choose the **Rename** button.
➔ The **Edit sample group name** dialog box is displayed.

4 Enter the new name and choose the **Save** button.
➔ The new name of the sample group is displayed on the **Sample groups** card.

5 Save the project.

To delete a sample group in the development software

1 In the development software, to navigate to the **Sample groups** card from the **Navigation** area, do one of the following:
- Choose the run from the **Runs** menu. On the run tab, choose the **Sample groups** button.
- Choose the analysis from the **Analysis** menu. On the analysis tab, choose the ⚙ button. In the **Settings** combo box, choose the **Sample selection** tab.

2 On the **Sample groups** card, choose the sample group.

3 Choose the **Delete** button.

➔ The **Warning** dialog box is displayed.

4 Choose the **Confirm** button.

ⓘ You cannot restore deleted sample groups.

➔ The sample group is deleted from the **Sample groups** card.

5 Save the project.

Related topics

- Projects in the development software (294)
- Clustering in the development software (338)
- Analyses in the development software (358)
- Unassigned sample setups in the development software (402)
- Analysis packages in the development software (412)

Editing lane settings via copy and paste in the development software

Instead of adding and/or editing lane settings manually, you can copy and paste them between unassigned sample setups and/or runs of the same project in the development software.

Adding and editing lane settings of a run in the development software (325)

Adding run settings and lane settings to unassigned sample setups in the development software (406)

About rules

The following rules apply for copy and paste:

- You can only copy and paste between setups of the same project, not across projects.
- The *source setup* is the unassigned sample setup or run that you copy lane settings from.
- The *target setup* is the unassigned sample setup or run that you paste lane settings to.
- Both source setup and target setup can be an unassigned sample setup or a run.
- Source and target setup can be the same, i.e., you can copy and paste within the same setup or between different setups.
- Both source setup and target setup must be in plate view or table view.
- If you copy a single nanowell plate lane in the source setup, you can paste it to any nanowell plate lane in the target setup.
- The copied nanowell plate lanes are highlighted.
- You can paste repeatedly. The copied lane settings are retained on the clipboard until you clear the clipboard or copy different lane settings.

In **table view**, you can copy 1 row only. However, you can paste to several rows at the same time (resulting in merged lanes).

In **plate view**, the following additional rules apply:

- You can copy and paste several tiles at the same time (not necessarily resulting in merged lanes).
- You can only copy and paste adjacent tiles, i.e., there can be not gaps between the tiles.
- You can copy and paste several tiles if you choose the same number and distribution of tiles across nanowell plates in the source setup and the target setup.

- You can copy several tiles from the same nanowell plate and choose 1 tile only in the target setup if there are enough tiles below the selected tile in the target setup. The tiles are pasted starting from the selected tile towards the end of the nanowell plate.

To edit lane settings via copy and paste in the development software

1 In the development software, choose the target setup:
   - From the **Runs** menu, choose a run.
   - Alternatively, from the **Unassigned sample setup** menu, choose an unassigned sample setup.

   ➔ The sample setup tab or run tab is displayed in the work area.

2 Choose the source setup:
   - From the **Runs** menu, choose a run.
   - Alternatively, from the **Unassigned sample setup** menu, choose an unassigned sample setup.

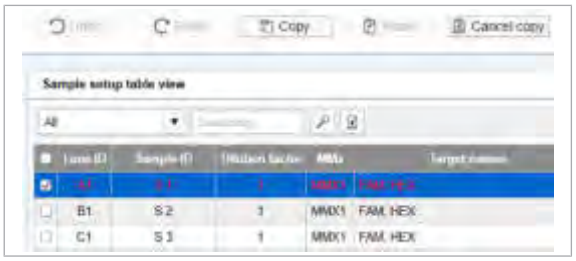
   ➔ The sample setup tab or run tab is displayed in the work area.

3 Ensure that both the source setup and the target setup are displayed in the same view (plate view or table view).

4 To copy the lane settings **in plate view**, do the following:
   - Choose the tab of the source setup.
   - On the **Sample setup plate view** card, choose one or several tiles.
   - Choose the **Copy** button.
   - Optionally, to clear the clipboard, choose the **Cancel copy** button.

   ⓘ To deselect the tiles, press Esc.

   ➔ The source tiles are highlighted.



5 To copy the lane settings **in table view**, do the following:
   - Choose the tab of the source setup.
   - On the **Sample setup table view** card, choose a row.
   - Choose the **Copy** button.
   - Optionally, to clear the clipboard, choose the **Cancel copy** button.

   ➔ The source row is highlighted in red.

6 Paste the lane settings:
   - Choose the tab of the target setup.
   - Choose one or several tiles (in plate view) or rows (in table view).
   - Choose the **Paste** button.

- Optionally, to undo the paste operation, choose the **Undo** button.

7 Save the project.

Clustering in the development software

Clustering differentiates between positive and negative nanowells.

In this section

About clustering in the development software

Clustering differentiates between positive nanowells that are counted as containing the target and negative nanowells that are counted as not containing the target. Clustering provides the data basis for the following analyses.

For clustering, the following applies:

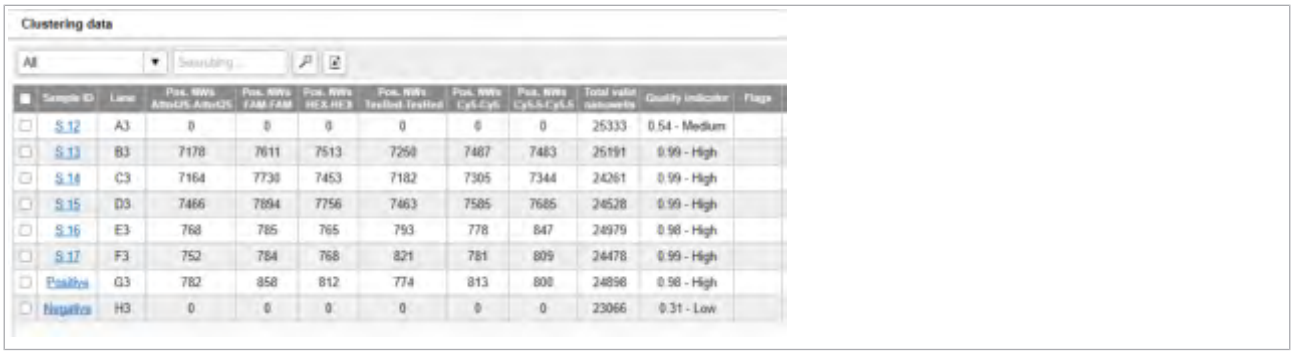
- The development software automatically performs initial clustering when you choose the clustering from the **Navigation** area. You can then adjust the clustering.
- Clustering is done across all runs of a project, regardless of the run type (development run or diagnostic run).
- All samples that were processed with the same combination of master mix reagent and nanowell plate type are clustered together.
- Consequently, a project in the development software always contains 1 clustering per combination of master mix reagent and nanowell plate type that is used in any of its runs.
- As long as the master mix reagents are not specified (e.g., by editing the lane settings), the development software assigns a default master mix reagent to all samples that were processed with the same combination of nanowell plate type and detection formats.
- Merged lanes are listed individually on a clustering tab and their scatter plots are displayed separately.

The development software adds, updates, and/or deletes the clustering tabs when you do one of the following:

- Open a raw data file as a new project:
  - Clustering tabs are added.
- Import a raw data file into an existing project:
  - All samples with a combination of master mix reagent and nanowell plate type that matches an existing clustering are added to that clustering tab.
  - For all other samples, clustering tabs are added.
- Change the master mix reagent for samples:
  - If the new combination of master mix reagent and nanowell plate type matches an existing clustering, the samples are moved to that clustering tab.
  - If the new combination of master mix reagent and plate type does not match an existing clustering, a clustering tab is added.
  - Clustering tabs without samples are deleted.
- Delete a run from a project:
  - The samples of that run are deleted from the affected clustering tabs.
  - Clustering tabs without samples are deleted.

List of columns on the Clustering data card

On clustering tabs, the columns on the **Clustering data** card display the sample and clustering information.



Sample ID column

The sample ID of the sample as entered in the lane settings on the run tab.

Merged lanes are always clustered and listed separately.

List of columns on the Sample setup table view card (323)

Lane column

The position of the sample in the sample setup.

Columns for number of positive nanowells

The **Pos. NWs {0}-{1}** columns display the number of positive nanowells of the sample determined from the current clustering settings.

The **Clustering data** card contains a separate **Pos. NWs {0}-{1}** column per dye that is enabled in the lane settings on the run tab.

The placeholders in the curly brackets are replaced as follows:

- **{0}** is replaced with the dye name.
- **{1}** is replaced with the target name as entered in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

Total valid nanowells column

The total number of valid nanowells of the sample, i.e., the sum of positive and negative nanowells.

The system may invalidate some nanowells, e.g., nanowells that cannot be imaged properly due to dust particles.

Quality indicator column

For the automatic clustering methods, the quality indicator (QI) evaluates the actual clustering for a nanowell plate lane. If applicable, the number of clusters, the separation and size of the positive and negative clusters, the relative fluorescence intensities of the clusters, and the cluster tightness are considered for QI calculation.

Consequently, the quality indicator is not reliable for negative controls (1 cluster only) or indel tests (3 clusters in 2 channels).

The quality indicator is only suitable for comparison of similar reaction mixtures, e.g., during test optimization.

In the **Quality indicator** column, the numerical value of the quality indicator and the derived classification are displayed:

- **Low** for QI < 0.33
- **Medium** for 0.33 < QI < 0.67
- **High** for QI > 0.67

For the manual clustering method, **Undefined** is displayed.

The quality indicator does not distinguish between the channels, but is calculated across all channels of a nanowell plate lane.

List of clustering settings in the development software (342)

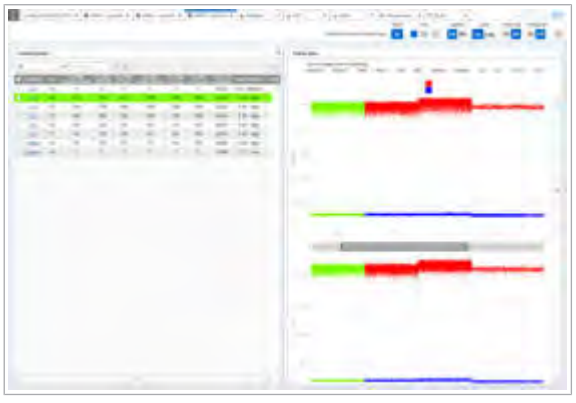
Flags column The flags associated with the sample.

Changing the display options for the scatter plots in the development software

On the clustering tabs, you can change the display options for the scatter plots.

By default, all samples that are listed on the **Clustering data** card on a clustering tab are displayed in the scatter plots.

About the display options (132)



To change the display options for the scatter plots in the development software

1. In the development software, in the **Navigation** area, choose a clustering from the **Clustering** menu.
   ➔ The clustering tab is displayed.
2. To highlight a sample in the scatter plots in green, mouse over the corresponding row on the **Clustering data** card.
3. To display the scatter plots for specific samples only, select the check boxes of the samples on the **Clustering data** card.
   ℹ Clearing the check boxes of samples on the **Clustering data** card does **not** exclude such sample from clustering. Even if they are not displayed in the scatter plots, they are still included in the clustering.
4. To display all samples in the scatter plots again, do one of the following:
   - Select the check boxes of all samples in the table.
   - Clear the check boxes of all samples in the table.
5. To adjust the available screen space for the scatter plots, do the following:

- To hide the **Navigation** area, choose the button.
- To hide or display the **Clustering data** card, choose the **Table** button above the scatter plots.

6 To display the scatter plots for different channels next to each other, choose the **View** buttons.

7 To hide or display the dye to target name mapping and a legend for the color-coding of the scatter plots, choose the **Legend** buttons.

8 To toggle between a linear and a logarithmic scale for the fluorescence axes, choose the **Scale** buttons.

9 To display or hide a heatmap, choose the **Heatmap** buttons.

10 To display or hide a histogram, choose the **Histogram** buttons.

11 Save the project.

Adjusting the clustering in the development software

To change the differentiation between positive and negative nanowells that is automatically done by the development software, adjust the clustering.

By itself, you cannot exclude samples from clustering. However, you can assign a separate master mix reagent to such samples. This will move these samples to a separate clustering for the resulting combination of nanowell plate type and master mix reagent.

In this section

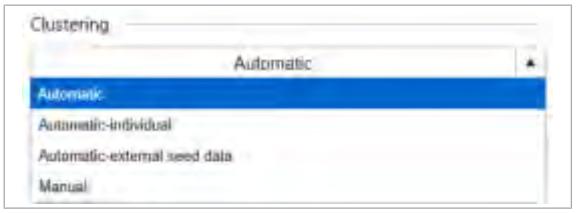
List of clustering settings in the development software

The clustering settings allow you to select the clustering method, the plot type, the channels, and the axis ranges.

The choice of clustering settings influences the availability of other clustering settings.

To display the clustering settings, in the top right corner on the clustering tab, choose the ⚙ button.

Clustering drop-down list



Determines the clustering method:

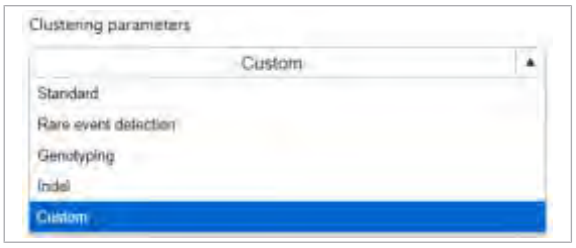
- **Automatic**
  The clustering is calculated as if all scatter points originated from one nanowell plate lane.
- **Automatic (individual)**
  The clustering is calculated separately for each nanowell plate lane.
- **Automatic - External seed data**
  The clustering uses the exported clustering settings from a previous automatic clustering for calculation.
- **Manual**
  The user adjusts the clustering thresholds.

Default value = **Automatic**

For the automatic clustering methods, the development software differentiates automatically between positive and negative nanowells using built-in algorithms. In the clustering data table, a quality indicator is displayed that classifies the reliability of the clustering.

For the manual clustering method, the quality indicator is not available.

Clustering parameters drop-down list



For the **Automatic** clustering method and the **Automatic (individual)** clustering method only: Predefined balances for the sensitivity specificity parameter and the competition cross-reactivity parameter that are optimized for specific applications:

- **Standard**
- **Rare event detection**
- **Genotyping**
- **Indel**
- **Custom**

Default value = **Custom**

The **Custom** option of the clustering parameters allows you to set the balances manually in the **Sensitivity specificity** field and the **Competition cross-reactivity** field.

Sensitivity specificity field

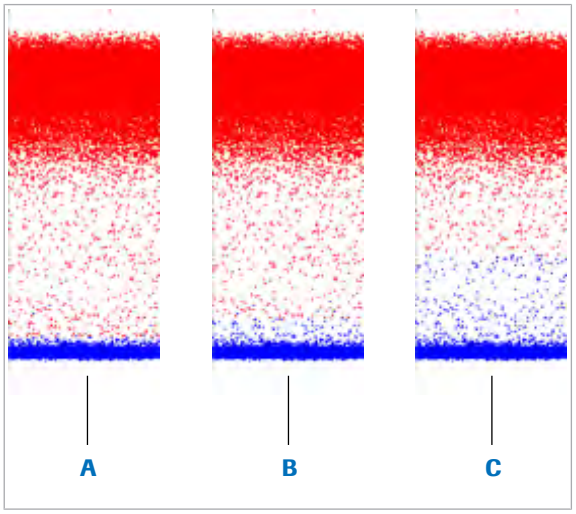
For the **Custom** option of the clustering parameters only: Editable value between 0.0000 and 1.0000 that determines the balance between sensitivity and specificity:

- 0.0000 = maximum sensitivity
- 1.0000 = maximum specificity

The lower the value, the closer the threshold is set to the negative cluster.

Default value = 1.0000

Precision = 4 decimal places



A 0.0000 **B** 0.5000 **C** 1.0000

The figure illustrates for 1 nanowell plate lane how a change in the value affects the very small number of scatter points between the negative and the positive clusters:

- Left = 0.0000 (maximum sensitivity):
  - Higher sensitivity increases the number of nanowells that are counted as positive.
  - Maximum sensitivity sets the lowest possible threshold for a nanowell to be counted as positive.
- Middle = 0.5000
- Right = 1.0000 (maximum specificity):
  - Higher specificity increases the number of nanowells that are considered as outliers and are counted as negative.
  - Maximum specificity sets the highest possible threshold for a nanowell to be counted as positive.

Competition cross-reactivity field

For the **Custom** option of the clustering parameters only: Editable value between 0.0000 and 1.0000 that accounts for competition and cross-reactivity:

- 0.0000 = no competition, no cross-reactivity
- 1.0000 = maximum competition and cross-reactivity

The higher the value, the more the reaction artifacts from competition and cross-reactivity are taken into account for clustering.

Default value = 0.0000

Precision = 4 decimal places

If 2 targets compete for reaction components, the fluorescence of nanowells that contain both targets is lower in both channels than the fluorescence of nanowells that contain 1 of the targets only.

If 2 targets cross-react, a positive reaction in 1 channel raises the baseline for the negative nanowells in the other channel.

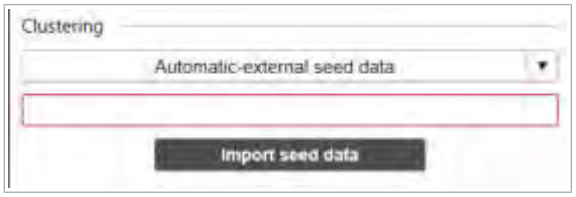
The figure illustrates the effects of such reaction artifacts in a 2D scatter plot:

- Competition:
  - Without competition, the double-positive cluster (green) has the same fluorescence intensities as the single-positive clusters (yellow and blue).
  - With competition, the green cluster would be below the yellow cluster and left from the blue cluster.
- Cross-reactivity:
  - Without cross-reactivity, the single-positive clusters (yellow and blue) lie on the same baseline as the double-negative cluster (brown).
  - With cross-reactivity, the yellow cluster would be to the right of the brown cluster and/or the blue cluster would be above the brown cluster.

Export seed data button and Import seed data button

Allows you to transfer the custom clustering parameters to another automatic clustering and to use the custom clustering parameters in analysis packages.

The **Export seed data** button is only available for the **Automatic** clustering method with the **Custom** option of the clustering parameters.



The **Import seed data** button is only available for the **Automatic – External seed data** clustering method.

A seed data file has a *.sdxml* file extension.

Graph drop-down list

Determines the type of scatter plots used to visualize the fluorescence intensities:

- **1D scatter plot**
- **2D scatter plot**
- **3D scatter plot**

Default value = **1D scatter plot**

In a 1D scatter plot, the fluorescence intensity of a channel is plotted against the nanowell index that is randomized for visualization purposes only.

In a 2D scatter plot or a 3D scatter plot, the nanowell fluorescence intensities of 2 or 3 channels, respectively, are plotted against each other.

The scatter plots that use the same channels are linked: changes in 1 of the scatter plots are automatically taken over into the other scatter plots.

The 2D and 3D scatter plots are only available if enough channels are available.

To facilitate the clustering for indel analysis, use the 2D scatter plot type.

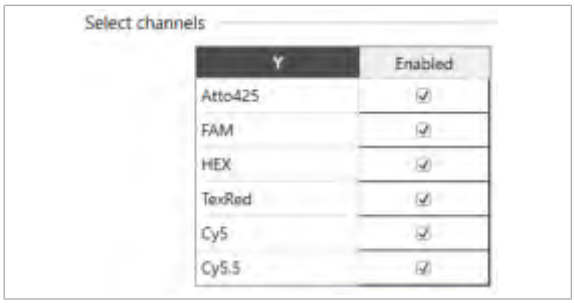
For 2D scatter plots, the following applies:

- For the **Manual** clustering method, the **Threshold** button, the **Lasso** button, and the **Spider** button are displayed below the clustering method indicator.
- However, the **Lasso** button and the **Spider** button are only available if exactly 2 targets are enabled for the master mix reagent in the lane settings.
- A manual clustering via the **Lasso** button or the **Spider** button cannot be used in the clustering settings of an analysis package.

For 3D scatter plots, the following applies:

- For a 3D scatter plot, you must enable exactly 3 channels in the **Select channels** table.
- The 3D scatter plot is for visualization purposes only. You cannot adjust the thresholds in a 3D scatter plot.

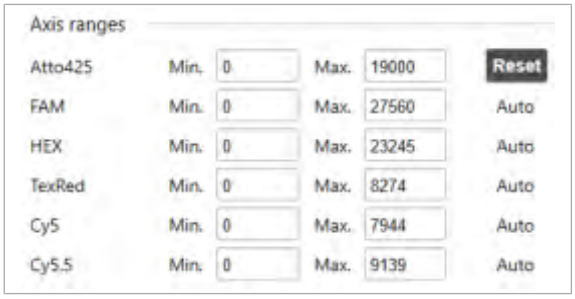
Select channels table



Allows you to include or exclude channels from the scatter plots.

For the **2D scatter plot** plot type or the **3D scatter plot** plot type, you must enable the corresponding number of channels.

Axis ranges group box



In the **Min.** field and the **Max.** field, enter the start and end values for the intensity-axes of the scatter plots (e.g., the y-axis of the 1D scatter plot).

By default, the maximums of the axis ranges are set to display all scatter points.

To reset the axis ranges, choose the **Reset** button.

Adjusting the clustering settings for the automatic clustering methods

For the automatic clustering methods, you can adjust clustering parameters, the plot type, the enabled channels, and the axis ranges.

To import the custom clustering parameters from an automatic clustering, use the **Automatic – External seed data** clustering method.

About compatibility of seed data files

A seed data file can only be imported if the following prerequisites are met:

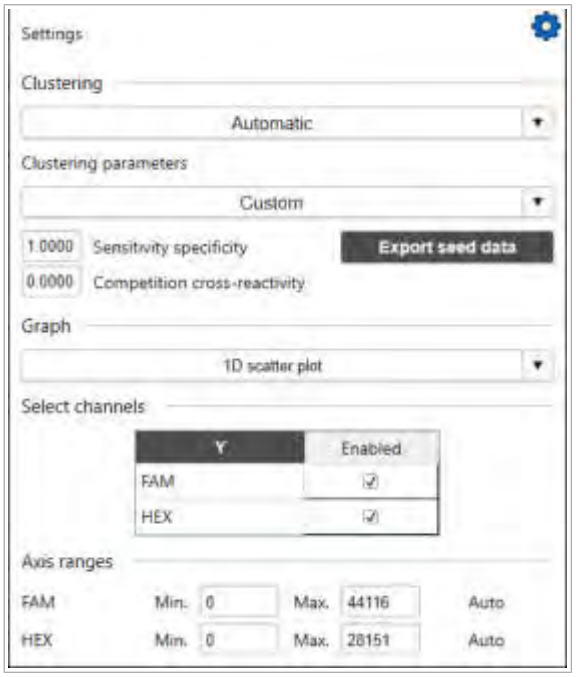
- The seed data file was not modified, i.e., the signature can be verified.
- The nanowell plate type in the seed data file is the same as in the clustering.
- The detection formats match.

Ensure that you use a seed data file that is compatible with the master mix reagent.

☐ For **Automatic – External seed data** clustering method:
Seed data file (SDXML file)

Exporting custom clustering parameters as seed data files (356)

To adjust the clustering settings for the Automatic clustering method or the Automatic (individual) clustering method



1 In the development software, in the **Navigation** area, choose the clustering from the **Clustering** menu.
   ➔ The clustering tab is displayed.

2 In the top right corner, choose the ⚙ button.
   ➔ The **Settings** combo box is displayed.

3 From the **Clustering** drop-down list, choose the **Automatic** option or the **Automatic (individual)** option.

4 To set the clustering parameters, from the **Clustering parameters** drop-down list, choose an option:
   - **Standard**
   - **Rare event detection**
   - **Genotyping**
   - **Indel**
   - **Custom**

5 For the **Custom** option, to shift the balance between sensitivity and specificity, enter a value between 0.0000 and 1.0000 in the **Sensitivity specificity** field:
   - 0.000 = maximum sensitivity
   - 1.0000 = maximum specificity

6 For the **Custom** option, to shift the balance between competition and cross-reactivity, enter a value between 0.0000 and 1.0000 in the **Competition cross-reactivity** field:
   - 0.0000 = maximum competition
   - 1.0000 = maximum cross-reactivity

7 From the **Graph** drop-down list, choose an option:
   - **1D scatter plot**
   - **2D scatter plot**

   ⓘ The 3D scatter plot is for visualization purposes only. You cannot adjust the thresholds in a 3D scatter plot.

8 In the **Select channels** table, enable the channels that you want to plot.

9 Optionally, in the **Axis ranges** fields, enter the minimum and maximum values for the intensity axes of the scatter plots. To reset the axis ranges, choose the **Reset** button.

10 Click outside the **Settings** combo box. Alternatively, choose the ⚙ button.

➔ The scatter plots and the values on the **Clustering data** card are recalculated and displayed.

11 Save the project.

To adjust the clustering settings for Automatic - External seed data clustering method

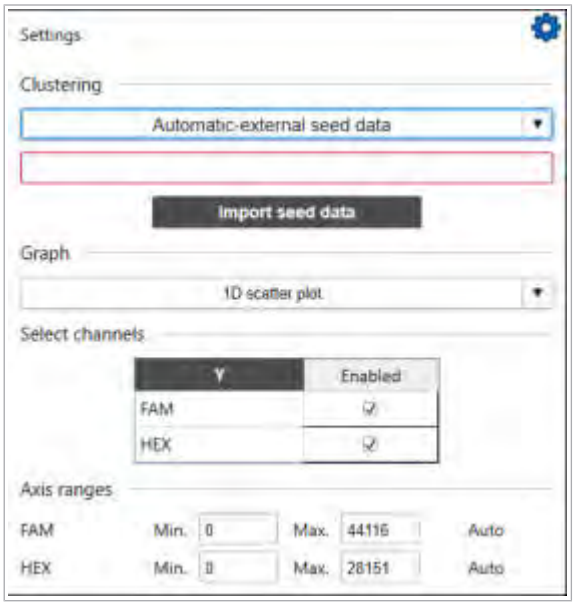
1 Optionally, if the seed data file is stored on an external storage device, connect the external storage device to the computer running the development software.

2 In the development software, in the **Navigation** area, choose the clustering from the **Clustering** menu.

➔ The clustering tab is displayed.

3 In the top right corner, choose the ⚙ button.

➔ The **Settings** combo box is displayed.



4 From the **Clustering** drop-down list, choose the **Automatic - External seed data** option.

5 Choose the **Import seed data** button.

6 Navigate to the seed data file (SDXML file) and choose the **Open** button.

7 From the **Graph** drop-down list, choose an option:

- **1D scatter plot**
- **2D scatter plot**

ⓘ The 3D scatter plot is for visualization purposes only. You cannot adjust the thresholds in a 3D scatter plot.

8 In the **Select channels** table, enable the channels that you want to plot.

9 Optionally, in the **Axis ranges** fields, enter the minimum and maximum values for the intensity axes of the scatter plots. To reset the axis ranges, choose the **Reset** button.

10 Click outside the **Settings** combo box. Alternatively, choose the ⚙ button.

➔ The scatter plots and the values on the **Clustering data** card are recalculated and displayed.

11 Save the project.

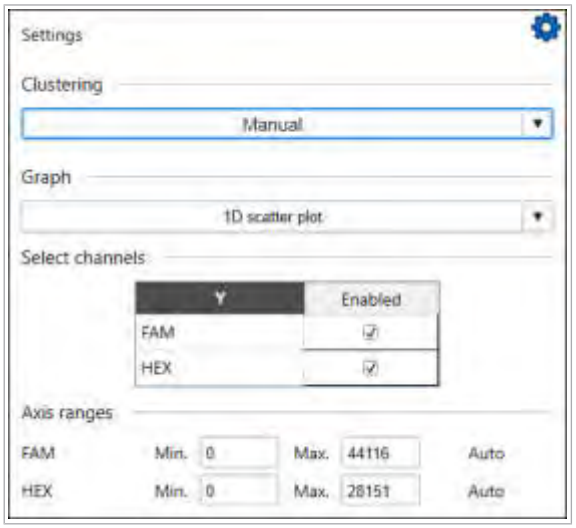
12 Optionally, disconnect the external storage device.

Adjusting the clustering settings and thresholds for manual clustering

For the manual clustering method, you can adjust the plot type, the enabled channels, and the axis ranges in the clustering settings. In the scatter plots, you must adjust the thresholds manually.

With the **Manual** clustering method, you can adjust the thresholds manually in 1D scatter plots and 2D scatter plots only.

A manual clustering via the **Lasso** button or the **Spider** button cannot be used in the clustering settings of an analysis package.



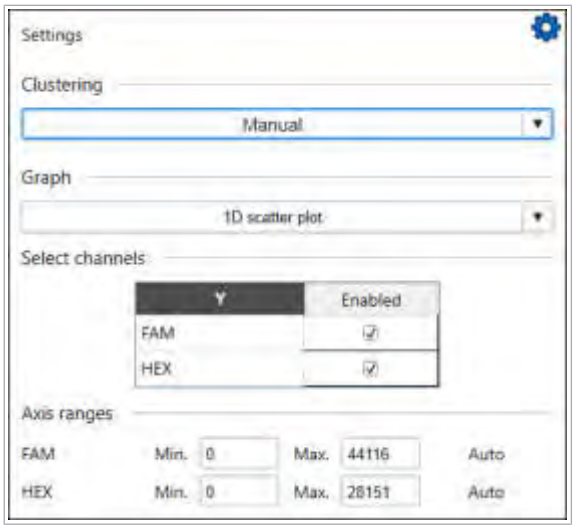
To adjust the clustering settings for the Manual clustering method

1. In the development software, in the **Navigation** area, choose the clustering from the **Clustering** menu.
   ➔ The clustering tab is displayed.
2. In the top right corner, choose the ⚙ button.
   ➔ The **Settings** combo box is displayed.
3. From the **Clustering** drop-down list, choose the **Manual** option.
4. From the **Graph** drop-down list, choose an option:
   - **1D scatter plot**
   - **2D scatter plot**

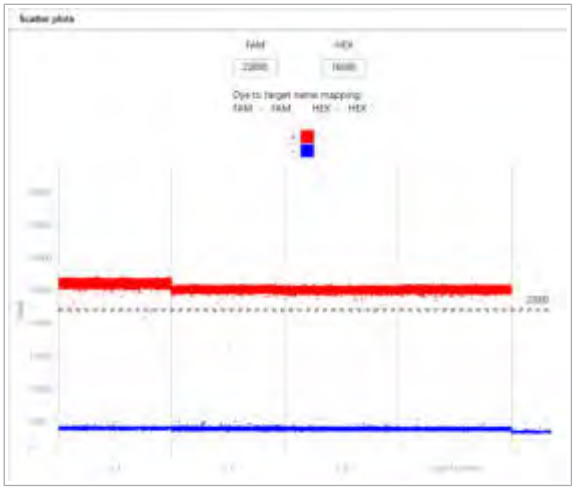
   ℹ The 3D scatter plot is for visualization purposes only. You cannot adjust the thresholds in a 3D scatter plot.
5. In the **Select channels** table, enable the channels that you want to plot.
6. Optionally, in the **Axis ranges** fields, enter the minimum and maximum values for the intensity axes of the scatter plots. To reset the axis ranges, choose the **Reset** button.
7. Click outside the **Settings** combo box. Alternatively, choose the ⚙ button.
   ➔ The values on the **Clustering data** card are deleted.
   ➔ The scatter plots are displayed.
8. Save the project.
9. Depending on the selected plot type, continue with adjusting the thresholds in the scatter plots as described in:
   - To adjust the threshold in a 1D scatter plot (manual clustering) (351)

- To adjust the thresholds in a 2D scatter plot with the Threshold button (manual clustering) (352)
- To adjust the thresholds in a 2D scatter plot with the Lasso button (manual clustering) (353)
- To adjust the thresholds in a 2D scatter plot with the Spider button (manual clustering) (354)
- To calculate the values in the clustering data table for a 3D scatter plot (manual clustering) (355)

To adjust the threshold in a 1D scatter plot (manual clustering)



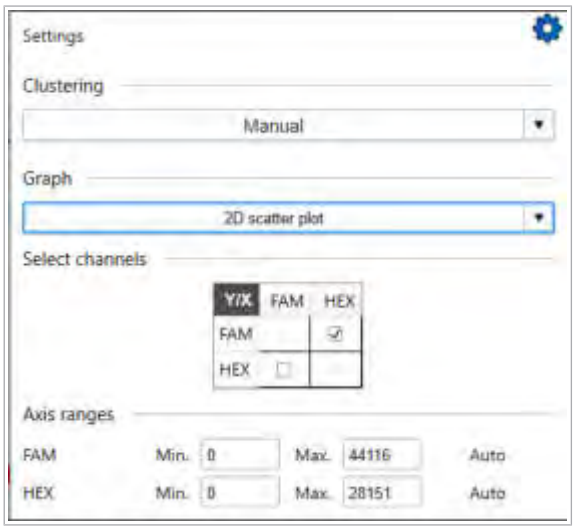
1 Adjust the clustering settings as described in To adjust the clustering settings for the Manual clustering method (350). Choose the **1D scatter plot** option.
   ➔ The values on the **Clustering data** card are deleted.
   ➔ The scatter plots including threshold indicators (dashed lines) are displayed.
   ➔ The scatter points are color-coded.
   ➔ The threshold values are displayed above the scatter plots.

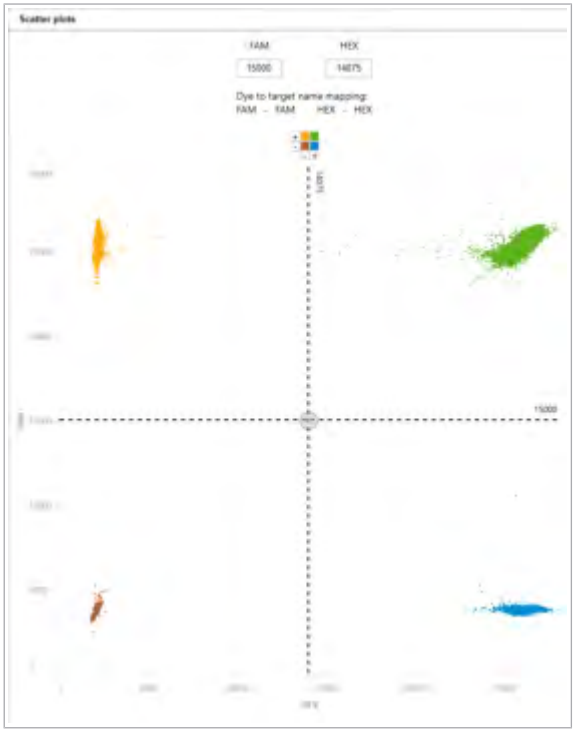


2 To adjust a threshold, do the following:
   - Mouse over a threshold indicator (dashed line) until the cursor changes to a double arrow.
   - Move the threshold indicator via drag and drop.
   ➔ The coloring of the scatter points is updated.

3 Choose the **Calculate** button.
   ➔ The values on the **Clustering data** card are calculated and displayed.

4 Save the project.





To adjust the thresholds in a 2D scatter plot with the Threshold button (manual clustering)

1 Adjust the clustering settings as described in To adjust the clustering settings for the Manual clustering method (350). Choose the **2D scatter plot** option.
   - ➔ The values on the **Clustering data** card are deleted.
   - ➔ The scatter plots including threshold indicators (dashed lines) are displayed.
   - ➔ The **Threshold** button for the manual clustering is selected.
   - ➔ The scatter points are color-coded according to quadrant.
   - ➔ The threshold values are displayed above the scatter plots.

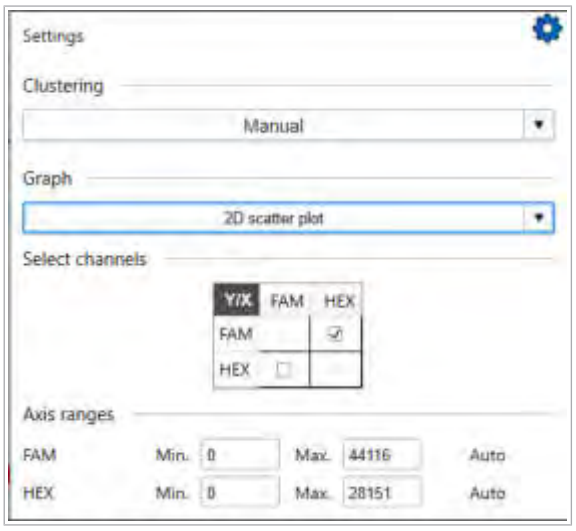
2 To adjust a threshold in the x-direction or y-direction only, do the following:
   - Mouse over a threshold indicator (dashed line) until the cursor changes to a double arrow.
   - Move the threshold indicator via drag and drop.
   - ➔ The coloring of the scatter points is updated.

3 To adjust the thresholds in both x- and y-direction simultaneously, do the following:
   - Mouse over the intercept indicator (gray circle) until the cursor changes to a quad arrow.
   - Move the interception indicator via drag and drop.
   - ➔ The coloring of the scatter points is updated.

4 Choose the **Calculate** button.
   - ➔ The values on the **Clustering data** card are calculated and displayed.

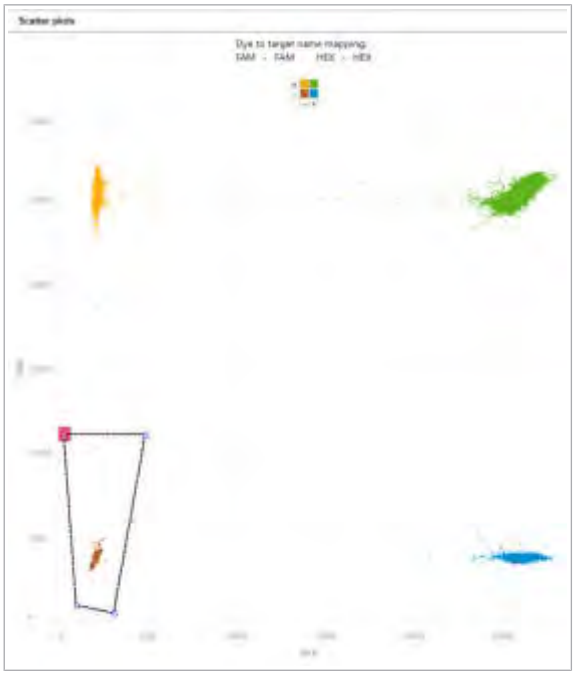
5 Save the project.

To adjust the thresholds in a 2D scatter plot with the Lasso button (manual clustering)



1 Adjust the clustering settings as described in To adjust the clustering settings for the Manual clustering method (350). Choose the **2D scatter plot** option.
   - ➔ The values on the **Clustering data** card are deleted.
   - ➔ The scatter plots including threshold indicators (dashed lines) are displayed.
   - ➔ The **Threshold** button for the manual clustering is selected.
   - ➔ The scatter points are color-coded according to quadrant.
   - ➔ The threshold values are displayed above the scatter plots.

2 Choose the **Lasso** button.
   - ⓘ The **Lasso** button is only available if exactly 2 targets are enabled for the master mix reagent in the lane settings.
   - ➔ The threshold indicators and the threshold values are deleted from the scatter plots.
   - ➔ The coloring of the scatter points is updated.
   - ➔ A box to select the cluster positions (positive-negative, negative-positive, double-negative, double-positive) is displayed.



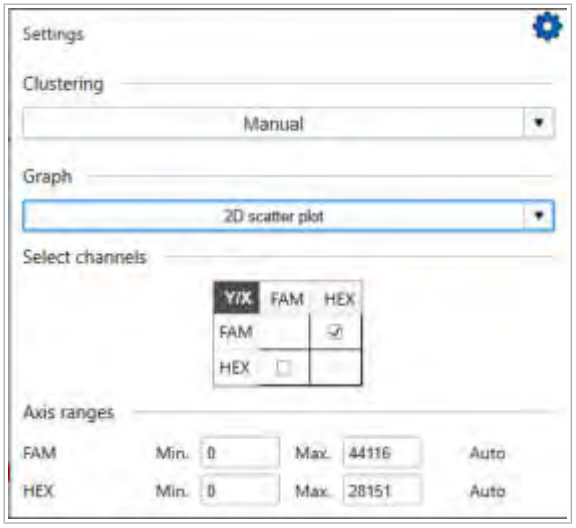
3 To mark the scatter points that belong to a cluster position, do the following:
   - In the box, choose a cluster position. To achieve a helpful update of the color-coding of the scatter points, choose the cluster positions in the following order:
     double-positive, positive-negative and negative-positive, double-negative.
   - Click in the scatter plot to set the start point.
   - Click in the scatter plot repeatedly to circle the scatter points for the selected cluster position. The clicks are joined by straight lines.
   - To close the selection area, mouse over the start point until the cursor changes to a red square and click.
   - To remove the lines and start again, press Esc.
   - ➔ The coloring of the scatter points is updated.

4 Choose the **Calculate** button.

→ The values on the **Clustering data** card are calculated and displayed.

5 Save the project.

To adjust the thresholds in a 2D scatter plot with the Spider button (manual clustering)



1 Adjust the clustering settings as described in To adjust the clustering settings for the Manual clustering method (350). Choose the **2D scatter plot** option.

→ The values on the **Clustering data** card are deleted.

→ The scatter plots including threshold indicators (dashed lines) are displayed.

→ The **Threshold** button for the manual clustering is selected.

→ The scatter points are color-coded according to quadrant.

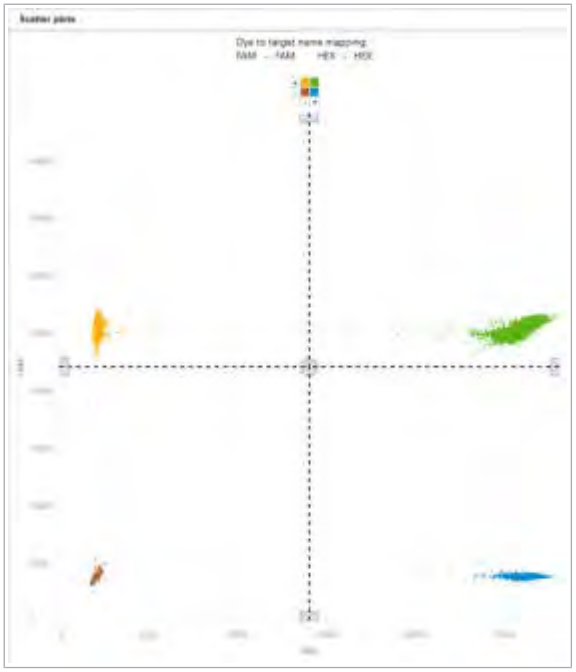
→ The threshold values are displayed above the scatter plots.

2 Choose the **Spider** button.

ⓘ The **Spider** button is only available if exactly 2 targets are enabled for the master mix reagent in the lane settings.

→ An intercept indicator (gray circle) and endpoint indicators (gray rectangles) are added to the threshold indicators (dashed lines).

→ The color-coding of the scatter points is updated.



3 To adjust the intercept of the thresholds, do the following:

- Mouse over the intercept indicator (gray circle) until the cursor changes to a quad arrow.
- Move the intercept indicator via drag and drop.

→ The coloring of the scatter points is updated.

4 To adjust the endpoint of a threshold, do the following:

- Mouse over an endpoint indicator until the cursor changes to a quad arrow.
- Move the endpoint indicator via drag and drop.

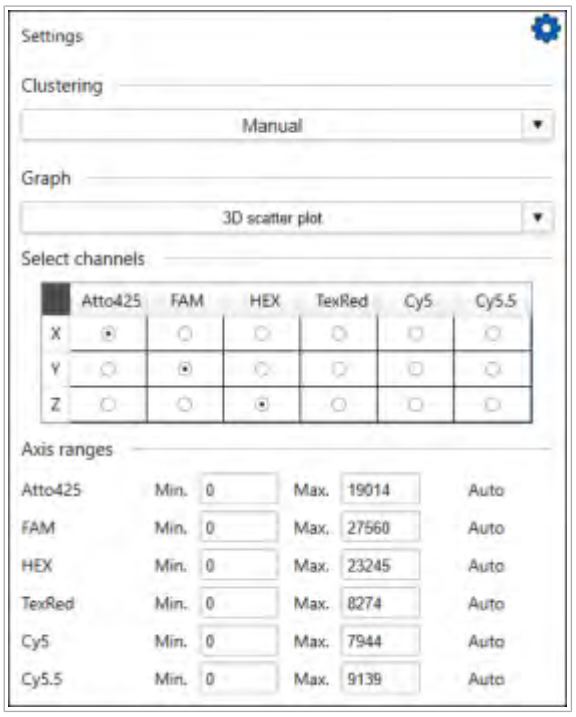
→ The coloring of the scatter points is updated.

5 Choose the **Calculate** button.

→ The values on the **Clustering data** card are calculated and displayed.

6 Save the project.

To calculate the values in the clustering data table for a 3D scatter plot (manual clustering)



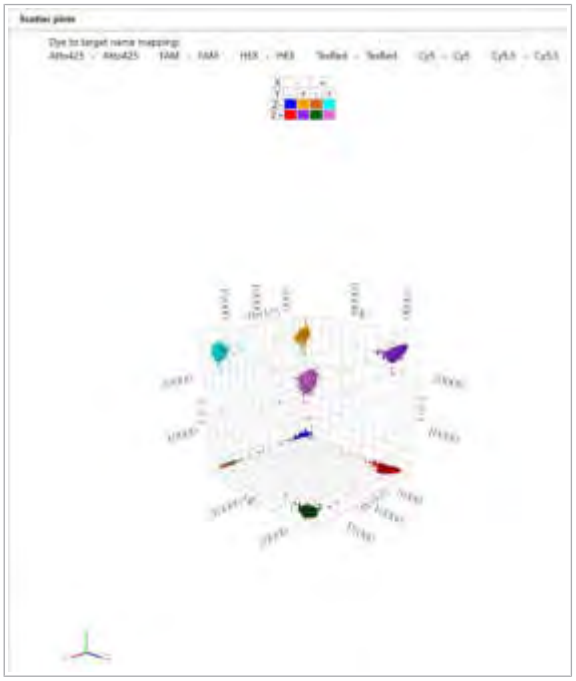
1 Adjust the clustering settings as described in To adjust the clustering settings for the Manual clustering method (350). Choose the **3D scatter plot** option.

➔ The values on the **Clustering data** card are deleted.

➔ The scatter plot is displayed.

➔ The scatter points are color-coded.

➔ The threshold values and a color legend are displayed above the scatter plot.



2 To turn the 3D-view, click in the scatter plot. Drag and drop the view.

ⓘ The 3D scatter plot is for visualization purposes only. You cannot adjust the thresholds in a 3D scatter plot.

3 Choose the **Calculate** button.

➔ The values on the **Clustering data** card are calculated and displayed.

4 Save the project.

Exporting custom clustering parameters as seed data files

You can export the custom clustering parameters from an automatic clustering as a seed data file to transfer the clustering parameters to another automatic clustering and to use them in analysis packages.

A seed data file is specific for the nanowell plate type.

A seed data file is exported as signed XML file and is named *PlateType_SeedData_YYYYMMDDhhmmss.sdxml* with the date and time of the export.

A seed data file has a *.sdxml* file extension.

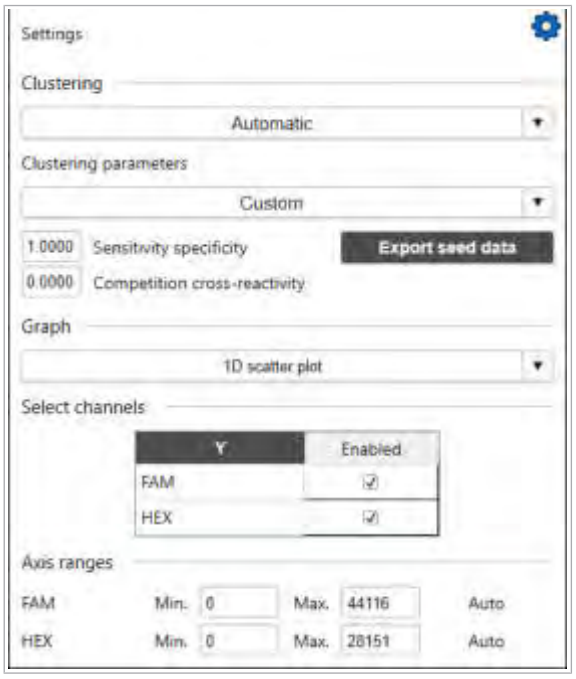
List of naming placeholders (154)

- ☐ Optionally, external storage device, e.g., USB flash drive

- ☐ Custom clustering parameters adjusted in automatic clustering

To export custom clustering parameters as seed data file

1. Optionally, to export to an external storage device, connect the external storage device to the computer running the development software.
2. In the development software, choose an automatic clustering with custom clustering parameters from the **Clustering** menu.
   ➔ The clustering tab is displayed in the work area.
3. In the top right corner, choose the ⚙ button.
   ➔ The **Settings** combo box is displayed.



4 Choose the **Export seed data** button.

ⓘ You can only export a seed data file from an automatic clustering with custom clustering parameters.

5 Navigate to a folder. Optionally, enter a different name for the seed data file. Choose the **Save** button.

➔ The SDXML file is exported.

6 Optionally, disconnect the external storage device.

Related topics

- Projects in the development software (294)
- Runs in the development software (309)
- Analyses in the development software (358)
- Unassigned sample setups in the development software (402)
- Analysis packages in the development software (412)

Analyses in the development software

Analyses determine the final qualitative and quantitative results.

Merged lanes are analyzed together. Therefore, a set of merged lanes has 1 entry on an analysis tab.

In this section

Working with analyses

In the development software, you can duplicate, rename, and delete analyses.

In the development software, analyses are displayed as follows:

- Listed in the **Analysis** menu in the **Navigation** area
- Displayed as analysis tabs in the work area

By default, the analysis tabs are named as the analysis and numbered consecutively.

You cannot rename or delete the default **Abs Quant - All** analysis.

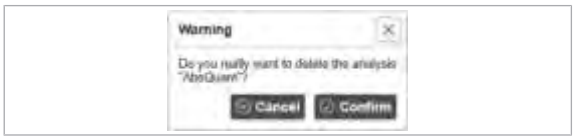
To duplicate an analysis

1 In the **Navigation** area, choose the analysis from the **Analysis** menu. Choose ••• **> Duplicate**.

➔ The analysis tab of the duplicate analysis is displayed in the work area.

➔ The duplicate analysis is listed in the **Analysis** menu in the **Navigation** area.

➔ The duplicate analysis is named as the original analysis plus the suffix " - copy x" (x = consecutive number).



To delete an analysis

1 In the **Navigation** area, choose the analysis from the **Analysis** menu. Choose ••• **> Delete**.

2 In the **Warning** dialog box, choose the **Confirm** button.

➔ The analysis is deleted from the project.

To rename an analysis

1 In the **Navigation** area, choose the analysis from the **Analysis** menu. Choose ••• **> Rename**.

2 In the dialog box, enter the new name.

3 Choose the **Save** button.

➔ The analysis tab is renamed.

➔ The analysis listed in the **Analysis** menu is renamed.

Absolute quantification analysis

Absolute quantification (Abs Quant) analysis determines the presence and the concentration of known targets in samples.

By default, each project in the development software contains an **Abs Quant – All** analysis that includes all samples and controls of the project.

You can either edit the **Abs Quant – All** analysis or perform a new absolute quantification analysis on a specified subset of samples and controls.

In this section

List of tabs and settings for absolute quantification analysis

The settings provide all parameters necessary for absolute quantification analysis.

➔ **Navigation > Analysis > ••• > Abs Quant >** ⚙

The settings are ordered on tabs in the **Settings** combo box.

The availability of settings on a tab depends on the current settings on the other tabs.

Sample selection tab

On the **Sample selection** tab, choose the samples for the analysis.

The table lists all samples of the project with the sample IDs as entered in the lane settings on the run tabs.

By default, no samples are selected for analysis.

To perform statistics, you can work with sample groups. The **Sample groups** card lists all sample groups of the project.

Working with sample groups in the development software (328)

Controls tab

On the **Controls** tab, mark the positions of controls in the sample setups and enter the valid ranges for the controls.

If you choose a merged lane, the whole set of merged lanes is selected automatically.

The table on the left of the tab lists the combinations of master mix reagent and target that match the following criteria:

- A sample with that combination was selected on the **Sample selection** tab.
- The combination is not set as internal control on the **Internal controls** tab.

The **Run:** drop-down list lists all runs that contain samples that were selected on the **Sample selection** tab.

For a diagnostic run that was imported with clustering and analysis settings, assumed control positions are striped if the corresponding channels were measured on

the analyzer but the tests were not included in the analysis package. By default, such positions are analyzed as samples, not as controls.

The table on the right of the tab lists the defined controls for the selected combination of master mix reagent and target.

Controls are target-specific:
If the control for a target is invalid, the system automatically invalidates the final results for that target for all samples of the same run.

Controls (165)

Lower limit field and Upper limit field

The fields define the valid range for a control.

The lower limit must be lower than the upper limit.

For negative controls, the lower limit is always 0 and cannot be changed.

Default values for positive controls:
- Lower limit = 1.0000 cp/µl
- Upper limit = 1000.0000 cp/µl

Default value for negative controls:
- Upper limit = 0.0000 cp/µl

Internal controls tab

On the **Internal controls** tab, choose the combination of master mix reagent and target used as internal control and enter the valid concentration range for the internal control.

From the **Target** drop-down lists, only those targets are available for which no controls were defined on the **Controls** tab.

If a master mix reagent only contains 1 target, it is not available as internal control.

Internal controls are measured as a separate target and are therefore lane-specific:
If the internal control in a nanowell plate lane is invalid, the system automatically invalidates the final results for all targets that are tested in that nanowell plate lane.

Controls (165)

Lower limit field and Upper limit field

The fields define the valid concentration range for the internal control.

The lower limit must be lower than the upper limit.

Default values:

- Lower limit = 1.0000 cp/µl
- Upper limit = 1000.0000 cp/µl

Target limits tab

On the **Target limits** tab, optionally enter the limit of detection and/or the limits of quantification.

Lower limit of detection field

A limit of detection > 0 accounts for noise in the data, i.e., if there are positive nanowells even if the nanowell plate lane contains no target molecules.

The initial result and the final result for a target are negative if the calculated raw concentration of the target is below the limit of detection.

You can see the indication to set a limit of detection in the clustering for a target.

The concentration value to be entered as the limit of detection can be derived from the value in the **Concentration [copies/µL]** column or the **Raw concentration [copies/µL]** column on the **Results** panel.

The lower limit of detection must be lower than the lower limit of quantification (if enabled).

Default value:

- Lower limit of detection = 0.0000 cp/µl

Limits of quantification check box, Lower limit of quantification field, and Upper limit of quantification field

If the limit of quantification is enabled, the calculation of the target concentration is suppressed outside of the entered quantification range. This is to account for the increase in uncertainty for very low or very high target concentrations.

On the **Results** panel, final results outside the quantification range are flagged. Instead of the calculated target concentration, the quantification limit that is not met is displayed as final quantitative result.

The lower limit of quantification must be lower than the upper limit of quantification.

The lower limit of quantification must be higher than the lower limit of detection.

Default values:

- Limit of quantification = disabled
- Lower limit of quantification = 0.0000 cp/µl
- Upper limit of quantification = 50000.0000 cp/µl

List of result columns for absolute quantification analysis

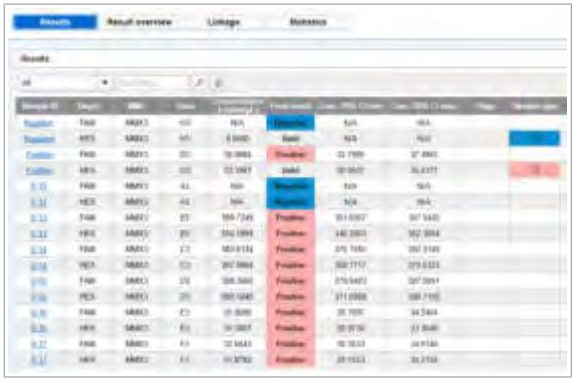
An absolute quantification tab displays the results of an absolute quantification analysis on the **Results** panel, the **Result overview** panel, the **Linkage** panel, and the **Statistics** panel.

➔ **Navigation > Analysis > ••• > Abs Quant**

The panels only display results for samples that were selected on the **Sample selection** tab in the **Settings** combo box.

Merged lanes are analyzed together. Therefore, a set of merged lanes has 1 entry on an analysis tab.

Results panel



The **Results** panel displays the results per target separately for each sample and control.

By default, not all available columns are visible on the **Results** panel.

Configuring table columns (142)

Sample ID column

The sample ID of the sample or control as entered in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

Target column

The tested target as enabled in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

MMx column

The used master mix reagent as entered in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

Lane column

The position of the sample or control in the run. Merged lanes are indicated by the icon.

About the positions of nanowell plate lanes in sample setups (153)

Concentration [copies/µL] column

The calculated final concentration of the target in the sample or control (final quantitative result).

"N/A" is displayed if one of the following applies:

- The final result for the target is negative.
- The final result for the target is invalid.

If the target concentration falls outside a configured limit of quantification, the quantification limit that is not met is displayed as final quantitative result.

About color-coding of final results for samples (149)

Final result column

Final (qualitative) result for the sample or control. For samples, final results consider the corresponding control results.

The final results for samples are color-coded, i.e., the result names are underlaid with the corresponding color.

About color-coding of final results for samples (149)

About final results (173)

Conc. 95% CI min. column and Conc. 95% CI max. column

The values specify the confidence interval for the 95% confidence level (based on the applied Poisson distribution and not accounting for other error sources): The probability is 95% that the concentration of the target in the sample or control lies within the specified range.

Flags column

The flags associated with the sample or control.

Critical flags that invalidate the final result are displayed in bold.

List of flags (489)

Sample type column

Color-coding and icon for the control type.

About color-coding of controls (148)

Merged lanes column

Name of the set of merged lanes as displayed in the lane settings on the run tab.

About the positions of nanowell plate lanes in sample setups (153)

Total copies column

Absolute number of target molecules in the sample or control.

Initial result column

Initial (qualitative) result for the target. For samples, initial results are regardless of the corresponding control results.

Both samples and controls can have the following initial results for a target:

- Negative
- Positive
- Invalid

A sample or control has an invalid initial result if it was invalidated at any point during the workflow, e.g., during partitioning. A corresponding critical flag is displayed in the **Flags** column.

Plate type column

Nanowell plate type used for processing the sample.

Nanowell plates (159)

No. of positive nanowells column

Number of positive nanowells for the sample or control as determined in the clustering.

List of columns on the Clustering data card (339)

Total valid nanowells column

Number of valid nanowells for the sample or control as displayed in the clustering.

The number of valid nanowells is the total of the positive and the negative nanowells.

List of columns on the Clustering data card (339)

Dilution factor column

Dilution factor as entered in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

Run name column

Run name on the analyzer in which the sample or control was processed.

The run name is used as name of the run tab in the development software.

Conc. 68% CI min. column and Conc. 68% CI max. column

The values specify the confidence interval for the 68% confidence level (based on the applied Poisson distribution and not accounting for other error sources): The probability is 68% that the concentration of the target in the sample or control lies within the specified range.

The probability is lower because the specified range is smaller than the range specified by the **Conc. 95% CI min.** column and the **Conc. 95% CI max.** column.

Copies per nanowell column

Average number of target molecules per valid nanowell for the sample or control.

Relative confidence column

The confidence interval normalized by the final quantitative result (based on the applied Poisson distribution and not accounting for other error sources).

The relative confidence is a measure for the accuracy of the calculations.

Negative nanowells column

Number of negative nanowells for the sample or the control as determined in the clustering.

List of columns on the Clustering data card (339)

Clustering method column

Clustering method as set on the clustering tab.

List of clustering settings in the development software (342)

Raw concentration [copies/µL] column

The calculated initial concentration of the target in the sample or control (initial quantitative result).

Raw values are regardless of applied limits. For samples, raw values are also regardless of the corresponding control results.

Result overview panel

The **Result overview** panel summarizes the results per target for each sample or control for the selected master mix reagent.

Run column

Run name on the analyzer in which the sample or control was processed.

The run name is used as name of the run tab in the development software.

Lane column

The position of the sample or control in the run. Merged lanes are indicated by the icon.

About the positions of nanowell plate lanes in sample setups (153)

Sample ID column

The sample ID of the sample or control as entered in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

Columns for targets

For each tested target, the final quantitative and qualitative results are displayed in 1 column:

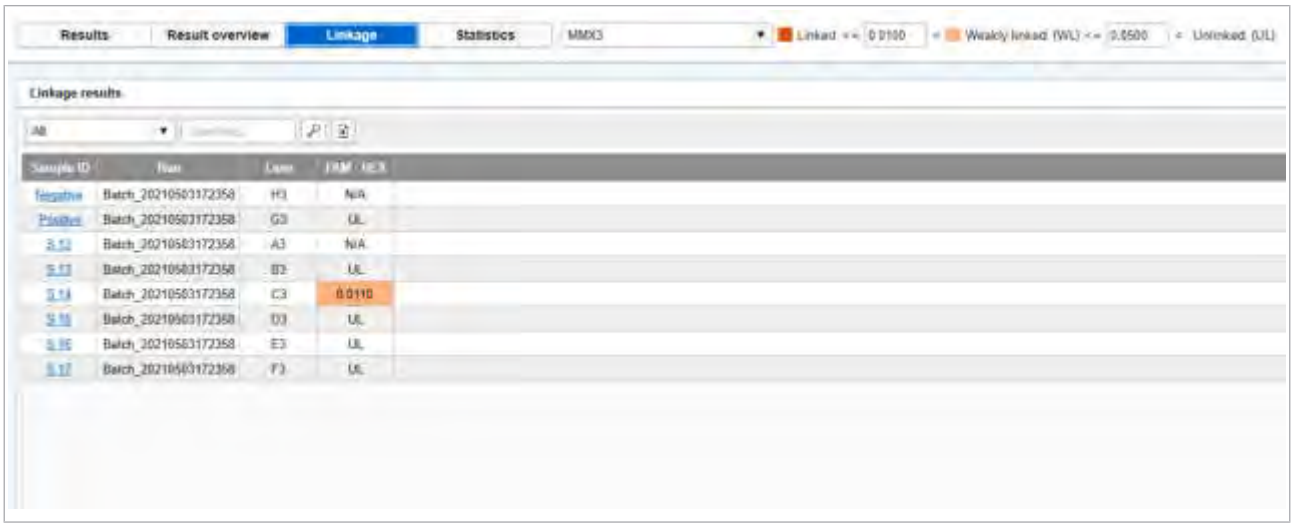
- Concentration
- Final result

The tested targets are displayed as the column headers.

Concentration [copies/µL] column (364)

Final result column (364)

Linkage panel



Linkage is the occurrence of different targets that are located on the same target molecule and therefore in the same nanowell:

- If 2 targets are unlinked, the targets are all located on different target molecules.
  The fraction of double-positive nanowells is the product of the fraction of nanowells positive for target 1 and the fraction of nanowells positive for target 2.
- If 2 targets are perfectly linked, the targets are always located on the same target molecules.
  All positive nanowells are double-positive.

Linkage may occur due to incomplete target separation during sample preparation.

The **Linkage** panel displays the p-value of a chi-square test with a null hypothesis that the considered targets are not linked. Due to the high number of nanowells, the p-value changes significantly with only small changes in the percentage of linked targets.

Examples for 100000 nanowells and 25000 positive nanowells for each target 1 and target 2:

Percentage of linked targets	p-value
0.01%	0.9811
0.1%	0.8125
0.5%	0.2351
0.8%	0.0573
1%	0.0174
1.5%	0.0004

Examples for linkage

Linkage may negatively affect target quantification. Therefore, the displayed p-value can be used as a quality control for multiplex tests.

If the selected master mix reagent contains 1 target only, no linkage can be determined.

Sample ID column

The sample ID of the sample or control as entered in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

Run column

Run name on the analyzer in which the sample or control was processed.

The run name is used as name of the run tab in the development software.

Lane column

The position of the sample or control in the run. Merged lanes are indicated by the icon.

About the positions of nanowell plate lanes in sample setups (153)

Columns for target combinations

The p-value of a chi-square test with a null hypothesis that the considered targets are not linked.

The linkage of the targets is classified as follows:

- **Linked**
- **Weakly linked**
- **Unlinked**

For linked and weakly linked, a numerical value is displayed. For unlinked, "UL" is displayed.

The thresholds between linked, weakly linked, and unlinked can be edited in the legend above the table.

The following applies:

- Default values:
  Linked ≤ 0.0100 < **Weakly linked** ≤ 0.0500
- Possible values:
  Linked ≤ 0.0001 < **Weakly linked** ≤ 0.9999

Statistics panel

The **Statistics** panel displays statistical information for the sample groups that contain samples that were selected for the analysis.

Group column

The name of the sample group as entered on the run tab or in the **Settings** combo box.

If not all samples of a sample group are included in the analysis, the sample group name is appended with the number of included samples in brackets, e.g., "(3 out of 4)". Merged lanes are counted separately.

Working with sample groups in the development software (328)

Target column

The tested target as enabled in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

MMx column

The used master mix reagent as entered in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

Concentration mean [copies/µL]

The mean of the concentrations (final quantitative results) across the samples of the sample group.

If not all samples of a sample group are included in the analysis, the mean is calculated from the included samples only.

"N/A" is displayed if the sample group contains a sample for which no final quantitative result is available.

Concentration SD [copies/µL] column

The standard deviation of the concentration mean.

"N/A" is displayed if the concentration mean cannot be calculated.

Editing the default Abs Quant – All analysis

By default, each project contains an **Abs Quant – All** analysis that includes all samples of the project. You can edit the analysis settings for the **Abs Quant – All** analysis, except you cannot exclude samples.

If you want to perform an absolute quantification analysis on a subset of samples only, you must add a new absolute quantification analysis to the project.

Performing absolute quantification analysis (373)

☐ Previous steps of the development workflow completed

Overview of development workflow with unassigned sample setup (195)

Overview of development workflow without unassigned sample setup (194)

To display the Abs Quant – All analysis

1 In the development software, in the **Navigation** area, choose **Analysis** > ▪▪▪ > **Abs Quant – All**.
   - ➔ The **Abs Quant – All** tab is displayed in the work area.
   - ➔ The **Abs Quant – All** analysis is calculated.
   - ➔ The **Results** panel is displayed on the **Abs Quant – All** tab.
   - ➔ The **Results** panel displays 1 entry for each sample or control.

2 To display a summary of the results, do the following:
   - Choose the **Result overview** button.
   - From the drop-down list, choose the master mix reagent.

3 To display the bar charts as described in Displaying the bar charts (400), do the following:
   - At the top right of the **Result overview** panel, choose the button.
   - Optionally, adjust the display of the bar charts.

4 To display the calculated linkage between the targets, do the following.
   - Choose the **Linkage** button.
   - From the drop-down list, choose the master mix reagent.
   - Optionally, edit the thresholds between linked, weakly linked, and/or unlinked in the legend above the table.

5 To display the statistics for the sample groups, choose the **Statistics** button.

To edit the Abs Quant - All analysis

1 In the development software, in the **Navigation** area, choose **Analysis** > ▪▪▪ > **Abs Quant - All**.
   ➔ The **Abs Quant - All** tab is displayed in the work area.
   ➔ The **Abs Quant - All** analysis is calculated.
   ➔ The **Results** panel is displayed on the **Abs Quant - All** tab.
   ➔ The **Results** panel displays 1 entry for each sample or control.

2 To edit the **Abs Quant - All** analysis, choose the ⚙ button.
   ➔ The **Sample selection** tab in the **Settings** combo box is displayed.

3 Optionally, you can work with sample groups as described in Working with sample groups in the development software (328).

4 In the **Settings** combo box, choose the **Controls** tab.

5 For each nanowell plate lane (i.e., position on a nanowell plate) that contains a control, do the following:
   - From the table, choose the combination of master mix reagent and target.
   - If the same combination is used in several runs, from the **Run** drop-down list, choose the run.
   - In the graphical representation of the sample setup of the selected run, choose the nanowell plate lane that contains a control.
   - For a positive control, choose the **Positive** option. In the **Lower limit** field and the **Upper limit** field, enter the concentration range.
   - For a negative control, choose the **Negative** option. In the **Upper limit** field, enter the concentration value. (For a negative control, the lower limit of the concentration range is always 0.)

   ⓘ The lower and upper limits determine the valid ranges for the controls.

   ➔ The nanowell plate lanes are color-coded according to control types.
   ➔ The controls are listed in the table.

6 In the **Settings** combo box, choose the **Internal controls** tab.

7 For each master mix reagent that contains an internal control, do the following:

- From the **Target** drop-down list, choose the target that was used as internal control.
- In the **Lower limit** field and the **Upper limit** field, enter the valid concentration range for the internal control.

ⓘ In the **Target** drop-down lists, only the targets are available for which no controls were defined on the **Controls** tab.
For each master mix reagent, you can set 1 target as an internal control.
If a master mix reagent only contains 1 target, it is not available as an internal control.

8 Optionally, in the **Settings** combo box, choose the **Target limits** tab.

9 For each combination of master mix reagent and target, you can do the following:

- From the table, choose the combination of master mix reagent and target.
- To account for noise in the data (if there are positive nanowells even if the nanowell plate lane contains no target molecules), enter a value > 0 in the **Lower limit of detection** field.
- To suppress the calculation of the concentration for very low or very high target concentrations, select the **Limits of quantification** check box. In the **Lower limit of quantification** field and the **Upper limit of quantification** field, enter the quantification range.

ⓘ Results outside the quantification ranges are displayed qualitatively only on the **Results** panel.

➔ The table is updated.

10 Click outside the **Settings** combo box. Alternatively, choose the ⚙ button.

➔ The **Abs Quant - All** analysis is recalculated.

➔ The **Results** panel is displayed on the **Abs Quant - All** tab.

Performing absolute quantification analysis

Perform absolute quantification analysis to determine the absolute concentrations of targets in specified samples.

☐ Previous steps of the development workflow completed

Overview of development workflow with unassigned sample setup (195)

Overview of development workflow without unassigned sample setup (194)

To add an absolute quantification analysis

1 In the development software, in the **Navigation** area, choose **Analysis** > ••• > **Abs Quant**.
   ➔ A new absolute quantification tab is displayed in the work area and listed in the **Analysis** menu.
   ➔ The **Settings** combo box is displayed.

2 On the **Sample selection** tab, select the samples for the analysis.
   ⓘ The table lists all samples of the project. The **Sample groups** card lists all sample groups of the project.

3 Optionally, you can work with sample groups as described in Working with sample groups in the development software (328).

4 Choose the **Update analysis** button.

5 Optionally, to return to the selection of samples before the last time you chose the **Update analysis** button, choose the **Reset selection** button.

6 In the **Settings** combo box, choose the **Controls** tab.

7 For each nanowell plate lane (i.e., position on a nanowell plate) that contains a control, do the following:
   - From the table, choose the combination of master mix reagent and target.
   - If the same combination is used in several runs, from the **Run** drop-down list, choose the run.
   - In the graphical representation of the sample setup of the selected run, choose the nanowell plate lane that contains a control.
   - For a positive control, choose the **Positive** option. In the **Lower limit** field and the **Upper limit** field, enter the concentration range.
   - For a negative control, choose the **Negative** option. In the **Upper limit** field, enter the concentration value. (For a negative control, the lower limit of the concentration range is always 0.)

   ⓘ The lower and upper limits determine the valid ranges for the controls.
   ➔ The nanowell plate lanes are color-coded according to control types.
   ➔ The controls are listed in the table.

8 In the **Settings** combo box, choose the **Internal controls** tab.

9 For each master mix reagent that contains an internal control, do the following:

- From the **Target** drop-down list, choose the target that was used as internal control.
- In the **Lower limit** field and the **Upper limit** field, enter the valid concentration range for the internal control.

ⓘ In the **Target** drop-down lists, only the targets are available for which no controls were defined on the **Controls** tab.
For each master mix reagent, you can set 1 target as an internal control.
If a master mix reagent only contains 1 target, it is not available as an internal control.

10 Optionally, in the **Settings** combo box, choose the **Target limits** tab.

11 For each combination of master mix reagent and target, you can do the following:

- From the table, choose the combination of master mix reagent and target.
- To account for noise in the data (if there are positive nanowells even if the nanowell plate lane contains no target molecules), enter a value > 0 in the **Lower limit of detection** field.
- To suppress the calculation of the concentration for very low or very high target concentrations, select the **Limits of quantification** check box. In the **Lower limit of quantification** field and the **Upper limit of quantification** field, enter the quantification range.

ⓘ Results outside the quantification ranges are displayed qualitatively only on the **Results** panel.

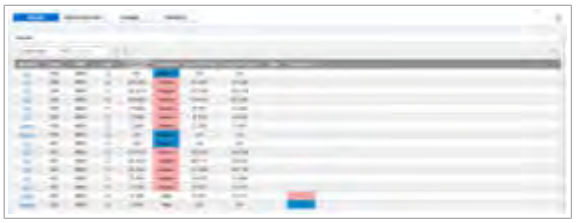
➔ The table is updated.

12 Click outside the **Settings** combo box. Alternatively, choose the ⚙ button.

➔ The absolute quantification analysis is calculated.

➔ The **Results** panel is displayed on the absolute quantification tab.

13 Save the project.



14 To display a summary of the results, do the following:

- Choose the **Result overview** button.
- From the drop-down list, choose the master mix reagent.

15 To display the bar charts as described in Displaying the bar charts (400), do the following:

- At the top right of the **Result overview** panel, choose the 📊 button.
- Optionally, adjust the display of the bar charts.

16 To display the calculated linkage between the targets, do the following.
- Choose the **Linkage** button.
- From the drop-down list, choose the master mix reagent.
- Optionally, edit the thresholds between linked, weakly linked, and/or unlinked in the legend above the table.

17 To display the statistics for the sample groups, choose the **Statistics** button.

To edit an absolute quantification analysis

1 In the development software, in the **Navigation** area, choose the absolute quantification analysis from the **Analysis** menu.
➔ The absolute quantification tab is displayed in the work area.

2 To display the **Settings** combo box, choose the ⚙ button.

3 To include and/or exclude samples from the analysis, do the following:
- Choose the **Sample selection** tab.
- Select the samples you want to include in the analysis.
- Choose the **Update analysis** button.

4 To edit the parameters of the analysis, do the following:
- Choose the **Controls** tab, the **Internal controls** tab, and/or the **Target limits** tab, respectively.
- Enter the changes.

5 Click outside the **Settings** combo box. Alternatively, choose the ⚙ button.
➔ The absolute quantification analysis is recalculated.

6 Save the project.

CNV analysis

CNV (copy number variation) analysis determines the copy number of a known target of interest by comparison with the copy numbers of known reference targets.

In this section

Performing CNV analysis (386)

List of tabs and settings for CNV analysis

The settings provide all parameters necessary for CNV analysis.

➔ **Navigation > Analysis > ••• > CNV >** ⚙

The settings are ordered on tabs in the **Settings** combo box.

The availability of settings on a tab depends on the current settings on the other tabs.

Sample selection tab

On the **Sample selection** tab, choose the samples for the analysis.

The table lists all samples of the project with the sample IDs as entered in the lane settings on the run tabs.

By default, no samples are selected for analysis.

To perform statistics, you can work with sample groups. The **Sample groups** card lists all sample groups of the project.

Working with sample groups in the development software (328)

Analysis setup tab

On the **Analysis setup** tab, select the targets of interest and the reference targets.

The table lists all combinations of master mix reagent and target of the samples that were selected on the **Sample selection** tab.

If you select several reference targets, the development software takes the mean of their copy numbers for analysis.

If the current selection causes problems with the calculation of results, a warning is displayed on the right of the tab. For result calculation, at least 1 target of interest and 1 reference target must be selected.

Controls tab

On the **Controls** tab, mark the positions of controls in the sample setups and enter the valid ranges for the controls.

If you choose a merged lane, the whole set of merged lanes is selected automatically.

The table on the left lists the combinations of master mix reagent and target of interest for which a sample was selected on the **Sample selection** tab.

The **Run:** drop-down list lists all runs that contain samples that were selected on the **Sample selection** tab.

For a diagnostic run that was imported with clustering and analysis settings, assumed control positions are striped if the corresponding channels were measured on the analyzer but the tests were not included in the analysis package. By default, such positions are analyzed as samples, not as controls.

The table on the right lists the defined controls for the selected combination of master mix reagent and target of interest.

Controls are target-specific:
If the control for a target is invalid, the system automatically invalidates the final results for that target for all samples of the same run.

Lower limit field and Upper limit field for negative controls

The fields define the valid concentration range for a negative control.

For negative controls, the lower limit is always 0 and cannot be changed.

Default value for negative controls:

- Upper limit = 0.0000 cp/µl

Min. copy number field and Max. copy number field for copy number controls

The fields define the valid copy number range for copy number controls.

The lower limit must be lower than the upper limit.

Default values for copy number controls:

- Min. copy number = 1.8000 copies
- Max. copy number = 2.2000 copies

Target limits tab

On the **Target limits** tab, optionally enter the limits of validity for targets of interest and reference targets.

For targets of interest, enter the reference target copy number and the limits of the normal copy number.

Limit of validity check box, Lower limit of validity field, and Upper limit of validity field

If the limit of validity is enabled, the measured concentration of the target molecules in the reference target and/or the target of interest must fall within the configured range.

If a concentration is outside the configured range, the corresponding final (qualitative) result is invalid.

The lower limit of validity must be lower than the upper limit of validity.

Default values:

- Limit of validity = disabled
- Lower limit of validity = 0.0000 cp/µl
- Upper limit of validity = 50000.0000 cp/µl

Reference target copy number field

The expected copy number of the reference target.

The reference target copy number is used to normalize the ratio of the copy numbers of the reference target and the target of interest to allow for comparison with the configured range for normal copy number.

Default value:

- Reference target copy number = 2.0000

Lower limit of copy number field and Upper limit of copy number field for normal copy number

The expected normal range of the copy number of the target of interest.

The configured range sets the thresholds for the final (qualitative) results for the targets of interest:

- The final result is low if the calculated copy number is lower than the configured lower limit of copy number.
- The final result is normal if the calculated copy number lies within the configured range of copy number.

- The final result is high if the calculated copy number is higher than the configured upper limit of copy number.

Default values:

- Lower limit of copy number = 1.8000
- Upper limit of copy number = 2.2000

List of result columns for CNV analysis

A CNV tab displays the results of a CNV analysis on the **Results** panel, the **Result overview** panel, and the **Statistics** panel.

➔ **Navigation > Analysis > ••• > CNV**

The panels only display results for samples that were selected on the **Sample selection** tab in the **Settings** combo box.

Merged lanes are analyzed together. Therefore, a set of merged lanes has 1 entry on an analysis tab.

Results panel

The **Results** panel displays the results per target of interest separately for each sample and control.

By default, not all available columns are visible on the **Results** panel.

Configuring table columns (142)

Sample ID column

The sample ID of the sample or control as entered in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

TOI column

The tested target of interest as selected on the **Analysis setup** tab.

Analysis setup tab (377)

MMx (TOI) column

The master mix reagent used with the target of interest as entered in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

Lane column

The position of the sample or control in the run. Merged lanes are indicated by the icon.

About the positions of nanowell plate lanes in sample setups (153)

Copy number column

The calculated final copy number of the target of interest in the sample or control (final quantitative result).

"N/A" is displayed if one of the following applies:

- The final result for the target of interest is invalid.
- The nanowell plate lane contains no target molecules (e.g., valid negative control).

Final result column

Final (qualitative) result for the sample or control. For samples, final results consider the corresponding control results.

The final results for samples are color-coded, i.e., the result names are underlaid with the corresponding color.

About color-coding of final results for samples (149)

About final results (173)

CN 95% CI min. column and CN 95% CI max. column

The values specify the confidence interval for the 95% confidence level (based on the applied Poisson distribution and not accounting for other error sources): The probability is 95% that the copy number of the target of interest in the sample or control lies within the specified range.

Flags column

The flags associated with the sample or control.

Critical flags that invalidate the final result are displayed in bold.

List of flags (489)

Sample type column

Color-coding and icon for the control type.

About color-coding of controls (148)

Merged lanes column

Name of the set of merged lanes as displayed in the lane settings on the run tab.

About the positions of nanowell plate lanes in sample setups (153)

Ratio column

The final ratio of the copy numbers of the reference target and the target of interest.

If the analysis contains several reference targets, the development software takes the mean of their copy numbers for analysis.

Ratio 95% CI min. column and Ratio 95% CI max. column

The values specify the confidence interval for the 95% confidence level (based on the applied Poisson distribution and not accounting for other error sources): The probability is 95% that the ratio of the copy numbers of the reference target and the target of interest lies within the specified range.

Initial result column

Initial (qualitative) result for the target of interest. For samples, initial results are regardless of the corresponding control results.

Both samples and controls can have the following initial results for the target of interest:

- Low
- Normal
- High
- Invalid

A sample or control has an invalid initial result if it was invalidated at any point during the workflow, e.g., during partitioning. A corresponding critical flag is displayed in the **Flags** column.

Run name column

Run name on the analyzer in which the sample or control was processed.

The run name is used as name of the run tab in the development software.

CN 68% CI min. column and CN 68% CI max. column

The values specify the confidence interval for the 68% confidence level (based on the applied Poisson distribution and not accounting for other error sources): The probability is 68% that the copy number of the target of interest in the sample or control lies within the specified range.

The probability is lower because the specified range is smaller than the range specified by the **CN 95% CI min.** column and the **CN 95% CI max.** column.

Ratio 68% CI min. column and Ratio 68% CI max. column

The values specify the confidence interval for the 68% confidence level (based on the applied Poisson distribution and not accounting for other error sources): The probability is 68% that the ratio of the copy numbers of the reference target and the target of interest lies within the specified range.

The probability is lower because the specified range is smaller than the range specified by the **Ratio 95% CI min.** column and the **Ratio 95% CI max.** column.

Copy number relative confidence column

The confidence interval normalized by the final quantitative result (based on the applied Poisson distribution and not accounting for other error sources).

The relative confidence is a measure for the accuracy of the calculations.

Raw copy number column

The calculated initial copy number of the target of interest in the sample or control (initial quantitative result).

Raw values are regardless of applied limits. For samples, raw values are also regardless of the corresponding control results.

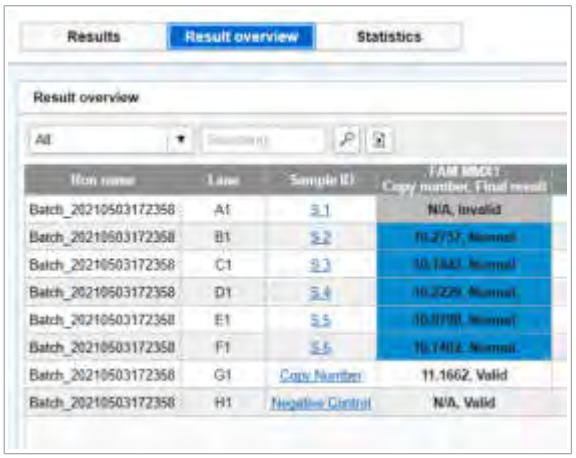
Raw ratio column

The initial ratio of the copy numbers of the reference target and the target of interest.

If the analysis contains several reference targets, the development software takes the mean of their copy numbers for analysis.

Raw values are regardless of applied limits. For samples, raw values are also regardless of the corresponding control results.

Result overview panel



The **Result overview** panel summarizes the results per sample or control.

Run name column

Run name on the analyzer in which the sample or control was processed.

The run name is used as name of the run tab in the development software.

Lane column

The position of the sample or control in the run. Merged lanes are indicated by the icon.

About the positions of nanowell plate lanes in sample setups (153)

Sample ID column

The sample ID of the sample or control as entered in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

Columns for combinations of target of interest and master mix reagent

For each combination of target of interest and master mix reagent, the final quantitative and qualitative results are displayed in 1 column:

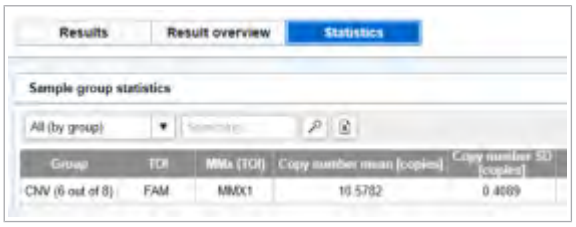
- Copy number
- Final result

The combinations of target of interests and master mix reagents are displayed as the column headers.

Copy number column (381)

Final result column (381)

Statistics panel



The **Statistics** panel displays statistical information for the sample groups that contain samples that were selected for the analysis.

Group column

The name of the sample group as entered on the run tab or in the **Settings** combo box.

If not all samples of a sample group are included in the analysis, the sample group name is appended with the number of included samples in brackets, e.g., "(3 out of 4)". Merged lanes are counted separately.

Working with sample groups in the development software (328)

TOI column

The tested target of interest as selected on the **Analysis setup** tab.

List of columns on the Sample setup table view card (323)

MMx (TOI) column

The master mix reagent used with the target of interest as entered in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

Copy number mean [copies] column

The mean of the copy numbers for the targets of interest (final quantitative results) across the samples of the sample group.

If not all samples of a sample group are included in the analysis, the mean is calculated from the included samples only.

"N/A" is displayed if the sample group contains a sample for which no final quantitative result is available.

Copy number SD [copies] column

The standard deviation of the copy number mean.

"N/A" is displayed if the copy number mean cannot be calculated.

Performing CNV analysis

Perform CNV analysis to determine the differences of the number of copies of genomic segments between samples and reference standards.

☐ Previous steps of the development workflow completed

Overview of development workflow with unassigned sample setup (195)

Overview of development workflow without unassigned sample setup (194)

To add a CNV analysis

1 In the development software, in the **Navigation** area, choose **Analysis** > ••• > **CNV**.
   ➔ A new CNV tab is displayed in the work area and listed in the **Analysis** menu.
   ➔ The **Settings** combo box is displayed.

2 On the **Sample selection** tab, select the samples for the analysis.
   ⓘ The table lists all samples of the project. The **Sample groups** card lists all sample groups of the project.

3 Optionally, you can work with sample groups as described in Working with sample groups in the development software (328).

4 Choose the **Update analysis** button.

5 Optionally, to return to the selection of samples before the last time you chose the **Update analysis** button, choose the **Reset selection** button.

6 In the **Settings** combo box, choose the **Analysis setup** tab.

7 For each combination of master mix reagent and target, do the following:
   - To set a combination as a target of interest, choose the **Target of interest** option.
   - To set a combination as a reference target, choose the **Reference target** option.
   - To exclude a combination from the analysis, keep the **Exclude** option.

   ⓘ If results cannot be calculated from the selection, a warning is displayed.

8 In the **Settings** combo box, choose the **Controls** tab.

9 For each nanowell plate lane (i.e., position on a nanowell plate) that contains a control, do the following:

- From the table, choose the combination of master mix reagent and target of interest.
- If the same combination is used in several runs, from the **Run:** drop-down list, choose the run.
- In the graphical representation of the sample setup, choose the nanowell plate lane that contains a control.
- For a negative control, choose the **Negative** option. In the **Upper limit** field, enter the concentration value. (For a negative control, the lower limit of the concentration range is always 0.)
- For a copy number control, choose the **Copy number** option. In the **Min. copy number** field and the **Max. copy number** field, enter the range for the number of copies.

ⓘ The limits determine the valid ranges for the controls.

➔ The nanowell plate lanes are color-coded according to control types.

➔ The controls are listed in the table.

10 In the **Settings** combo box, choose the **Target limits** tab.

11 For each combination of master mix reagent and target of interest, do the following:

- From the table, choose the combination of master mix reagent and target of interest.
- Enter the expected copy number for the reference target in the **Reference target copy number** field.
- Enter the expected normal range for the copy number of the target of interest in the **Lower limit of copy number** field and the **Upper limit of copy number** field.

➔ The table is updated.

12 For each combination of master mix reagent and reference target, you can do the following:

- From the table, choose the combination of master mix reagent and reference target.
- To ensure the concentration of target molecules falls within the validity range, select the **Limit of validity** check box.
- In the **Lower limit of validity** field and the **Upper limit of validity** field, enter the validity range.

➔ The validity range is displayed in the table.

13 Click outside the **Settings** combo box. Alternatively, choose the ⚙ button.

➔ The CNV analysis is calculated.

➔ The **Results** panel is displayed on the CNV tab.

14 Save the project.

15 To display a summary of the results, choose the **Result overview** button.

16 To display the bar charts as described in Displaying the bar charts (400), do the following:

- At the top right of the **Result overview** panel, choose the button.
- Optionally, adjust the display of the bar charts.

17 To display the statistics for the sample groups, choose the **Statistics** button.

To edit a CNV analysis

1 In the development software, in the **Navigation** area, choose the CNV analysis from the **Analysis** menu.

➔ The CNV tab is displayed in the work area.

2 To display the **Settings** combo box, choose the button.

3 To include and/or exclude samples from the analysis, do the following:

- Choose the **Sample selection** tab.
- Select the samples you want to include in the analysis.
- Choose the **Update analysis** button.

4 To edit the parameters of the analysis, do the following:

- Choose the **Analysis setup** tab, the **Controls** tab, and/or the **Target limits** tab, respectively.
- Enter the changes.

5 Click outside the **Settings** combo box. Alternatively, choose the button again.

➔ The CNV analysis is recalculated.

6 Save the project.

Indel analysis

Indel (insertion - deletion) analysis determines the presence of unknown mutations in a variant target by simultaneously detecting the variant target and an adjacent reference target.

If both the reference target and the variant target are detected (i.e., there are double-positive nanowells), the sequence of the variant target is unchanged. This is the so-called wild-type sequence.

If the reference target is detected but the variant target is not detected (i.e., there are positive-negative nanowells), the sequence of the variant target is changed. This is the so-called variant sequence.

To facilitate the clustering for indel analysis, use the 2D scatter plot type.

In this section

List of tabs and settings for indel analysis

The settings provide all parameters necessary for indel analysis.

➔ **Navigation > Analysis > ••• > Indel >** ⚙

The settings are ordered on tabs in the **Settings** combo box.

The availability of settings on a tab depends on the current settings on the other tabs.

Sample selection tab

On the **Sample selection** tab, choose the samples for the analysis.

The table lists all samples of the project with the sample IDs as entered in the lane settings on the run tabs.

By default, no samples are selected for analysis.

To perform statistics, you can work with sample groups. The **Sample groups** card lists all sample groups of the project.

Working with sample groups in the development software (328)

Analysis setup tab

On the **Analysis setup** tab, create the analysis setups:

- Choose the combinations of master mix reagent, variant target, and reference target.
- Enter the minimum percentage of the variant sequence.
- Optionally, enter the limits of validity.

MMx drop-down list

Lists the master mix reagents for which a sample was included in the analysis on the **Sample selection** tab.

Variant drop-down list and Reference target drop-down list

List the targets for which a sample was included in the analysis on the **Sample selection** tab.

Variant target and reference target must be different:
If you choose a target from one of the drop-down lists, it is not available anymore from the other drop-down list.

Min. variant [%] field

Defines the minimum percentage of the variant sequence that must be present in the sample for it to be variant positive.

Default value:

- Minimum percentage of the variant = 1.0000 %

Limit of validity (for the total concentration of the variant and the wild type) check box, Lower limit of validity field, and Upper limit of validity field

If the limit of validity is enabled, the sum of the measured concentrations of the variant sequence and the wild-type sequence must fall within the configured range.

If the concentration is outside the configured range, the corresponding final (qualitative) result is invalid.

The lower limit of validity must be lower than the upper limit of validity.

Default values:

- Limit of validity = enabled
- Lower limit of validity = 200.0000 cp/µl
- Upper limit of validity = 500000.0000 cp/µl

Controls tab

On the **Controls** tab, mark the positions of controls in the sample setups and enter the valid ranges for the controls.

If you choose a merged lane, the whole set of merged lanes is selected automatically.

The table on the left lists the combinations of master mix reagent, variant target, and reference target for which a sample was included in the analysis on the **Sample selection** tab.

The **Run:** drop-down list lists all runs that contain samples that were selected on the **Sample selection** tab.

For a diagnostic run that was imported with clustering and analysis settings, assumed control positions are striped if the corresponding channels were measured on the analyzer but the tests were not included in the analysis package. By default, such positions are analyzed as samples, not as controls.

The table on the right lists the defined controls for the selected combination of master mix reagent, variant target, and reference target.

Controls are target-specific:
If the control for a target is invalid, the system automatically invalidates the final results for that target for all samples of the same run.

Controls (165)

Lower limit field and Upper limit field

The fields define the valid range for a control.

The lower limit must be lower than the upper limit.

For negative controls, the lower limit is always 0 and cannot be changed.

Default values for variant controls:

- Lower limit = 1.0000 %
- Upper limit = 100.0000 %

Default values for wild type controls:

- Lower limit = 1.0000 cp/µl
- Upper limit = 1000.0000 cp/µl

Default value for negative controls:

- Upper limit = 0.0000 cp/µl

List of result columns for indel analysis

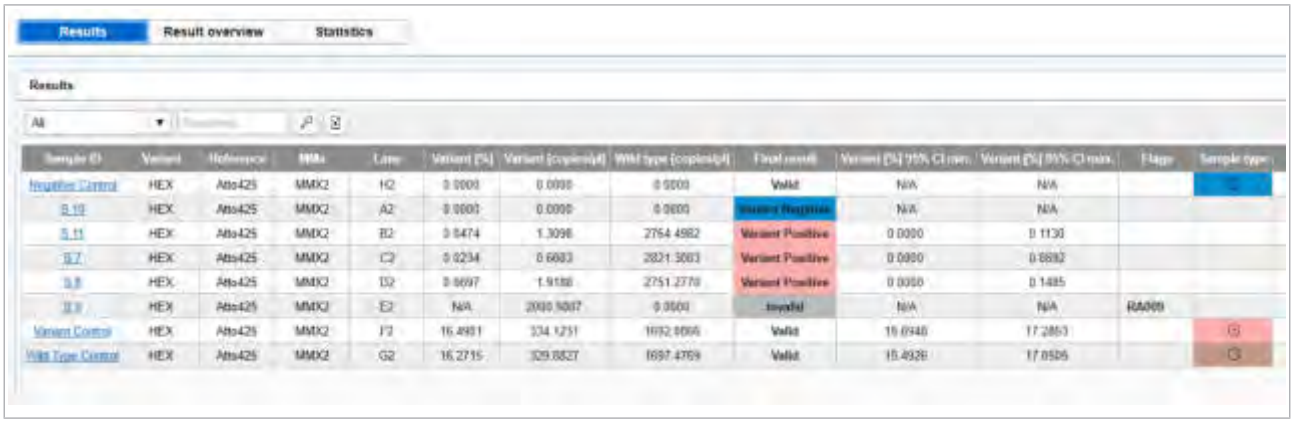
An indel tab displays the results of an indel analysis on the **Results** panel, the **Result overview** panel, and the **Statistics** panel.

➔ **Navigation > Analysis > ••• > Indel**

The panels only display results for samples that were selected on the **Sample selection** tab in the **Settings** combo box.

Merged lanes are analyzed together. Therefore, a set of merged lanes has 1 entry on an analysis tab.

Results panel



The **Results** panel displays the results per variant separately for each sample and control.

By default, not all available columns are visible on the **Results** panel.

Configuring table columns (142)

Sample ID column

The sample ID of the sample or control as entered in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

Variant column

The tested variant target as selected on the **Analysis setup** tab.

Analysis setup tab (390)

Reference column

The tested reference target as selected on the **Analysis setup** tab.

Analysis setup tab (390)

MMx column

The used master mix reagent as entered in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

Lane column

The position of the sample or control in the run. Merged lanes are indicated by the icon.

About the positions of nanowell plate lanes in sample setups (153)

Variant [%] column

Percentage of the variant sequence in the sample or control (final quantitative result).

Variant [copies/µl] column

Concentration of the variant sequence in the sample or control.

Wild type [copies/µl] column

Concentration of the wild-type sequence in the sample or control.

Final result column

Final (qualitative) result for the sample or control. For samples, final results consider the corresponding control results.

The final results for samples are color-coded, i.e., the result names are underlaid with the corresponding color.

About color-coding of final results for samples (149)

About final results (173)

Variant [%] 95% CI min. column and Variant [%] 95% CI max. column

The values specify the confidence interval for the 95% confidence level (based on the applied Poisson distribution and not accounting for other error sources): The probability is 95% that the percentage of the variant sequence in the sample or control lies within the specified range.

Flags column

The flags associated with the sample or control.

Critical flags that invalidate the final result are displayed in bold.

List of flags (489)

Sample type column

Color-coding and icon for the control type.

About color-coding of controls (148)

Merged lanes column

Name of the set of merged lanes as displayed in the lane settings on the run tab.

About the positions of nanowell plate lanes in sample setups (153)

Variant [copies] column

Absolute number of copies of the variant sequence in the sample or control.

Wild type copies column

Absolute number of copies of the wild-type sequence in the sample or control.

Initial result column

Initial (qualitative) result for the variant sequence. For samples, initial results are regardless of the corresponding control results.

Both samples and controls can have the following initial results for the variant sequence:

- Negative
- Positive
- Invalid

A sample or control has an invalid initial result if it was invalidated at any point during the workflow, e.g., during partitioning. A corresponding critical flag is displayed in the **Flags** column.

Plate type column

Nanowell plate type used for processing the sample.

Nanowell plates (159)

No. of positive nanowells column

Number of positive nanowells for the sample or control as determined in the clustering.

List of columns on the Clustering data card (339)

Total valid nanowells column

Number of valid nanowells for the sample or control as displayed in the clustering.

The number of valid nanowells is the total of the positive and the negative nanowells.

List of columns on the Clustering data card (339)

Dilution factor column

Dilution factor as entered in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

Run name column

Run name on the analyzer in which the sample or control was processed.

The run name is used as name of the run tab in the development software.

Variant [%] 68% CI min. column and Variant [%] 68% CI max. column

The values specify the confidence interval for the 68% confidence level (based on the applied Poisson distribution and not accounting for other error sources): The probability is 68% that the percentage of the variant sequence in the sample or control lies within the specified range.

The probability is lower because the specified range is smaller than the range specified by the **Variant [%] 95% CI min.** column and the **Variant [%] 95% CI max.** column.

Variant [copies/nanowell] column

The average number of copies of the variant sequence per valid nanowell for the sample or control.

Wild type [copies/nanowell] column

The average number of copies of the wild-type sequence per valid nanowell for the sample or control.

Negative nanowells column

Number of negative nanowells for the sample or the control as determined in the clustering.

List of columns on the Clustering data card (339)

Clustering method column

Clustering method as set on the clustering tab.

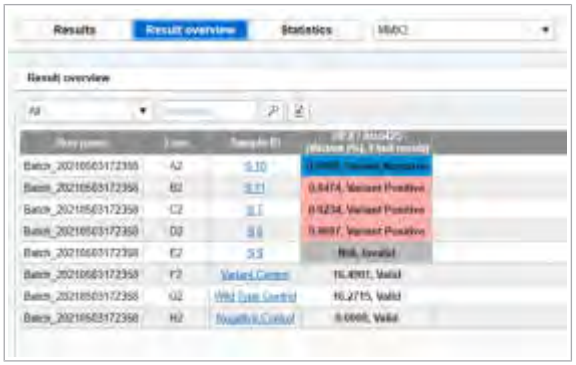
List of clustering settings in the development software (342)

Raw variant [%] column

The calculated initial percentage of the variant sequence in the sample or control (initial quantitative result).

Raw values are regardless of applied limits. For samples, raw values are also regardless of the corresponding control results.

Result overview panel



The **Result overview** panel summarizes the results per sample or control for the selected master mix reagent.

Run name column

Run name on the analyzer in which the sample or control was processed.

The run name is used as name of the run tab in the development software.

Lane column

The position of the sample or control in the run. Merged lanes are indicated by the icon.

About the positions of nanowell plate lanes in sample setups (153)

Sample ID column

The sample ID of the sample or control as entered in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

Columns for combinations of variant target and reference target

For each combination of variant target and reference target, the final quantitative and qualitative results are displayed in 1 column:

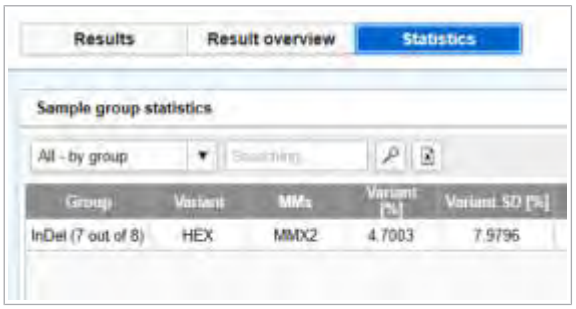
- Percentage of variant sequence
- Final result

The combinations of variant targets and reference targets are displayed as the column headers.

Variant [%] column (393)

Final result column (393)

Statistics panel



The **Statistics** panel displays statistical information for the sample groups that contain samples that were selected for the analysis.

Group column

The name of the sample group as entered on the run tab or in the **Settings** combo box.

If not all samples of a sample group are included in the analysis, the sample group name is appended with the number of included samples in brackets, e.g., "(3 out of 4)". Merged lanes are counted separately.

Working with sample groups in the development software (328)

Variant column

The tested variant target as selected on the **Analysis setup** tab.

Analysis setup tab (390)

MMx column

The used master mix reagent as entered in the lane settings on the run tab.

List of columns on the Sample setup table view card (323)

Variant [%] column

The mean of the percentages of the variant sequence (final quantitative results) across the samples of the sample group.

If not all samples of a sample group are included in the analysis, the mean is calculated from the included samples only.

"N/A" is displayed if the sample group contains a sample for which no final quantitative result is available.

Variant SD [%] column

The standard deviation of the percentage mean.

"N/A" is displayed if the percentage mean cannot be calculated.

Performing indel analysis

Perform indel analysis to determine the presence (insertion) or absence (deletion) of bases in a genomic sequence.

☐ Previous steps of the development workflow completed

Overview of development workflow with unassigned sample setup (195)

Overview of development workflow without unassigned sample setup (194)

To add an indel analysis

1 In the development software, in the **Navigation** area, choose **Analysis** > ••• > **Indel**.
   ➔ A new indel tab is displayed in the work area and listed in the **Analysis** menu.
   ➔ The **Settings** combo box is displayed.

2 On the **Sample selection** tab, select the samples for the analysis.
   ⓘ The table lists all samples of the project. The **Sample groups** card lists all sample groups of the project.

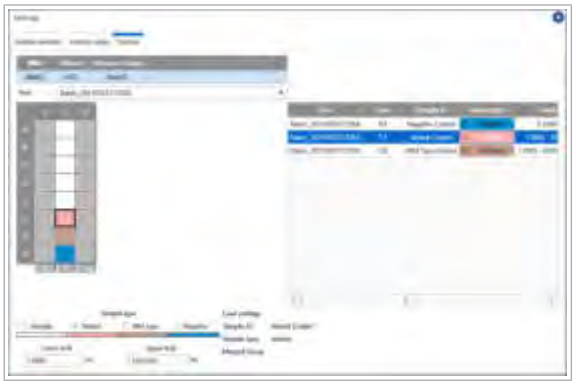
3 Optionally, you can work with sample groups as described in Working with sample groups in the development software (328).

4 Choose the **Update analysis** button.

5 Optionally, to return to the selection of samples before the last time you chose the **Update analysis** button, choose the **Reset selection** button.

6 In the **Settings** combo box, choose the **Analysis setup** tab.

7 Add at least 1 analysis setup:
   - Choose the **New** button.
   - From the **MMx** drop-down list, choose the master mix reagent.
   - From the **Variant** drop-down list, choose the variant target.
   - From the **Reference target** drop-down list, choose the reference target.
   - In the **Min. variant [%]** field, enter the minimum required percentage of the variant sequence.
   - Optionally, in the **Lower limit of validity** field and the **Upper limit of validity** field, edit the validity range.



- Optionally, clear the **Limit of validity (for the total concentration of the variant and the wild type)** check box.

8 In the **Settings** combo box, choose the **Controls** tab.

9 For each nanowell plate lane (i.e., position on a nanowell plate) that contains a control, do the following:

- From the table, choose the combination of master mix reagent, variant, and reference.
- If the same combination is used in several runs, from the **Run:** drop-down list, choose the run.
- In the graphical representation of the sample setup, choose the nanowell plate lane that contains a control.
- For a variant control, choose the **Variant** option. In the **Lower limit** field and the **Upper limit** field, enter the percentage range.
- For a wild type control, choose the **Wild type** option. In the **Lower limit** field and the **Upper limit** field, enter the concentration range.
- For a negative control, choose the **Negative** option. In the **Upper limit** field, enter the concentration value. (For a negative control, the lower limit of the concentration range is always 0.)

ⓘ The lower and upper limits determine the valid ranges for the controls.

➔ The nanowell plate lanes are color-coded according to control types.

➔ The controls are listed in the table.

10 Click outside the **Settings** combo box. Alternatively, choose the ⚙ button.

➔ The indel analysis is calculated.

➔ The **Results** panel is displayed on the indel tab.

11 Save the project.

12 To display a summary of the results, do the following:

- Choose the **Result overview** button.
- From the drop-down list, choose the master mix reagent.

13 To display the bar charts as described in Displaying the bar charts (400), do the following:

- At the top right of the **Result overview** panel, choose the 📊 button.
- Optionally, adjust the display of the bar charts.

14 To display the statistics for the sample groups, choose the **Statistics** button.

To edit an indel analysis

1 In the development software, in the **Navigation** area, choose the indel analysis from the **Analysis** menu.
➔ The indel tab is displayed in the work area.

2 To display the **Settings** combo box, choose the ⚙ button.

3 To include and/or exclude samples from the analysis, do the following:
- Choose the **Sample selection** tab.
- Select the samples you want to include in the analysis.
- Choose the **Update analysis** button.

4 To edit the parameters of the analysis, do the following:
- Choose the **Analysis setup** tab and/or the **Controls** tab, respectively.
- Enter the changes.

5 Click outside the **Settings** combo box. Alternatively, choose the ⚙ button.
➔ The indel analysis is recalculated.

6 Save the project.

Displaying the bar charts

For each analysis, you can display the final quantitative results as bar charts on the **Result overview** panel.

About the bar charts (135)

☐ Analysis performed

To display the bar charts

1 In the development software, in the **Navigation** area, choose the analysis from the **Analysis** menu.
➔ The analysis tab is displayed in the work area.

2 Choose the **Result overview** button.
➔ The **Result overview** panel is displayed.

3 To display the bar charts, at the top right of the **Result overview** panel, choose the button.
➔ On the right of the **Result overview** panel, a bar chart per sample or control is displayed.
➔ Above the bar charts, the field and buttons for the display options of the bar charts are displayed.

4 To change the maximum value for the concentration axes, do the following:
   - To change the maximum value, enter the value in the **Range** field. Press Enter.
   - To return to the default value, choose the **Reset** button.

   ℹ The **Reset** button is only displayed after you entered a different value.

5 To change the scale of the concentration axes, do the following:
   - To display a logarithmic scale, choose **Scale > Log.**.
   - To display a linear scale, choose **Scale > Lin.**.

6 To change the display of the error bars, do the following:
   - To hide the error bars, choose **Error bar > Off**.
   - To display the error bars, choose **Error bar > On**.

7 To hide the bar charts, choose the button.

Related topics

- Projects in the development software (294)
- Runs in the development software (309)
- Clustering in the development software (338)
- Unassigned sample setups in the development software (402)
- Analysis packages in the development software (412)

Unassigned sample setups in the development software

You can use unassigned sample setups in your project to plan development runs.

It is not required to use unassigned sample setups in your project. You can directly add the same information later to the raw data file (run) of the development run.

In this section

About unassigned sample setups in the development software

Unassigned sample setups are a planning tool for development runs. It allows you to use an unassigned sample setup report as a help for pipetting.

You can add run settings and lane settings to unassigned sample setups.

About run settings

Run settings comprise the following information that applies to the complete sample setup and the subsequent development run:

- Nanowell plate IDs and types
- Detection formats (channels, dyes, and integration times)
- Run notes

By default, all channels are enabled.

About lane settings

Lane settings comprise the following information that applies to individual nanowell plate lanes, i.e., samples:

- Sample ID

- Dilution factor of sample
- Name of master mix reagent
- ID of master mix reagent or master reagent
- Expiry date of master mix reagent or master reagent
- Lot number of master mix reagent or master reagent
- Target and dye settings
- Notes and sample preparation notes

By default, the targets are named as the dyes.

The following applies to lane settings:

- Changes to a master mix reagent, e.g., a name change or changed target and dye settings, are applied across the project wherever the same master mix reagent is used.
- If you enter the same lane settings for multiple nanowell plate lanes, the nanowell plate lanes are merged automatically.
- For merged lanes, empty lane settings are considered as identical.
- Changes to 1 merged lane are applied automatically to all other merged lanes of the same set.
- It is recommended to use the fields for the ID, expiry date, and lot number to track your own master mix reagents.

List of columns on the Sample setup table view card (323)

About detection formats

The detection formats define the channels, the dye per channel, and the integration time for the detection of fluorescence by the analyzer.

The following applies:

- In the run settings, in the **Detection format** combo box, enable the channels for all dyes that are contained in any of the master mix reagents used in the development run.
- You cannot use different dyes that are detected in the same channel in 1 development run.
- In the lane settings, in the **Target and dye settings** table, you define which subset of the detected dyes is contained in the individual master mix reagents and you map the targets to the dyes.
- Only dyes that are enabled in the run settings are available in the lane settings.
- You can only reuse a master mix reagent across a project if the runs or unassigned sample setups use the same detection formats.

To use the planned configuration of the detection formats for the development run, you must configure the run profile on the analyzer accordingly.

Editing run profiles on the Edit run profile panel in the analyzer software (303)

About merged lanes

Merged lanes emulate the partitioning of a larger sample volume into a higher number of nanowells. The system treats the nanowells of a set of merged lanes as if they belong to 1 nanowell plate lane. Merged lanes therefore facilitate detection of very low target concentrations.

Up to 8 nanowell plate lanes can be merged.

A set of merged lanes has the following characteristics:

- The same reaction mixture is pipetted into the merged lanes.
- The merged lanes are analyzed together. A set of merged lanes gets 1 final result.

In the development software, nanowell plate lanes with identical lane settings are merged automatically. Empty lane settings are considered as identical.

The position of a set of merged lanes in a sample setup is denoted by the lowest position of the included nanowell plate lanes.
Example:
If the nanowell plate lanes A1, B1, and C1 are merged, the position of the set of merged lanes is denoted as "A1".
The position is also used as name for the set of merged lanes.

About the positions of nanowell plate lanes in sample setups (153)

Display of unassigned sample setups

In the development software, unassigned sample setups are displayed as follows:

- Listed in the **Unassigned sample setup** menu in the **Navigation** area
- Displayed as sample setup tabs in the work area

By default, the unassigned sample setups are named "Sample setup" and numbered consecutively.

About the sample setup tabs (136)

Working with unassigned sample setups in the development software

To facilitate the use of unassigned sample setups, you can create, duplicate, rename, and delete unassigned sample setups.

If you create a project, an unassigned sample setup with 1 universal nanowell plate is added automatically.

For adding information to unassigned sample setups (i.e., run settings and lane settings), refer to Adding run settings and lane settings to unassigned sample setups in the development software (406).

☐ Project in the development software

To add an unassigned sample setup to a project in the development software

1 In the development software, open or create a project as described in Working with projects in the development software (295).

2 In the **Navigation** area, choose **Unassigned sample setup** > ••• > **Create new**.

➔ An unassigned sample setup with 1 universal nanowell plate is added to your project and listed in the **Unassigned sample setup** menu.

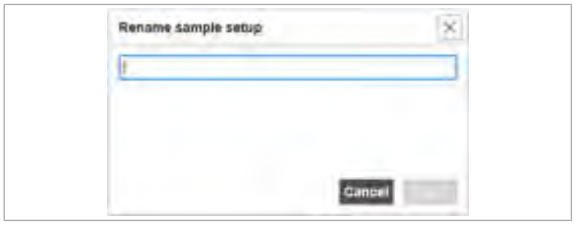
➔ The sample setup tab of the unassigned sample setup is displayed in the work area.

3 Save the project.

To rename an unassigned sample setup in the development software

1 In the development software, in the **Navigation** area, choose the unassigned sample setup from the **Unassigned sample setup** menu.

2 Choose ••• > **Rename**.



3 In the **Rename sample setup** dialog box, enter the new name. Choose the **Save** button.

➔ The sample setup tab is renamed.

➔ The unassigned sample setup listed in the **Unassigned sample setup** menu is renamed.

4 Save the project.

To delete an unassigned sample setup in the development software

1 In the development software, in the **Navigation** area, choose the unassigned sample setup from the **Unassigned sample setup** menu.

2 Choose ••• **> Delete**.

3 In the **Warning** dialog box, choose the **Confirm** button.

➔ The sample setup tab is closed.

➔ The unassigned sample setup is deleted from the **Unassigned sample setup** menu.

4 Save the project.

To duplicate an unassigned sample setup in the development software

1 In the development software, in the **Navigation** area, choose the unassigned sample setup from the **Unassigned sample setup** menu.

2 Choose ••• **> Duplicate**.

➔ The duplicated unassigned sample setup is created and named as "copy" and numbered consecutively.

➔ The duplicated unassigned sample setup is listed in the **Unassigned sample setup** menu.

➔ The sample setup tab of the duplicated unassigned sample setup is displayed in the work area.

3 Save the project.

Adding run settings and lane settings to unassigned sample setups in the development software

You can add run settings and lane settings to unassigned sample setups.

It is not required to add all information to the unassigned sample setup. You can add some information and directly add the rest of the information to the development run after import of the raw data file.

To transfer the information from the unassigned sample setup to the development run, the unassigned sample setup can be assigned to the run if the unassigned sample setup is matching or partially matching.

Working with raw data files and runs in the development software (317)

To add run settings to an unassigned sample setup in the development software

1 In the development software, in the **Navigation** area, choose the unassigned sample setup from the **Unassigned sample setup** menu.

2 On the sample setup tab, choose the **Run settings** button.

➔ The **Run settings** card is displayed on the sample setup tab.

3 CAUTION! Risk of compromised image integrity. Avoid scratches, finger prints, dust, or other artifacts on the nanowell plate lanes.

On the **Run settings** card, for each nanowell plate, do the following:

- From the **Plate type** drop-down list, choose the nanowell plate type.
- Optionally, choose the **Plate ID** field. Scan or enter the nanowell plate ID. If required, press Enter.

ⓘ You can use different types of nanowell plates in 1 development run.
The unassigned sample setup can later be assigned to the run only if the nanowell plate types and IDs in the unassigned sample setup and in the actual development run match.
The unassigned sample setup can only be assigned automatically if it contains the nanowell plate IDs.

➔ The nanowell plates are added to the unassigned sample setup.

➔ In plate view, the column footer is color-coded according to nanowell plate type. If you entered the nanowell plate IDs, the last 5 digits of the nanowell plate ID are displayed in the column footer.

4 Choose the **Detection formats** button.

➔ The **Detection format** combo box is displayed.

5 To edit the detection formats, do the following:
- To disable a channel, choose the **Disabled** button.
- To enable a channel, select the **Enabled** check box.
- For each enabled channel, choose the dye from the **Dye** drop-down list.

ⓘ Ensure that you disable empty channels.
Only the enabled dyes can be assigned in the lane settings.
The unassigned sample setup can later be assigned to the run only if the detection formats in the unassigned sample setup and in the actual development run match.

6 Disable the channels for dyes that are not contained in the master mix reagents.

7 Optionally, to change the integration time, select the **Advanced Settings** check box. Enter the integration time in the corresponding fields.

8 Choose the **Save** button.

9 Optionally, on the **Run settings** card, enter a comment in the **Additional run notes:** field.

10 Save the project.

To add lane settings to an unassigned sample setup in the development software

1 In the development software, in the **Navigation** area, choose the unassigned sample setup from the **Unassigned sample setup** menu.

2 On the sample setup tab, choose the **Lane settings** button.

➔ The **Lane settings** card is displayed.

3 Choose one or several tiles (in plate view) or rows (in table view).

4 To enter the sample ID for the selected tiles or rows, do the following:
- Choose the **Sample ID** field.
- Scan or enter the sample ID.
- If required, press Enter.

➔ The sample ID is displayed on the selected tiles or in the selected rows.

5 Optionally, to enter a dilution factor for the selected tiles or rows, do the following:
- Choose the **Dilution factor** field.
- Enter the dilution factor.
- Press Enter.

6 To add a new master mix reagent to the project and assign it to the selected tiles or rows, do the following:
- Choose the **MMx** field.
- Enter the name of the master mix reagent.
- Press Enter.

➔ The master mix reagent is displayed on the selected tiles or in the selected rows.

➔ By default, in plate view, all tiles with the same master mix reagent are displayed with the same color.

7 To assign a master mix reagent that exists in the project to the selected tiles or rows, do the following:
- Next to the **MMx** field, choose the ▾ button.
- From the drop-down list, choose the master mix reagent.

ⓘ You can only assign an existing master mix reagent if the dyes that are enabled in the run settings match.
If you assign an existing master mix reagent, the target and dye settings are taken over from the master mix reagent.

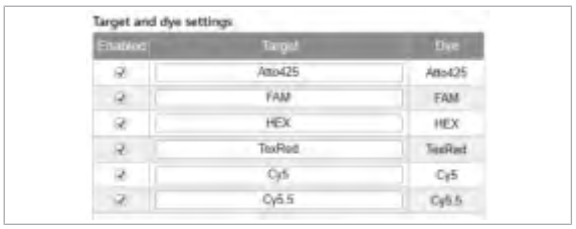
➔ The master mix reagent is displayed on the selected tiles or in the selected rows.

➔ By default, in plate view, all tiles with the same master mix reagent are displayed with the same color.

8 Optionally, to rename the assigned master mix reagent across the project, do the following:
- Next to the next to the **MMx** field, choose the ✎ button.
- In the **Edit MMx name** dialog box, enter a new name.
- Choose the **Save** button.

➔ The master mix reagent is renamed across the project.

9 Optionally, for the selected tiles or rows, choose the following fields and scan or enter the additional information for the master mix reagent or master reagent:
- **MMx ID**
- **MMx expiry date**
- **MMx lot number**



10 Optionally, in the **Target and dye settings** table, disable targets for the selected tiles or rows.

ⓘ Only the dyes for channels that were enabled in the run settings are displayed.
At least 1 target must be enabled for each master mix reagent.
Disabled targets are excluded from clustering and analysis later in the development workflow.
Ensure that you disable empty channels.

11 To map the targets to the dyes, rename the targets:

- Choose the **Target** field.
- Enter the name of the target.
- Press Enter.

ⓘ You can display the mappings on the clustering tabs later in the development workflow.

12 Optionally, add notes and/or sample preparation notes.

13 Repeat steps **3** to **12** for all other tiles or rows.

14 Optionally, to undo or redo changes, choose the buttons above the tiles (in plate view) or rows (in table view):

- To undo a change, choose the **Undo** button.
- To redo a change, choose the **Redo** button.
- To reset all lane settings to default values, choose the **Reset** button.

ⓘ The last 15 steps are retained and can be undone or redone, including a reset to default.

15 Save the project.

Creating a sample setup report of an unassigned sample setup in the development software

After you planned your development run in an unassigned sample setup, create (and print) the sample setup report as a help for pipetting.

☐ Unassigned sample setup completed

▸ To create a sample setup report of an unassigned sample setup in the development software

1 In the development software, in the **Navigation** area, choose the unassigned sample setup from the **Unassigned sample setup** menu.

2 Choose ••• **> Create a sample setup report**.

3 Navigate to a folder. Enter a name for the report and choose the **Save** button.
   ➔ The sample setup report is saved as PDF file.
   ➔ If a program for viewing PDF files is installed on your computer, the PDF is displayed.

4 Print the sample setup report as a guide for pipetting.

Related topics

- Projects in the development software (294)
- Runs in the development software (309)
- Clustering in the development software (338)
- Analyses in the development software (358)
- Analysis packages in the development software (412)

Analysis packages in the development software

Analysis packages provide all parameters necessary to plan and to perform diagnostic runs and to generate diagnostic results as part of diagnostic workflows.

An analysis package is based upon a development workflow:
In an analysis package, you can only include tests from analyses that are part of the project.

By default, each project contains an **Abs Quant – All** analysis. If you do not add further analyses to the project, you can only use the tests from the **Abs Quant – All** analysis for the analysis packages.

In this section

List of settings for analysis packages

You must enter the settings for an analysis package to create it.

In this section

Create analysis package dialog box

In the **Create analysis package** dialog box, you enter the name for the analysis package and you choose the nanowell plate type.

➔ **Navigation > Analysis package > ••• > Create analysis package**

Ensure that you enter the information correctly. You cannot change it later.

Analysis package name field

Field to enter the name that identifies the analysis package in the development software, the analyzer software, and the web application.

The name is automatically appended with the version number "(V0.0)".

Ensure that you enter a unique and meaningful name for the analysis package. You cannot change the name of the analysis package later.

Analysis packages are additionally identified by Version, Name GUID, and Version GUID.

Manage analysis packages (579)

Plate type drop-down list

Drop-down list to choose the nanowell plate type compatible with the analysis package, i.e., the nanowell plate type you must use to perform the tests of the analysis package on a sample.

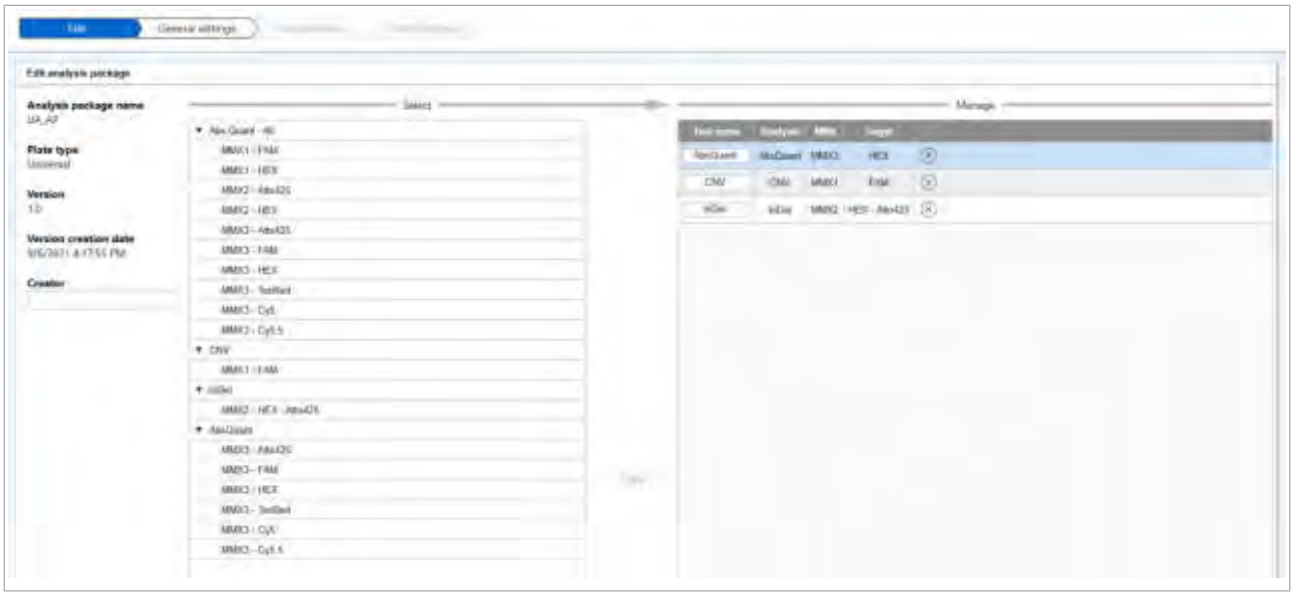
It is not required to choose a nanowell plate type used in a run of the project that is used to create the analysis package.

Ensure that you choose the correct nanowell plate type. You cannot change the nanowell plate type later. If you choose the wrong nanowell plate type, you must delete the analysis package and create a new one.

Edit panel

On the **Edit** panel, you choose the tests for the analysis package and enter the issuer name of the analysis package.

➔ **Navigation > Analysis package > ••• > Create analysis package > Edit**



Creator field — Field to enter the creator of the analysis package.

In the analyzer software, the creator is displayed on the **Manage analysis packages** panel.

Select table — The **Select** table lists all analyses of the project and their tests.

Manage table — The **Manage** table lists all tests that are selected for the analysis package.

General settings panel

On the **General settings** panel, you set the global parameters that apply to all tests of the analysis package and you can document the history of the analysis package.

➔ **Navigation > Analysis package > ••• > Create analysis package > General settings**

The **General settings** panel comprises the following cards:

- **General settings**
- **History**

General settings card

On the **General settings** card, you set the global parameters that apply to all tests of the analysis package.

Number of merged lanes drop-down list

Drop-down list to choose the number of nanowell plate lanes to be merged in the sample setup (1 to 8).

The number applies to both samples and controls in the sample setup.

Default value = 1 (no merged nanowell plate lanes)

Run profile drop-down list

Drop-down list to choose the run profile for the analysis package.

All runs of the project and the run profiles used on the analyzer are listed chronologically with the latest run on top.

Time limit between plate filling and starting a run check box and minutes field

Check box and field to set a maximum duration between partitioning of the nanowell plates and the start of the diagnostic run.

Default value (check box) = cleared
Default value (field) = 360 minutes

Result export restrictions options

Enable or disable the export of raw data files and analyses of diagnostic runs from the web application:

- **Unable to export**
- **Export raw data**
- **Export raw data and analyses**

Default value = **Export raw data**

Report label field

Free text field to enter the text used on the analysis package report.

To create an analysis package report (433)

History card

On the **History** card, you can document the change history of the analysis package.

Comment field

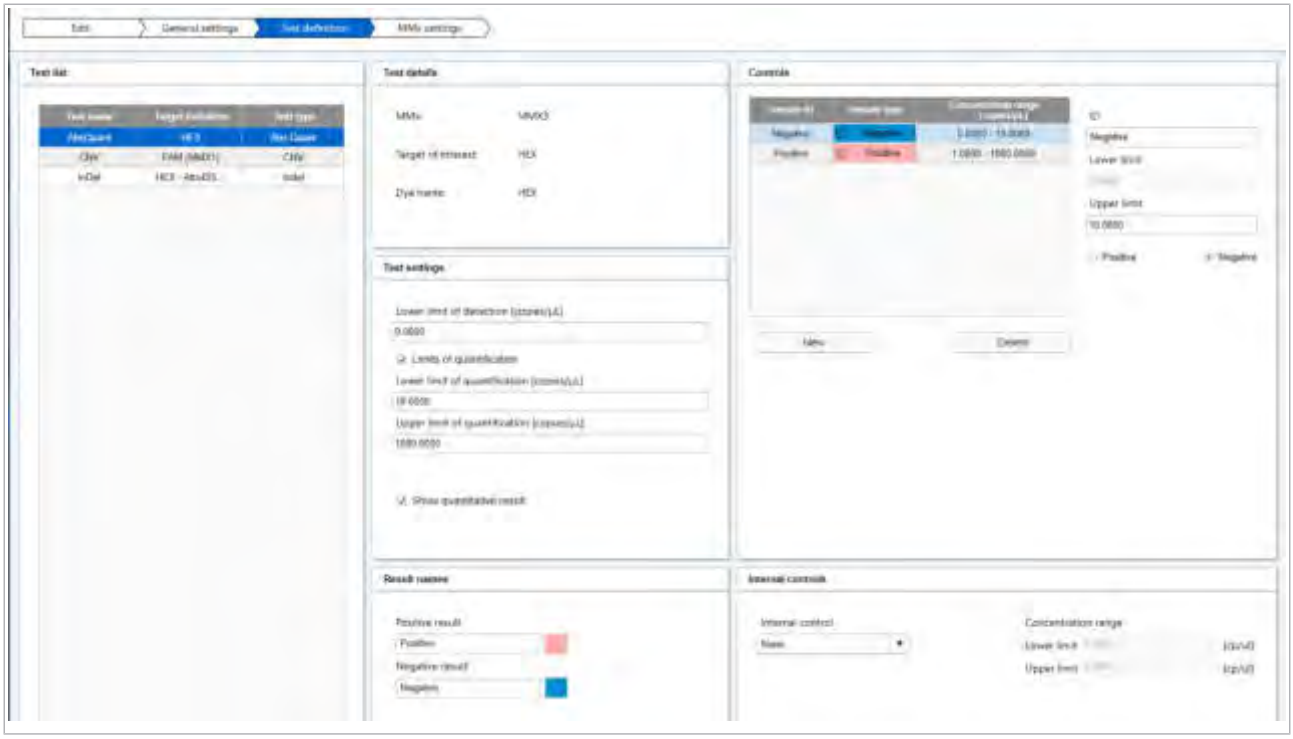
Free text field.

For example, enter a change description whenever you create a new version of an analysis package.

Test definition panel for absolute quantification tests

On the **Test definition** panel, you set the parameters that apply to the individual tests of the analysis package.

➔ **Navigation > Analysis package > ••• > Create analysis package > Test definition**



The required parameters depend on the test type (absolute quantification, CNV, indel).

The values are pre-entered from the analyses that are used to create the analysis package.

The **Test definition** panel comprises the following cards:

- **Test list**
- **Test details**
- **Test settings**
- **Result names**
- **Controls**
- **Internal controls**

Test list card

Card that lists all tests of the analysis package, i.e., the tests that you chose on the **Edit** panel for the analysis package.

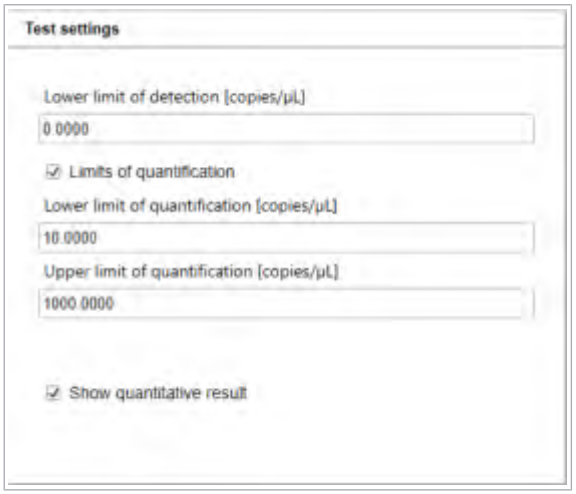
To display the other test-specific cards, choose a test from the table on the **Test list** card.

Test details card

Card that lists the name of the master mix reagent, the target name, and the dye name.

The **Test details** card is read-only.

Test settings card



Card to enter the limits of detection and quantification, and to configure the display of final quantitative results.

Lower limit of detection [copies/µL] field

A limit of detection > 0 accounts for noise in the data, i.e., if there are positive nanowells even if the nanowell plate lane contains no target molecules.

The initial result and the final result for a target are negative if the calculated raw concentration of the target is below the limit of detection.

The lower limit of detection must be lower than the lower limit of quantification (if enabled).

Precision = 4 decimal places

Limits of quantification check box, Lower limit of quantification [copies/µL] field, and Upper limit of quantification [copies/µL] field

If the limit of quantification is enabled, the calculation of the target concentration is suppressed outside of the entered quantification range. This is to account for the increase in uncertainty for very low or very high target concentrations.

On the **Results** panel, final results outside the quantification range are flagged. Instead of the calculated target concentration, the quantification limit that is not met is displayed as final quantitative result.

The lower limit of quantification must be lower than the upper limit of quantification.

The lower limit of quantification must be higher than the lower limit of detection.

Precision = 4 decimal places

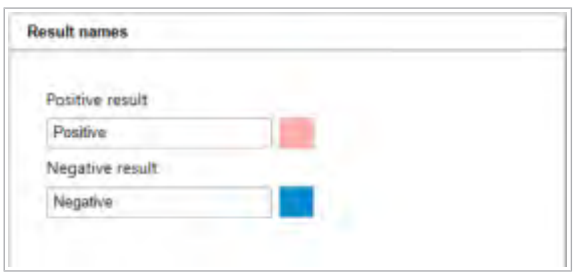
Show quantitative result check box

Enable or disable the calculation and display of the concentrations (final quantitative results).

If the check box is cleared, all final results are only displayed qualitatively.

Default value = enabled

Result names card



Card to enter the names that are displayed for valid final qualitative results.

Default values:

- "Positive"
- "Negative"

Controls card

Card that lists the controls defined for the test and their settings.

You can edit and delete the pre-defined controls, and add new controls.

The controls that are defined here are automatically added to the diagnostic sample setup.

Controls table

Lists the controls that were defined in the analyses that are used to create the analysis package.

To add a control, choose the **New** button.

To delete a control, choose the **Delete** button.

ID field

Field to enter the name of a control. The entry is displayed as the sample ID in the diagnostic sample setup.

Lower limit field and Upper limit field

The fields define the valid range for a control.

The lower limit must be lower than the upper limit.

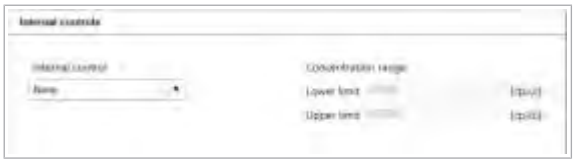
For negative controls, the lower limit is always 0 and cannot be changed.

Precision = 4 decimal places

Positive option and Negative option

Options to define the type of control.

Internal controls card



Card to configure the internal control.

Internal control drop-down list

Lists the targets that are available as internal controls.

The internal control that is defined here is automatically added to the diagnostic sample setup.

To exclude the use of an internal control, choose the **None** option.

Lower limit field and Upper limit field

The fields define the valid concentration range for the internal control.

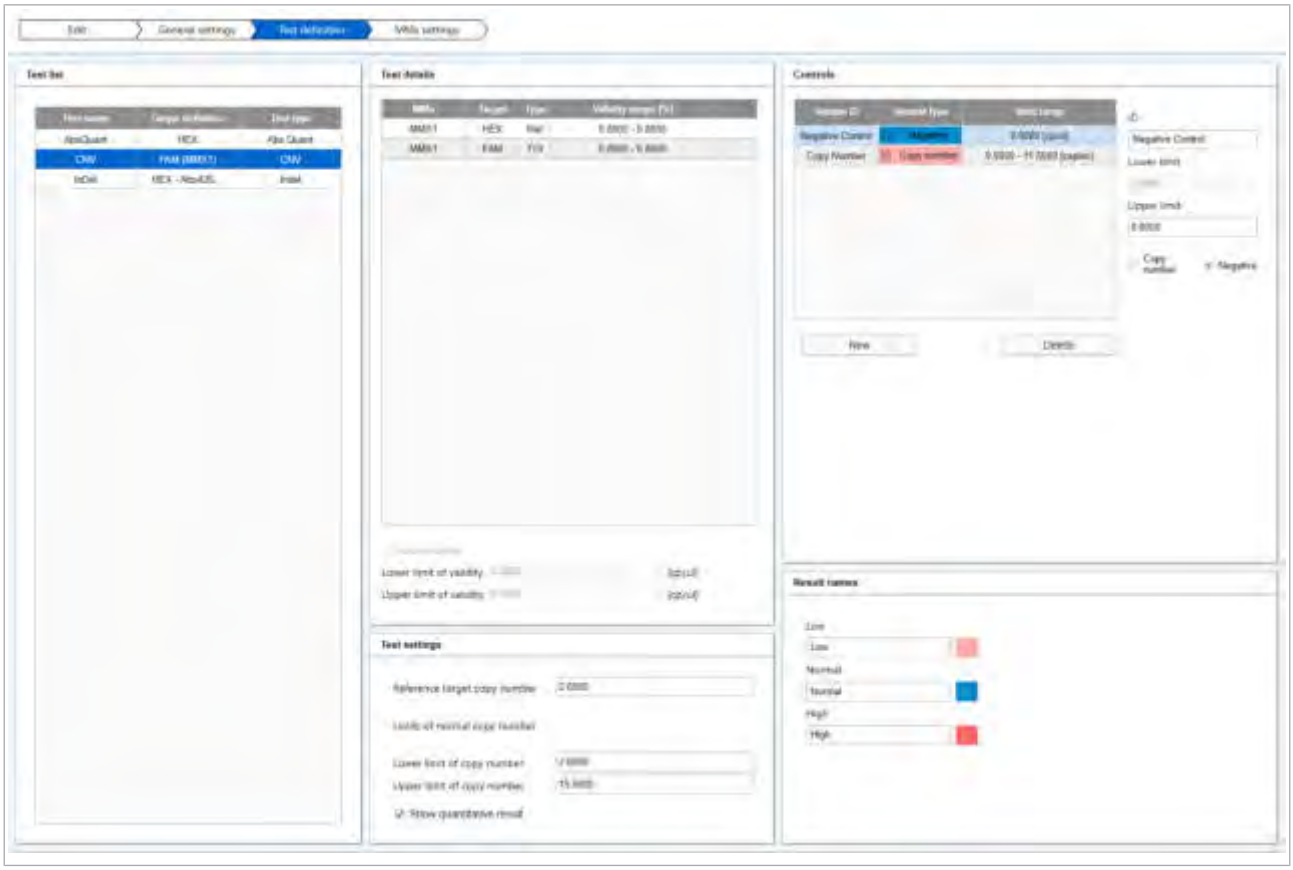
The lower limit must be lower than the upper limit.

Precision = 4 decimal places

Test definition panel for CNV tests

On the **Test definition** panel, you set the parameters that apply to the individual tests of the analysis package.

➔ **Navigation > Analysis package > ••• > Create analysis package > Test definition**



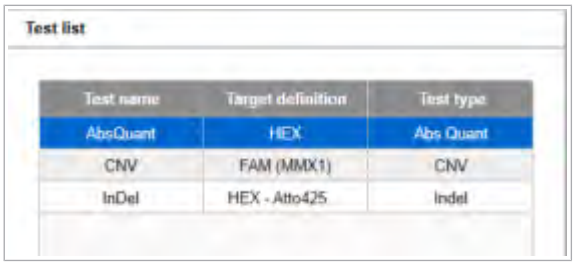
The required parameters depend on the test type (absolute quantification, CNV, indel).

The values are pre-entered from the analyses that are used to create the analysis package.

The **Test definition** panel comprises the following cards:

- **Test list**
- **Test details**
- **Test settings**
- **Controls**
- **Result names**

Test list card



Card that lists all tests of the analysis package, i.e., the tests that you chose on the **Edit** panel for the analysis package.

To display the other test-specific cards, choose a test from the table on the **Test list** card.

Test details card

Card that lists the defined reference targets and the target of interest and that allows you to enter limits of validity.

Limit of validity check box, Lower limit of validity field, and Upper limit of validity field

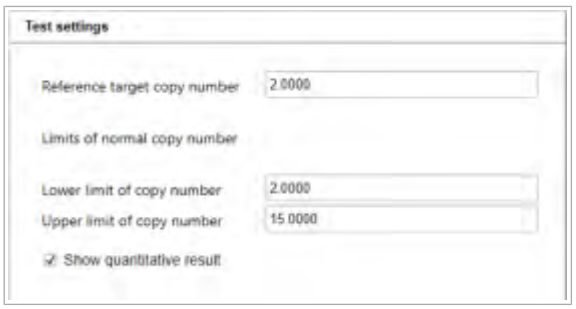
If the limit of validity is enabled, the measured concentration of the target molecules in the reference target and/or the target of interest must fall within the configured range.

If a concentration is outside the configured range, the corresponding final (qualitative) result is invalid.

The lower limit of validity must be lower than the upper limit of validity.

Precision = 4 decimal places

Test settings card



Card to enter the reference target copy number and the limits of normal copy number, and to configure the display of final quantitative results

Reference target copy number field

The expected copy number of the reference target.

The reference target copy number is used to normalize the ratio of the copy numbers of the reference target and the target of interest to allow for comparison with the configured range for normal copy number.

Precision = 4 decimal places

Lower limit of copy number field and Upper limit of copy number field for normal copy number

The expected normal range of the copy number of the target of interest.

The configured range sets the thresholds for the final (qualitative) results for the targets of interest:

- The final result is low if the calculated copy number is lower than the configured lower limit of copy number.
- The final result is normal if the calculated copy number lies within the configured range of copy number.
- The final result is high if the calculated copy number is higher than the configured upper limit of copy number.

Precision = 4 decimal places

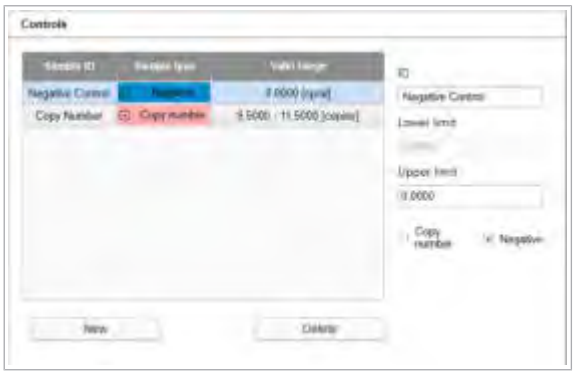
Show quantitative result check box

Enable or disable the calculation and display of the concentration of the target of interest (final quantitative results).

If the check box is cleared, all final results are only displayed qualitatively.

Default value = enabled

Controls card



Card that lists the controls defined for the test and their settings.

You can edit and delete the pre-defined controls, and add new controls.

The controls that are defined here are automatically added to the diagnostic sample setup.

Controls table

Lists the controls that were defined in the analyses that are used to create the analysis package.

To add a control, choose the **New** button.

To delete a control, choose the **Delete** button.

ID field

Field to enter the name of a control. The entry is displayed as the sample ID in the diagnostic sample setup.

Lower limit field and Upper limit field

The fields define the valid range for a control.

The lower limit must be lower than the upper limit.

For negative controls, the lower limit is always 0 and cannot be changed.

Precision = 4 decimal places

Copy number option and Negative option

Options to define the type of control.

Result names card

Card to enter the names that are displayed for valid final qualitative results.

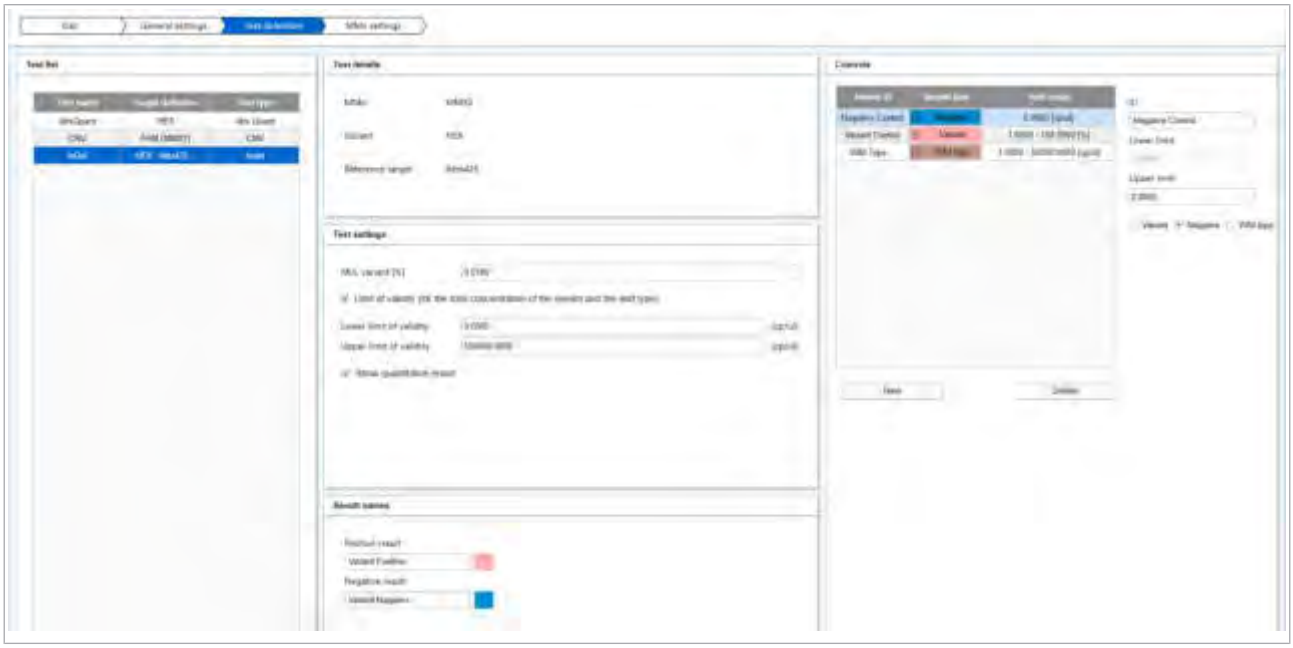
Default values:

- "Low"
- "Normal"
- "High"

Test definition panel for indel tests

On the **Test definition** panel, you set the parameters that apply to the individual tests of the analysis package.

➔ **Navigation > Analysis package > ••• > Create analysis package > Test definition**



The required parameters depend on the test type (absolute quantification, CNV, indel).

The values are pre-entered from the analyses that are used to create the analysis package.

The **Test definition** panel comprises the following cards:

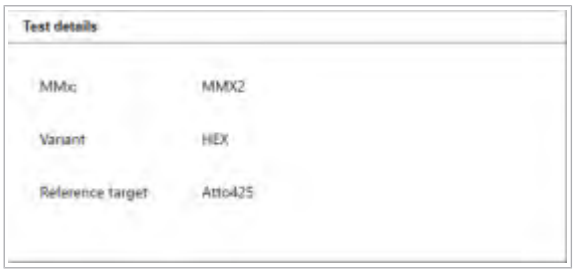
- **Test list**
- **Test details**
- **Test settings**
- **Result names**
- **Controls**

Test list card

Card that lists all tests of the analysis package, i.e., the tests that you chose on the **Edit** panel for the analysis package.

To display the other test-specific cards, choose a test from the table on the **Test list** card.

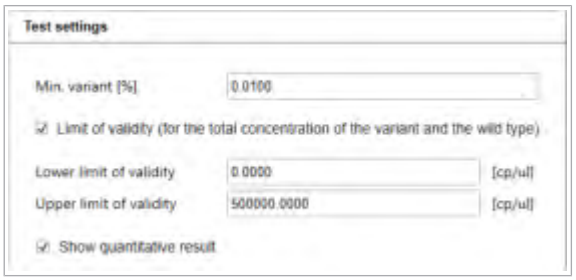
Test details card



Card that lists the name of the master mix reagent, the name of the variant target, and the name of the reference target.

The **Test details** card is read-only.

Test settings card



Card to enter the minimum percentage of the variant sequence, the limits of validity, and to configure the display of final quantitative results.

Min. variant [%] field

Defines the minimum percentage of the variant sequence that must be present in the sample for it to be variant positive.

Precision = 4 decimal places

Limit of validity (for the total concentration of the variant and the wild type) check box, Lower limit of validity field, and Upper limit of validity field

If the limit of validity is enabled, the sum of the measured concentrations of the variant sequence and the wild-type sequence must fall within the configured range.

If the concentration is outside the configured range, the corresponding final (qualitative) result is invalid.

The lower limit of validity must be lower than the upper limit of validity.

Precision = 4 decimal places

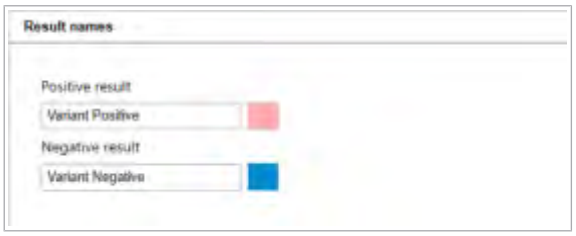
Show quantitative result check box

Enable or disable the calculation and display of the percentage of the variant sequence (final quantitative results).

If the check box is cleared, all final results are only displayed qualitatively.

Default value = enabled

Result names card



Card to enter the names that are displayed for valid final qualitative results.

Default values:

- "Variant Positive"
- "Variant Negative"

Controls card

Card that lists the controls defined for the test and their settings.

You can edit and delete the pre-defined controls, and add new controls.

The controls that are defined here are automatically added to the diagnostic sample setup.

Controls table

Lists the controls that were defined in the analyses that are used to create the analysis package.

To add a control, choose the **New** button.

To delete a control, choose the **Delete** button.

ID field

Field to enter the name of a control. The entry is displayed as the sample ID in the diagnostic sample setup.

Lower limit field and Upper limit field

The fields define the valid range for a control.

The lower limit must be lower than the upper limit.

For negative controls, the lower limit is always 0 and cannot be changed.

Precision = 4 decimal places

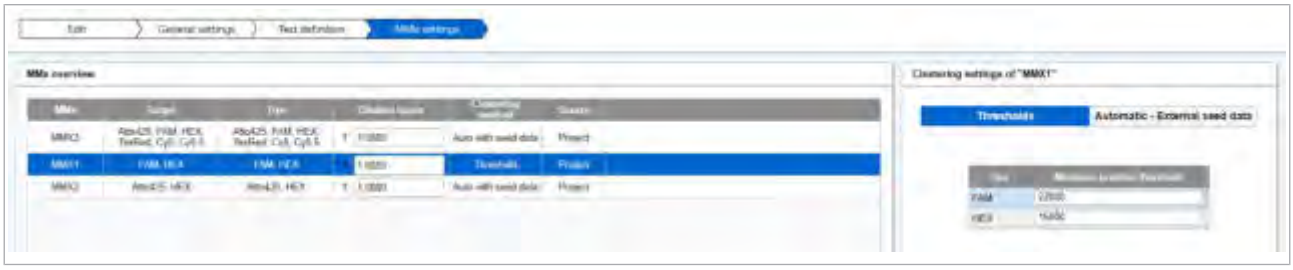
Variant option, Negative option, and Wild type option

Options to define the type of control.

MMx settings panel

On the **MMx settings** panel, you set the dilution factors and the clustering settings for each test.

➔ **Navigation > Analysis package > ••• > Create analysis package > MMx settings**



The **MMx settings** panel comprises the following cards:

- **MMx overview**
- **Clustering settings of "{0}"**

MMx overview card

Card that lists the settings for the master mix reagents for each test of the analysis package.

Dilution factor column

For each test, enter the dilution factor.

Default value = 1.0000

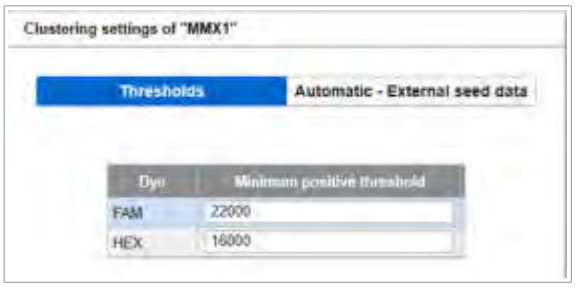
Precision = 4 decimal places

Example:
A dilution factor of 2 (i.e., a dilution of 1:2) means half of the reaction mixture consists of sample.

By default (dilution of 1:1), the development software calculates the quantitative results in relation to the volume of the reaction mixture.

If you enter a dilution factor, the development software automatically uses it as a multiplication factor to calculate the quantitative results in relation to the sample volume.

Card for clustering settings of master mix reagent



The **Clustering settings of "{0}"** card lists the clustering settings for the master mix reagent of the analysis package that is selected on the **MMx overview** card.

The placeholder {0} is replaced with the name of the master mix reagent, e.g., Clustering settings of "MMX1".

By default, the clustering settings are taken over from the clustering tabs for the analyses that are used to create the analysis package, as indicated by the **Project** entry in the **Source** column of the **MMx overview** card:

- A manual clustering method of the project is taken over as the **Thresholds** clustering method for the analysis package.
  Exception: If the clustering was determined via the **Lasso** button or the **Spider** button in a 2D scatter plot, you must enter the threshold values manually or import a seed data file. A manual clustering via the **Lasso** button or the **Spider** button cannot be used in the clustering settings of an analysis package.
- Any automatic clustering method is taken over as the **Automatic – External seed data** clustering method for the analysis package.

When you change the clustering settings, this is indicated by the **Manual** entry in the **Source** column of the **MMx overview** card.

You cannot reset the clustering settings to the values that were initially taken over from the project.

When you make any changes on the card for the clustering settings, the clustering settings taken over from the project are lost.

Thresholds button and Minimum positive threshold fields

If you want to enter thresholds values manually for each dye, choose the **Thresholds** button. In the **Minimum positive threshold** fields, enter the threshold values.

Automatic – External seed data button and Import seed data button

If you want to use an external seed data file as source for the clustering, choose the **Automatic – External seed data** button.

Ensure that you use a seed data file that is compatible with the master mix reagent.

Working with analysis packages

You can create, update, export, and delete analysis packages, and create analysis package reports.

An analysis package has a *.dpcrAp* file extension.

When creating an analysis package, you must follow the order of the breadcrumb (**Edit > General settings > Test definition > MMx settings**) that is displayed above the cards.

If there are changes on an analysis package tab and you must update the version, an * is added to the tab entry in the **Navigation** area.

Do not change previous steps in the project while you create or update an analysis package. For example, do not change the clustering settings for tests included in the analysis package. Such changes will not be taken over into the analysis package automatically.
Instead, complete the analysis package first. Then apply the changes in the project and update the analysis package accordingly.

You can export your own analysis package from the development software and then import it in the analyzer software for LDT runs.

Manage analysis packages (579)

☐ Previous steps of the development workflow completed

To create an analysis package

1 In the development software, open a project as described in Working with projects in the development software (295).

2 In the **Navigation** area, choose **Analysis package > ••• > Create analysis package**.
➔ The **Create analysis package** dialog box is displayed.

3 In the **Create analysis package** dialog box, do the following:

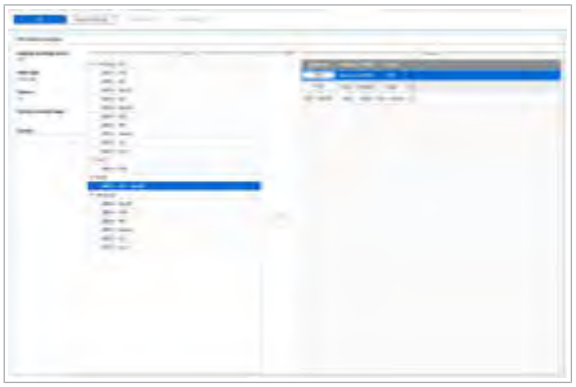
- In the **Analysis package name** field, enter a name for the analysis package.
- From the **Plate type** drop-down list, choose the nanowell plate type.
- Choose the **Confirm** button.

ⓘ Ensure that you choose the correct plate type. You cannot change the plate type later.

➔ The analysis package is created.

➔ The tab of the analysis package is displayed in the work area.

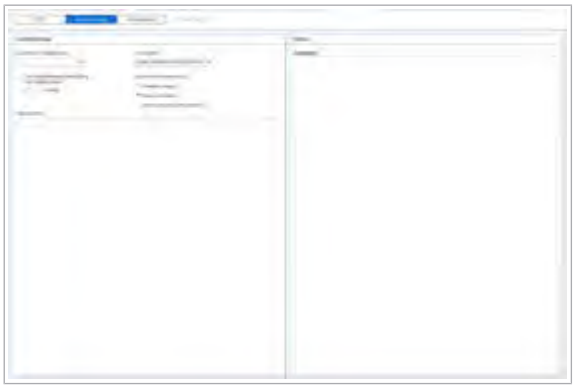
➔ In the **Navigation** area, the analysis package is listed in the **Analysis package** menu with version number "(V0.0)".



4 On the **Edit analysis package** card on the analysis package tab, do the following:

- Optionally, in the **Creator** field, enter the name of the issuer of the analysis package.
- To add a test to the analysis package, choose a combination of analysis type, master mix reagent, and target from the **Select** table. Choose the **Copy** button.
- To remove a test from the analysis package, choose the test from the **Manage** table. Choose the ⊗ button.
- Optionally, in the **Test name** field, enter a name for the test.

5 In the breadcrumb, choose the **General settings** button.



6 On the **General settings** card, do the following:

- Optionally, from the **Number of merged lanes** drop-down list, choose the number of nanowell plate lanes to be merged in the sample setup (1 = no merged nanowell plate lanes).
- Optionally, to set a maximum duration between partitioning of the nanowell plates and the start of the diagnostic run, select the **Time limit between plate filling and starting a run** check box. Enter the duration value in the **minutes** field.
- From the **Run profile** drop-down list, choose the run profile to be used (all run profiles from runs of the project are listed).
- Choose a **Result export restrictions** option.
- Optionally, in the **Report label** field, enter a label text for the analysis package report.

7 Optionally, on the **History** card, enter a comment.

ⓘ Enter a change description on the **History** card whenever you create a new version of an analysis package.

8 In the breadcrumb, choose the **Test definition** button.

9 On the **Test list** card, choose a test.

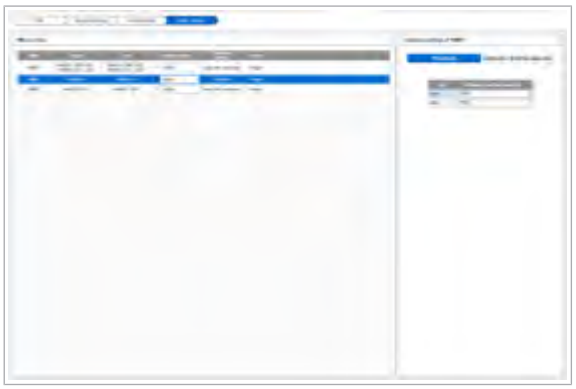
➔ The cards for the test details and settings are displayed.

10 Check, enter, and/or edit the information in the following cards (if applicable):

- **Test details**
- **Test settings**
- **Controls**
- **Internal controls**
- **Result names**

11 Repeat steps **9** to **10** for all tests listed on the **Test list** card.

12 In the breadcrumb, choose the **MMx settings** button.



13 On the **MMx overview** card, choose a master mix reagent. Optionally, change the dilution factor.

➔ The card for the clustering settings is displayed.

➔ The clustering settings are taken over from the project.

14 Optionally, on the **Clustering settings of "{0}"** card, edit the clustering method and/or the clustering settings:

- To cluster with a threshold value > 0, choose the **Thresholds** button. For each dye, enter the minimum positive threshold value.
- To cluster with seed data, choose the **Automatic - External seed data** button. Choose the **Import seed data** button. Navigate to the SDXML file and choose the **Open** button.

ⓘ This step is required if the clustering in the project was determined via the **Lasso** button or the **Spider** button and therefore cannot be used in the clustering settings.

15 In the **Navigation** area, choose the analysis package from the **Analysis package** menu. Choose ••• **> Update version**.

16 In the **Increment version number** dialog box, do one of the following:

- To update the version number to "1.0", choose the **Major** button.
- To update the version number to "0.1", choose the **Minor** button.
- Choose the **Update** button.

ⓘ You cannot save changes to an analysis package without updating the version.

➔ The version of the analysis package is updated in the **Analysis package** menu.

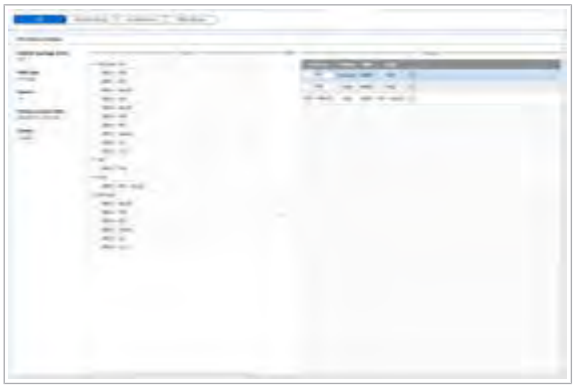
17 Save the project.

To update an analysis package

1 In the development software, open the project as described in To open a project in the development software (296).

2 In the **Navigation** area, choose the analysis package from the **Analysis package** menu.

➔ The tab of the analysis package is displayed in the work area.



3 To navigate in the analysis package, choose the buttons in the breadcrumb.

4 Enter the changes in the analysis package settings as described in To create an analysis package (429).

ⓘ An * is added to the tab entry in the **Navigation** area, indicating that there are changes.

5 Enter a change description in **General settings > History**.

6 Optionally, to discard all changes, in the **Navigation** area, choose the analysis package from the **Analysis package** menu. Choose ••• **> Discard changes**.

➔ All entered changes are deleted from the analysis package again.

7 To save the changes, in the **Navigation** area, choose the analysis package from the **Analysis package** menu. Choose ••• **> Update version**.

ⓘ You can only update the version if you entered at least 1 change.

8 In the **Increment version number** dialog box, do on of the following:

- For a major update, e.g., to "2.0", choose the **Major** button.
- For a minor update, e.g., to "1.1", choose the **Minor** button.
- Choose the **Update** button.

ⓘ You cannot go back to an earlier version of an analysis package.

➔ The version of the analysis package is updated in the **Analysis package** menu.

9 Save the project.

To create an analysis package report

1 In the development software, open the project as described in To open a project in the development software (296).

2 In the **Navigation** area, choose the analysis package from the **Analysis package** menu. Choose ••• > **Generate report**.

3 Navigate to a folder. Enter a name for the report and choose the **Save** button.

➔ The analysis package report is saved as PDF file.

To export an analysis package from the development software

1 In the development software, open the project as described in To open a project in the development software (296).

2 In the **Navigation** area, choose the analysis package from the **Analysis package** menu. Choose ••• > **Export**.

3 Navigate to a network folder that is accessible from the analyzer. Enter a name for the analysis package and choose the **Save** button.

➔ The analysis package is exported as *dpcrAp* file.

To delete an analysis package

1 In the development software, open the project as described in To open a project in the development software (296).

2 In the **Navigation** area, choose the analysis package from the **Analysis package** menu. Choose ••• > **Remove**.

3 In the **Warning** dialog box, choose the **Confirm** button.

ⓘ You cannot restore a deleted analysis package.

➔ The analysis package is deleted.

Related topics

- Projects in the development software (294)
- Runs in the development software (309)
- Clustering in the development software (338)

- Analyses in the development software (358)
- Unassigned sample setups in the development software (402)

After routine operation

In this chapter 15

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Shutting down the partitioning engine

Shut down the partitioning engine if you do not work with it for any length of time, e.g., over night.

For routine shutdown of the partitioning engine, do not simply press the power switch. Instead, follow the shutdown procedure and only press the power switch when prompted to do so.

Only press the power switch outside of the shutdown procedure if immediate shutdown is required, e.g., in case of system failure or emergency shutdown.

Restarting an unresponsive partitioning engine (506)

Always unload the partitioning engine before you shut it down.

Partitioning the nanowell plates (221)

- ☐ Partitioning engine unloaded
- ☐ Nanowell plate drawer closed
- ☐ Partitioning engine in **Ready** status

To shut down the partitioning engine

1 In the global information area, choose ≡ **> Shut Down Instrument**.

2 Wait until the shutdown is complete and the ⏻ icon is displayed on the screen.

3 At the back of the partitioning engine, press the power switch.

Logging off from the web application

Log off from the web application after use.

Save all changes before logoff.

If you close the browser window or browser tab directly, you lose all unsaved changes.

If configured in the password settings, the current user is logged off automatically after the inactivity time has elapsed.

Password settings (599)

To log off from the web application

1 In the global information area, choose the logon indicator.
   ➔ The **Logoff** dialog box is displayed.

2 Choose the **Yes** button.
   ➔ If there are unsaved changes, the **Unsaved changes** dialog box is displayed.

3 Optionally, to log off and discard all unsaved changes, choose the **Yes** button.
   ➔ You are logged off from the web application.
   ➔ The **Logon** dialog box is displayed.

Logging off from the analyzer software

Log off from the analyzer software if you leave the analyzer unattended for any length of time.

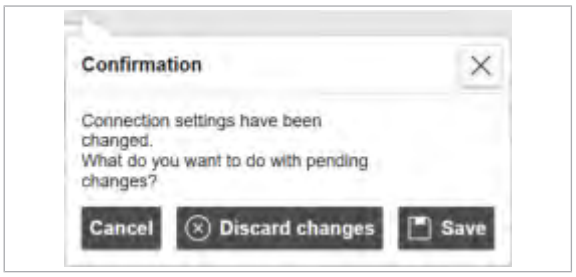
If configured in the password settings, the current user is logged off automatically after the inactivity time has elapsed.

Password settings (599)

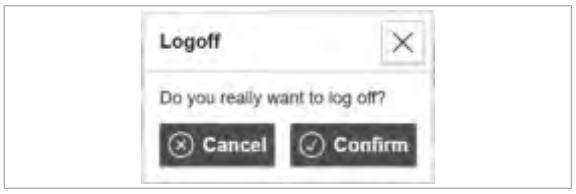
☐ Logged on to the analyzer software

To log off from the analyzer software

1 In the global information area, choose the **Logoff** button.



2 Optionally, if there are pending changes, in the **Confirmation** dialog box, do one of the following:
- To abort the logoff and return to the analyzer software, choose the **Cancel** button.
- To discard the changes and continue with the logoff, choose the **Discard changes** button.
- To save the changes and continue with the logoff, choose the **Save** button.



3 To log off, in the **Logoff** dialog box, choose the **Confirm** button.

➔ You are logged off from the analyzer software.

Shutting down the analyzer

Shut down the analyzer if you do not work with it for any length of time, e.g., over night.

The ⏻ button to shut down the analyzer is only available in the analyzer software if the nanowell plate stack drawer is closed and the analyzer is in **Analyzer not initialized** status, **Analyzer ready** status, or **Analyzer paused** status.

For routine shutdown of the analyzer, do not simply press the power button. Instead, follow the shutdown procedure and only press the power button after the touch screen turns dark.

Only press the power button outside of the shutdown procedure if immediate shutdown is required, e.g., in case of system failure or emergency failure.

Restarting an unresponsive analyzer (519)

Unload the analyzer before you shut it down.

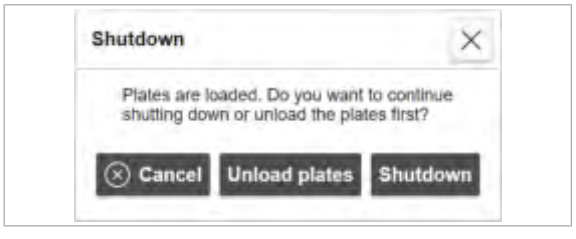
Unloading the analyzer (227)

3 minutes

- ☐ Nanowell plate stack drawer closed
- ☐ Analyzer in **Analyzer not initialized** status, **Analyzer ready** status, or **Analyzer paused** status

To shut down the analyzer

1 In the global information area, choose the ⏻ button.
➔ The **Shutdown** dialog box is displayed.



2 To unload the analyzer if there are still nanowell plates loaded, do the following:
- To open the nanowell plate stack drawer, choose the **Unload plates** button.
- Unload the nanowell plates as described in Unloading the analyzer (227).
- To close the nanowell plate stack drawer, in the global information area, choose the ⏏ button.
- In the global information area, choose the ⏻ button again.

3 To shut down the analyzer, in the **Shutdown** dialog box, choose the **Confirm** button.

4 Wait until the touch screen turns dark.

5 On the right side of the analyzer, press the power button.

Closing the development software

Close the development software after use.

Save all changes before closing.

To close the development software

1 To close the development software, do one of the following:

- In the **Navigation** area, choose **File** > ••• > **Close**.
- In the top right corner of the software window, choose the ✕ button.

➔ The **Close** dialog box is displayed.

2 Do one of the following:

- To close the development software without saving the current project, choose the **Exit** button. (All unsaved changes to the project are lost.)
- To save the current project and then to close the development software, choose the **Save and exit** button.

➔ The development software is closed.

Non-routine operation

In this chapter 16

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Non-routine operation in the web application

Deleting sample setups in the web application

You can delete sample setups in the web application before the run is started on the analyzer.

In the web application, the batch tiles of not yet processed sample setups are displayed in the **Sample setups** column on the dashboard. The batch tiles are in **Incomplete setup** status, **Pending partitioning** status, **Ready to start run** status, or **Ready to start run (loaded)** status.

When you delete a sample setup, the orders are not allocated again and are displayed again on the **Orders** screen in assignment mode. To process the orders, you must create a new sample setup.

Creating sample setups in the web application (255)

- ☐ Not yet processed sample setup in the web application

- ☐ Diagnostic operator user role

To delete a sample setup

1. In the web application, in the **Sample setups** column on the dashboard, choose a batch tile.
   ➔ The **Sample setup** screen is displayed.
2. To delete the sample setup, choose the **Delete** button.
   ➔ The **Delete sample setup** dialog box is displayed.

3 Choose the **Confirm** button.
   ➔ The sample setup is deleted.
   ➔ The corresponding batch tile is deleted from the dashboard.
   ➔ The orders of the deleted sample setup are not allocated again and are displayed again on the **Orders** screen in assignment mode.

Non-routine operation in the analyzer software

In this section

Managing screenshots in the analyzer software

On the **Manage screenshots** panel in the analyzer software, you view, export, and delete the screenshots that were taken of the analyzer software.

The **Manage screenshots** panel lists all screenshots taken by any user, not only the screenshots taken by the currently logged on user.

You can export the screenshots to a network share or external storage device.

You can access the **Manage screenshots** panel with any user role.

About screenshooting

To take a screenshot of the currently displayed panel of the analyzer software or of a message callout, choose the button.

The screenshots are saved automatically on the analyzer and listed on the **Manage screenshots** panel.

By default, the screenshots are saved as PNG files and are named:
SRC_YYYY_MM_DD_hhmmss.png
with the date and the time the screenshot was created.

About the global information area of the analyzer software (106)

List of naming placeholders (154)

- ☐ Optionally, external storage device, e.g., USB flash drive

To export screenshots

1 Optionally, to export to an external storage device, connect the external storage device to the analyzer.

2 In the analyzer software, choose **Administration > Manage screenshots**.
   ➔ The **Manage screenshots** panel is displayed.
   ➔ The table lists all screenshots that are currently stored on the analyzer.

3 Optionally, sort, search, or filter the table.

4 To display a preview of a screenshot, choose the screenshot.
   ⓘ If you choose several screenshots, the preview of the last chosen screenshot is displayed.

5 From the table, choose the screenshot.
   ⓘ You can export several screenshots at once.

6 Choose the **Export** button.
   ➔ The **Export** dialog box is displayed.

7 To change the export path, choose the ··· button.

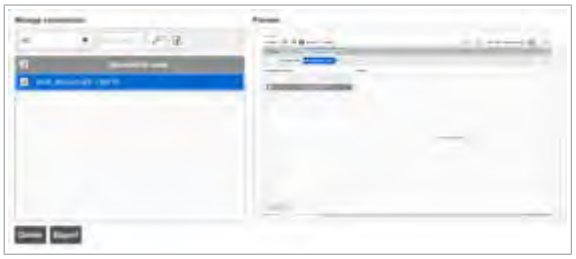
8 In the folder browser, navigate to a folder.

9 Choose the **Confirm** button.

10 In the **Export** dialog box, choose the **Export** button.
   ➔ The screenshots are exported to the folder.

11 Optionally, disconnect the external storage device.

To delete screenshots



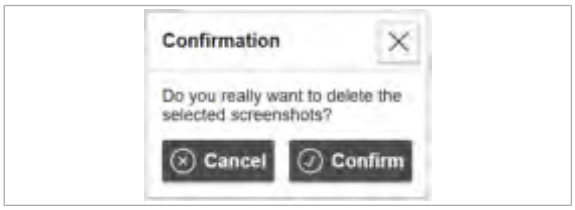
1 In the analyzer software, choose **Administration > Manage screenshots**.
   ➔ The **Manage screenshots** panel is displayed.
   ➔ The table lists all screenshots that are currently stored on the analyzer.

2 Optionally, sort, search, or filter the table.

3 To display a preview of a screenshot, choose the screenshot.
   ⓘ If you choose several screenshots, the preview of the last chosen screenshot is displayed.

4 From the table, choose the screenshot.
   ⓘ You can delete several screenshots at once.

5 Choose the **Delete** button.
   ➔ The **Confirmation** dialog box is displayed.



6 Choose the **Confirm** button.
➔ The screenshots are deleted from the analyzer.

Audit trails in the analyzer software

System and user actions are logged as audit trails.

About the message indicator (108)

About the messages panel (121)

In this section

About audit trails in the analyzer software

The system logs system and user actions as audit trails with user information and time stamp.

The system displays and handles audit trails as information messages on the messages panel.

About audit trails reports

An audit trails report contains all audit trails currently stored on the analyzer. Creating an audit trails report does not change any data on the analyzer.

Audit trails reports are saved as CSV files.

Audit trails reports are named:
Audit Trail_SN_YYYYMMDD-hhmmss.csv
with the date and time the audit trails report was created.

You can only save audit trails reports in a network share or on an external storage device. You cannot save an audit trails report on the analyzer.

List of naming placeholders (154)

About archiving of audit trails

Archiving includes the audit trails that are older than the number of days configured for archiving. The compressed archive file contains a CSV file of the archived audit trails (*AuditTrails.csv*).

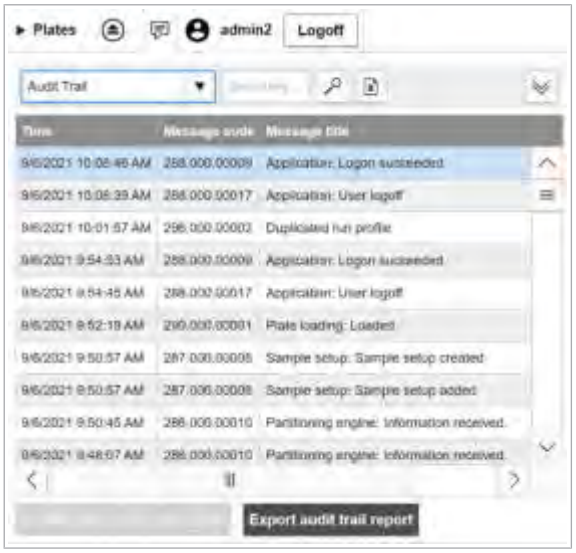
After archiving is completed successfully, the archived audit trails are deleted from the analyzer.

Creating audit trails reports in the analyzer software

You can create audit trails reports from the audit trails.

- ☐ Optionally, external storage device, e.g., USB flash drive
- ☐ Enough memory in the network share or on the external storage device

To create an audit trails report in the analyzer software



1. Optionally, to save to an external storage device, connect the external storage device to the analyzer.
2. To display the messages panel, in the global information area of the analyzer software, choose the message indicator.
3. Optionally, to display the audit trail entries only, from the filter drop-down list, choose the **Audit trail** option.
4. Optionally, sort, search, or filter the table.
5. Choose the **Export audit trail report** button.
   ➔ The **Select folder** dialog box is displayed.
6. In the folder browser, navigate to a folder.
7. Choose the **Confirm** button.
   ➔ The audit trails report is saved in the folder.
8. Optionally, disconnect the external storage device.

Aborting a run on the analyzer

You can abort the run on the analyzer.

All results from an aborted run are invalid.

- ☐ Run processing on the analyzer
- ☐ **Monitoring** panel displayed in the analyzer software
- ☐ Diagnostic operator user role or development operator user role

To abort a run on the analyzer

1. On the **Monitoring** panel in the analyzer software, choose the **Abort run** button.
   ➔ The **Confirmation** dialog box is displayed.
2. Choose the **Confirm** button.
   ➔ The run is aborted.
   ➔ All results are invalid.
3. Wait until **Awaiting plate removal** is displayed on the **Monitoring** panel.
4. Unload the analyzer as described in Unloading the analyzer (227).

Restarting the analyzer

After some configuration tasks, you must restart the analyzer for the changes to take effect.

The following configuration tasks require a restart of the analyzer:

- Entering or changing the external IP address
- Importing a new version of the currently active language package
- Changing the system language

Unload the analyzer before you restart it.

Unloading the analyzer (227)

- ☐ Nanowell plate stack drawer closed
- ☐ Analyzer in **Analyzer not initialized** status, **Analyzer ready** status, or **Analyzer paused** status

To restart the analyzer

1. Shut down the analyzer as described in Shutting down the analyzer (440).
2. Wait a few seconds.
3. Start up the analyzer as described in Starting up the analyzer (235).

Displaying system information

You can access the system information in the partitioning engine software, the analyzer software, and the development software.

☐ To download the license information from the partitioning engine:
External storage device, e.g., USB flash drive

To display the system information in the partitioning engine software

1 In the partitioning engine software, in the global information area, choose ≡ > **Information**.
   ➔ The **Information** panel is displayed.
   ➔ The **Information** panel lists the software version, system version, serial number, and network address.

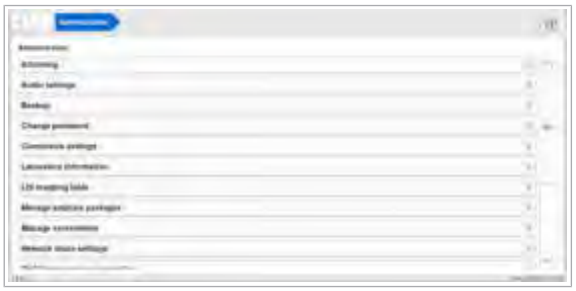
2 To close the **Information** panel, choose the **Close** button.

3 To download the license information, do the following:
   - Connect the external storage device to the partitioning engine.
   - Choose the **Copy Licence** button.
   - Wait until the download is completed.
   - Disconnect the external storage device.

To display the system information in the analyzer software

1 In the analyzer software, choose the **Administration** tab.
   ➔ The **Administration** panel is displayed.

2 If required, choose the **Administration** element of the breadcrumb.



3 In the top right corner, choose the ⓘ button.
➔ The **About** dialog box is displayed.
➔ The **About** tab displays general information about the analyzer and the analyzer software.

4 To display application information about the analyzer software, choose the **Application** tab.

5 To display license information, choose the **Legal notice** tab.

6 To display information about the intended use, choose the **Intended use** tab.

7 To close the **About** dialog box, choose the ✕ button.

To display system information in the development software

1 In the development software, in the **Navigation** area, choose **File** > ••• > **Help** > **About**.
➔ The **About** dialog box is displayed.
➔ The **About** tab displays general information about the development software.

2 To display application information about the development software, choose the **Application** tab.

3 To display license information, choose the **Legal notice** tab.

4 To display information about the intended use, choose the **Intended use** tab.

5 To close the **About** dialog box, choose the **Close** button.

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Maintenance

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Maintenance

In this chapter 17

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Maintenance schedule

The table lists all maintenance actions and their schedule.

Maintenance action	Frequency	Procedure
Replacing the partitioning fluid bottle and/or the liquid waste bottle.	When the partitioning fluid bottle is empty or expired, or the waste bottle is full.	Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460)
Cleaning up not allocated orders.	On demand or before performing manual archiving.	Cleaning up not allocated orders (466)
Performing manual archiving.	When automatic archiving is not configured (or fails), or if disk space is low.	Performing manual archiving (467)
Performing manual backup.	When automatic backup is not configured (or fails).	Performing a manual backup (469)
Cleaning the outside of the partitioning engine.	Weekly.	Cleaning the outside of the partitioning engine (473)
Cleaning the nanowell plate drawer of the partitioning engine.	Monthly	Cleaning the nanowell plate drawer of the partitioning engine (474)
Cleaning the outside of the analyzer.	Weekly.	Cleaning the outside of the analyzer (476)
Cleaning the nanowell plate stack drawer of the analyzer.	Half-yearly	Cleaning the nanowell plate stack drawer of the analyzer (477)
Decontaminating the nanowell plate drawer of the partitioning engine.	On demand if the nanowell plate drawer may be contaminated.	Cleaning the nanowell plate drawer of the partitioning engine (474)
Decontaminating the nanowell plate stack drawer of the analyzer.	On demand if the nanowell plate stack drawer may be contaminated.	Cleaning the nanowell plate stack drawer of the analyzer (477)
Decontaminating the aspiration needle of the partitioning engine.	When a liquid waste bottle was loaded in the position of the partitioning fluid bottle.	Decontaminating the aspiration needle of the partitioning engine (479)
Preventive maintenance.	Yearly.	About preventive maintenance (482)

Maintenance schedule

Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine

When the partitioning fluid bottle is empty or expired, or when the liquid waste bottle is full, replace the partitioning fluid bottle and/or the liquid waste bottle.

⚠ CAUTION!

Sharp aspiration needle

The aspiration needle in the partitioning engine is sharp. Contact with the aspiration needle may result in personal injury.

- Carefully follow the instructions in this publication for replacing the bottles on the partitioning engine and for decontaminating the aspiration needle.
- When replacing the bottles on the partitioning engine or when decontaminating the aspiration needle, pay extra attention to the aspiration needle.

NOTICE!

Incorrect loading of the partitioning engine

The partitioning fluid bottles and the liquid waste bottles are indistinguishable by their overall appearance. Loading a bottle in the wrong position may contaminate the partitioning engine, and/or the partitioning fluid and the partitioning fluid bottle.

- Store partitioning fluid bottles and liquid waste bottles in a way to allow for proper distinction.
- Mark all waste bottles with a permanent marker as waste bottles. Mark empty or expired partitioning fluid bottles as waste bottles immediately after unloading them from the partitioning engine.
- Dispose of liquid waste bottles according to local regulations directly after unloading them from the partitioning engine.
- If you inadvertently loaded a bottle in the wrong position, immediately unload it again and dispose of it according to local regulations.
- Before loading a partitioning fluid bottle and using the partitioning engine again after incorrect loading, decontaminate the aspiration needle.
- If you suspect a contamination of the aspiration needle, decontaminate the aspiration needle before using the partitioning engine again.

If the partitioning fluid bottle is empty, always replace both the liquid waste bottle and the empty partitioning fluid bottle.

If the partitioning fluid is expired, consider the fill levels of the partitioning fluid bottle and the liquid waste bottle for the replacement of the liquid waste bottle.

If the liquid waste bottle is full, replace the liquid waste bottle.

Follow laboratory best practices and change your lab gloves following any handling of waste materials.

When the partitioning fluid bottle is empty or the liquid waste bottle is full, the corresponding fill status in the **Liquids** panel of the partitioning engine software turns red. Additionally, a message is displayed in the global information area.

About the global information area of the partitioning engine software (83)

About the Liquids panel (87)

- If the partitioning fluid bottle is empty or expired
- If the liquid waste bottle is full

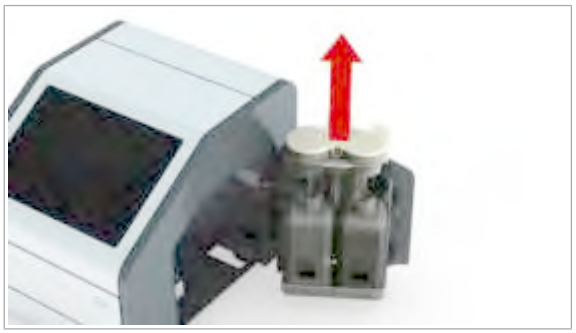
5 minutes per bottle

- ☐ New partitioning fluid bottle
- ☐ Liquid waste bottle
- ☐ Screw caps

- ☐ Replacement indicated in user interface

To replace the partitioning fluid bottle and the liquid waste bottle

1 To open the fluids door on the right side of the partitioning engine, do the following:
   - Push the front edge inside until the fluids door disengages.
   - Open the fluids door completely.



2 Lift the aspiration and dispensing arm completely until the aspiration needle is clear of the bottle opening and the aspiration and dispensing arm locks into place in the upper position.

3 Unload the liquid waste bottle. Close the liquid waste bottle with a screw cap. Dispose of the full liquid waste bottle according to local regulations.

ⓘ Do not empty and reuse the liquid waste bottle. Use empty or expired partitioning fluid bottles as liquid waste bottles instead.

4 Unload the partitioning fluid bottle. Mark it as waste bottle using a permanent marker. Load it as liquid waste bottle in the fluids door with the label facing to the front.

5 Unscrew the screw cap of the new partitioning fluid bottle. Keep the screw cap for later use.

6 CAUTION! Risk of contamination.
Ensure that you do not load a liquid waste bottle in the position of the partitioning fluid bottle.

Load the partitioning fluid bottle in the fluids door with the label facing to the front.

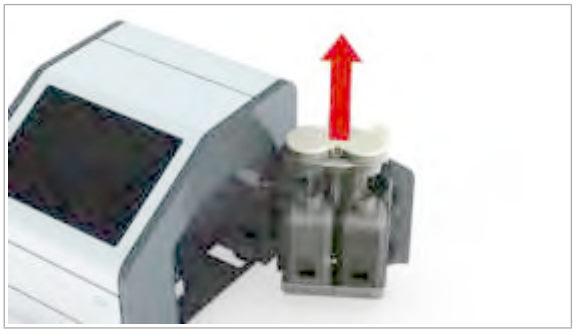
7 Lower the aspiration and dispensing arm completely.

8 Close the fluids door until it engages with an audible click.

9 Prime the partitioning engine on demand as described in Priming the partitioning engine (232):
- In the global information area of the partitioning engine software, choose ≡ > **Prime Instrument**.
- Wait until priming is complete.

To replace the partitioning fluid bottle

1 To open the fluids door on the right side of the partitioning engine, do the following:
- Push the front edge inside until the fluids door disengages.
- Open the fluids door completely.



2 Lift the aspiration and dispensing arm completely until the aspiration needle is clear of the bottle opening and the aspiration and dispensing arm locks into place in the upper position.

3 Unload the partitioning fluid bottle. Close the bottle with a screw cap.

ⓘ Depending on fill level, keep the partitioning fluid bottle as liquid waste bottle.

4 If you keep the unloaded partitioning fluid bottle as a waste bottle, immediately mark it as waste bottle using a permanent marker. Store partitioning fluid bottles and waste bottles in a way to allow for proper distinction.

5 Unscrew the screw cap of the new partitioning fluid bottle. Keep the screw cap for later use.

6 CAUTION! Risk of contamination.
Ensure that you do not load a liquid waste bottle in the position of the partitioning fluid bottle.

Load the partitioning fluid bottle in the fluids door with the label facing to the front.

7 Lower the aspiration and dispensing arm completely.

8 Close the fluids door until it engages with an audible click.

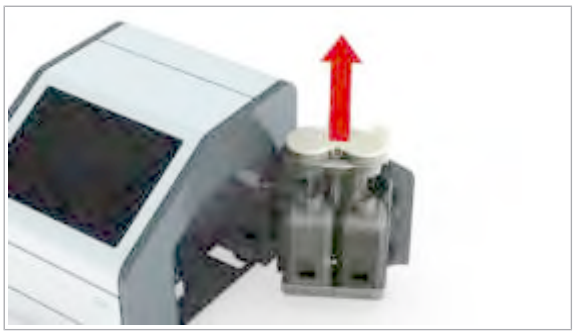
9 Prime the partitioning engine on demand as described in Priming the partitioning engine (232):

- In the global information area of the partitioning engine software, choose ≡ > **Prime Instrument**.
- Wait until priming is complete.

To replace the liquid waste bottle

1 To open the fluids door on the right side of the partitioning engine, do the following:

- Push the front edge inside until the fluids door disengages.
- Open the fluids door completely.



2 Lift the aspiration and dispensing arm completely until the aspiration needle is clear of the bottle opening and the aspiration and dispensing arm locks into place in the upper position.

3 Unload the liquid waste bottle. Close the liquid waste bottle with a screw cap. Dispose of the full liquid waste bottle according to local regulations.

ⓘ Do not empty and reuse the liquid waste bottle. Use empty or expired partitioning fluid bottles as liquid waste bottles instead.

4 Unscrew the screw cap of a liquid waste bottle. Keep the screw cap for later use.

5 Load a liquid waste bottle in the fluids door with the label facing to the front.

6 Lower the aspiration and dispensing arm completely.

7 Close the fluids door until it engages with an audible click.

8 Prime the partitioning engine on demand as described in Priming the partitioning engine (232):

- In the global information area of the partitioning engine software, choose ☰ > **Prime Instrument**.
- Wait until priming is complete.

Data maintenance on the analyzer

Data maintenance comprises the cleanup of not allocated orders, archiving, and backup.

Archiving and backup are maintenance actions that can be scheduled to be performed automatically at a predefined time.

If necessary, e.g., if automatic execution is not configured or fails, perform archiving and backup manually.

Scheduling automatic archiving (560)

Scheduling automatic backups (566)

In this section

Cleaning up not allocated orders

On the **Archiving** panel, to delete outdated orders from the system, clean up the not allocated orders.

For cleaning up not allocated orders, the **Archive data older than (in days)** setting of automatic archiving also applies. For example, if you automatically archive data older than 30 days, only not allocated orders that are older than 30 days are deleted.

Clean up the not allocated orders regularly. Clean up the not allocated orders before manual archiving.

Performing manual archiving (467)

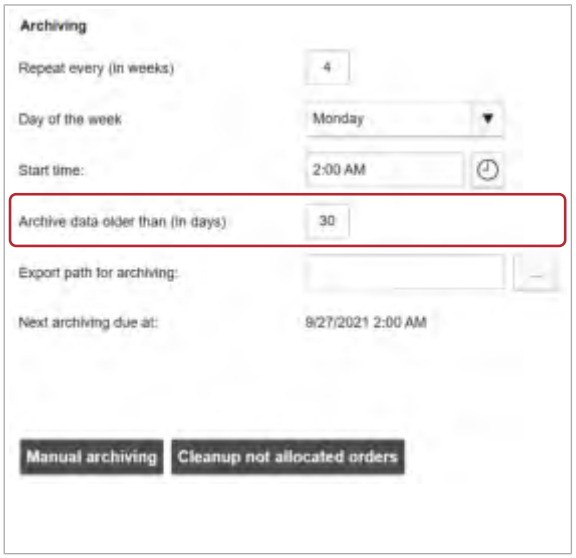
On demand

- ☐ Analyzer in **Analyzer ready** status
- ☐ Administrator user role

To clean up not allocated orders

1 In the analyzer software, choose **Administration > Archiving**.

➔ The **Archiving** panel is displayed.



2 Optionally, to change how far back not allocated orders are deleted, do the following:
- In the **Archive data older than (in days)** field, change the value.
- Choose the **Save** button.

ⓘ The time period also applies to automatic and manual archiving.

3 Choose the **Clean up not allocated orders** button.

➔ The **Clean up not allocated orders** dialog box is displayed.

4 Choose the **Confirm** button.

➔ All not allocated orders that are older than the value configured in the **Archive data older than (in days)** field are deleted from the system.

5 Optionally, if you changed the time period in step **2**, change it back:
- In the **Archive data older than (in days)** field, change the value.
- Choose the **Save** button.

Performing manual archiving

On the **Archiving** panel, to free up disk space on the analyzer on demand, perform manual archiving.

Reasons to perform manual archiving include the following:
- Automatic archiving is not configured.
- Automatic archiving fails.
- A message is displayed that disk space is low.

⚠ CAUTION!

Unprotected archive files

Insecure transfer or storage of archive files may allow for data manipulation, which may cause incorrect, invalid, or delayed results, and/or unauthorized access to personal information.

- Ensure that archive files are transferred securely, are stored in a secure location, and are protected from any unauthorized access and disaster.
- Ensure that any external storage devices (such as USB flash drives) that contain archive files are protected against unauthorized access.

For manual archiving, the **Archive data older than (in days)** setting of automatic archiving also applies. For example, if you automatically archive data older than 30 days, a manual archiving also includes only data that is older than 30 days.

As archiving can take a long time and you cannot work with the system during archiving, perform manual archiving at a time when the system is not needed.

To exclude not allocated orders from archiving, clean up the not allocated orders before manual archiving.

Cleaning up not allocated orders (466)

On demand

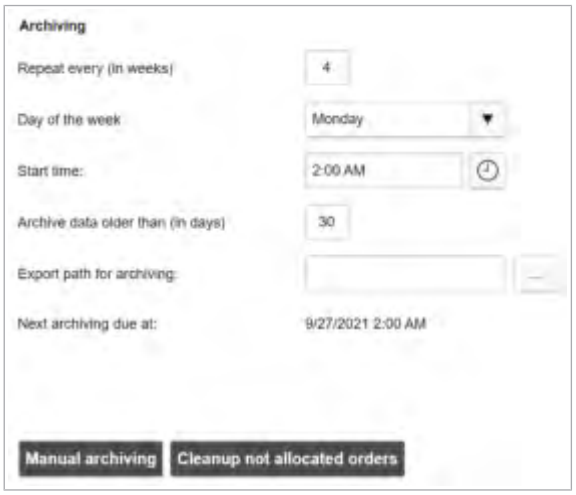
Depending on the amount of data, archiving may take a long time.

- ☐ Optionally, external storage device, e.g., USB flash drive

- ☐ Enough memory in the network share or on the external storage device
- ☐ Analyzer in **Analyzer ready** status
- ☐ Administrator user role

To perform manual archiving

1. Optionally, to archive to an external storage device, connect the external storage device to the analyzer.
2. In the analyzer software, choose **Administration > Archiving**.
   ➔ The **Archiving** panel is displayed.



3 Optionally, to change how far back the data is cleaned up and archived, do the following:
   - In the **Archive data older than (in days)** field, change the value.
   - Choose the **Save** button.

   ⓘ The value also applies to automatic archiving.

4 Optionally, to clean up not allocated orders before archiving, choose the **Cleanup not allocated orders** button.

5 Choose the **Manual archiving** button.
   ➔ The **Manual archiving** dialog box is displayed.

6 Optionally, to change the export path, choose the ... button.

   ⓘ The folder configured for automatic archiving is automatically pre-entered in the **Export path** field.

   ➔ The **Select folder** dialog box is displayed.

7 In the folder browser, navigate to a folder.

8 Choose the **Confirm** button.

9 In the **Manual archiving** dialog box, choose the **Export** button.
   ➔ The archive is saved as ZIP file in the folder.

10 Optionally, disconnect the external storage device.

11 Optionally, if you changed the time period in step **3**, change it back:
   - In the **Archive data older than (in days)** field, change the value.
   - Choose the **Save** button.

Performing a manual backup

On the **Backup** panel, to save the system status on demand, e.g., when automatic backup is not configured or failed, perform a manual backup.

As a backup can take a long time and you cannot work with the system during the backup, perform a manual backup at a time when the system is not needed.

⚠ CAUTION!

Unprotected backup files

Insecure transfer or storage of backup files may allow for data manipulation, which may cause incorrect, invalid, or delayed results, and/or unauthorized access to personal information.

- Ensure that backup files are transferred securely, are stored in a secure location, and are protected from any unauthorized access and disaster.
- Ensure that any external storage devices (such as USB flash drives) that contain backup files are protected against unauthorized access.

On demand

Depending on the amount of data, a backup may take a long time.

- ☐ Optionally, external storage device, e.g., USB flash drive

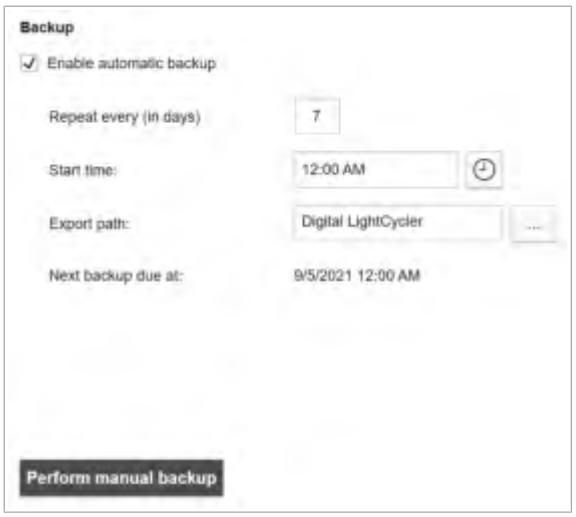
- ☐ Enough memory in the network share or on the external storage device
- ☐ Analyzer in **Analyzer ready** status
- ☐ Administrator user role

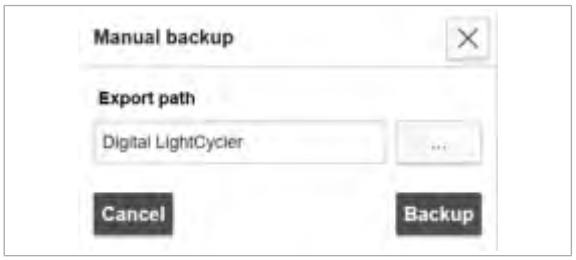
To perform a manual backup

1 Optionally, to save the backup to an external storage device, connect the external storage device to the analyzer.

2 In the analyzer software, choose **Administration > Backup**.
➔ The **Backup** panel is displayed.

3 Choose the **Perform manual backup** button.
➔ The **Manual backup** dialog box is displayed.





4 Optionally, to change the export path, choose the ··· button.

ⓘ The folder configured for automatic backups is automatically pre-entered in the **Export path** field.

➔ The **Select folder** dialog box is displayed.

5 In the folder browser, navigate to a folder.

6 Choose the **Confirm** button.

7 In the **Manual backup** dialog box, choose the **Backup** button.

➔ The backup is saved as ZIP file in the folder.

8 Optionally, disconnect the external storage device.

Cleaning and decontamination

Do not perform any cleaning or decontamination that is not described in this publication.

For cleaning and/or decontamination, always consider the following:

- Use only the allowed cleaning and/or decontamination solutions. Refer to the individual cleaning and decontamination procedures for the specified cleaning and decontamination solutions.
- Do not use technical or denatured ethanol or isopropanol.
- Instead of deionized water you can use distilled or otherwise purified water.
- Do not spray liquid directly on any part of the instruments.
- Moisten the lint-free cloths away from the instruments and wipe the surfaces and parts as described in the procedures only.
- Take care when applying liquid to a lint-free cloth. The cloth should be damp, not saturated, to prevent drops of liquid from falling onto the system.
- Use decontamination solutions where indicated only.
- Before using decontamination solutions, carefully read the precautions on the bottle labels or on the safety data sheet of the manufacturers.
- Change lab gloves after each cleaning step.
- Dispose of the material as potentially infective material.

In this section

Allowed cleaning and decontamination solutions

Use only the cleaning and decontamination solutions for the system that are listed below.

When cleaning and/or decontaminating the instruments, use the following cleaning and decontamination solutions only:

- Deionized or distilled water
- 70% ethanol p.a.

- 70% isopropanol p.a.
- DNA AWAY™ Surface Decontaminant (Molecular BioProducts, Inc.)

Refer to the individual cleaning and decontamination procedures for the cleaning and decontamination solutions specified for them.

Cleaning the partitioning engine

Regularly clean the outside and the nanowell plate drawer of the partitioning engine.

In this section

Cleaning the outside of the partitioning engine

Regularly clean the outside of the partitioning engine (housing and touch-screen monitor).

⚠ WARNING!

Risk of fire and burns

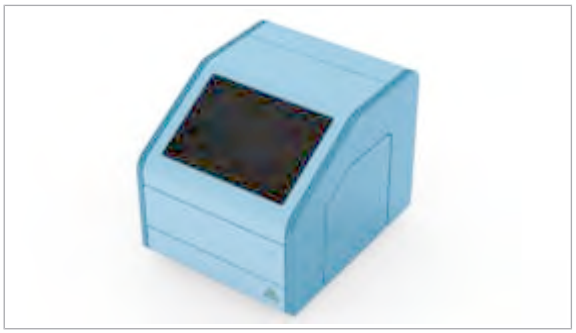
Alcohol is a flammable substance.

- ▸ Keep all sources of ignition (such as sparks, flames, or heat) away from the partitioning engine when you perform maintenance.
- ▸ When you use alcohol on or around the partitioning engine, use no more than 20 mL at a time.

Weekly

- ☐ Powder-free lab gloves
- ☐ Eye protection
- ☐ Personal protective equipment
- ☐ Lint-free cloths
- ☐ 70% ethanol p.a.

To clean the outside of the partitioning engine



1 Moisten a lint-free cloth with 70% ethanol p.a. and clean the housing of the partitioning engine.

2 Moisten a lint-free cloth with 70% ethanol p.a. and clean the touch-screen monitor of the partitioning engine.

Cleaning the nanowell plate drawer of the partitioning engine

Regularly clean the nanowell plate drawer of the partitioning engine.

⚠ WARNING!

Risk of fire and burns

Alcohol is a flammable substance.

- Keep all sources of ignition (such as sparks, flames, or heat) away from the partitioning engine when you perform maintenance.
- When you use alcohol on or around the partitioning engine, use no more than 20 mL at a time.

⚠ CAUTION!

Moving drawer

The nanowell plate drawer of the partitioning engine opens and closes during operation. An opening drawer may strike you. A closing drawer may pinch your fingers.

- Keep away from the nanowell plate drawer during operation.
- Do not try to close the nanowell plate drawer manually by pushing against it.
- Leave sufficient free space around the partitioning engine to allow for unobstructed movement of the nanowell plate drawer.

Decontaminating the nanowell plate drawer

Perform the cleaning procedure below also to decontaminate the nanowell plate drawer of the partitioning engine if it may be contaminated, e.g., in case of accidental contact with sample material.

Monthly

- ☐ Powder-free lab gloves
- ☐ Eye protection
- ☐ Personal protective equipment
- ☐ Lint-free cloths
- ☐ 70% isopropanol p.a.
- ☐ DNA AWAY™ Surface Decontaminant
- ☐ Deionized or distilled water

To clean the nanowell plate drawer of the partitioning engine

1. On the **Plate Setup** panel in the partitioning engine software, choose the **Load** button.
   ➔ The nanowell plate drawer opens.
2. If a nanowell plate is loaded, unload it from the nanowell plate drawer.
3. Moisten a lint-free cloth with 70% isopropanol and wipe the nanowell plate drawer.
   ⓘ Do not use excessive force while wiping.
4. Wait until the isopropanol has evaporated and the nanowell plate drawer is dry.
5. Moisten a lint-free cloth with DNA AWAY™ Surface Decontaminant and wipe the nanowell plate drawer.
   ⓘ Do not use excessive force while wiping.

6 Moisten a lint-free cloth with deionized water and wipe the nanowell plate drawer.

ⓘ Do not use excessive force while wiping.

7 Wait until the nanowell plate drawer is dry.

8 To close the nanowell plate drawer, on the **Plate Setup** panel in the partitioning engine software, choose the **Close** button.

Cleaning the analyzer

Regularly clean the outside and the nanowell plate stack drawer of the analyzer.

In this section

Cleaning the outside of the analyzer

Regularly clean the outside of the analyzer (housing and touch-screen monitor).

⚠ WARNING!

Risk of fire and burns

Alcohol is a flammable substance.

- Keep all sources of ignition (such as sparks, flames, or heat) away from the analyzer when you perform maintenance.
- When you use alcohol on or around the analyzer, use no more than 20 mL at a time.

Checking around the analyzer

You must check the area around the analyzer regularly to ensure that the air flow is unrestricted and that books, papers, or other supplies are not interfering with the free air flow.

Weekly

- ☐ Powder-free lab gloves
- ☐ Eye protection
- ☐ Personal protective equipment
- ☐ Lint-free cloths
- ☐ 70% ethanol p.a.

- ☐ Analyzer is unloaded
- ☐ Analyzer is shut down

Shutting down the analyzer (440)

To clean the outside of the analyzer

1 Moisten a lint-free cloth with 70% ethanol p.a. and clean the housing of the analyzer.

2 Moisten a lint-free cloth with 70% ethanol p.a. and clean the touch-screen monitor of the analyzer.

Cleaning the nanowell plate stack drawer of the analyzer

Regularly clean the nanowell plate stack drawer of the analyzer.

⚠ CAUTION!

Moving drawer

The nanowell plate stack drawer of the analyzer opens and closes during operation. An opening drawer may strike you. A closing drawer may pinch your fingers.

- Keep away from the nanowell plate stack drawer during operation.
- Do not try to close the nanowell plate stack drawer manually by pushing against it.
- Leave sufficient free space around the analyzer to allow for unobstructed movement of the nanowell plate stack drawer.

Decontaminating the nanowell plate stack drawer

Perform the cleaning procedure below also to decontaminate the nanowell plate stack drawer of the analyzer if it may be contaminated, e.g., in case of nanowell plate loss due to hardware defects.

Half-yearly

- ☐ Powder-free lab gloves
- ☐ Eye protection
- ☐ Personal protective equipment
- ☐ Lint-free cloths
- ☐ DNA AWAY™ Surface Decontaminant (Molecular BioProducts, Inc.)
- ☐ Deionized or distilled water

To clean the nanowell plate stack drawer of the analyzer

1 To open the nanowell plate stack drawer, in the global information area of the analyzer software, choose the ⏏ button.
   ➔ The nanowell plate stack drawer opens.

2 If any nanowell plates are loaded, unload the nanowell plate stack from the nanowell plate stack drawer.

3 Moisten a lint-free cloth with DNA AWAY™ Surface Decontaminant and wipe the nanowell plate stack drawer.
   ⓘ Do not use excessive force while wiping.

4 Moisten a lint-free cloth with deionized water and wipe the nanowell plate stack drawer.
   ⓘ Do not use excessive force while wiping.

5 Wait until the nanowell plate stack drawer is dry.

6 To close the nanowell plate stack drawer, in the global information area of the analyzer software, choose the ⏏ button.
   ➔ The nanowell plate stack drawer closes.

Decontamination

If the nanowell plate drawer or the aspiration needle of the partitioning engine, or the nanowell plate stack drawer of the analyzer may be contaminated, you must decontaminate them.

If the inside of the partitioning engine or the inside of the analyzer may be contaminated, contact your Roche Service representative.

Decontaminating the nanowell plate drawer of the partitioning engine

If the nanowell plate drawer of the partitioning engine may be contaminated, e.g., in case of accidental contact with sample material, decontaminate it by performing the cleaning procedure for the nanowell plate drawer.

Cleaning the nanowell plate drawer of the partitioning engine (474)

Decontamination the nanowell plate stack drawer of the analyzer

If the nanowell plate stack drawer of the analyzer may be contaminated, e.g., in case of nanowell plate loss due to hardware defects, decontaminate it by performing the cleaning procedure for the nanowell plate stack drawer.

Cleaning the nanowell plate stack drawer of the analyzer (477)

Decontaminating the aspiration needle of the partitioning engine

If you load a liquid waste bottle in the position of the partitioning fluid bottle, the aspiration needle may become contaminated and you must decontaminate it.

After closing the fluids door, the incorrect loading of a liquid waste bottle is indicated in the global information area of the partitioning engine software.

You cannot start partitioning if a liquid waste bottle is loaded in the position of the partitioning fluid bottle. Therefore, the inside of the partitioning engine will not be contaminated.

Mark all waste bottles with a permanent marker as waste bottles. Mark empty or expired partitioning fluid bottles as waste bottles immediately after unloading them from the partitioning engine.

⚠ WARNING!

Risk of fire and burns

Alcohol is a flammable substance.

- Keep all sources of ignition (such as sparks, flames, or heat) away from the partitioning engine when you perform maintenance.
- When you use alcohol on or around the partitioning engine, use no more than 20 mL at a time.

⚠ CAUTION!

Sharp aspiration needle

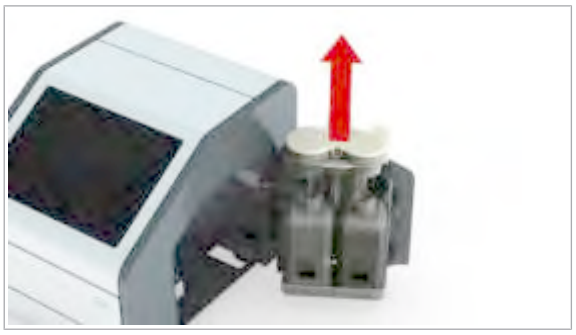
The aspiration needle in the partitioning engine is sharp. Contact with the aspiration needle may result in personal injury.

- Carefully follow the instructions in this publication for replacing the bottles on the partitioning engine and for decontaminating the aspiration needle.
- When replacing the bottles on the partitioning engine or when decontaminating the aspiration needle, pay extra attention to the aspiration needle.

- ☐ Powder-free lab gloves
- ☐ Eye protection
- ☐ Personal protective equipment
- ☐ Lint-free cloths
- ☐ 70% isopropanol p.a.
- ☐ New partitioning fluid bottle
- ☐ Screw cap

To decontaminate the aspiration needle of the partitioning engine

1 To open the fluids door on the right side of the partitioning engine, do the following:
- Push the front edge inside until the fluids door disengages.
- Open the fluids door completely.



2 Lift the aspiration and dispensing arm completely until the aspiration needle is clear of the bottle opening and the aspiration and dispensing arm locks into place in the upper position.

3 Remove the bottle from the partitioning fluid bottle position. Close the bottle with a screw cap. Dispose of the bottle according to local regulations.

4 Moisten a lint-free cloth with 70% isopropanol.

5 Wipe the aspiration needle with the moistened cloth.

6 Wait until the isopropanol has evaporated and the aspiration needle is dry.

7 Unscrew the screw cap of the new partitioning fluid bottle. Keep the screw cap for later use.

8 Place the new partitioning fluid bottle in the fluids door with the label facing to the front.

9 Lower the aspiration and dispensing arm completely.

10 Close the fluids door until it engages with an audible click.

11 Prime the partitioning engine twice as described in Priming the partitioning engine (232).

About preventive maintenance

On the **Preventive maintenance** panel, you view the preventive maintenance settings.

You need administrator user role to view the preventive maintenance settings.

Preventive maintenance is performed by your Roche Service representative.

Preventive maintenance settings

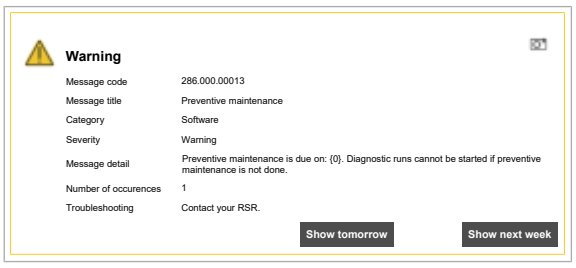
The following preventive maintenance settings are displayed on the **Preventive maintenance** panel:

- **Repeat every (in days)**:
  Number of days between scheduled preventive maintenance.
- **Prior warning message (in weeks)**:
  Number of weeks before next due preventive maintenance that a warning message is displayed.
- **Next maintenance due at**:
  Due date of next preventive maintenance.

The preventive maintenance settings are configured upon system installation.

The preventive maintenance settings are read-only. To change the preventive maintenance settings, contact your Roche Service representative.

System behavior



When the configured warning period starts before the due date of the next preventive maintenance, a warning message is displayed.

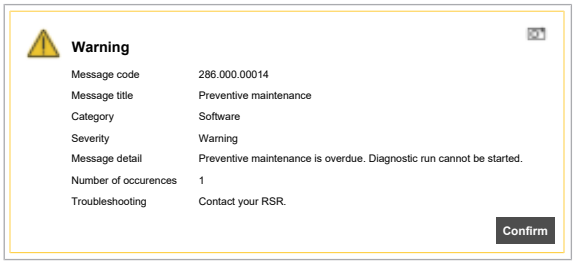
On the message callout, you must decide when the warning message is displayed again:

- To display the warning again the next day, choose the **Show tomorrow** button.
- To display the warning again next week, choose the **Show next week** button.

When the warning message is displayed, contact your Roche Service representative. Preventive maintenance is performed by your Roche Service representative.

When preventive maintenance is completed, the counter is reset, and the next due date is recalculated and displayed on the **Preventive maintenance** panel.

If the preventive maintenance is not performed before the due date, the preventive maintenance becomes overdue.



If preventive maintenance is overdue, the following applies:

- On the **Preventive maintenance** panel, preventive maintenance is displayed as overdue.
- You cannot perform diagnostic runs on the analyzer.
- For diagnostic operator user role, diagnostic approver user role, and administrator user role, an error message is displayed in the analyzer software and the web application.
- You can still perform development runs on the analyzer.
- For development operator user role, a warning message is displayed in the analyzer software.

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Troubleshooting

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Flags

In this chapter 18

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List of flags

Flags are assigned to samples and controls and inform you about issues or user actions that have occurred during the workflow.

Flags are listed in the web application, the analyzer software, and/or the development software, depending on the workflow.

For additional information about a flag, you can display a flag callout in the software components of the system.

Displaying the flag callouts (494)

About flag severity

Flags are raised in the following severity, resulting in different consequences for the sample or control:

- **Critical**:
  All initial and final results for this sample or control are invalidated.
- **Informational**:
  The flag provides additional information only.

Flags are sorted according to their severity. The most severe flags are listed first.

Table of flags

Flag code	Severity	Description	Actions
I001	Critical	**Analyzer: Internal system temperature is out of range.**	Check the following: ▪ The air inlet underneath the analyzer is not blocked. ▪ The air outlet at the back of the analyzer is not blocked. ▪ The ambient temperature in the laboratory lies within the range specified for operation. Environmental conditions for the system (183)
IP001	Critical	**Image processing: Focus position may be suboptimal due to missing focus image.**	Restart the analyzer. If the flag occurs repeatedly, contact your Roche Service representative. Restarting the analyzer (451)
IP002	Critical	**Image Processing: LED-check failed.**	Restart the analyzer. If the flag occurs repeatedly, contact your Roche Service representative. Restarting the analyzer (451)

Table of flags

Flag code	Severity	Description	Actions
IP003	Informational	No nanowell columns detected within the expected overlap area during stitching	Restart the analyzer. If the flag occurs repeatedly, contact your Roche Service representative. Restarting the analyzer (451)
IP004	Critical	Data integrity check failed	Restart the analyzer. If the flag occurs repeatedly, contact your Roche Service representative. Restarting the analyzer (451)
PE001	Critical	Partitioning engine: Lane partitioning failed	Restart the partitioning engine. If the flag occurs repeatedly, contact your Roche Service representative. Restarting the analyzer (451)
PE002	Informational	Partitioning engine: Lane partitioning data missing	Restart the partitioning engine. If the flag occurs repeatedly, contact your Roche Service representative. Restarting the analyzer (451)
PE003	Critical	Partitioning engine: Empty lane	
RA000	Critical	Unhandled exception in results interpretation.	Restart the analyzer. If the flag occurs repeatedly, contact your Roche Service representative. Restarting the analyzer (451)
RA001	Informational	Upper limit of quantification not met.	
RA002	Informational	Lower limit of quantification not met.	
RA003	Critical	Positive control concentration is too high.	
RA004	Critical	Positive control concentration is too low.	
RA005	Critical	Negative control concentration is too high.	
RA006	Critical	Internal control concentration is too high.	
RA007	Critical	Internal control concentration is too low.	
RA008	Critical	Too many invalid nanowells	If the flag occurs repeatedly, contact your Roche Service representative.
RA009	Critical	Integrity check failed.	If the flag occurs repeatedly, contact your Roche Service representative.
RA011	Critical	Too many artifact nanowells	Ensure there are no scratches, finger prints, dust, or other artifacts on the nanowell plate lanes that compromise the image integrity. If the flag occurs repeatedly, contact your Roche Service representative.
RA012	Critical	Merging verification failed.	If the flag occurs repeatedly, contact your Roche Service representative.
RA013	Critical	Copy number control value is too high.	
RA014	Critical	Copy number control value is too low.	
RA015	Critical	TOI concentration is above upper limit of validity.	
RA016	Critical	TOI concentration is below upper limit of validity.	

Table of flags

Flag code	Severity	Description	Actions
RA017	Critical	Reference target concentration is above upper limit of validity.	
RA018	Critical	Reference target concentration is below upper limit of validity.	
RA019	Critical	Wild type control concentration is too high.	
RA020	Critical	Wild type control concentration is too low.	
RA021	Critical	Percentage of variant control is too high.	
RA022	Critical	Percentage of variant control is too low.	
RA023	Critical	Total concentration is above upper limit of validity.	
RA024	Critical	Total concentration is below lower limit of validity.	
RA025	Critical	Internal control channel has no negative nanowells.	Result calculation is not possible if the number of negative nanowells is zero. The used target concentration saturates the nanowell lane. Dilute the sample to reduce the target concentration.
RA026	Critical	An unexpected cluster is present.	
RA027	Informational	Lane has no valid nanowells.	
RA028	Critical	Target channel has no negative nanowells.	Result calculation is not possible if the number of negative nanowells is zero. The used target concentration saturates the nanowell lane. Dilute the sample to reduce the target concentration.
RA029	Critical	Positive control is invalid.	
RA030	Critical	Negative control is invalid.	
RA031	Critical	Copy number control is invalid.	
RA032	Critical	Wild type control is invalid.	
RA033	Critical	Variant control is invalid.	
RA034	Critical	Wild type concentration has no value.	
RA035	Critical	Variant concentration has no value.	
RA036	Critical	Variant percentage has no value.	
RA037	Critical	Copy number has no value.	
RA041	Critical	Critical instrument flag	Restart the analyzer. If the flag occurs repeatedly, contact your Roche Service representative. Restarting the analyzer (451)
RA042	Critical	Initial control result is invalid.	
RA043	Critical	Positive control is invalid.	
RA045	Critical	Initial result of internal control is invalid.	
RA048	Critical	Variant control is invalid.	
RC005	Critical	Not enough valid nanowells	If the flag occurs repeatedly, contact your Roche Service representative.
RD000	Critical	Indel analysis failed.	If the flag occurs repeatedly, contact your Roche Service representative.

Table of flags

Flag code	Severity	Description	Actions
RD001	Critical	Verification of input data failed.	If the flag occurs repeatedly, contact your Roche Service representative.
RD002	Critical	Merging verification failed.	If the flag occurs repeatedly, contact your Roche Service representative.
RD004	Informational	An unexpected cluster is present.	
RD005	Critical	Lane has no valid nanowells.	
RD006	Critical	Lane has no negative nanowells.	Result calculation is not possible if the number of negative nanowells is zero. The used target concentration saturates the nanowell lane. Dilute the sample to reduce the target concentration.
RF001	Informational	Normalized fluorescence trimmed	
RF002	Critical	Lane has no valid nanowells.	
RL000	Critical	Integrity check calculation failed.	If the flag occurs repeatedly, contact your Roche Service representative.
RM000	Critical	Integrity check on lane failed.	If the flag occurs repeatedly, contact your Roche Service representative.
RN000	Critical	CNV analysis failed.	If the flag occurs repeatedly, contact your Roche Service representative.
RN001	Critical	Verification of input data failed.	If the flag occurs repeatedly, contact your Roche Service representative.
RN002	Critical	Merging verification failed.	If the flag occurs repeatedly, contact your Roche Service representative.
RN004	Critical	Lane has no valid nanowells.	
RN006	Critical	Reference target concentration is zero.	
RN007	Critical	TOI concentration has no value.	
RN008	Critical	Reference target concentration has no value.	
RQ000	Critical	Absolute quantification failed.	If the flag occurs repeatedly, contact your Roche Service representative.
RQ001	Critical	Verification of input data failed.	If the flag occurs repeatedly, contact your Roche Service representative.
RQ002	Critical	Merging verification failed.	If the flag occurs repeatedly, contact your Roche Service representative.
RQ003	Informational	Potential linkage imprecision due to low approximation iterations	
RQ004	Critical	Lane has no valid nanowells.	
RQ005	Critical	Channel has no negative nanowells.	Result calculation is not possible if the number of negative nanowells is zero. The used target concentration saturates the nanowell lane. Dilute the sample to reduce the target concentration.
RX001	Informational	Corrected fluorescence trimmed	
S001	Informational	System: Manual entry of plate barcode	
S002	Critical	System: Analysis package violation.The maximum time between partitioning and starting the run was exceeded.	
S003	Informational	System: Run aborted by operator.	

Table of flags

Flag code	Severity	Description	Actions
S004	Critical	System: Run aborted by operator before images were captured.	
S005	Informational	System: Run failed.	
S006	Critical	System: Run failed before images were captured.	
S007	Informational	System: Preventive maintenance is overdue.	
S008	Critical	System: Unexpected run abort	
S009	Critical	System: Result calculation failure	
S010	Informational	System - direct imaging run/ thermocycling bypassed	
S011	Informational	System - direct imaging run/plate re-imaged	
S012	Informational	System - LED-check cannot be performed due to abort of the run	
S013	Critical	This lane was not imaged during a direct imaging run.	
SS001	Critical	Sample setup - lane marked as invalid by operator	
SS002	Critical	Sample setup: Plate marked as invalid by operator.	
TC001	Critical	Temperature out of range	Check the following: ▪ The air inlet underneath the analyzer is not blocked. ▪ The air outlet at the back of the analyzer is not blocked. ▪ The ambient temperature in the laboratory lies within the range specified for operation. Environmental conditions for the system (183)
TC002	Critical	Thermocycler: Temperature homogeneity out of range	Restart the analyzer. If the flag occurs repeatedly, contact your Roche Service representative. Restarting the analyzer (451)

Table of flags

If the same flag occurs repeatedly without cause, contact your Roche Service representative.

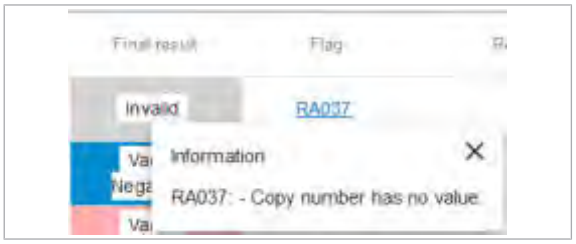
Displaying the flag callouts

In the web application, the analyzer software, and the development software, you can display flag callouts from the flags.

In the web application and the development software, flags are displayed together with results.

In the analyzer software, partitioning flags are displayed together with the sample setups of diagnostic runs.

A flag callout always contains the flag severity and the flag description.



To display the flag callouts in the web application

1 In the web application, in the **Results** column on the dashboard, navigate to the **Results of** screen:
   - For incomplete runs, choose the batch tile.
   - For completed runs, choose the **{count} completed batches** tile. Choose the batch and choose the **View** button.

   ➔ The **Results of** screen is displayed.

2 Choose the **Samples** tab or the **Controls** tab.

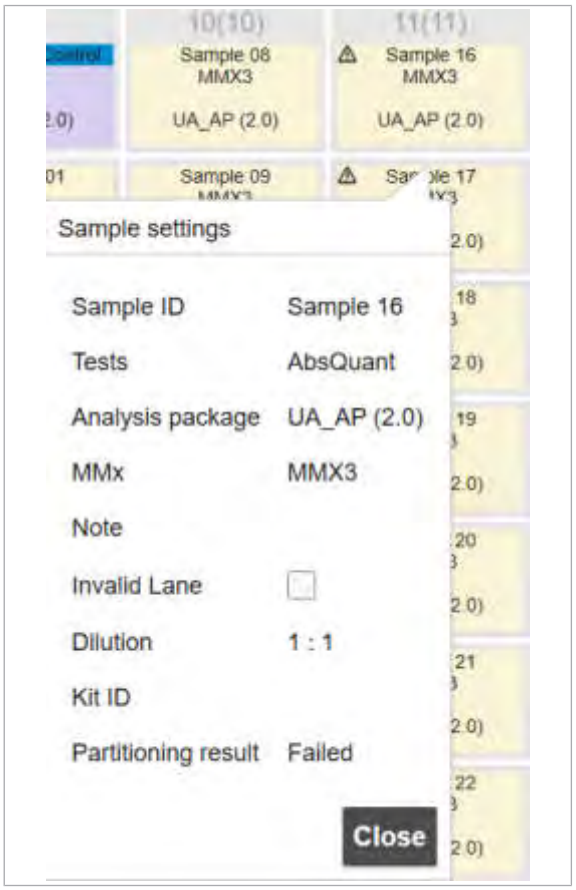
3 In the **Flag** column, choose a flag link.

   ➔ The flag callout is displayed.

To display the flag callouts in the analyzer software for diagnostic runs

1 In the analyzer software, choose **Routine > Diagnostic run > Sample setup**.

   ➔ The **Sample setup** panel is displayed.



2 Mouse over the flag indicator.
➔ The flag callout is displayed.

To display the flag callouts in the development software

1 In the development software, in the **Navigation** area, choose an analysis from the **Analysis** menu.
➔ The analysis tab is displayed in the work area.

2 Choose the **Results** button.

3 Mouse over an entry in the **Flags** column.
➔ The flag callout is displayed.

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Troubleshooting the partitioning engine

In this chapter 19

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List of messages on the partitioning engine

Messages alert you to events that prevent normal operation of the partitioning engine.

In the partitioning engine software, messages are displayed in the global information area.

About the global information area of the partitioning engine software (83)

Message	Actions
Bottle compartment is empty	Load a partitioning fluid bottle and a liquid waste bottle. Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460)
Bottle tag id/version is wrong	Replace the partitioning fluid bottle and the liquid waste bottle. Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460)
Down-Holder Sub-Controller	Refer to the event viewer for additional information. Displaying the event viewer in the partitioning engine software (503)
Drive Controller	Refer to the event viewer for additional information. Displaying the event viewer in the partitioning engine software (503)
Error	Try again. If the message persists, contact your Roche Service representative.
Error while copying licences to USB	Try again. If the message persists, contact your Roche Service representative.
Information	No action required.
No plate barcode was detected	▪ Reload the nanowell plate. ▪ If the message persists, unload the nanowell plate. In a diagnostic workflow, invalidate the nanowell plate. In a development workflow, consider pipetting a new nanowell plate. ▪ If the message persists for multiple nanowell plates, contact your Roche Service representative. Partitioning the nanowell plates (221) Invalidating nanowell plate lanes and/or nanowell plates in the web application (535)
No Version Information	Contact your Roche Service representative.
Oil bottle is missing	Load a partitioning fluid bottle. Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460)
Oil bottle is not available	Load a partitioning fluid bottle. Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460)

Partitioning engine messages

Message	Actions
Oil bottle signature is wrong	Replace the partitioning fluid bottle. ›🗎 Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460)
Oil expiry date is elapsed	Replace the partitioning fluid bottle. ›🗎 Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460)
Oil fill state is not available	▪ Shut down the partitioning engine. ▪ Wait for 5 seconds. ▪ Start up the partitioning engine again. ▪ If required, initialize the partitioning engine. ›🗎 Shutting down the partitioning engine (437) ›🗎 Starting up the partitioning engine (231) ›🗎 Initializing the partitioning engine (505)
Oil onboard stability expired	Replace the partitioning fluid bottle. ›🗎 Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460)
Oil Pump Controller	Refer to the event viewer for additional information. ›🗎 Displaying the event viewer in the partitioning engine software (503)
Partitioning Engine Controller	Refer to the event viewer for additional information. ›🗎 Displaying the event viewer in the partitioning engine software (503)
Plate expiry date is elapsed	▪ Unload the nanowell plate. ▪ In a diagnostic workflow, invalidate the nanowell plate. ▪ In a development workflow, consider pipetting a new nanowell plate. ›🗎 Invalidating nanowell plate lanes and/or nanowell plates in the web application (535)
Plate reused or empty	▪ Unload the nanowell plate. ▪ Check if the nanowell plate is empty, i.e., not pipetted. ▪ Pipette an empty nanowell plate and try again. ▪ You cannot reload already partitioned nanowell plates. ›🗎 Partitioning the nanowell plates (221)
Plate-Drawer Sub-Controller	Refer to the event viewer for additional information. ›🗎 Displaying the event viewer in the partitioning engine software (503)

Partitioning engine messages

Message	Actions
Please exchange supply bottle	▪ Unload the bottle from the position of the partitioning fluid bottle. ▪ If the loaded bottle was a liquid waste bottle, decontaminate the aspiration needle. ▪ Load a partitioning fluid bottle. Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460) Decontaminating the aspiration needle of the partitioning engine (479)
Please exchange waste bottle	Replace the liquid waste bottle. Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460)
Please remove plate from drawer	Unload the nanowell plate.
Real-Time Controller not available	▪ Shut down the partitioning engine. ▪ Wait for 5 seconds. ▪ Start up the partitioning engine again. ▪ If required, initialize the partitioning engine. Shutting down the partitioning engine (437) Starting up the partitioning engine (231) Initializing the partitioning engine (505)
Real-Time-Controller	Refer to the event viewer for additional information. Displaying the event viewer in the partitioning engine software (503)
Shutdown can not be executed	Try again. If the message persists, contact your Roche Service representative.
The plate barcode could not be read	▪ Reload the nanowell plate. ▪ If the message persists, unload the nanowell plate. In a diagnostic workflow, invalidate the nanowell plate. In a development workflow, consider pipetting a new nanowell plate. ▪ If the message persists for multiple nanowell plates, contact your Roche Service representative. Partitioning the nanowell plates (221) Invalidating nanowell plate lanes and/or nanowell plates in the web application (535)
Waiting for Real-Time-Controller	▪ Shut down the partitioning engine. ▪ Wait for 5 seconds. ▪ Start up the partitioning engine again. ▪ If required, initialize the partitioning engine. Shutting down the partitioning engine (437) Starting up the partitioning engine (231) Initializing the partitioning engine (505)
Warning	Try again. If the message persists, contact your Roche Service representative.

Partitioning engine messages

Message	Actions
Waste bottle is missing	Load a liquid waste bottle. ›🗎 Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460)
Waste bottle is not available	Load a liquid waste bottle. ›🗎 Replacing the partitioning fluid bottle and/or the liquid waste bottle on the partitioning engine (460)
Waste fill state is not available	▪ Shut down the partitioning engine. ▪ Wait for 5 seconds. ▪ Start up the partitioning engine again. ▪ If required, initialize the partitioning engine. ›🗎 Shutting down the partitioning engine (437) ›🗎 Starting up the partitioning engine (231) ›🗎 Initializing the partitioning engine (505)

Partitioning engine messages

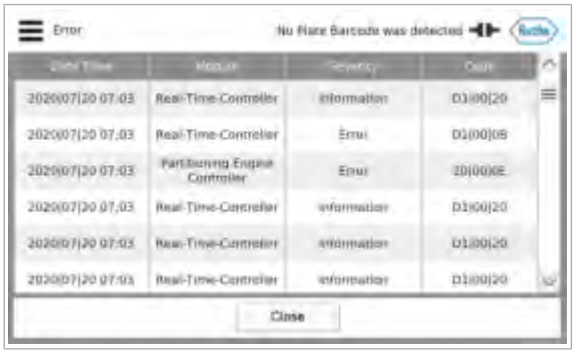
If any of the messages persists even after the recommended actions were performed, contact your Roche Service representative.

Displaying the event viewer in the partitioning engine software

The partitioning engine logs events in the event viewer with event severity and event code.

To display the event viewer in the partitioning engine software

1 In the global information area, choose ≡ > **Event Viewer**.



2 To close the event viewer, choose the **Close** button.

Copying the logs from the partitioning engine to an external storage device

The logs from the partitioning engine contain relevant data required by Roche for troubleshooting purposes.

If you encounter a problem with the partitioning engine and contact your Roche Service representative, you may be asked to provide the logs.

Roche reviews the logs upon your request only.

- ☐ External storage device, e.g., USB flash drive
- ☐ Enough memory on the external storage device

To copy the logs from the partitioning engine to an external storage device

1. At the back of the partitioning engine, remove the cover.
2. Connect the external storage device to the partitioning engine.
3. In the global information area, choose ≡ > **Copy Logs to USB**.
4. Wait until the logs are copied.
5. Disconnect the external storage device.
6. At the back of the partitioning engine, attach the cover.

Initializing the partitioning engine

When an error occurred on the partitioning engine, you must initialize it.

You can only continue to work with the partitioning engine after initialization.

During startup of the partitioning engine, initialization is done automatically.

☐ Error on the partitioning engine

To initialize the partitioning engine

1 In the global information area, choose the ≡ button.

2 From the drop-down menu, choose the **Initialize Instrument** command.

3 Wait until initialization is complete and the partitioning engine is in **Ready** status.

Restarting an unresponsive partitioning engine

If the partitioning engine and/or the partitioning engine software are unresponsive, you must restart the partitioning engine.

Always confirm that the partitioning engine and/or the partitioning engine are unresponsive before you restart the partitioning engine:

- Ensure the partitioning engine is not busy and therefore not responding.
- Try to initialize the partitioning engine following the normal initialization procedure.
- Try to shut down the partitioning engine following the normal shutdown procedure.

Initializing the partitioning engine (505)

Shutting down the partitioning engine (437)

Only follow the procedure below if the partitioning engine and/or the partitioning engine software are unresponsive.

☐ Partitioning engine and/or partitioning engine software unresponsive

To restart an unresponsive partitioning engine

1. If an external storage device is connected to the partitioning engine, disconnect it.
2. At the back of the partitioning engine, switch the power switch to the off position.
3. Wait a few seconds.
4. Start up the partitioning engine as described in Starting up the partitioning engine (231) and follow the instructions on the screen.
5. If the partitioning engine does not start up or if the error persists, contact your Roche Service representative.

Troubleshooting the analyzer

In this chapter 20

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Messages in the analyzer software

Messages inform and alert you.

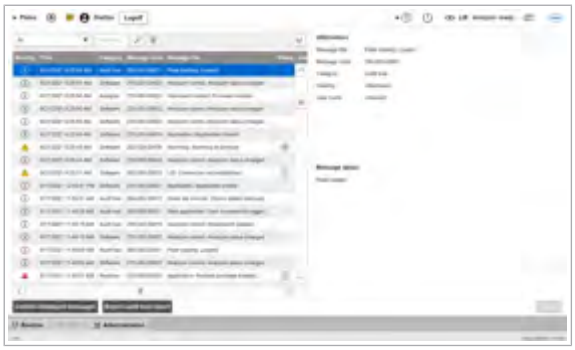
Depending on the severity of the message and your system configuration, an additional callout and an acoustic signal may be displayed to alert you to messages.

Audio settings (563)

In this section

About messages in the analyzer software

Messages inform you about the analyzer status and alert you to critical events.



Messages are listed on the messages panel in the analyzer software.

If a message requires further user action, the action is described on the detail panel of the message.

To resolve the event, perform the described actions.

If the error persists or if in doubt, contact your Roche Service representative.

About the messages panel (121)

About the message codes

Each message is uniquely identified by its message code.

The message code is displayed in the **Message code** column of the messages table and on the detail panel of a message.

About the message severity

The messages are categorized by the severity of the event that triggered the message:

- Error messages:

  - Triggered by errors. Working with the analyzer is not possible anymore. Immediate action is required to resolve the error.
  - Error messages always need confirmation.
- Warning messages:
  - Triggered by warnings. Working with the analyzer is possible for the moment. No immediate action is required, but it may be necessary to resolve the warning soon.
  - Some warning messages need confirmation.
- Information messages:
  - Triggered by normal operation. Working with the analyzer is not affected. No action is required.
  - Information messages never need confirmation.

The message severity is indicated as follows:

- On the message callout (if applicable)
- In the **Severity** column of the messages table
- On the detail panel of a message

About the message indicator (108)

About the messages panel (121)

About the message callouts

For some messages, an additional callout is displayed.

If a callout is displayed, the corresponding message always needs to be confirmed.

The **Number of occurences** value indicates how often the event occurred that triggered the callout.

If the callout includes an action (e.g., to confirm the messages), the action applies to all messages that are represented by the callout.

To take a screenshot of the callout, choose the button.

Managing screenshots in the analyzer software (447)

About archiving of messages

Archiving includes the confirmed messages that are older than the number of days configured for archiving. The compressed archive file contains a CSV file of the archived messages (Messages.csv).

After archiving is completed successfully, the archived messages are deleted from the analyzer.

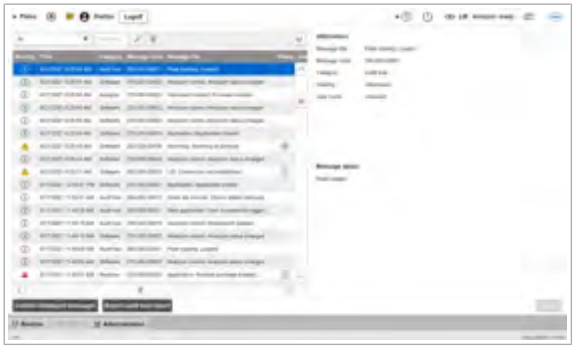
Archiving (557)

Displaying and confirming messages in the analyzer software

You must confirm some messages.

You can either confirm each message separately or all displayed messages at once.

When there are messages that need confirmation



To display and confirm messages in the analyzer software

1 In the global information area of the analyzer software, choose the message indicator.
   ➔ The messages panel is displayed.

2 Optionally, you can do the following:
   - Configure the columns of the messages table.
   - Sort and/or filter the messages table.
   - Export the table entries to Excel.

3 To display the details of a message, choose the message.
   ➔ The message details are displayed on the right in the detail panel.

4 To confirm a message, choose the message. On the detail panel, choose the **Confirm** button.
   ➔ The confirmation is logged with user information and time stamp.

5 To confirm all unconfirmed messages that are currently displayed in the table, choose the **Confirm displayed messages** button.
   ⓘ Unconfirmed messages that are currently not displayed (e.g., because the table is filtered) are not confirmed.
   ➔ The confirmation is logged with user information and time stamp.

6 To hide the messages panel, choose the message indicator again.

Problem reports on the analyzer

On the **Problem report** panel, you export basic problem reports, create custom problem reports, and/or create logs reports.

You can access the **Problem report** panel with any user role.

In this section

About problem reports

Problem reports contain relevant data required by Roche for troubleshooting purposes.

If you encounter a problem with the analyzer and contact your Roche Service representative, you may be asked to provide a problem report.

Roche reviews your problem reports upon your request only.

There are the following types of problem reports:

- Basic problem report
- Custom problem reports:
  - Advanced problem report
  - Extended problem report
  - Complete problem report
- Logs reports:
  - For today
  - For the last 7 days (counted including today)
  - For the last 30 days (counted including today)
  - For all

Basic and custom problem reports always belong to a specific run and contain system and run information from the time the run finished.

Logs reports are problem reports that cover a specified time period and contain system and run information from that period.

About basic problem reports

The analyzer automatically creates a basic problem report each time a run is finished:

- Run completed without errors (including the manual run abort by the user)
- Run aborted after error or alarm

The basic problem reports are stored on the analyzer. You can export basic problem reports to a network share or external storage device.

About custom problem reports

You can manually create custom problem reports from a basic problem report, i.e., for the same run. The custom problem reports (advanced, extended, complete) differ in the extent of data that is included.

A complete problem report contains the images from the corresponding run. As the analyzer stores only the images of the last 5 runs, you cannot create custom problem reports for older runs.

You can only save custom problem reports in a network share or on an external storage device. You cannot save a custom problem report on the analyzer.

Depending on the type of custom problem report, creating a problem report may take a long time and result in a large file.

About logs reports

You can manually create logs reports for a specified time period.

You can only save logs reports in a network share or on an external storage device. You cannot save a logs report on the analyzer.

About problem report files

A problem report is saved as a single, compressed 7z file.

The files are password-protected. Problem reports can be accessed by Roche only.

By default, the files of basic and custom problem reports are named:
PR_SN_RunName_TypeOfReport.7z.

You cannot change the name of a basic problem report.

By default, an advanced, extended, or complete problem report has the same name (except the problem report type) as the basic problem report it is created from. You can change the name when creating the custom problem report.

The files of logs reports are named:
PR_SN_Logs_YYYYMMDD_YYYYMMDD.7z
with the start and end date of the included time period.

You can change the name when creating the logs report.

Names of custom problem reports and logs report must not contain the following characters:
? * < > / \ : " | ’

List of naming placeholders (154)

Exporting a basic problem report

On the **Problem report** panel, you export basic problem reports that were created automatically by the analyzer.

- ☐ Optionally, external storage device, e.g., USB flash drive
- ☐ Enough memory in the network share or on the external storage device

To export a basic problem report

1. Optionally, to export to an external storage device, connect the external storage device to the analyzer.
2. In the analyzer software, choose **Administration > Problem report**.
   ➔ The **Problem report** panel is displayed.
3. Optionally, sort, search, or filter the table.

4 From the table, choose a problem report.

5 Choose the **Export** button.
➔ The **Select folder** dialog box is displayed.

6 In the folder browser, navigate to a folder.

7 Choose the **Confirm** button.
➔ A progress indicator is displayed.

8 Wait until the export of the problem report is finished.
ⓘ If you cancel the export, all files that are already exported to the folder are deleted again.
➔ The basic problem report is exported as a 7z file to the folder.

9 Optionally, disconnect the external storage device.

Creating a custom problem report

On the **Problem report** panel, to create problem reports that include additional data, you create custom problem reports from basic problem reports.

Depending on the information and files stored on the analyzer, not all types of custom problem reports may be available.

Depending on the type of problem report (advanced, extended, complete) and the amount of data, creating a custom problem report may take a long time.

☐ Optionally, external storage device, e.g., USB flash drive

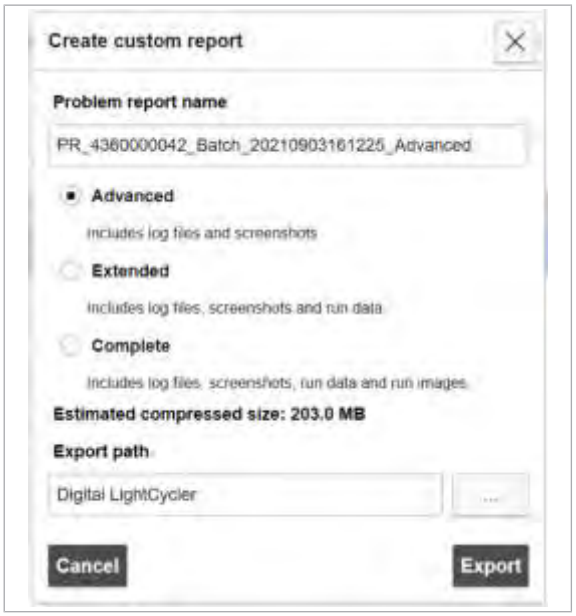
☐ Enough memory in the network share or on the external storage device

To create a custom problem report

1 Optionally, to save to an external storage device, connect the external storage device to the analyzer.

2 In the analyzer software, choose **Administration > Problem report**.
➔ The **Problem report** panel is displayed.

3 Optionally, sort, search, or filter the table.



4 From the table, choose a problem report.

5 Choose the **Create custom report** button.
➔ The **Create custom report** combo box is displayed.

6 Optionally, change the name for the problem report.
ⓘ The name must not contain the following characters:
? * < > / \ : " | ’

7 Choose the type of the custom problem report:
- **Advanced**
- **Extended**
- **Complete**

➔ The estimated file size of the problem report is displayed in the combo box.

8 To change the export path, choose the ··· button.
➔ The **Select folder** dialog box is displayed.

9 In the folder browser, navigate to a folder.

10 Choose the **Confirm** button.

11 In the **Create custom report** combo box, choose the **Export** button.
➔ A progress indicator is displayed.

12 Wait until the creation of the problem report is finished.
ⓘ If you cancel the creation, all files that are already saved in the folder are deleted again.
➔ The custom problem report is saved as a 7z file in the folder.

13 Optionally, disconnect the external storage device.

Creating a logs report

On the **Problem report** panel, to create problem reports that contain data from a specified time period (and not from a specific run), you create logs reports.

☐ Optionally, external storage device, e.g., USB flash drive

☐ Enough memory in the network share or on the external storage device

To create a logs report

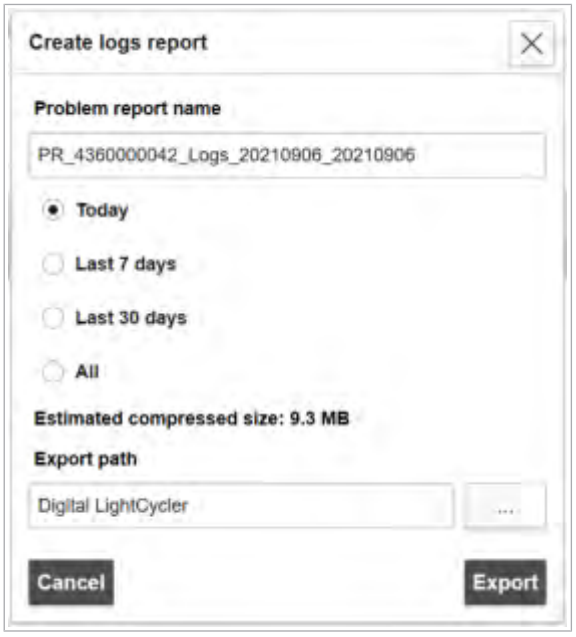
1 Optionally, to save to an external storage device, connect the external storage device to the analyzer.

2 In the analyzer software, choose **Administration > Problem report**.

➔ The **Problem report** panel is displayed.

3 Choose the **Create logs report** button.

➔ The **Create logs report** combo box is displayed.



4 Optionally, change the name for the logs report.

ⓘ The name must not contain the following characters:
? * < > / \ : " | ’

5 Choose for which time period the logs shall be included:

- **Today**
- **Last 7 days** (counted including today)
- **Last 30 days** (counted including today)
- **All**

➔ The estimated file size of the logs report is displayed in the combo box.

6 To change the export path, choose the ··· button.

➔ The **Select folder** dialog box is displayed.

7 In the folder browser, navigate to a folder.

8 Choose the **Confirm** button.

9 In the **Create logs report** combo box, choose the **Export** button.

➔ A progress indicator is displayed.

10 Wait until the creation of the problem report is finished.

ⓘ If you cancel the creation, all files that are already saved in the folder are deleted again.

➔ The custom problem report is saved as a 7z file in the folder.

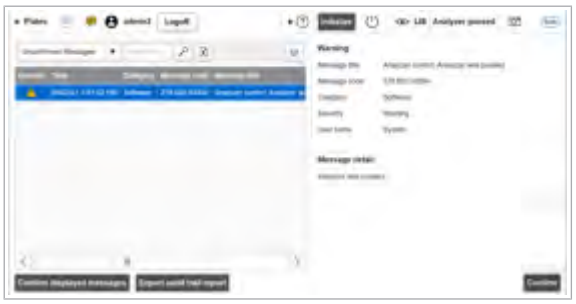
11 Optionally, disconnect the external storage device.

Initializing a paused analyzer

If the analyzer is paused, you must initialize the analyzer before you can continue working.

Whenever an alarm callout or error callout is displayed, take a screenshot of the callout.

- ☐ **Initialize** button displayed in the global information area
- ☐ Analyzer in **Analyzer paused** status



To initialize a paused analyzer

1. In the global information area, choose the **Initialize** button.
   ➔ The analyzer is initialized.
2. If the error persists, contact your Roche Service representative.

Restarting an unresponsive analyzer

If the analyzer and/or the analyzer software are unresponsive, you must restart the analyzer.

Always confirm that the analyzer and/or the analyzer software are unresponsive before you restart the analyzer:

- Ensure the analyzer is not busy and therefore not responding.
- If a message is displayed, follow the message instructions.
- Try to shut down the analyzer following the normal shutdown procedure.

Messages in the analyzer software (509)

Shutting down the analyzer (440)

Only follow the procedure below if the analyzer and/or the analyzer software are unresponsive.

☐ Analyzer and/or analyzer software unresponsive

To restart an unresponsive analyzer

1. If an external storage device is connected to the analyzer, disconnect it.
2. At the right side of the analyzer, press the power button.
3. Wait a few seconds.
4. Start up the analyzer as described in Starting up the analyzer (235) and follow the instructions on the screen.
5. If the analyzer does not start up or if the error persists, contact your Roche Service representative.

Nanowell plate loading errors on the analyzer

On the **Plates** panel in the analyzer software, the statuses of the loaded nanowell plates indicate if there is a nanowell plate loading error.

Before you can start the run on the analyzer, you must resolve all nanowell plate loading errors so that all loaded nanowell plates are in **Valid** status.

For development runs only, you can always resolve nanowell plate loading errors by unloading the affected nanowell plates from the analyzer.

About the nanowell plate status (114)

About run prerequisites (172)

In this section

Table of nanowell plate loading errors

The following table lists the possible statuses of loaded nanowell plates on the **Plates** panel in the analyzer software, the causes, and possible actions.

Status on Plates panel	Cause	Actions
Barcode scan failed	The nanowell plate ID could not be read.	Perform a procedure to resolve the nanowell plate ID reading error. Resolving a nanowell plate ID reading error (521)

Statuses of loaded nanowell plates

Status on Plates panel	Cause	Actions
Invalid barcode	The nanowell plate ID does not meet the barcode criteria defined on the system.	Unload the nanowell plate. For a development run, either start the run without the affected nanowell plate or replace it with a freshly pipetted and partitioned nanowell plate. For a diagnostic run, invalidate the nanowell plate in the web application. Then, start the run without the invalidated nanowell plate. Invalidating nanowell plate lanes and/or nanowell plates in the web application (535)
Duplicate barcode	While resolving a nanowell plate ID reading error, you entered the nanowell plate ID of another loaded nanowell plate (both affected nanowell plates are indicated).	Correct the manually entered nanowell plate ID. Resolving a nanowell plate ID reading error (521)
Expired	The nanowell plate is expired.	Unload the nanowell plate. For a development run, either start the run without the affected nanowell plate or replace it with a freshly pipetted and partitioned nanowell plate. For a diagnostic run, invalidate the nanowell plate in the web application. Then, start the run without the invalidated nanowell plate.
Results already exist	The nanowell plate was already processed in a previous run.	Unload the nanowell plate.
Not partitioned	The nanowell plate is not yet partitioned.	Unload the nanowell plate. Partition it on a partitioning engine that is assigned to this analyzer. Reload the nanowell plate.
	The nanowell plate was partitioned on a partitioning engine that is not assigned to this analyzer.	Unload the nanowell plate. Run it on the analyzer the partitioning engine is assigned to.
	The assigned analyzer did not receive the partitioning data, e.g., because the connection failed. The partitioning data is lost.	Unload the nanowell plate. For a development run, either start the run without the affected nanowell plate or replace it with a freshly pipetted and partitioned nanowell plate. For a diagnostic run, invalidate the nanowell plate in the web application. Then, start the run without the invalidated nanowell plate.

Statuses of loaded nanowell plates

Resolving a nanowell plate ID reading error

If the analyzer cannot read a nanowell plate ID, you must scan or enter the nanowell plate ID manually.

In this case only, the **Manual entry** button on the **Plates** panel is available.

⚠ CAUTION!

Incorrect manual entering of nanowell plate ID

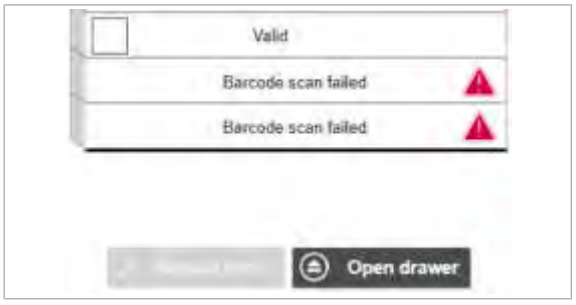
Incorrect manual entering of a nanowell plate ID may cause incorrect results due to incorrect assignment between order and result.

- If you scan or enter a nanowell plate ID manually, ensure that you scan or enter the nanowell plate ID correctly.
- If you must open the nanowell plate stack drawer and remove the nanowell plates, ensure that you keep the order of the nanowell plates in the stack to facilitate identification of the affected nanowell plate.

The procedure to resolve a nanowell plate ID reading error depends on the availability of the nanowell plate ID in a sample setup report or other planning of the run:

- If you have the nanowell plate ID available independently from the nanowell plate itself, you can leave the nanowell plate stack drawer closed.
- If you need to refer to the nanowell plate itself for the nanowell plate ID, you must open the nanowell plate stack drawer and unload the nanowell plates.

About multiple nanowell plate ID reading errors



You can only resolve 1 nanowell plate ID reading error. If there is more than 1 nanowell plate ID reading error, the **Manual entry** button on the **Plates** panel is not available.

If there are multiple nanowell plate ID reading errors, you must unload and discard the affected nanowell plates except 1.

About unresolved nanowell plate ID reading errors

If you cannot resolve a nanowell plate ID reading error, you must do the following:

- For development runs, unload the affected nanowell plates from the analyzer. Then, either start the development run without the affected nanowell plates or replace them with freshly pipetted and partitioned nanowell plates.
- For diagnostic runs, unload the affected nanowell plates from the analyzer. In the web application, invalidate the nanowell plates in the sample setup. Then, start the diagnostic run without the invalidated nanowell plates.

Invalidating nanowell plate lanes and/or nanowell plates in the web application (535)

☐ Nanowell plate status: **Barcode scan failed**

To resolve a nanowell plate ID reading error with nanowell plate ID available (without opening of the nanowell plate stack drawer)

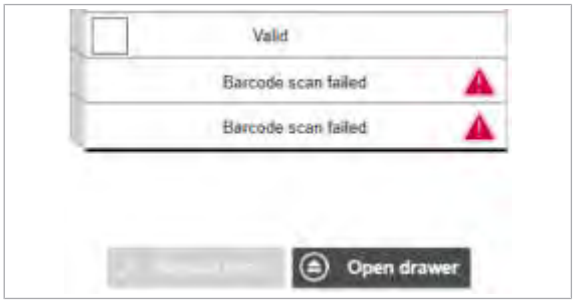
1 Ensure that there are nanowell plate ID reading errors:

- To open the nanowell plate stack drawer, choose the **Open drawer** button.
- Check the placement of the nanowell plates in the nanowell plate stack drawer.
- To close the nanowell plate stack drawer, choose the **Close drawer** button.

➔ The analyzer reads the nanowell plate IDs again.

➔ The **Plates** panel is refreshed.

➔ If the nanowell plate ID reading errors persist, continue with the following steps.



2 Optionally, if there is more than 1 nanowell plate ID reading error, do the following:

- To open the nanowell plate stack drawer, choose the **Open drawer** button.
- Unload the affected nanowell plates except 1.
- Discard the unloaded nanowell plates according to local regulations. For a diagnostic run, invalidate the unloaded nanowell plates in the sample setup in the web application.
- To close the nanowell plate stack drawer, choose the **Close drawer** button.

➔ The analyzer reads the nanowell plate IDs again.

➔ The **Plates** panel is refreshed.

➔ If a single nanowell plate ID reading error persists, the **Manual entry** button is available. Continue with the following steps.

3 Compare the information on the **Plates** panel with your sample setup report or other planning. Identify the affected nanowell plate and determine its nanowell plate ID.

4 On the **Plates** panel, choose the **Manual entry** button.

5 In the table of nanowell plates, choose the field for the nanowell plate ID of the affected nanowell plate.

➔ The numeric keyboard is displayed.

6 CAUTION! Risk of incorrect, invalid, or delayed results.
Ensure that you enter the correct nanowell plate ID.

On the numeric keyboard, enter the nanowell plate ID.

7 Choose the **Enter** button.

8 On the **Plates** panel, choose the **Accept changes** button.

➔ The nanowell plate status is updated.

➔ The nanowell plate ID reading error is resolved.

To resolve a nanowell plate ID reading error without nanowell plate ID available (with opening of the nanowell plate stack drawer)

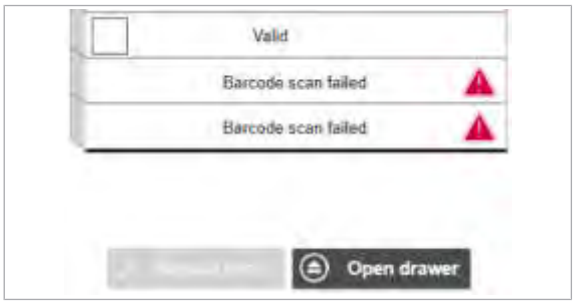
1 Ensure that there are nanowell plate ID reading errors:

- To open the nanowell plate stack drawer, choose the **Open drawer** button.
- Check the placement of the nanowell plates in the nanowell plate stack drawer.
- To close the nanowell plate stack drawer, choose the **Close drawer** button.

➔ The analyzer reads the nanowell plate IDs again.

➔ The **Plates** panel is refreshed.

➔ If the nanowell plate ID reading errors persist, continue with the following steps.



2 Optionally, if there is more than 1 nanowell plate ID reading error, do the following:
   - To open the nanowell plate stack drawer, choose the **Open drawer** button.
   - Unload the affected nanowell plates except 1.
   - Discard the unloaded nanowell plates according to local regulations. For a diagnostic run, invalidate the unloaded nanowell plates in the sample setup in the web application.
   - To close the nanowell plate stack drawer, choose the **Close drawer** button.
   - ➔ The analyzer reads the nanowell plate IDs again.
   - ➔ The **Plates** panel is refreshed.
   - ➔ If a single nanowell plate ID reading error persists, the **Manual entry** button is available. Continue with the following steps.

3 On the **Plates** panel, identify the affected nanowell plate and take note of its position in the stack.

4 To open the nanowell plate stack drawer, choose the **Open drawer** button.

5 Remove the nanowell plate stack from the nanowell plate stack drawer.

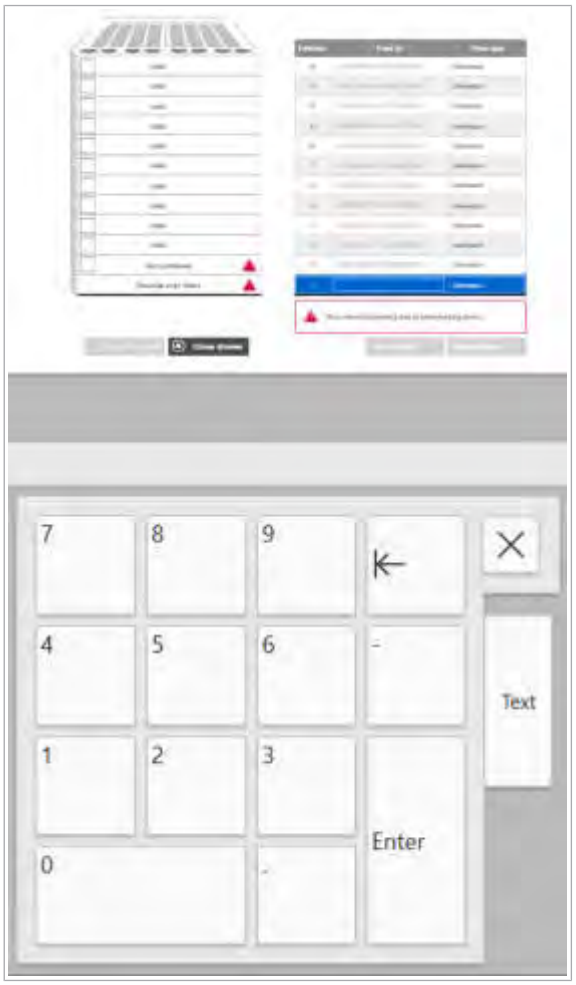
   ⓘ Ensure that you keep the order of the nanowell plates in the stack.

6 Identify the affected nanowell plate in the stack and determine its nanowell plate ID.

   ⓘ You can only use the nanowell plate if the barcode and/or the nanowell plate ID on the label are readable.

7 On the **Plates** panel, choose the **Manual entry** button.

8 In the table of nanowell plates, choose the field for the nanowell plate ID of the affected nanowell plate.
   - ➔ The numeric keyboard is displayed.



9 CAUTION! Risk of incorrect, invalid, or delayed results.
Ensure that you enter the correct nanowell plate ID.

Scan or enter the nanowell plate ID of the affected nanowell plate.

10 On the numeric keyboard, choose the **Enter** button.

11 Reload the nanowell plate stack in the nanowell plate stack drawer.

12 To close the nanowell plate stack drawer, choose the **Close drawer** button.

➔ The nanowell plate status is updated.

➔ The nanowell plate ID reading error is resolved.

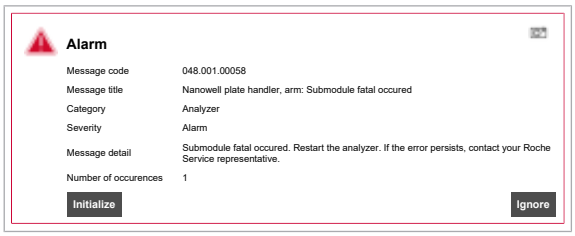
Resolving an alarm of the analyzer

If an alarm occurrs on the analyzer, you cannot work with the analyzer until the issue is resolved.

Whenever an alarm callout or error callout is displayed, take a screenshot of the callout.

- ☐ Alarm callout displayed with **Category** = **Analyzer**, **Severity** = **Alarm**, **Ignore** button, and **Initialize** button
- ☐ Analyzer in **Error** status

To resolve an alarm of the analyzer



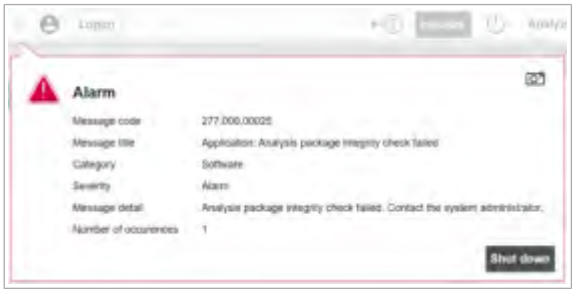
1. To take a screenshot of the alarm callout, choose the button.
2. If you can deduce from the message details that a restart of the analyzer cannot resolve the issue, e.g., because of a blown fuse, continue directly with step **7**.
3. Choose the **Initialize** button.
   ➔ The callout is closed, the corresponding message is confirmed, and the analyzer is restarted.
4. Shut down the analyzer as described in Shutting down the analyzer (440).
5. On the right side of the analyzer, press the power switch.
6. To start up the analyzer again, on the right side of the analyzer, press the power switch again.
7. If the error persists or if you can deduce from the message details that a restart of the analyzer cannot resolve the issue, do the following:
   - Choose the **Ignore** button.
   - Contact your Roche Service representative.

Resolving an alarm of the analyzer software

If an alarm occurs in the analyzer software, you cannot work with the analyzer until the issue is resolved.

Whenever an alarm callout or error callout is displayed, take a screenshot of the callout.

☐ Alarm callout displayed with **Category** = **Software**, **Severity** = **Alarm**, and **Shut down** button.



To resolve an alarm of the analyzer software

1. To take a screenshot of the alarm callout, choose the button.
2. Choose the **Shut down** button.
   ➔ The alarm callout is closed, the corresponding message is confirmed, and the analyzer software is shut down.
3. Wait until shutdown is complete and the touch screen turns dark.
4. Start up the analyzer as described in Starting up the analyzer (235).
5. If the error persists, contact your Roche Service representative.

Troubleshooting in the development software

In this chapter 21

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Locating the log files in the development software

The log files contain relevant data required by Roche for troubleshooting purposes.

If you encounter a problem with the development software and contact your Roche Service representative, you may be asked to provide the log files.

Roche reviews the log files upon your request only.

- ☐ Optionally, external storage device, e.g., USB flash drive

- ☐ Enough memory

To locate the log files

1. In the development software, in the **Navigation** area, choose **File** > ⋯ > **Help** > **Logs**.
   ➔ A Windows Explorer is displayed at the location of the log files.
2. From the Windows Explorer, copy the log files.

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Troubleshooting in the web application

In this chapter 22

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Invalidating nanowell plate lanes and/or nanowell plates in the web application

If nanowell plate lanes and/or nanowell plates of a diagnostic sample setup are compromised, invalidate the nanowell plate lanes and/or the nanowell plates in the web application before you start the diagnostic run.

Examples for compromising events include:

- Pipetting errors
- Skipped partitioning of nanowell plate lanes that contain reaction mixtures (partitioning indicator remains gray)
- Dropped nanowell plates

If you invalidate nanowell plate lanes and/or nanowell plates in the web application, the following applies:

- The system invalidates all results from invalidated nanowell plate lanes.
- If you invalidate a nanowell plate lane that contains a control, all orders of the sample setup for that test get an invalid result.
- If you invalidate a nanowell plate, all nanowell plate lanes of that nanowell plate are invalidated.
- If you invalidate all nanowell plate lanes of a nanowell plate, the whole nanowell plate is invalidated.
- You must discard invalidated nanowell plates. You cannot process invalid nanowell plates on the analyzer.

Invalidating the compromised nanowell plate lanes and/or nanowell plates allows you to invalidate the subsequent results without discarding the whole sample setup and the already partitioned nanowell plates.

You cannot exchange an invalid nanowell plate in a diagnostic workflow.

⚠ CAUTION!

Missing measurements or invalidated controls

Invalidating a nanowell plate lane that is required for result calculation or contains a control may cause invalid or delayed results.

- Take extra care to avoid wrongly invalidating a nanowell plate lane that is required for result calculation or that contains a control.
- If you must invalidate a nanowell plate lane, consider the implications for result calculation and for the final results.

☐ Sample setup in the web application

☐ Diagnostic operator user role

To invalidate a nanowell plate lane in the web application

1 In the web application, in the **Sample setups** column on the dashboard, choose a batch tile.
   ➔ The **Sample setup** screen is displayed.

2 To invalidate a nanowell plate lane, choose the tile twice.
   ⓘ You can also choose several tiles at once.
   ➔ The **Sample settings:** combo box is displayed.

3 Select the **Invalid lane** check box.

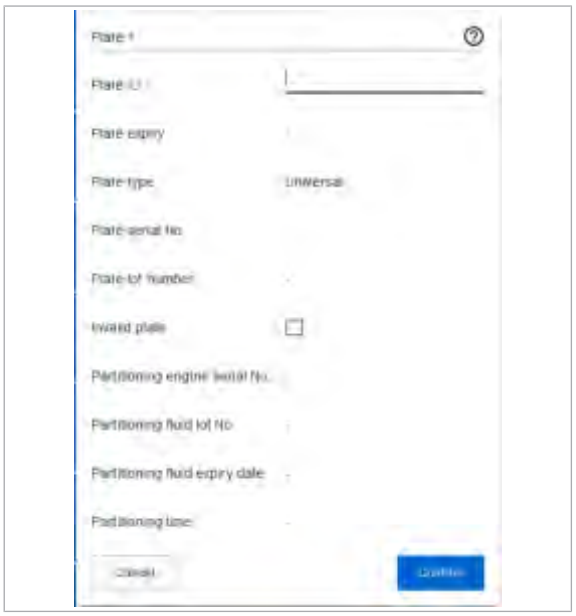
4 Choose the **Confirm** button.
   ➔ On the **Sample setup** screen, the tile is grayed out.

5 Choose the **Confirm** button.
   ➔ All results from invalidated nanowell plate lanes are invalid.
   ➔ If the invalid nanowell plate lane contains a control, all orders of the sample setup for that test get an invalid result.

To invalidate a nanowell plate in the web application

1 In the web application, in the **Sample setups** column on the dashboard, choose a batch tile.
   ➔ The **Sample setup** screen is displayed.

2 To invalidate a nanowell plate, choose the column header twice.
   ➔ The **Plate:** combo box is displayed.



3 Select the **Invalid plate** check box.

4 Choose the **Confirm** button.
   ➔ On the **Sample setup** screen, the nanowell plate is grayed out.

5 Choose the **Confirm** button.
   ➔ The nanowell plate is invalid. You cannot process the nanowell plate on the analyzer.
   ➔ All results from invalidated nanowell plates are invalid.

Sending results again in the web application

In the web application, you can send again results of completed batches that are already in **Sent** status.

You cannot send again results of completed batches that are still in **Send queued** status or that were generated with an analysis package in **In validation** status.

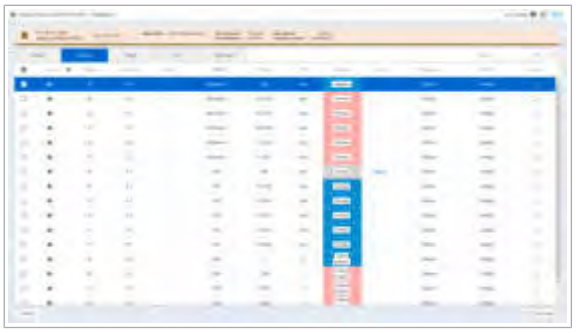
About failed sending of results

If automatic sending of results is configured but sending of a result fails (e.g., because of a lost connection), the system retries 3 times to send to result. If sending still fails, the status of the result changes to **Sent** and you must send again the result manually.

- ☐ Completed batch with results in **Sent** status available in the web application
- ☐ Diagnostic approver user role

To send results again in the web application

1. In the web application, in the **Results** column on the dashboard, choose the **Completed batches** tile.
   ➔ The **Completed batches** screen is displayed.
2. From the table, select the batch that has results that you want to send again. Choose the **View** button.
   ➔ The **Results of** screen is displayed.



3. Navigate to the results in **Sent** status that you want to send again:
   - From the drop-down list, choose the analysis package.
   - Choose the **Samples** tab.
   - Alternatively, use the search function.

   ⓘ Results in **Sent** status are marked with the ➤ icon in the **Status** column.
4. Select 1 or several results in **Sent** status.
   ⓘ You can send again several results at the same time.
   If you choose results in a different status, the **Send again** button is unavailable.
5. To send the results again, choose the **Send again** button.
   ➔ The **Confirmation** dialog box is displayed.

6 Enter your password and choose the **Send again** button.

➔ The result status changes to **Send queued** or **Sent**, respectively, marked with an icon or an icon in the **Status** column (depending on LIS connection status).

➔ Your user name replaces the previous entry in the **Send by** column.

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Configuration

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User management in the analyzer software

In this chapter 23

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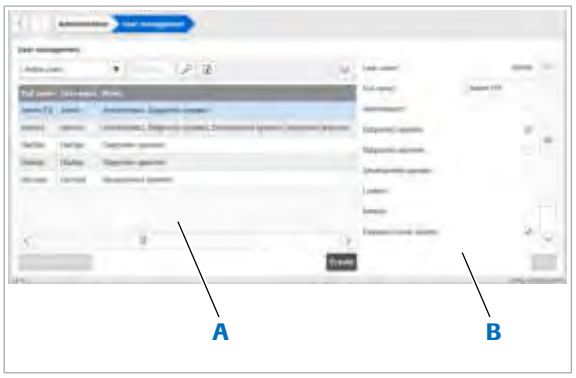
User management



A Table **B** Detail panel

On the **User management** panel, you manage user accounts.

The **User management** panel consists of the following elements:

- Table of users
- Detail panel displaying the user settings

To access the **User management** panel, you need administrator user role.

In this section

About user management

User management is performed in the analyzer software. The users are then synchronized to the web application.

There is no user management for the partitioning engine software and the development software. You do not need to log on to the partitioning engine or the development software.

About user roles

The user roles define the actions that users of that user role can perform in the analyzer software and the web application.

The following user roles are predefined in the system:

User roles	Permitted actions in the analyzer software	Permitted actions in the web application
Administrator	▪ All tasks on the **Administration** panel	▪ No access

Predefined user roles

User roles	Permitted actions in the analyzer software	Permitted actions in the web application
Diagnostic approver	▪ Change own password ▪ Manage problem reports ▪ Manage screenshots	▪ View orders, sample setups, run information, and results ▪ Send results ▪ Export raw data files
Diagnostic operator	▪ Perform diagnostic runs ▪ Change own password ▪ Manage problem reports ▪ Manage screenshots	▪ Add, edit, and import orders ▪ Create, edit, and delete sample setups ▪ Create sample setup reports ▪ Enter run information ▪ Enter result notes ▪ Release results ▪ Create result reports ▪ Export raw data files
Development operator	▪ Perform development runs ▪ Manage run profiles ▪ Manage raw data files (batches) ▪ Change own password ▪ Manage problem reports ▪ Manage screenshots	▪ No access

Predefined user roles

You cannot create, edit, or delete user roles.

Each user must have at least 1 user role. If a user has more than 1 user role, they can perform all tasks of the separate user roles.

About users

Each person using the system must have their own, unique user account. Do not use shared user accounts.

A user is identified by the credentials that are used to log on to the system, i.e., user name and password.

Users created in the analyzer software are automatically synchronized to the web application. Use the same credentials to log on to the web application.

You cannot delete users. To deny system access temporarily, lock a user. To deny system access permanently, retire a user.

A default user "Admin FN" with administrator user role is predefined in the system.

To ensure full system access in case of a lost administrator password, create a second user with administrator user role directly after installation of the system.

About passwords

Passwords must comply with the global password policy configured in the analyzer software in **Administration > Password settings**.

Password settings (599)

List of user settings

User management requires the configuration of the user settings.

➔ **Administration > User management**

User name

Field to enter the user name.

The user name is part of the credentials that users must enter to log on to the analyzer software and the web application.

After a user is created, you cannot change the user name.

For user names, the following rules apply:

- Must be unique
- Not case-sensitive
- 3 to 30 characters

Full name

Field to enter the full name of the user.

The full name of the logged on user is displayed in the global information area of the analyzer software and the web application.

For full names, the following rule applies:

- 3 to 50 characters

Password

Field to enter the password.

The password is part of the credentials that users must enter to log on to the analyzer software and the web application.

For passwords, the following rules apply:

- Case-sensitive
- 4 to 20 characters

Additionally, the password must conform to the global password policy configured in **Administration > Password settings**.

Password settings (599)

Administrator Check box to assign administrator user role.

Diagnostic operator Check box to assign diagnostic operator user role.

Diagnostic approver Check box to assign diagnostic approver user role.

Development operator Check box to assign development operator user role.

Locked: Check box to lock a user.

A locked user cannot log on to the analyzer or the web application.

Lock a user manually to deny system access temporarily.

If a user tries to log on and reaches the maximum number of failed logon attempts that is configured in the global password policy (**Administration > Password settings**), the user is locked automatically.

To unlock a user and to grant system access again, clear the check box.

You cannot lock the default administrator account "Admin FN".

Default value = unlocked

Retired: Check box to retire a user.

Retire a user to deny system access permanently, e.g., users that ceased working in the laboratory.

You can unretire a user. However, if you want to deny system access only temporarily, lock and unlock such users instead.

You cannot retire the default administrator account "Admin FN".

Default value = not retired

Password never expires

Check box to prevent the mandatory change of a user's password after the expiry period that is configured in the global password policy (**Administration > Password settings**).

You can only apply this setting to each user individually. You cannot apply this option globally to all users.

Default value = disabled

Change password at next logon:

Check box to force a user to change their password at the next logon, e.g., for new users or after the administrator changed a user's password.

If this setting is enabled, the user must change their password in the analyzer software or the web application, depending on where they log on first. The new password is then synchronized to the other software component.

After the user has changed their password, this setting is disabled again.

Default value = enabled

Allow EDI access

Check box to allow access to the analyzer via EDI connection.

Default value = disabled

Managing users

On the **User management** panel, you create, edit, lock, unlock, and retire users, and change their passwords.

You must create a separate user for each person using the system.

⚠ CAUTION!

Weak passwords

Weak passwords may allow unauthorized access to the system, data manipulation or loss, or unauthorized access to personal information, which may cause incorrect, invalid, or delayed results.

- Use strong passwords.
- Do not share passwords.
- Do not write down passwords.
- Do not share user accounts.

You cannot delete users. To deny system access temporarily, lock a user. To deny system access permanently, retire a user.

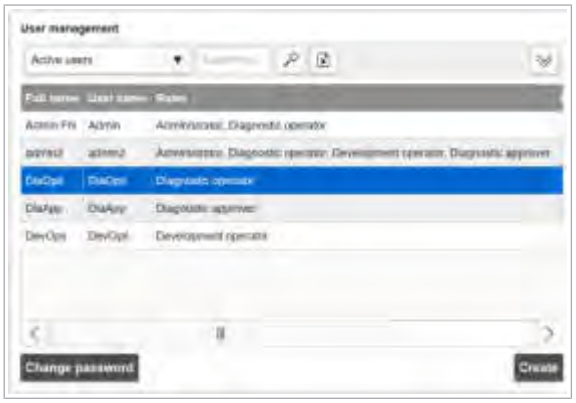
To ensure full system access in case of a lost administrator password, create a second user with administrator user role directly after installation of the system.

☐ Administrator user role

To create a user

1 Choose **Administration > User management**.
➔ The **User management** panel is displayed.

2 Choose the **Create** button.



3 In the **Enter user details** dialog box, enter the required information:
   - **Full name**
   - **User name**
   - **Password**
   - **Diagnostic operator** and/or **Development operator**

   ⓘ Ensure that you enter the correct user name. You cannot change it later.
   You must assign an operator user role in this step. For administrator user role or diagnostic approver user role, you must change the user role later in the detail panel.

4 Choose the **Confirm** button.
   ➔ The user is created and added to the table on the **User management** panel.

5 Optionally, in the detail panel, change the user role and/or apply additional settings:
   - **Administrator**, **Diagnostic operator**, **Diagnostic approver** and/or **Development operator**
   - **Locked**
   - **Retired**
   - **Password never expires**
   - **Change password at next logon:**
   - **Allow EDI access**

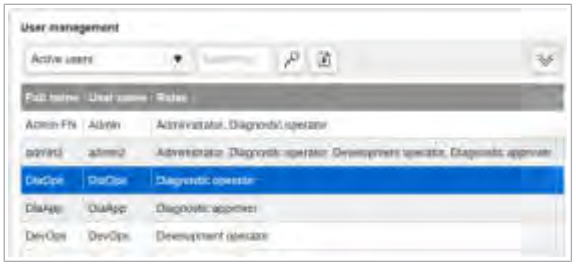
   ⓘ If you lock or retire the user, the user cannot log on to the system.

6 Choose the **Save** button.

To edit a user

1 Choose **Administration > User management**.
   ➔ The **User management** panel is displayed.

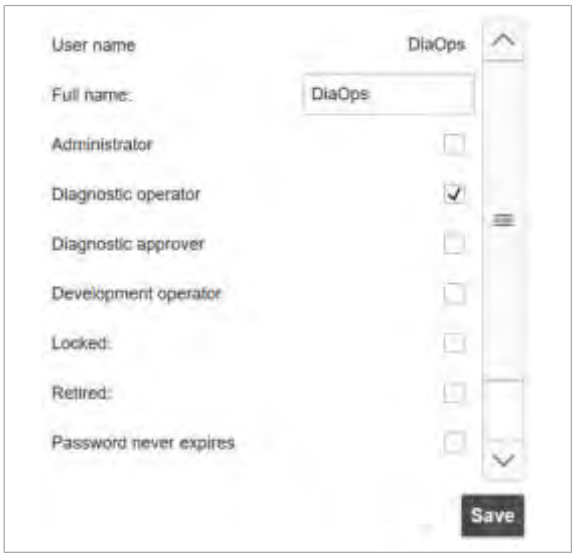
2 Optionally, sort, search, or filter the table.



3 From the table, choose a user.

4 To change the full name, enter the new full name in the **Full name** field.

   ⓘ You cannot change the user name.



5 To assign or to remove a user role, select or clear the corresponding check box:
- **Administrator**
- **Diagnostic operator**
- **Diagnostic approver**
- **Development operator**

6 To allow or deny system access, do one of the following:
- To prevent a user temporarily from logging on, select the **Locked:** check box.
- To allow a user to log on again, clear the **Locked:** check box.
- To prevent a user permanently from logging on, select the **Retired:** check box.

ⓘ You must retire users that are not used anymore. You cannot delete a user.
You cannot lock or retire the default administrator user "Admin FN".

7 To change the individual password requirements of the user, select or clear the corresponding check boxes:
- **Password never expires**
- **Change password at next logon:**

8 To allow or deny the user the EDI access, select or clear the **Allow EDI access** check box.

9 Choose the **Save** button.

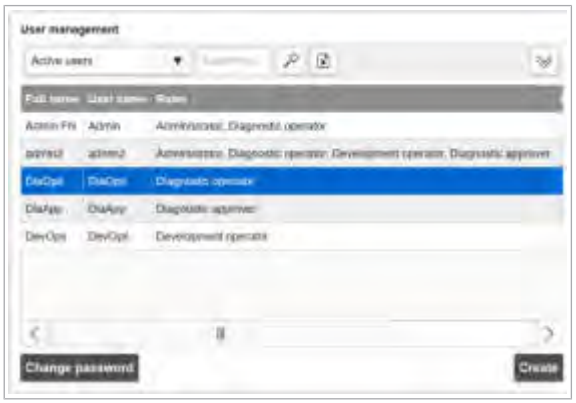
To change a user's password

1 Choose **Administration > User management**.
➔ The **User management** panel is displayed.

2 Optionally, sort, search, or filter the table.

3 From the table, choose a user.

4 Choose the **Change password** button.



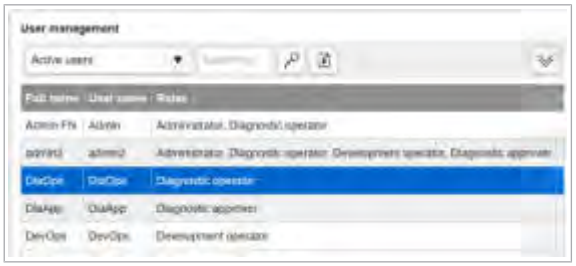
5 In the **Change password** dialog box, enter the new password twice. Choose the **Confirm** button.

6 Choose the **Save** button.

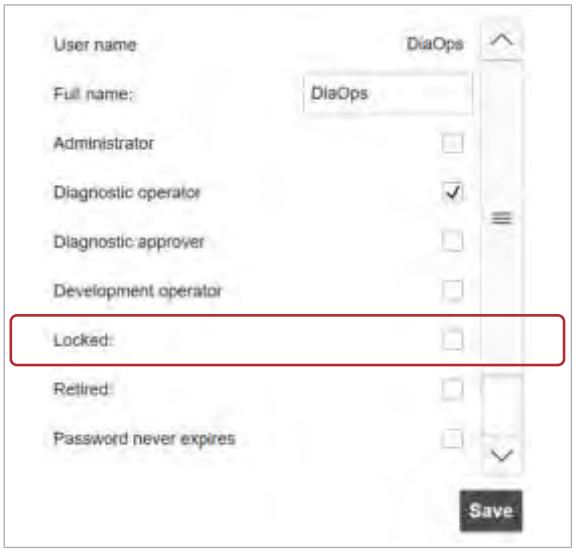
To lock or unlock a user

1 Choose **Administration > User management**.
➔ The **User management** panel is displayed.

2 Optionally, sort, search, or filter the table.



3 From the table, choose a user.



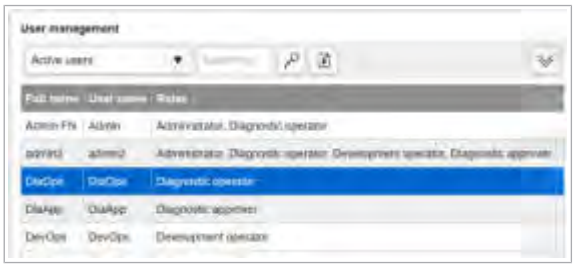
4 In the detail panel, do one of the following:
- To lock a user, select the **Locked:** check box.
- To unlock a user, clear the **Locked:** check box.

5 Choose the **Save** button.
➔ In the table on the **User management** panel, a locked user is indicated by an ✓ icon in the **Locked** column.

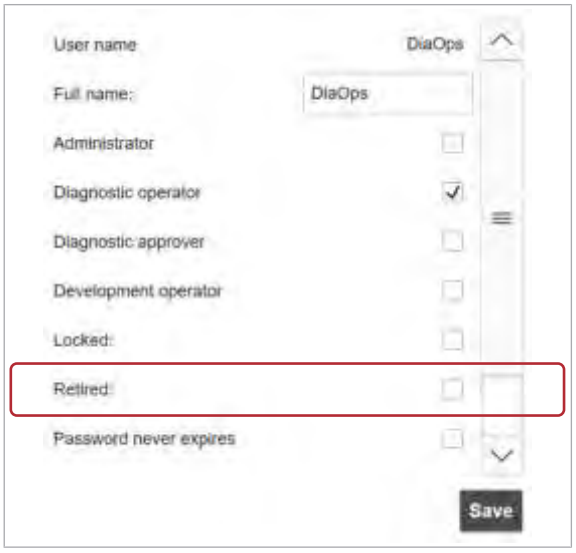
To retire a user

1 Choose **Administration > User management**.
➔ The **User management** panel is displayed.

2 Optionally, sort, search, or filter the table.



3 From the table, choose a user.



4 In the detail panel, select the **Retired:** check box.

ⓘ It is possible to unretire a user. However, to prevent a user temporarily from logging on, use the **Locked:** check box instead.

5 Choose the **Save** button.

ⓘ By default, the table on the **User management** panel lists the active users only. To display the retired users, from the filter drop-down list, choose the **All** option.

➔ In the table on the **User management** panel, a retired user is indicated by an ✓ icon in the **Retired** column.

Administration of the analyzer software

In this chapter 24

Archiving

On the **Archiving** panel, you schedule automatic archiving, perform manual archiving, and clean up not allocated orders.

To access the **Archiving** panel, you need administrator user role.

In this section

About archiving

Archiving allows you to store auditable data and to free up disk space on the analyzer. Archive regularly to maintain system performance.

The database of the system is stored on the hard disk of the analyzer. Therefore, archiving comprises data from the analyzer, the web application, and the partitioning engine.

All archived data is deleted from the analyzer when the archiving completes successfully.

If archiving fails, the data remains on the analyzer.

You can only save archives in a network share or on an external storage device. You cannot save an archive on the analyzer.

For archiving, the analyzer must be in **Analyzer ready** status. During archiving, the analyzer is in **Archiving** status.

During archiving, you cannot do any of the following on the analyzer and/or in the web application:

- Perform runs.
- Access data that is affected by archiving, e.g., view results that are applicable for archiving.

- Perform a function that accesses data that is affected by archiving, e.g., create a result report for results that are applicable for archiving.

About automatic archiving

Automatic archiving allows you to free up disk space on the analyzer regularly without manual intervention.

Scheduling automatic archiving helps to prevent unscheduled downtime of the system because of insufficient disk space.

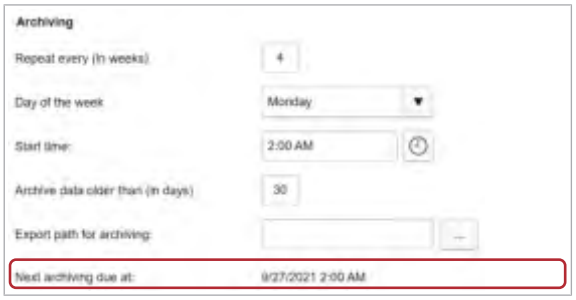
As archiving can take a long time, schedule automatic archiving for a time when the system is not needed, e.g., during the night.

The following table lists the **Archiving** settings:

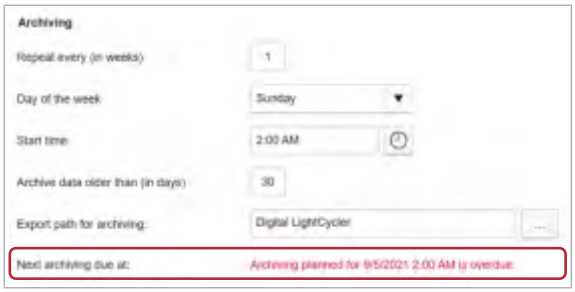
Archiving setting	Possible values	Default value
Repeat every (in days)	1-52 weeks	4 weeks
Day of the week	▪ Monday ▪ Tuesday ▪ Wednesday ▪ Thursday ▪ Friday ▪ Saturday ▪ Sunday	Monday
Start time:	Anytime	2 a.m.
Archive data older than (in days)	1-365 days	30 days
Export path	▪ Network share ▪ External storage device	n/a

Archiving settings

Automatic archiving is always enabled (and cannot be disabled), but will always fail until a valid path to a folder is configured.



When you save the archive settings, the date for the next due archiving is calculated from the last time automatic archiving was performed plus the configured repetition period. The next due date is displayed on the **Archiving** panel.



Archiving is displayed as overdue on the **Archiving** panel if the next due date is in the past because one of the following applies:

- The next due date that is calculated when saving the archive settings is already in the past.
- A scheduled automatic archiving failed.
  For example, automatic archiving fails if the analyzer is shut down at the scheduled execution time, or if the export folder is unavailable or has not enough memory.

If archiving is overdue, a corresponding warning message is displayed upon startup of the analyzer. The system does not retry an overdue automatic archiving.

Performing manual archiving or a failed automatic archiving does not change the next due date for the automatic archiving. The date is not recalculated.

To resolve the overdue automatic archiving, you can either wait until the next due archiving or you can change the archive settings to schedule the next automatic archiving earlier.

About manual archiving

Manual archiving allows you to free up disk space on demand.

If automatic archiving fails or a message is displayed that disk space is low, perform manual archiving to prevent unscheduled downtime of the system.

For manual archiving, the **Archive data older than (in days)** setting of automatic archiving also applies. For example, if you automatically archive data older than 30 days, a manual archiving also includes only data that is older than 30 days.

Performing manual archiving (467)

About cleaning up not allocated orders

Cleaning up not allocated orders allows you to delete outdated orders from the system. The orders are deleted from the **Orders** screen in the web application.

You must refresh the screen in the web application for the deleted orders not to be displayed anymore.

For cleaning up not allocated orders, the **Archive data older than (in days)** setting of automatic archiving also applies. For example, if you automatically archive data older than 30 days, only not allocated orders that are older than 30 days are deleted.

Clean up not allocated orders regularly. Clean up not allocated orders before you perform manual archiving.

Cleaning up not allocated orders (466)

About archived data

The following data is archived:

- Raw data files of diagnostic runs and development runs (as dpcrRaw files)
- Result reports of diagnostic runs (as PDF files)
- Audit trails (as CSV files)
- Messages (as CSV files)

If all completed batches are archived that are stored on the system, the **{count} completed batches** tile is no longer displayed on the dashboard of the web application.

About archive files

Archiving creates several separate files for the different archived data sets. The files are then compressed and saved as a single archive file (7z file).

To access the archived data again, decompress the archive file. The raw data files of the runs can be opened in the development software.

The archive files are named:
ARCH_YYYY-MM-DD_hh_mm_ss.7z
with the date and time the archive file was created.

List of naming placeholders (154)

Scheduling automatic archiving

To free up disk space on the analyzer regularly without manual intervention, schedule automatic archiving.

⚠ CAUTION!

Unprotected archive files

Insecure transfer or storage of archive files may allow for data manipulation, which may cause incorrect, invalid, or delayed results, and/or unauthorized access to personal information.

- Ensure that archive files are transferred securely, are stored in a secure location, and are protected from any unauthorized access and disaster.
- Ensure that any external storage devices (such as USB flash drives) that contain archive files are protected against unauthorized access.

If automatic archiving fails or disk space on the analyzer is low, perform manual archiving.

Performing manual archiving (467)

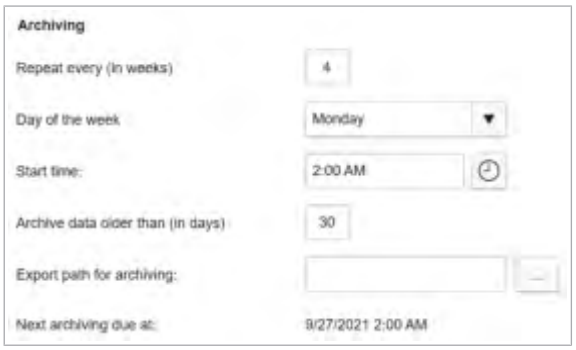
- ☐ Optionally, external storage device, e.g., USB flash drive

- ☐ Enough memory in the network share or on the external storage device
- ☐ Administrator user role

To schedule automatic archiving

1 Optionally, to configure archiving to an external storage device, connect the external storage device to the analyzer.

2 In the analyzer software, choose **Administration > Archiving**.
➔ The **Archiving** panel is displayed.



3 In the **Repeat every (in days)** field, enter the archiving frequency.

4 From the **Day of the week** drop-down list, choose a day of the week.

5 To configure the start time, do one of the following:
- Manually enter a time in the **Start time:** field.
- Choose the button and choose a time from the drop-down list.

ⓘ Schedule automatic archiving for a time when the analyzer is not needed, e.g., during the night.

6 In the **Archive data older than (in days)** field, enter a value.

ⓘ The value also applies to the cleanup of not allocated orders and to manual archiving.

7 To configure the export path to the archive folder, do the following:
- Choose the ··· button.
- In the folder browser, navigate to a folder.
- Choose the **Confirm** button.

8 In the **Archiving** panel, choose the **Save** button.

ⓘ If you configured automatic archiving to an external storage device, ensure that the external storage device is connected at the scheduled execution time. Automatic archiving fails if the configured export path is unavailable.

➔ Automatic archiving is performed as scheduled.

➔ The **Next archiving due at:** field lists the next scheduled archiving and the status of the archiving.

Audio settings

On the **Audio settings** panel, you configure if the analyzer plays an acoustic signal at the end of a run and/or when a message occurs.

To access the **Audio settings** panel, you need administrator user role.

By default, both acoustic signals are enabled.

Messages in the analyzer software (509)

☐ Administrator user role

To configure audio settings

1. In the analyzer software, choose **Administration > Audio settings**.
   ➔ The **Audio settings** panel is displayed.
2. To enable the audio signals, select the **End of run** check box and/or the **System messages** check box.
3. To disable the audio signals, clear the **End of run** check box and/or the **System messages** check box.
4. To change the volume of the signals, move the **Volume** slider.
   ⓘ The volume applies to any enabled audio setting. If you move the **Volume** slider to the **Off** position, you disable both audio signals.
5. Choose the **Save** button.

Backup

On the **Backup** panel, you schedule automatic backups and perform manual backups.

To access the **Backup** panel, you need administrator user role.

In this section

About backups

A backup saves the current system status and allows you to restore your system. Back up your system regularly to minimize data loss. Contact your Roche Service representative if a system restore becomes necessary.

The database of the system is stored on the hard disk of the analyzer. Therefore, backups comprise data from the analyzer, the web application, and the partitioning engine.

A backup does not change any data on the system.

You can only save a backup file in a network share or on an external storage device. You cannot save a backup file on the analyzer.

For a backup, the analyzer must be in **Analyzer ready** status. During the backup, the analyzer is in **Backup** status.

You cannot work on the system during a backup.

About automatic backups

Automatic backups allow you to save the system status regularly without manual intervention.

Scheduling automatic backups helps to prevent data loss.

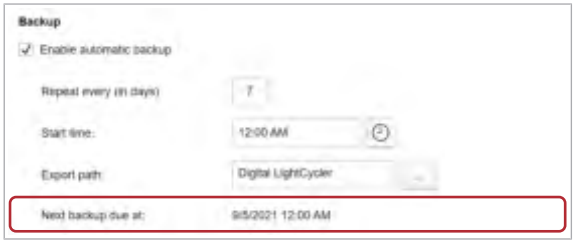
As a backup can take a long time, schedule automatic backups for a time when the system is not needed, e.g., during the night.

The following table lists the **Backup** settings:

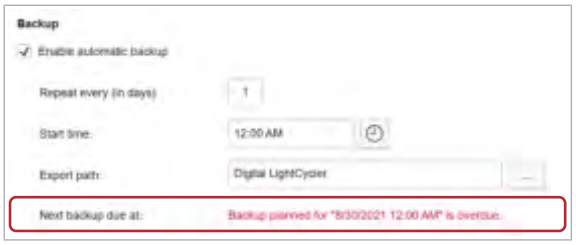
Backup setting	Possible values	Default value
Enable automatic backup	▪ Enabled ▪ Disabled	Disabled
Repeat every (in days)	1-30 days	7 days
Start time:	Anytime	2:00 a.m.
Export path	▪ Network share ▪ External storage device	n/a

Backup settings

By default, automatic backups are disabled.



When you enable automatic backups and save the backup settings, the date for the next due backup is calculated from the current date plus the configured repetition period. The next due date is displayed on the **Backup** panel.



The automatic backup is displayed as overdue on the **Backup** panel if the next due date is in the past because one of the following applies:

- The next due date that is calculated when saving the backup settings is already in the past.
- A scheduled automatic backup failed.
  For example, an automatic backup fails if the analyzer is shut down at the scheduled execution time, or if the backup folder is unavailable or has not enough memory.

If the backup is overdue, a corresponding warning message is displayed upon startup of the analyzer. The system does not retry an overdue automatic backup.

Performing a manual backup or a failed automatic backup does not change the next due date for the automatic backup. The date is not recalculated.

To resolve the overdue automatic backup, you can either wait until the next due backup or you can change the backup settings to schedule the next automatic backup earlier.

About manual backups

A manual backup allows you to save the system status on demand.

If the automatic backup fails, perform a manual backup.

Performing a manual backup (469)

About backup content

The following data is included in the backup file:

- Full database (e.g., orders and results)
- Analysis packages
- Analyzer-specific configurations
- Settings on the **Administration** panel (e.g., users and connection settings)
- Analyzer metadata (e.g., serial number of the analyzer and release configuration)

The following data is not part of the backup file:

- Raw data files
- Log files
- Audit trails
- Problem reports
- Screenshots
- Language packs and User Assistance packs

About backup files

A backup file is saved as a single, compressed 7z file.

The backup files are named *BKP_YYYY-MM-DD_hh_mm_ss_SN.7z* with the date and time the backup was created.

For data security, the backup files are password-protected. Contact your Roche Service representative if a system restore becomes necessary.

List of naming placeholders (154)

Scheduling automatic backups

To save the system status regularly, schedule automatic backups.

⚠ CAUTION!

Unprotected backup files

Insecure transfer or storage of backup files may allow for data manipulation, which may cause incorrect, invalid, or delayed results, and/or unauthorized access to personal information.

- Ensure that backup files are transferred securely, are stored in a secure location, and are protected from any unauthorized access and disaster.
- Ensure that any external storage devices (such as USB flash drives) that contain backup files are protected against unauthorized access.

If an automatic backup fails, perform a manual backup.

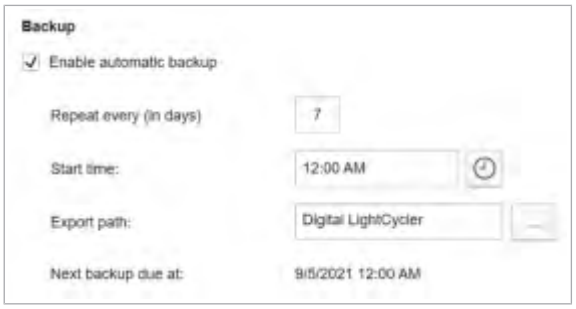
Performing a manual backup (469)

- ☐ Optionally, external storage device, e.g., USB flash drive

- ☐ Enough memory in the network share or on the external storage device
- ☐ Administrator user role

To schedule automatic backups

1. Optionally, to configure backups to an external storage device, connect the external storage device to the analyzer.
2. In the analyzer software, choose **Administration > Backup**.
   → The **Backup** panel is displayed.
3. Select the **Enable automatic backup** check box.
4. In the **Repeat every (in days)** field, enter the backup frequency.
5. To configure the start time, do one of the following:
   - Manually enter a time in the **Start time:** field.
   - Choose the button and choose a time from the drop-down list.
6. To configure the export path to the backup folder, do the following:
   - Choose the ··· button.
   - In the folder browser, navigate to a folder.
   - Choose the **Confirm** button.
7. In the **Backup** panel, choose the **Save** button.



If you configured automatic backups to an external storage device, ensure that the external storage device is connected at the scheduled execution time. Automatic backups fail if the configured export path is unavailable.

➔ Automatic backups are performed as scheduled.

➔ The **Next backup due at:** field lists the next planned backup and the status of the backup.

Connection settings

On the **Connection settings** panel, you connect the system to an LIS and/or AVENIO Connect, enable access via EDI, and/or enter the external IP address for NAT.

To access the **Connection settings** panel, you need administrator user role.

About connection indicators

When you connect the system to an LIS and/or to AVENIO Connect, separate connection indicators are added to the global information area of the analyzer software.

About the connection indicators (109)

In this section

List of connection settings

To configure a connection, you must enter the following connection settings.

➔ **Administration > Connection settings**

For network-specific information, contact your local IT administrator.

LIS group box

Sender

Field to enter the name that determines how your system is displayed in the LIS.

For the sender name, the following rule applies:

- 1 to 25 characters

Default value = "Digital LightCycler"

Communication protocol

Drop-down list to choose the protocol for the communication between the system and the LIS:

- **HL7 (MLLP1)**
- **HL7 (MLLP2)**

- **ASTM protocol**

Default value = **HL7 (MLLP2)**

IP address

Field to enter the IP address of the LIS.

For the IP address, the following rule applies:
- Must conform to the format of IPv4 addresses.

Default value = 127.0.0.1

Port

Field to enter the port of the LIS.

For the port, the following rule applies:
- Must be an integer number.

Default value = 55000

AVENIO Connect group box

Sender

Name of the system that is displayed in AVENIO Connect.

The **Sender** field is read-only. You cannot change the default name "Digital LightCycler".

Communication protocol

Drop-down list to choose the protocol for the communication between the system and AVENIO Connect:
- **HL7 (MLLP1)**
- **HL7 (MLLP2)**

Default value = **HL7 (MLLP2)**

IP address

Field to enter the IP address of AVENIO Connect.

For the IP address, the following rule applies:
- Must conform to the format of IPv4 addresses.

Default value = 127.0.0.1

Port

Field to enter the port of AVENIO Connect, e.g., 1788.

For the port, the following rule applies:
- Must be an integer number.

Default value = 1788

Export path for raw data

Field to enter the export path for the raw data files of AVENIO Connect runs.

To display the folder browser, choose the ··· button.

EDI group box

Server name

Field to enter the name of the EDI server.

For the server name, the following rules apply:

- 1 to 25 characters
- Forbidden characters:
  ? * < > \ / : " |

Default value = "EDI Server"

Port

Field for the preconfigured port for the EDI server, i.e., 50052.

The **Port** field is read-only. You cannot change the port.

Allow the EDI to log off a user

Check box to allow an EDI user to log off a locally logged on user.

Default value = enabled

Play sound if the EDI operates the drawer.

Check box to enable a system sound if the nanowell plate stack drawer of the analyzer is opened or closed remotely.

Default value = enabled

External IP address or NAT address group box

If your network uses a router, configure NAT with external IP address.

The external IP address is necessary to ensure that the web application and the EDI can connect.

If you enter or change the external IP address, you must restart the analyzer.

IP address

Field to enter the IP address for NAT as configured on the network equipment.

For the IP address, the following rule applies:

- Must conform to the format of IPv4 addresses.

Configuring connection settings

On the **Connection settings** panel, you configure the connections to an LIS and/or AVENIO Connect, enable access via EDI, and/or enter the external IP address for NAT.

For network-specific information, contact your local IT administrator.

If you connect the system to both an LIS and to AVENIO Connect, the IP addresses and ports must be different.

☐ Network-specific information (IP addresses, ports)

☐ Administrator user role

To connect the system to an LIS

1 In the analyzer software, choose **Administration > Connection settings**.
   ➔ The **Connection settings** panel is displayed.

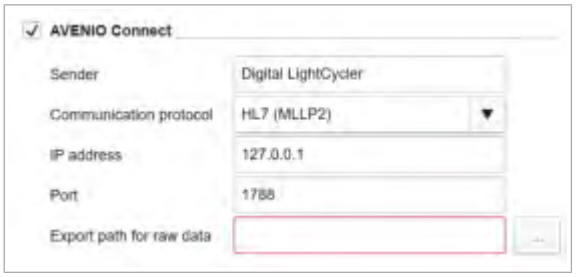
2 To connect the system to an LIS, select the **LIS** check box.

3 Optionally, in the **Sender** field, change the name for your system.
   ⓘ The name determines how your system is displayed in the LIS.

4 From the **Communication protocol** drop-down list, choose the protocol.
   ⓘ For network-specific information, contact your local IT administrator.

5 In the **IP address** field and in the **Port** field, enter the required information.
   ⓘ If you connect the system to both an LIS and to AVENIO Connect, the IP addresses and ports must be different.

6 Choose the **Save** button.
   ➔ A connection indicator for the LIS connection is added to the global information area of the analyzer software.



To connect the system to AVENIO Connect

1 In the analyzer software, choose **Administration > Connection settings**.
➔ The **Connection settings** panel is displayed.

2 To connect the system to AVENIO Connect, select the **AVENIO Connect** check box.

3 From the **Communication protocol** drop-down list, choose the protocol.

ⓘ For network-specific information, contact your local IT administrator.

4 In the **IP address** field, and in the **Port** field, enter the required information.

ⓘ If you connect the system to both an LIS and to AVENIO Connect, the IP addresses and ports must be different.

5 To configure the export path for the raw data files, choose the ··· button.
➔ The **Select folder** dialog box is displayed.

6 In the folder browser, navigate to a folder.

7 Choose the **Confirm** button.

8 Choose the **Save** button.
➔ A connection indicator for the connection to AVENIO Connect is added to the global information area of the analyzer software.

To enable system access via EDI

1 In the analyzer software, choose **Administration > Connection settings**.
➔ The **Connection settings** panel is displayed.

2 To enable system access via EDI, select the **EDI** check box.

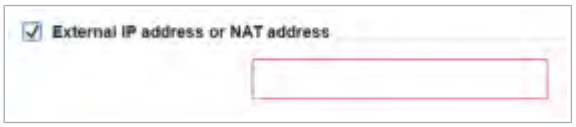
3 Optionally, in the **Server name** field, change the name.

4 Optionally, clear the **Allow the EDI to log off a user** check box and/or the **Play sound if the EDI operates the drawer.** check box.

5 Choose the **Save** button.

To configure NAT with external IP address

1 In the analyzer software, choose **Administration > Connection settings**.
➔ The **Connection settings** panel is displayed.



2 To enter the external IP address, select the **External IP address or NAT address** check box.

3 In the field, enter the IP address as configured on the router.

4 Choose the **Save** button.

5 Restart the system.

To disconnect the system

1 In the analyzer software, choose **Administration > Connection settings**.

➔ The **Connection settings** panel is displayed.

2 To disconnect the system from an LIS, clear the **LIS** check box.

3 To disconnect the system from AVENIO Connect, clear the **AVENIO Connect** check box.

4 To disable system access via EDI, clear the **EDI** check box.

5 If a router is not used anymore, clear the **External IP address or NAT address** check box.

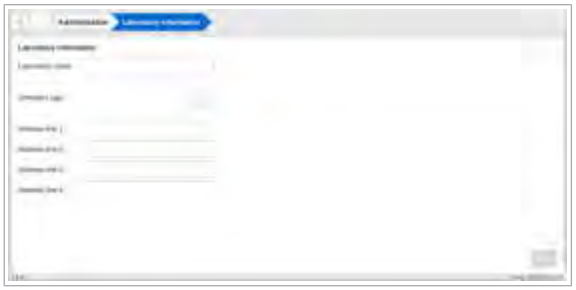
6 Choose the **Save** button.

ⓘ The network-specific information for LIS, AVENIO Connect, and EDI is retained. If you reconnect the system, you do not need to enter the information again.

➔ The connection indicators for LIS and AVENIO Connect are removed from the global information area of the analyzer software.

Laboratory information settings in the analyzer software

On the **Laboratory information** panel, you configure the name, address, and logo of your laboratory.



If configured, the laboratory information is included in all reports generated in the analyzer software and the web application.

For a logo file, the following restrictions apply:

- JPEG or PNG file
- File size: 10 MB or less
- Resolution: 1920 x 1080 pixels or less

The **Laboratory name** field is restricted in length from 1 to 50 characters.

To access the **Laboratory information** panel, you need administrator user role.

☐ Optional:
Logo file (JPEG or PNG file) saved in network share or on external storage device

☐ Administrator user role

To configure laboratory information settings in the analyzer software

1 Optionally, to import a logo file from an external storage device, connect the external storage device to the analyzer.

2 In the analyzer software, choose **Administration > Laboratory information**.
➔ The **Laboratory information** panel is displayed.

3 In the **Laboratory name** field, enter the name of your laboratory.

4 To add a logo, choose the ··· button.
➔ The **Select company logo** dialog box is displayed.

5 To choose the logo file, do the following:
- From the **File type** drop-down list, choose the file type.
- In the folder browser, navigate to the folder of the logo file.
- In the file browser, choose the logo file.
- Choose the **Confirm** button.

➔ A preview of the logo is displayed on the **Laboratory information** panel.

6 In the **Address line 1:** field, **Address line 2:** field, **Address line 3:** field, and **Address line 4:** field, enter the address of your laboratory.

7 Choose the **Save** button.
➔ The laboratory information is included in reports.

8 Optionally, disconnect the external storage device.

LIS mapping table

On the **LIS mapping table** panel, you edit LIS test names.

The LIS mapping table lists each test of an analysis package separately.

The LIS mapping table does not apply to development workflows.

To access the **LIS mapping table** panel, you need administrator user role.

About LIS test names

To allow for correct communication between the system and the LIS, the test names of all enabled analysis packages must be mapped unambiguously to unique LIS test names (1:1 relation).

The mapping ensures that the system can correctly process the received LIS orders and report the corresponding results.

The following rules apply:

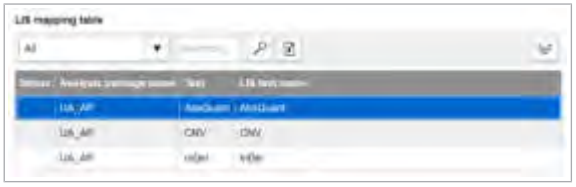
- By default, the test name is used as the LIS test name.
- If you disable a version of an analysis package by enabling another version, the system takes over the LIS test names from the disabled version to the enabled version.
- If enabling an analysis package results in conflicting LIS test names with a different enabled analysis package, you must immediately change the LIS test names in the LIS mapping table.
- In the **Status** column of the **LIS mapping table** panel, the conflicting LIS test names of **both** analysis packages are marked with an error icon. To resolve the conflict, it is sufficient to change the LIS test names of 1 analysis package.

Managing analysis packages (586)

☐ Administrator user role

To change a LIS test name

1 To display the **LIS mapping table** panel, do one of the following:
   - Choose **Administration > LIS mapping table**.
   - Choose **Administration > Manage analysis packages > LIS mapping table**.



If enabling an analysis package results in conflicting LIS test names, you must immediately change the LIS test names from the **Manage analysis packages** panel.

➔ The **LIS mapping table** panel is displayed.

➔ The table lists each test of an analysis package and the mapped LIS test name.

2 Optionally, sort, search, or filter the table.

3 To display the tests with conflicting LIS test names only, from the drop-down list, choose the **Conflicts** option.

4 From the table, choose a test.

5 Do the following:

- In the **Edit LIS test name** field, enter the new LIS test name.
- Choose the **Confirm** button.

6 Choose the **Close** button.

Manage analysis packages

On the **Manage analysis packages** panel, you manage the analysis packages for diagnostic runs.

To access the **Manage analysis packages** panel, you need administrator user role.

In this section

About analysis packages

Analysis packages provide all parameters necessary to plan and to perform diagnostic runs and to generate diagnostic results.

You use analysis packages in diagnostic workflows only.

You do not use analysis packages in development workflows. For the run parameters of development runs, you use run profiles only.

Run profiles in the analyzer software (298)

About the run parameters in analysis packages

Analysis packages contain the following information and parameters for diagnostic runs:

- General:
  - Name of analysis package
  - Version and creation date of analysis package
  - Issuer of analysis package
  - Nanowell plate type
  - Number of merged lanes
  - Run profile
  - Maximum time between partitioning and starting the run
  - Export settings for raw data files
  - Report label
- Test-specific:

- Test names
- Targets and dyes
- Names and dilution factors of master mix reagents
- Limits of detection, quantification, and/or validity
- Result names for final qualitative results
- Display of final quantitative results
- Control types, names, and valid ranges
- Analysis settings
- Clustering settings

About issuers of analysis packages

Analysis packages can have the following issuers:

- For IVD workflows, the analysis packages are issued by Roche. This is indicated by the Roche logo next to the name of the analysis package.
- For LDT workflows, you create your own analysis packages in the development software from the data that was created and analyzed in development workflows.

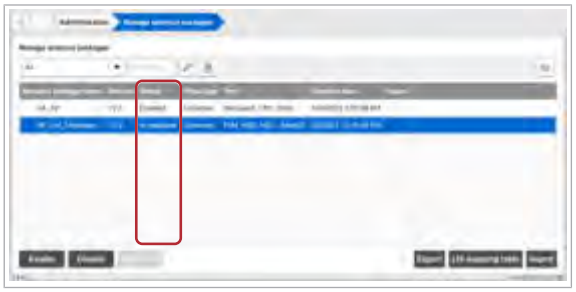
About analysis package files

An analysis package file has a *.dpcrAp* file extension.

You can import analysis packages from a network share or external storage device.

You can export analysis packages to a network share or external storage device.

About statuses of analysis packages



Analysis packages can be in the following statuses:

- **In validation**
- **Enabled**
- **Disabled**

After import into the analyzer software, an analysis package is in **In validation** status. You can perform diagnostic runs with such an analysis package, but the results are complete immediately after the diagnostic run finishes and cannot be released or sent to the LIS.

In the web application, analysis packages in **In validation** status are marked with an ◑ icon.

To perform diagnostic runs with results that you can release and send, you must enable the analysis package before the run, i.e., the analysis package must be in **Enabled** status.

Before you can enable an analysis package in **Disabled** status, you must revalidate it first to change its status to **In validation**.

To revalidate an analysis package (590)

About identification of analysis packages

Each analysis package is uniquely identified by the following identifiers:

- Name
- Version
- Name GUID
- Version GUID

The GUID information is derived from the name, version, and issuer of the analysis package. This is to ensure that the system can always differentiate between analysis packages that have different issuers, even if the name and the version are the same.

By default, only the name and the version are displayed in the table on the **Manage analysis packages** panel in the analyzer software (**Administration > Manage analysis packages**). You can configure the table to display the GUID columns as well.

Configuring table columns (142)

About importing analysis packages

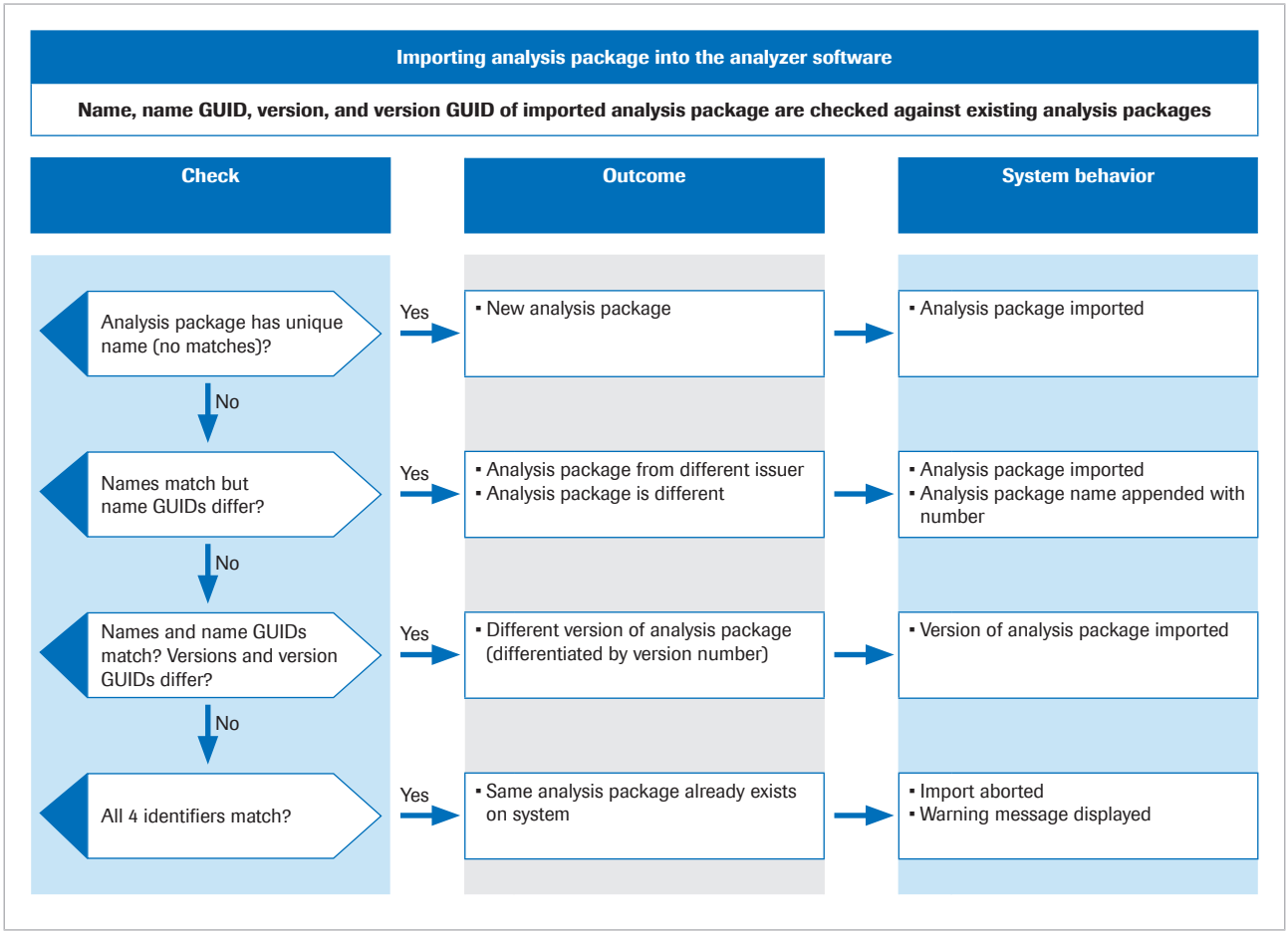
If you attempt to import an analysis package into the analyzer software, all 4 identifiers (name, name GUID, version, version GUID) are checked against the analysis packages that already exist in the analyzer software.

The system behavior depends on the outcome of the checks.

The following import logic is applied:

- The name does not match:
  - The analysis package is new.
  - The analysis package is imported.
- The name matches, but the name GUID differs (regardless of version and version GUID):
  - The analysis package has a different issuer and is classified as being different.
  - The analysis package is imported, but the name is appended with a consecutive number.
- The name and name GUID match, but the version and version GUID differ:
  - The analysis package is a different version of an existing analysis package.

  - The versions of the analysis package are differentiated by the version and version GUID.
  - The analysis package is imported.
- All 4 identifiers match:
  - The analysis package already exists.
  - The import is aborted.
  - A corresponding warning message is displayed.



Checks and outcomes for importing an analysis package

About enabling a version of an analysis package

There can be several versions of the same analysis package in the analyzer software, but only 1 version can be in **Enabled** status. All other versions must be in **In validation** status or **Disabled** status.

If there is a version of an analysis package in **Enabled** status and another version of the same analysis package in **In validation** status, the tests from the enabled analysis package are always assigned to LIS orders.

If you attempt to enable a version (e.g., the new version), the system automatically checks the other versions (e.g., the old versions) for the following:

- Their status in the analyzer software.
- If they are assigned to orders in the web application.

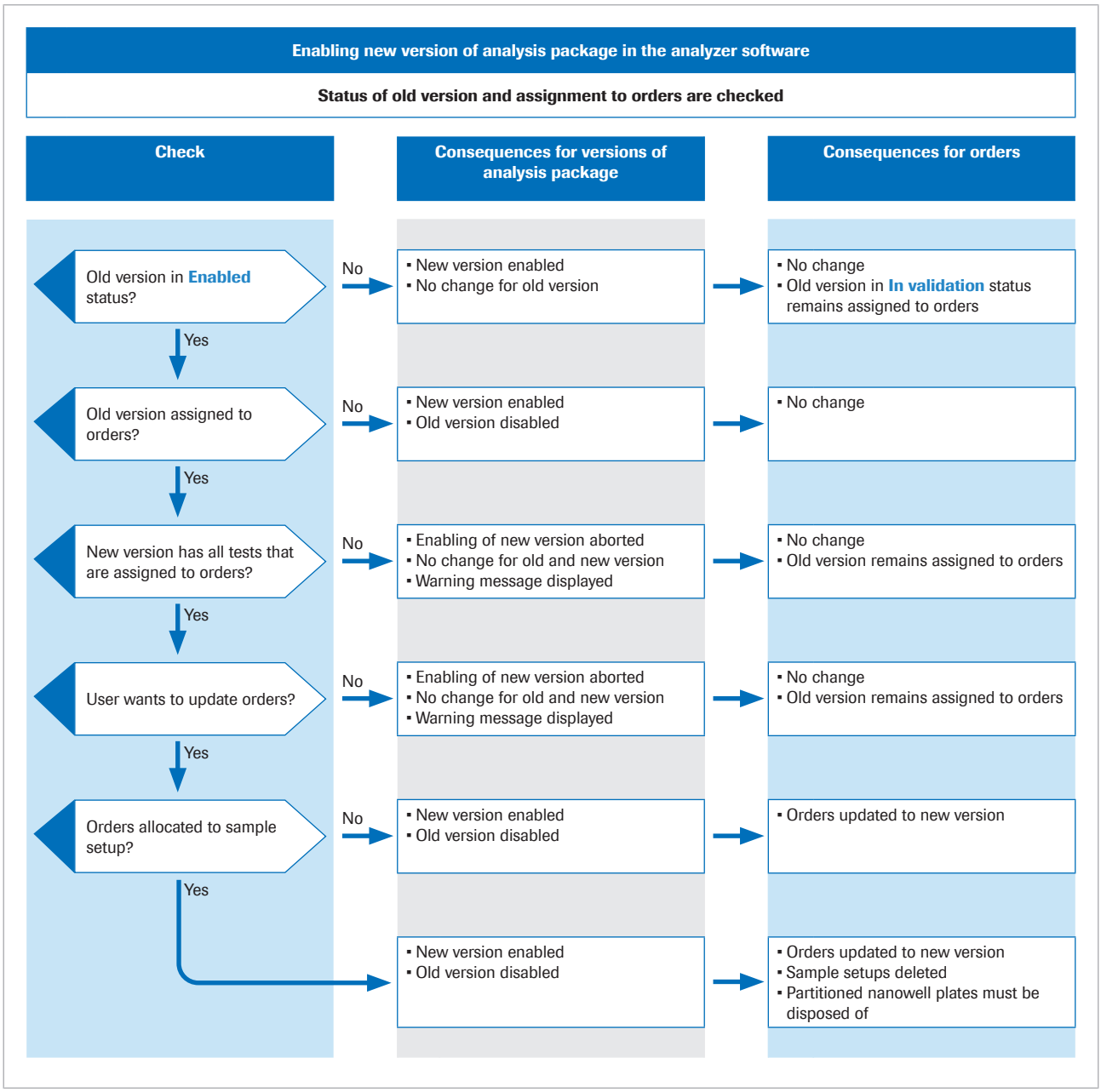
The system behavior depends on the outcome of the checks.

If **all** old versions are in **In validation** status or **Disabled** status, the new version is enabled directly.

- If an old version in **In validation** status is assigned to orders in the web application, these orders remain unchanged. They are not updated to the new, enabled version of the analysis package.
- Analysis packages in **Disabled** status cannot be assigned to orders.

If an old version is in **Enabled** status, the system automatically attempts to disable the old version before enabling the new version (because only 1 version can be in **Enabled** status):

- If the old version is not assigned to orders, the versions are enabled and disabled as attempted.
- If a test of the old version is assigned to orders but the new version lacks this test, the following applies:
  - The versions are neither enabled nor disabled.
  - The process is aborted and a corresponding warning message is displayed.
  - This also applies if a test is renamed in an analysis package. The system considers a renamed test as different, not as updated.
- If the old version is assigned to orders and the new version has all tests, you are asked if you want to delete the sample setups and/or update the orders:
  - If confirmed, the sample setups are deleted and the orders (including LIS orders) are updated to the new version.
    Any already partitioned nanowell plates cannot be reused but must be discarded.
    The versions are enabled and disabled as attempted.
  - If declined, the orders remain unchanged.
    The versions are neither enabled nor disabled.
    The process is aborted and a corresponding warning message is displayed.



Checks and outcomes for enabling a new version of an analysis package

To enable the new version of the analysis package **without** updating the orders, the old version must not be assigned to orders. To achieve this, do one of the following:

- Perform the diagnostic runs to finalize the orders for the old version of the analysis package.
- Delete the orders in the web application for the old version of the analysis package:
  1) For orders that are already allocated, delete the sample setups. The orders are then not allocated again.
     Dispose of any already partitioned nanowell plates according to local regulations.
  2) For all orders that are not allocated, deassign all tests and analysis packages.

You cannot delete LIS orders. If you do not want to update the LIS orders, you must perform the diagnostic runs.

Orders that are already processed, i.e., results in the web application, are not updated to the new version of the analysis package. However, the status of the analysis package they were processed with is displayed as **Disabled** on the **Results of** screen in the web application.

- Manage analysis packages (579)
- About the screens in the web application (94)
- Editing not allocated orders in the web application (252)

About enabling analysis packages and LIS test names

To allow for correct communication between the system and the LIS, the test names of all enabled analysis packages must be mapped unambiguously to unique LIS test names (1:1 relation).

The following rules apply:

- By default, the test name is used as the LIS test name.
- If you disable a version of an analysis package by enabling another version, the system takes over the LIS test names from the disabled version to the enabled version.
- If enabling an analysis package results in conflicting LIS test names with a different enabled analysis package, you must immediately change the LIS test names in the LIS mapping table.

- LIS mapping table (577)

About disabling analysis packages

If you attempt to disable an analysis package, the system checks if the analysis package is assigned to orders in the web application:

- You cannot disable an analysis package that is assigned to orders.
- A corresponding warning message is displayed.
- You must delete the orders in the web application before you can disable the analysis package.

- Manage analysis packages (579)
- Editing not allocated orders in the web application (252)
- Cleaning up not allocated orders (466)

Managing analysis packages

On the **Manage analysis packages** panel, you import, enable, disable, revalidate, and export analysis packages, and access the **LIS mapping table** panel.

You cannot delete an analysis package. Once imported, you can only disable it.

To map the test names in the enabled analysis packages to the LIS test names, you can access the **LIS mapping table** panel directly from the **Manage analysis packages** panel.

LIS mapping table (577)

- ☐ To import an analysis package:
  Analysis package (*.dpcrAp* file) saved in network share or on external storage device
- ☐ To export an analysis package:
  Optionally, external storage device, e.g., USB flash drive

- ☐ Administrator user role
- ☐ To enable, disable, or revalidate an analysis package:
  Analyzer in **Analyzer ready** status

To import an analysis package

1. Optionally, to import from an external storage device, connect the external storage device to the analyzer.
2. In the analyzer software, choose **Administration > Manage analysis packages**.
   ➔ The **Manage analysis packages** panel is displayed.
3. Choose the **Import** button.
   ➔ The **Import analysis package** dialog box is displayed.
4. In the folder browser, navigate to the folder of the analysis package.
5. In the file browser, choose the analysis package.
   ⓘ You cannot import the same analysis package twice.
6. Choose the **Import** button.
   ➔ The analysis package is listed on the **Manage analysis packages** panel.
   ➔ Depending on name and issuer of the analysis package, the name of the analysis package may be appended with a number.

➔ The analysis package is in **In validation** status.

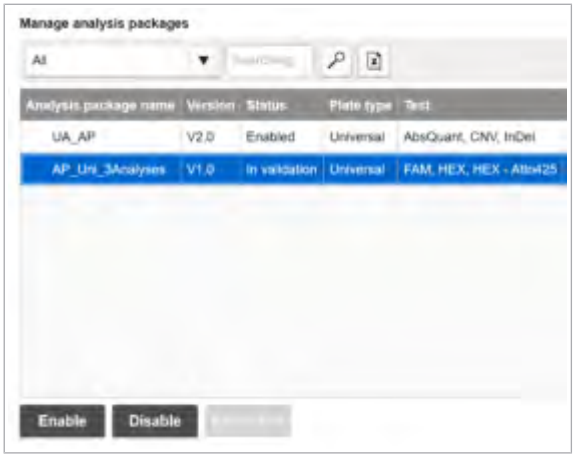
➔ You can perform diagnostic runs with an analysis package in **In validation** status, but the results are complete immediately after the diagnostic run finishes and cannot be released or sent.

7 Optionally, disconnect the external storage device.

To enable a new analysis package

1 In the analyzer software, choose **Administration > Manage analysis packages**.

➔ The **Manage analysis packages** panel is displayed.



2 Do the following:

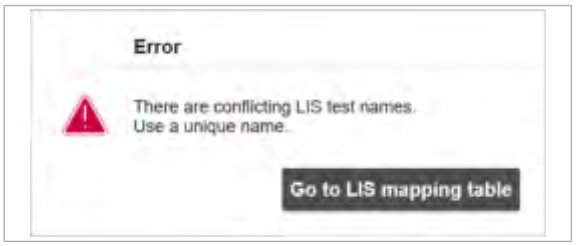
- To check for other versions of the analysis package that you want to enable, sort and/or filter the table accordingly.
- If another version of the analysis package exists in the analyzer software, continue with To enable a new version of an analysis package (587).

3 From the table, choose an analysis package in **In validation** status.

4 Choose the **Enable** button.

➔ The analysis package is in **Enabled** status.

➔ The system checks for conflicting LIS test names with the other enabled analysis packages. If duplicate LIS test names are found, an **Error** dialog box is displayed.



5 If required, resolve the conflicting LIS test names:

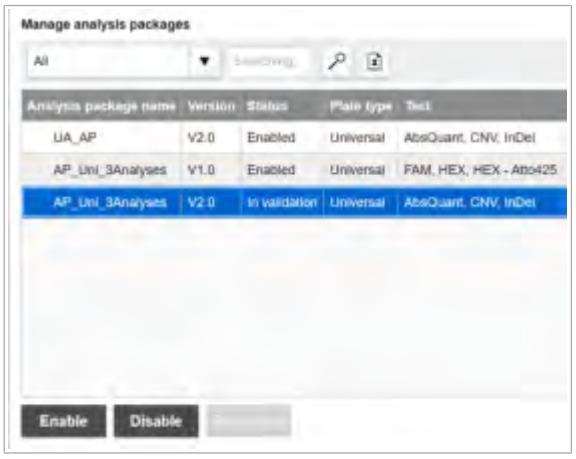
- In the **Error** dialog box, choose the **Go to LIS mapping table** button.
- In the **LIS mapping table** panel, change the LIS mapping names as described in LIS mapping table (577).
- Choose the **Close** button.

ⓘ In the **Status** column of the **LIS mapping table** panel, the conflicting LIS test names of **both** analysis packages are marked with an error icon. To resolve the conflict, it is sufficient to change the LIS test names of 1 analysis package.

To enable a new version of an analysis package

1 In the analyzer software, choose **Administration > Manage analysis packages**.

➔ The **Manage analysis packages** panel is displayed.



2 Do the following:
- To check for other versions of the analysis package that you want to enable, sort and/or filter the table accordingly.
- If no other version of the analysis package exists in the analyzer software, continue with To enable a new analysis package (587).

3 Optionally, if there is another version of the analysis package in **Enabled** status or in **In validation** status, check in the web application if that version of the analysis package is assigned to orders:
- In the web application, in the **Orders** column on the dashboard, choose the **View orders** tile.
- On the **Orders** screen, filter the orders for the analysis package.

ⓘ If the analysis package is assigned to orders but you want to prevent an update of the orders to the new version of the analysis package, you must either perform the diagnostic runs or delete the sample setups and orders.

4 In the analyzer software, from the table on the **Manage analysis packages** panel, choose the new version of the analysis package in **In validation** status.

5 Choose the **Enable** button.

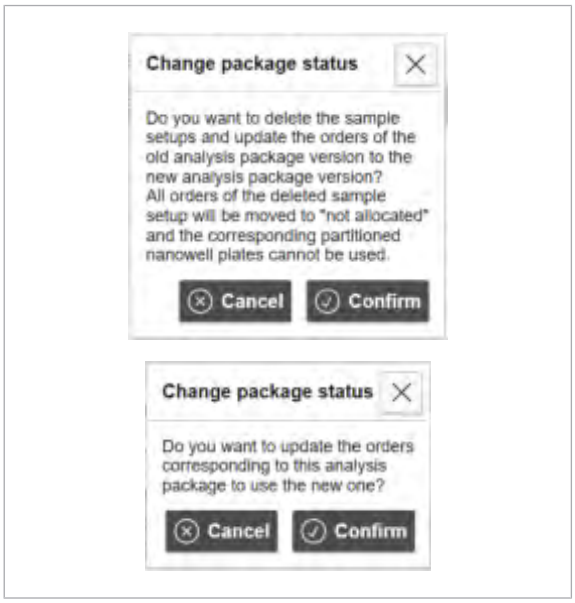
ⓘ You cannot enable a new version of an analysis package if it lacks a test that is still assigned to orders from the old version of the analysis package. First, you must delete the orders in the web application.

➔ The system checks if there exists a previously enabled version of the analysis package and if it is assigned to orders.

➔ If the analysis package can be enabled directly, it is set to **Enabled** status and a previously enabled version is set to **Disabled** status (if applicable).

➔ If a previously enabled version of the analysis package is assigned to orders, the **Change package status** dialog box is displayed.

➔ The system checks for conflicting LIS test names with the other enabled analysis packages. If duplicate LIS test names are found, an **Error** dialog box is displayed.

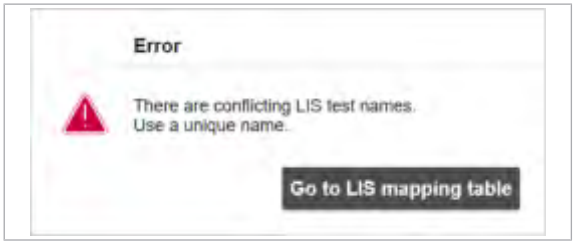


6 If required, to confirm the deletion of the sample setups and/or the update of the orders, in the **Change package status** dialog box, choose the **Confirm** button.

➔ The analysis package is set to **Enabled** status and the previously enabled version is set to **Disabled** status.

➔ In the web application, the sample setups are deleted and the orders are updated, indicated on the **Orders** screen.

➔ The system checks for conflicting LIS test names with the other enabled analysis packages. If duplicate LIS test names are found, an **Error** dialog box is displayed.



7 If required, resolve the conflicting LIS test names:

- In the **Error** dialog box, choose the **Go to LIS mapping table** button.
- In the **LIS mapping table** panel, change the LIS mapping names as described in LIS mapping table (577).
- Choose the **Close** button.

ⓘ On the **LIS mapping table** panel, the conflicting LIS test names of **both** analysis packages are marked with an error icon. To resolve the conflict, it is sufficient to change the LIS test names of 1 analysis package.

8 Optionally, in the **Orders** screen in the web application, choose the **Refresh** button.

➔ The updated orders are displayed.

To export an analysis package

1 Optionally, to export to an external storage device, connect the external storage device to the analyzer.

2 In the analyzer software, choose **Administration > Manage analysis packages**.

➔ The **Manage analysis packages** panel is displayed.

3 Optionally, sort, search, or filter the table.

4 From the table, choose an analysis package.

5 Choose the **Export** button.

➔ The **Select folder** dialog box is displayed.

6 In the folder browser, navigate to a folder.

7 Choose the **Confirm** button.

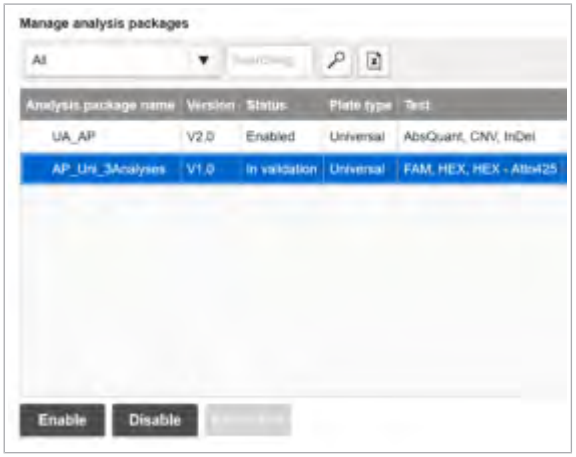
➔ The analysis package is exported to the folder.

8 Optionally, disconnect the external storage device.

To disable an analysis package

1 In the analyzer software, choose **Administration > Manage analysis packages**.
   ➔ The **Manage analysis packages** panel is displayed.

2 Optionally, sort, search, or filter the table.



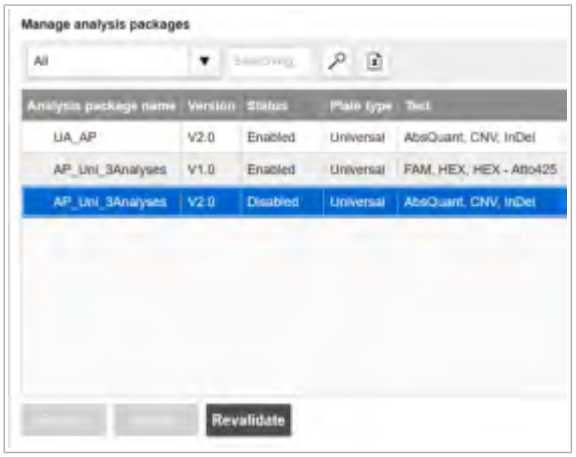
3 From the table, choose an analysis package in **Enabled** status or in **In validation** status.
   ⓘ You cannot disable an analysis package that is assigned to orders in the web application. You must delete the orders first.

4 Choose the **Disable** button.
   ➔ The analysis package is in **Disabled** status.
   ➔ You cannot perform diagnostic runs with an analysis package in **Disabled** status.

To revalidate an analysis package

1 In the analyzer software, choose **Administration > Manage analysis packages**.
   ➔ The **Manage analysis packages** panel is displayed.

2 Optionally, sort, search, or filter the table.



3 From the table, choose an analysis package in **Disabled** status.

4 Choose the **Revalidate** button.
   ➔ The analysis package is in **In validation** status.

Network share settings

On the **Network share settings** panel, you configure the paths to network shares, i.e., folders in the network, that you can then access in the folder browsers in the analyzer software.

Configuring network shares enables the navigation to import or export folders in folder browsers and facilitates the consistent use of folders, e.g., for archive files or backup files.

The Roche-provided firewall must allow access to network shares. Contact your Roche Service representative to configure the Roche-provided firewall.

To access the **Network share settings** panel, you need administrator user role.

In this section

About the Network share settings panel

The **Network share settings** panel lists all configured network shares, their status, and their use.

About statuses of network shares

When you access the **Network share settings** panel, the system tests if the network paths are accessible:

- The UNC paths themselves that are configured as network shares, e.g., \\server\Analyzer
- The network paths that are configured in other screens of the **Administration** tab and include the network shares, e.g., \\NetworkShare\Backup

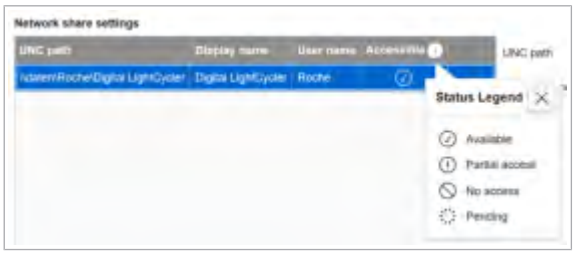
The icons in the **Accessible** column indicate the status of the network shares and their derived network paths:

Available:
- Network share is accessible.
- All network paths that include the network share are accessible.

Partial access:
- Network share is accessible.
- At least 1 of the network paths that include the network share is not accessible.

No access:
- Network share is not accessible.

Pending:
- Network share is not tested yet.



Directly after you access the **Network share settings** panel, all network shares are in **Pending** status. The status check and the update of the status icon may take some time.

To display a callout with the status legend, in the **Accessible** column header, choose the ⓘ button.

About use of network shares

If a network share is used, i.e., configured in a network path, the use is listed in the **Status of path used in settings** group box when you choose the network share from the table on the **Network share settings** panel.

The listed use includes the icons that indicate the status of the derived network paths:

Network path is accessible.

Network path is not accessible.

If no icon is displayed, the network path is currently being tested.

List of network share settings

You must enter the network share settings to configure network shares.

For network-specific information, contact your local IT administrator.

Use an analyzer-specific account on the network server.

UNC path Field to enter the UNC path.

The UNC path must conform to the following formats:

- \\server-name\path
- \\IP-address\path

Example:
\\server\Analyzer\Backup

If you include folders in the UNC path, ensure that these folders exist in the network.

Display name Name that is listed in folder browsers for the network share.

The display name must be unique.

User name User name of the analyzer-specific account on the server.

Password Password of the analyzer-specific account on the server.

Configuring network share settings

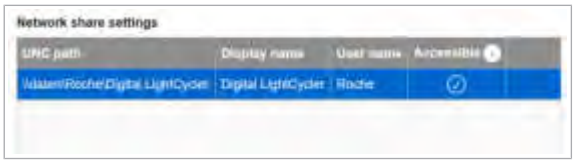
On the **Network share settings** panel, you create, edit, and delete network shares.

You cannot delete network shares that are used, e.g., for automatic export of raw data files. You must first delete all configured uses of the network share before you can delete the network share.

For network-specific information, contact your local IT administrator.

☐ Network-specific information (paths, account)

☐ Folders and subfolders created in the network
☐ Administrator user role



To create a network share

1 In the analyzer software, choose **Administration > Network share settings**.
   ➔ The **Network share settings** panel is displayed.

2 Choose the **Create** button.
   ➔ An empty row for a new network share setting in **Pending** status is added to the **Network share settings** table.
   ➔ The fields on the right of the **Network share settings** table are enabled for that network share setting.

3 Enter the required information:
   - **UNC path**
   - **Display name**
   - **User name**
   - **Password**

   ⓘ You must at least enter the UNC path and a display name.
   The display name must be unique.

4 Choose the **Test** button.

5 If the test of the network share setting is successful (i.e., the network share is accessible), choose the **Save** button.

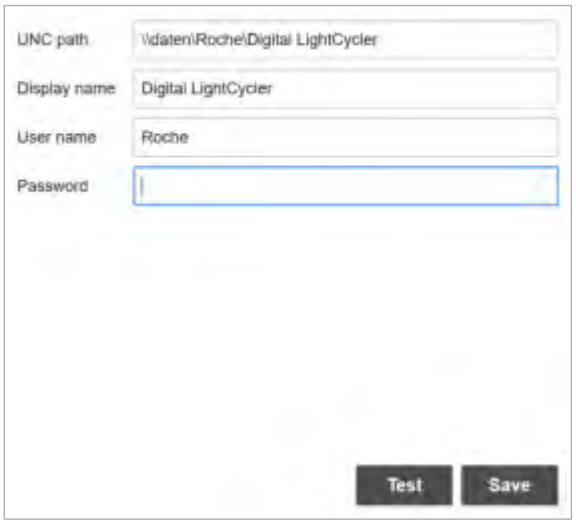
   ⓘ If you save the network share setting without testing it, the test is performed automatically. The result of the test is then displayed in the **Accessible** column.

   ➔ The network share is listed in the table on the **Network share settings** panel and in the folder browsers for import and export paths.

To edit a network share

1 In the analyzer software, choose **Administration > Network share settings**.
   ➔ The **Network share settings** panel is displayed.

2 From the table, choose the network share.



3 To change the information in a field, do the following:
- Choose the field.
- Edit the field content.
- Press Enter.

4 Choose the **Test** button.

5 If the test of the network share setting is successful (i.e., the network share is accessible), choose the **Save** button.

ℹ If you save the network share setting without testing it, the test is performed automatically. The result of the test is then displayed in the **Accessible** column.

➔ The edited network share is saved.

To delete a network share

1 In the analyzer software, choose **Administration > Network share settings**.

➔ The **Network share settings** panel is displayed.

2 From the table, choose a network share.

ℹ You cannot delete network shares that are used, e.g., as folder for automatic archiving.

3 Choose the **Delete** button.

➔ The **Remove network share** dialog box is displayed.

4 Choose the **Confirm** button.

➔ The network share is deleted from the **Network share settings** table and from the folder browsers in the analyzer software.

Partitioning engine connection

On the **Partitioning engine connection** panel, you assign partitioning engines to the analyzer.

To access the **Partitioning engine connection** panel, you need administrator user role.

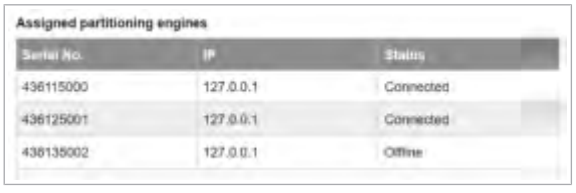
About partitioning engine connection

An analyzer only processes nanowell plates that were partitioned on an assigned partitioning engine. Therefore, you must at least assign 1 partitioning engine to each analyzer.

The assignment of the partitioning engine establishes the connection between the instruments and ensures that the partitioning data is sent to the analyzer and stored in the system database.

To assign a partitioning engine to an analyzer, the following prerequisites must be fulfilled:

- The partitioning engine and the analyzer must be connected to the same network.
- The partitioning engine must be started up to be detectable for the analyzer.
- The partitioning engine must not be assigned to a different analyzer.



In the analyzer software, a partitioning engine is identified by its serial number and IP address.

An assigned partitioning engine can have the following connection statuses:

- **Offline**
- **Connecting**
- **Connected**

A partitioning engine needs to be assigned to an analyzer only once:
After startup of the partitioning engine and the analyzer, the connection is automatically established again.

About multiple instrument configurations

You can assign several partitioning engines to each analyzer.

However, a partitioning engine can be assigned to 1 analyzer only at a time. To assign a partitioning engine to a different analyzer, you must deassign it first.

In a configuration with multiple partitioning engines and multiple analyzers, ensure that you assign each partitioning engine only to the analyzer it will be used with. Do not assign a partitioning engine to different analyzers. Otherwise, the partitioning engine will connect to the first available analyzer after startup, which might not be the analyzer it is used with. This could lead to loss of partitioning data.

⚠ CAUTION!

Incorrect assignment of partitioning engine to analyzer

An analyzer only processes nanowell plates that were partitioned on an assigned partitioning engine. If the partitioning engine you used to partition the nanowell plates is not assigned to the analyzer you want to process the nanowell plates on, the information from the partitioning engine may be lost, which may cause invalid or delayed results.

- Ensure that the partitioning engine is assigned to the analyzer.
- Pay extra attention to the assignment of the partitioning engines to the analyzers in a multiple instrument configuration (multiple partitioning engines and multiple analyzers).

- ☐ Partitioning engine and analyzer connected to the same network
- ☐ Partitioning engine started up
- ☐ Administrator user role

To assign or deassign a partitioning engine

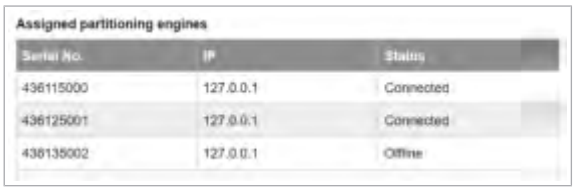
1 In the analyzer software, choose **Administration > Partitioning engine connection**.
   - ➔ The **Partitioning engine connection** panel is displayed.
   - ➔ The **Available in network** group box lists all unassigned partitioning engines that are detected by the analyzer.
   - ➔ The **Assigned partitioning engines** group box lists all partitioning engines that are assigned to the analyzer.

2 To assign a partitioning engine to the analyzer, do the following:

- In the **Available in network** group box, choose the partitioning engine.
- Choose the ⇨ button.

➔ The partitioning engine is assigned to the analyzer you are currently working on and listed in the **Assigned partitioning engines** group box.

➔ The partitioning engine cannot be assigned to other analyzers anymore.



3 To deassign a partitioning engine from the analyzer, do the following:

- In the **Assigned partitioning engines** group box, choose the partitioning engine.
- Choose the ⇦ button.

➔ The partitioning engine is unassigned from the analyzer you are currently working on and listed again in the **Available in network** group box.

➔ The partitioning engine can be assigned to other analyzers again.

Password settings

On the **Password settings** panel, you configure the global password policy all passwords must conform to.

To access the **Password settings** panel, you need administrator user role.

In this section

List of password settings

To define the global password policy, you can set the following requirements for all passwords.

➔ **Administration > Password settings**

By default, all password settings are enabled.

Idle time before automatic logoff (1-60 min)

Check box to enable auto logoff of users.
Field to enter the period of inactivity after which users are logged off automatically.

To prevent unauthorized system access, set a short inactivity time.

If a user is logged off automatically, the system discards any pending changes of the user.

Default value = 15 min

Number of days until password expiry (1-90)

Check box to enable automatic password expiry.
Field to enter the number of days after which users must change their passwords.

You cannot enter "0" here. If you want the password of a user never to expire, you must select the **Password never expires** check box in **Administration > User management** for the user.

You can only select the **Password never expires** check box for each user individually. You cannot select this option globally for all users.

Default value = 90 days

Password policy check box

Check box to enable the following list of password requirements.

You can only enable all or disable all password requirements. To disable a single password requirement, enter "0" in the corresponding field (if allowed).

Minimum password length (4–20)

Field to enter the minimum total length of passwords.

Default value = 6

Number of required uppercase letters in password (0–3)

Field to enter the minimum number of uppercase letters that are required in passwords.

Default value = 1

Number of required lowercase letters in password (0–3)

Field to enter the minimum number of lowercase letters that are required in passwords.

Default value = 1

Minimum number of digits in password (0–3)

Field to enter the minimum number of digits that are required in passwords.

Default value = 1

Number of required special characters in password (0–3)

Field to enter the minimum number of special characters that are required in passwords.

Default value = 0

Number of previous passwords not to be reused (0–5)

Field to enter the number of how far back old passwords cannot be used again.

Default value = 0

Lock user accounts after failed logon attempts (1–5).

Field to enter the maximum number of allowed failed logon attempts.

If a user tries to log on and reaches the maximum number of failed logon attempts, the user is locked automatically.

Default value = 3 attempts

Configuring password settings

On the **Password settings** panel, you enable and disable password settings, and enter their values.

If you change the password settings, the new settings only apply to passwords that are created later.

⚠ CAUTION!

Weak passwords

Weak passwords may allow unauthorized access to the system, data manipulation or loss, or unauthorized access to personal information, which may cause incorrect, invalid, or delayed results.

- Ensure that the configured global password policy enforces safe password handling.

☐ Administrator user role

To configure password settings

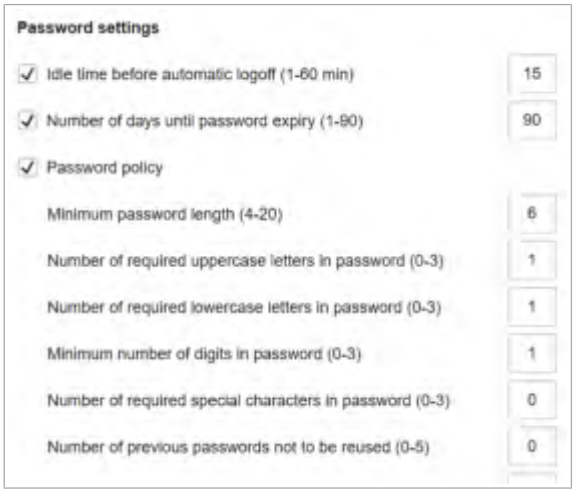
1 In the analyzer software, choose **Administration > Password settings**.
   ➔ The **Password settings** panel is displayed.

2 To enable a password setting, select the check box.
   ⓘ The more password settings you enable, the stronger passwords must be.

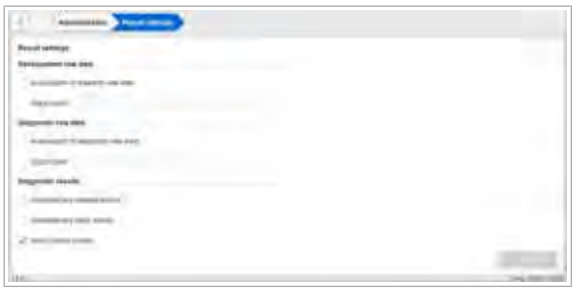
3 Optionally, change the value in the corresponding field.

4 To disable a password setting, clear the check box.

5 Choose the **Save** button.



Result settings

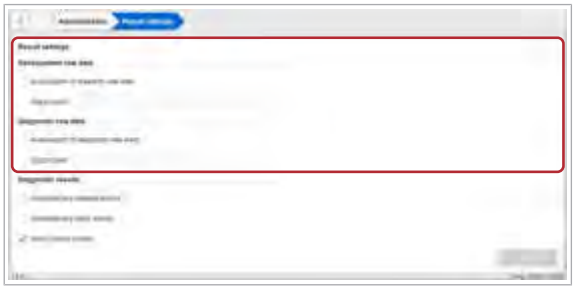


On the **Result settings** panel, you configure automatic export of raw data files and the diagnostic results settings.

To access the **Result settings** panel, you need administrator user role.

In this section

Automatic export of raw data files



On the **Result settings** panel, in the **Development raw data** group box and the **Diagnostic raw data** group box, you configure automatic export of raw data files.

To access the **Result settings** panel, you need administrator user role.

In this section

About automatic export of raw data files

Automatic export of the raw data files spares you the need to export the raw data manually.

By default, automatic export of the raw data files is disabled.

About raw data files and runs (309)

About export conditions

For a development run, the export of the raw data file is always possible.

For a diagnostic run, the export of the raw data file is only possible if the following conditions are met:

- All results of the diagnostic run must be complete, i.e., released and sent. The run must be listed on the **Completed batches** screen.
- The export of the raw data file must be enabled in the analysis packages used for the diagnostic run.

If a diagnostic run uses 2 or more analysis packages with different export settings, the most restrictive option is applied to the raw data file of that run.

Analysis packages in the development software (412)

About manual export

If the export path for automatic export is not available at the end of a run (e.g., because the network is down or the external storage device is not connected) or there is not enough memory, the automatic export fails and you must export the raw data manually.

Managing raw data files of development runs in the analyzer software (312)

Exporting raw data files of diagnostic runs from the web application (315)

Configuring automatic export of raw data files

On the **Result settings** panel, you configure the analyzer software to export the raw data files from diagnostic and/or development runs automatically to a network share or external storage device.

- ☐ Enough memory in the network share or on the external storage device
- ☐ Administrator user role

To configure automatic export of raw data files

1 Optionally, to configure export to an external storage device, connect the external storage device to the analyzer.

2 In the analyzer software, choose **Administration > Result settings**.
➔ The **Result settings** panel is displayed.

3 To configure automatic export of raw data files of development runs, in the **Development raw data** group box, do the following:
   - Select the **Auto-export of research raw data** check box.
   - Next to the **Export path** field, choose the ••• button.
   - In the folder browser, navigate to a folder.
   - Choose the **Confirm** button.

4 To configure automatic export of raw data files of diagnostic runs, in the **Diagnostic raw data** group box, do the following:
   - Select the **Auto-export of research raw data** check box.
   - Next to the **Export path** field, choose the ••• button.
   - In the folder browser, navigate to a folder.
   - Choose the **Confirm** button.

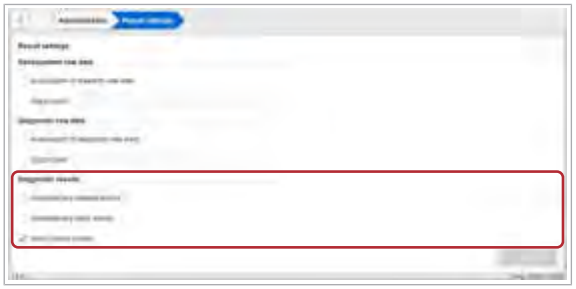
   ⓘ This setting only takes effect for diagnostic runs that are performed with analysis packages that allow export of the raw data.

5 Choose the **Save** button.

   ⓘ If you configured automatic export to an external storage device, ensure that the external storage device is connected at the end of a run. Automatic export fails if the configured export path is unavailable.

   ➔ After a run finishes, the raw data file is exported automatically to the folder.

Diagnostic results settings



On the **Result settings** panel, in the **Diagnostic results** group box, you configure the diagnostic results settings.

To access the **Result settings** panel, you need administrator user role.

In this section

About the diagnostic results settings

The diagnostic results settings spare you the need to release and send diagnostic results manually in the web application, and ensure that control results are included.

By default, the automatic release and sending of diagnostic results are disabled, and the sending of control results is enabled.

The diagnostic results settings do not apply to development runs.

About automatic release and send

The diagnostic results settings for release and sending of diagnostic results apply to the web application:

- If 1 or both settings are **disabled** in the analyzer software, you must release and/or send the diagnostic results manually in the web application.
- If both settings are **enabled** in the analyzer software, diagnostic results are automatically released and sent to the LIS. In the web application, the batches are immediately listed on the **Completed batches** screen after the diagnostic runs finish.

Even if the system is not connected to an LIS, you must still send the results to change their status from **Pending send** to **Send queued** or **Sent**, and complete the batches.

Results for orders with analysis packages in **In validation** status are complete immediately after the diagnostic run finishes. You cannot release such results or send them to the LIS.

About inclusion of control results

The diagnostic results setting for the sending of control results determines if control results are included when diagnostic results are sent to the LIS, regardless of how the diagnostic results are sent (manually or automatically).

Configuring diagnostic results settings

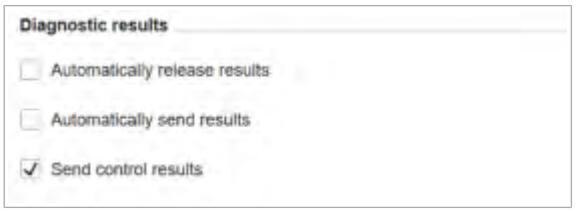
On the **Result settings** panel, you configure the analyzer software to send and/or release diagnostic results automatically, and/or to include control results when sending diagnostic results to the LIS.

If you enable any of the diagnostic results settings, they only apply to diagnostic results generated later. The system does not catch up on releasing and/or sending results or control results that were generated previously.

☐ Administrator user role

To configure diagnostic results settings

1 In the analyzer software, choose **Administration > Result settings**.
➔ The **Result settings** panel is displayed.



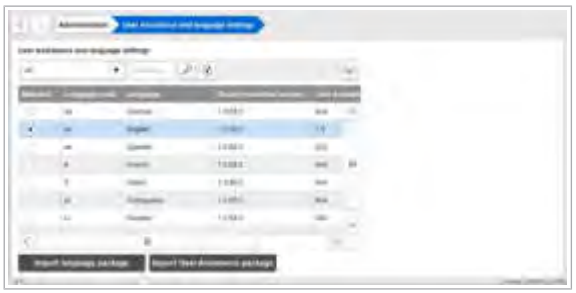
2 To configure the release setting for diagnostic results, do one of the following:
- To enable the automatic release of results, select the **Automatically release results** check box.
- To disable the automatic release of results, clear the **Automatically release results** check box.

3 To configure the sending setting for diagnostic results, do one of the following:
- To enable the automatic sending of results to the LIS, select the **Automatically send results** check box.
- To disable the automatic sending of results to the LIS, clear the **Automatically send results** check box.

4 To configure the setting for control results, do one of the following:
- To include control results when sending diagnostic results to the LIS, select the **Send control results** check box.
- To exclude control results when sending diagnostic results to the LIS, clear the **Send control results** check box.

5 Choose the **Save** button.

User Assistance and language settings



On the **User Assistance and language settings** panel, you configure the language of the user interface and the User Assistance for the analyzer software and the web application.

To access the **User Assistance and language settings** panel, you need administrator user role.

In the development software, the language of the user interface and the User Assistance is determined by the Windows language settings.

In this section

About language packages and User Assistance packages

Language configuration is done in the analyzer software. The same language then applies to the web application.

You can choose 1 language only for both the analyzer software and the web application, and the User Assistance.

If you change the language, the change is applied to all users. It is not possible to set individual users' languages.

About language packages

A language package contains the translations of the analyzer software and the web application in 1 language.

To display the analyzer software and the web application in a language, you must do the following:

1. Import the language package into the analyzer software.
2. Change the language in the analyzer software, i.e., choose the language package.

When you choose a different language package, or when you import a new version of the currently active language package, you must restart the analyzer for the change to take effect.

Restarting the analyzer (451)

About User Assistance packages

A User Assistance package contains the translation of the User Assistance publication that is accessible from the analyzer software and the web application.

For the language of the User Assistance, the following rules apply:

- If the User Assistance package is available in the same language as the active language package, the User Assistance is displayed in that language.
- If the User Assistance package is not available in the same language as the active language package, the User Assistance is displayed in English.
- You cannot choose the language of the User Assistance independently of the language of the user interface.

When you import a new version of the User Assistance package in the currently active language, the new User Assistance is displayed directly.

Importing language packages and User Assistance packages

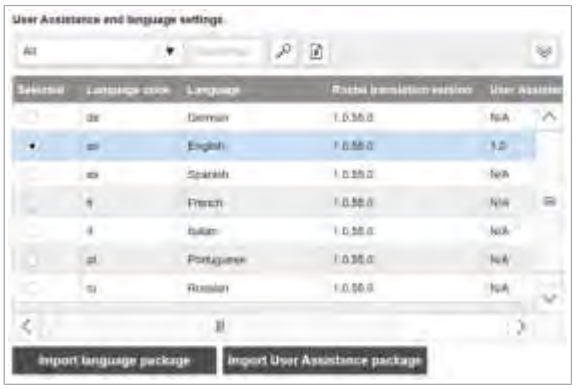
On the **User Assistance and language settings** panel, you import language packages and User Assistance packages.

☐ Language package and/or User Assistance package (ZIP files) saved in network share or on external storage device

☐ Administrator user role

To import a language package

1 Optionally, to import from an external storage device, connect the external storage device to the analyzer.



2 In the analyzer software, choose **Administration > User Assistance and language settings**.
   ➔ The **User Assistance and language settings** panel is displayed.

3 Choose the **Import language package** button.
   ➔ The **Import language package** dialog box is displayed.

4 In the folder browser, navigate to the folder of the language package.

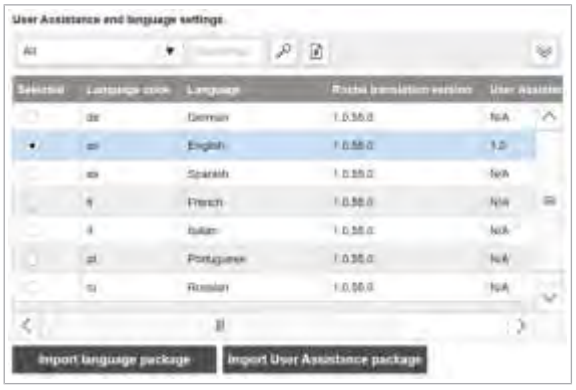
5 In the file browser, choose the language package.

6 Choose the **Import** button.
   ➔ The language package is installed in the analyzer software.
   ➔ The language package is listed in the table on the **User Assistance and language settings** panel.

7 Optionally, disconnect the external storage device.

8 If you imported a new version of the currently active language package, restart the analyzer as described in Restarting the analyzer (451).

To import a User Assistance package



1 Optionally, to import from an external storage device, connect the external storage device to the analyzer.

2 In the analyzer software, choose **Administration > User Assistance and language settings**.
   ➔ The **User Assistance and language settings** panel is displayed.

3 Choose the **Import User Assistance package** button.
   ➔ The **Import User Assistance package** dialog box is displayed.

4 In the folder browser, navigate to the folder of the User Assistance package.

5 In the file browser, choose the User Assistance package.

6 Choose the **Import** button.
   ➔ The User Assistance package is installed in the analyzer software.
   ➔ The User Assistance package is listed in the table on the **User Assistance and language settings** panel in the entry of the corresponding language package.

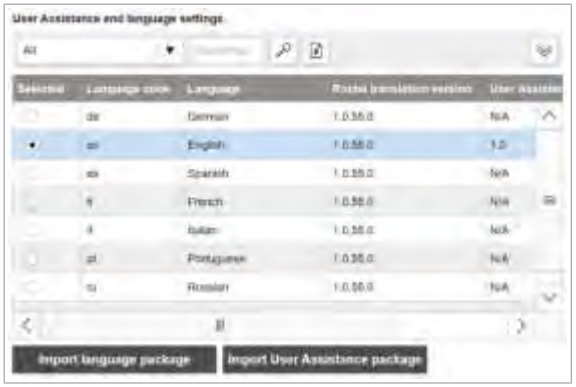
7 Optionally, disconnect the external storage device.

Changing the system language

On the **User Assistance and language settings** panel, you change the language of the analyzer software, the web application, and the User Assistance.

If you change the language, the change is applied to all users. It is not possible to set individual users' languages.

- ☐ Language package imported
- ☐ To display the User Assistance in the same language as the analyzer language:
  User Assistance package imported
- ☐ Administrator user role



To change the system language

1. In the analyzer software, choose **Administration > User Assistance and language settings**.
   ➔ The **User Assistance and language settings** panel is displayed.
2. Optionally, sort, search, or filter the table.
3. From the table, choose the language package.
4. Restart the analyzer as described in Restarting the analyzer (451).
   ➔ The user interface of the analyzer software and the web application is displayed in the configured language.
   ➔ If the corresponding User Assistance package is available in the analyzer software, the User Assistance is displayed in the same language.
   ➔ If the corresponding User Assistance package is not available in the same language, the User Assistance is displayed in English.

Settings in the development software

In this chapter 25

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Laboratory information settings in the development software

You can configure the name, address, and logo of your laboratory to be displayed on reports.

If configured, the laboratory information is included in all reports created in the development software.

For a logo file, the following restrictions apply:

- JPEG or PNG file
- File size: 10 MB or less
- Resolution: 1920 x 1080 pixels or less

☐ Optional:
Logo file (PNG or JPEG file)

To configure laboratory information settings in the development software

1 Optionally, to import a logo file from an external storage device, connect the external storage device to the computer running the development software.

2 In the development software, in the **Navigation** area, choose **File** > ••• > **Settings**.
➔ The **Settings** dialog box is displayed.

3 In the **Laboratory name:** field, enter the name of your laboratory.

4 To add a logo, choose the ••• button.

5 Navigate to the logo file and choose the **Open** button.
➔ A preview of the logo is displayed in the **Settings** dialog box.

6 In the **Address line 1:** field, **Address line 2:** field, **Address line 3:** field, and **Address line 4:** field, enter the address of your laboratory.

7 Choose the **Save** button.
➔ The laboratory information is added to reports.

8 Optionally, disconnect the external storage device.

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Analytical principles

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Analytical principles

In this chapter 26

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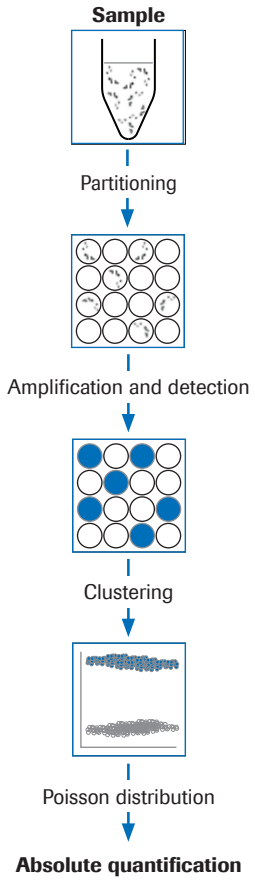
About digital PCR

Digital PCR allows for absolute quantification of a target nucleic acid sequence without a standard curve.

Digital PCR consists of the following steps:



The system partitions the sample into a large number of nanowells. This distributes the target molecules and results in nanowells that contain the target and other nanowells that do not contain the target.

The partitioned sample is run through an endpoint PCR amplification and detection.

The fluorescence of the amplified target molecules is detected separately for each nanowell.

Based on the detected fluorescence, the nanowells are clustered in 2 distinct groups, representing the concept of a "digital" measurement:

- Negative nanowells:
  All nanowells that show no fluorescence because they contain no target molecules.
- Positive nanowells:
  All nanowells that show fluorescence because they contain at least 1 target molecule.

To account for nanowells that contained more than 1 target molecule after partitioning, the number of target molecules in the positive nanowells is normalized using the Poisson distribution.

The concentration of the target in the sample is calculated.

Digital PCR requires that the target molecules are separated from each other during sample preparation. Only then are the target molecules distributed evenly across the nanowells after partitioning and can be detected independently, which allows for calculation of the concentration.

Advantages of digital PCR

The advantages of digital PCR compared to real-time PCR are the following:

- The target nucleic acid sequence is more concentrated compared to non-target nucleic acid sequences, resulting in less competition.

- Inhibitors are diluted relative to the target nucleic acid sequence, resulting in less inhibition.
- No dependence on Cq values or PCR efficiency, resulting in less influence of inhibitions.

The advantages result in higher precision, lower limit of detection, and better multiplexing performance. As no standards are required, there are lower reagents costs.

About tests and analyses

The system can apply 3 different analyses to determine results: absolute quantification, CNV, and indel.

About absolute quantification tests and analyses

An absolute quantification (Abs Quant) test detects the fluorescence of a known target nucleic acid sequence.

From the detected fluorescence, absolute quantification analysis calculates if the target is present (qualitative result) and the concentration of the target in the sample (quantitative result).

In CNV analysis and indel analysis, the system performs absolute quantification analysis in the background on each tested channel to provide the necessary parameters for CNV and indel result calculation.

About CNV tests and analyses

Copy number variation (CNV) is the occurrence of a variable number of copies of a known genomic sequence.

A variation is found by comparing the copy number of the target of interest with the normal copy number of at least 1 reference target. Target of interest and reference target are different genomic sequences and are tested independently.

A CNV test uses at least 2 channels:

- 1 channel detects the fluorescence in the presence of the target of interest.
- 1 channel detects the fluorescence in the presence of the reference target.

If you use more than 1 reference target, the mean of their copy numbers is taken for analysis.

From the detected fluorescences and the normal copy number of the reference target, CNV analysis calculates if there is a variation in the copy number of the target of interest (qualitative result) and the copy number of the target of interest (quantitative result).

CNV analysis requires that the individual copies of the genomic sequence are separated from each other during sample preparation. Only then can the copies be detected independently and can contribute to detecting a difference between the target of interest and the reference target. The system counts copies that are not separated as 1 copy.

About indel tests and analyses

Insertion-deletion (indel) is the occurrence of unknown mutations in a genomic sequence that are caused by the presence (insertion) or absence (deletion) of nucleotides.

Such mutations are found by simultaneously testing for a variant target and a reference target. The variant target spans the mutation site, the reference target spans an adjacent but stable site.

An indel test uses 2 channels:

- 1 channel shows fluorescence in the presence of the reference target.
- 1 channel shows fluorescence in the presence of the variant target.

The wild type sequence without any mutation in the variant target is found if the fluorescence of both the reference target and the variant target are detected (double positive).

The variant sequence with a mutation in the variant target is found if the fluorescence of the reference target is detected, but no fluorescence of the variant target is detected (positive-negative). This is why an indel test is also called a drop-off test.

An indel test allows for the detection of any mutation in the variant target. The mutated nucleotide sequence does not need to be known. Consequently, an indel test can test for different mutations at the same time.

From the detected fluorescences, indel analysis calculates if a mutation is present (qualitative result) and the percentage of the variant sequence in the sample (quantitative result).

Glossary

1D scatter plot

Scatter plot that shows a one-dimensional point set visualization.

2D scatter plot

Scatter plot that shows a two-dimensional point set visualization.

3D scatter plot

Scatter plot that shows a three-dimensional point set visualization.

absolute quantification

Quantification that is used to determine the absolute number of a target nucleic acid sequence.

amplification and detection

Process of generating multiple copies of nucleic acids and the concurrent or subsequent detection of these nucleic acids, usually using an automated thermal cycler, fluorescent probes and an optical detection system.

analysis package

Bundle of files that contains parameters and specifications relevant for one or multiple tests.

aspiration and dispensing arm

Component that is pushed into different bottles to aspirate and dispense liquids.

aspiration needle

Needle that is used to aspirate fluids.

ASTM protocol

Protocol defined by the ASTM International organization in the standards E.1381 and E.1394.

confidence interval

Range of values within which a value of a parameter will fall with a specified probability.

copy number variation

Genomic disorder that results in an abnormal number of copies of one or more genes, such as duplication, deletion, translocation, and inversion.

decontamination

Process that leads to the destruction of all nucleic acids.

detection unit

Unit consisting of one or more measuring channels in which the measurement takes place.

development run

Run during which tests for research and development purposes are performed.

development workflow

Workflow for research and development purposes.

diagnostic run

Run during which diagnostic tests are performed.

diagnostic workflow

Workflow for diagnostic purposes.

digital polymerase chain reaction

Polymerase chain reaction method that is used to directly quantify nucleic acid strands present in a sample. The sample is separated into a large number of nanowells and the reaction is carried out in each nanowell individually. This separation allows a more reliable collection and sensitive measurement of nucleic acid amounts.

dilution

Process of adding a material, usually a liquid or gas, to another material or substance for purposes of decreasing the concentration of the former.

dilution factor

Ratio of the volume of an initial, concentrated solution to the volume of the final, diluted solution.

fluids door

Door that gives access to the fluids on the system.

fluorescence

Brief visible electromagnetic radiation signal that is emitted as a result of absorption of radiation (photons) by an atom, molecule, or ion.

fluorescent dye

Fluorescent chemical compound that absorbs and re-emits light upon light excitation.

heatmap

Graphical representation of data where the intensity of color corresponds to the related analytical data.

high resolution nanowell plate

Nanowell plate with a higher number of nanowells that enables a detection of the target sequences with a high resolution.

high sensitivity nanowell plate

Nanowell plate with a higher volume per nanowell that enables a higher sensitivity regarding the target sequences.

histogram

Graphical representation of a frequency distribution of data, often by means of rectangles whose widths are the class intervals and whose heights are the corresponding frequencies.

HL7 protocol

Standardized protocol defined by the HL7 organization that is used for communication between healthcare applications.

indel

Small genetic variation happening through insertions or deletions of nucleotides in the genome of an organism.

inlet port

Opening on a nanowell plate into which a sample is pipetted.

liquid waste bottle

Bottle for the collection of liquid waste that is generated by the instrument.

master mix reagent

Reagent that is needed for various enzymatic reactions and may contain enzymes, associated buffers, primers, and probes.

master reagent

Reagent that is needed for PCR, but does not yet contain primers and probes.

merge lanes

Functionality that considers up to 8 nanowell plate lanes as if it were 1 lane in order to define a higher sample volume for 1 sample.

multiplex test

PCR or nucleic acid test that enables the simultaneous detection and discrimination of multiple DNA or RNA targets.

nanowell plate

Flat plate with nanowells that is used for digital PCR application.

nanowell plate drawer

Drawer that is used to load and unload single nanowell plates onto and from the instrument.

nanowell plate frame

Holding frame of the nanowell plate.

nanowell plate handler

Handler that moves nanowell plates in the analyzer.

nanowell plate lane

Lane that represents the path of a sample and upon which the sample is distributed into nanowells.

nanowell plate park position

Position where the nanowell plate is temporarily placed after thermal cycling and before being loaded onto the detection unit.

nanowell plate stack drawer

Drawer that is used to load and unload nanowell plate stacks onto and from the instrument.

Network Address Translation

Internet Protocol translation process that allows a network with private addresses to access information on the internet.

partitioning fluid

Fluid that is used to seal the nanowells of a nanowell plate.

partitioning fluid bottle

Bottle that contains partitioning fluid.

primer

Single-stranded nucleic acid that can initiate replication of a nucleic acid template.

probe

Single-stranded nucleic acid with a fluorescent dye that is used to identify specific DNA or RNA molecules by binding to specific amplicon sequences between primers.

reaction mixture

Mixture of reagents and sample.

Roche Service representative

Roche representative who may install instruments and/or perform preventive maintenance and/or service activities.

sample group

Group of samples that is created for statistical analysis.

scatter plot

Chart that displays values for variables for a set of data as a collection of scattered points, which can be clustered.

target nucleic acid sequence

Nucleic acid sequence that is of interest.

thermal cycler

Component of an instrument used to repetitively heat and cool a set of reactions to promote DNA denaturation, hybridization, and amplification in PCR.

thermal cycler unit

Unit where thermal cycling is performed.

uninterruptible power supply

Device with a battery that allows limited continued operation of an instrument or other device during a power outage.

universal nanowell plate

Nanowell plate that is used for applications that do not require high sensitivity nor high resolution detection of the target sequences.

wild type

Strain, gene, or characteristic which prevails among individuals in natural conditions.

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