x800 Data Manager

User Guide

Publication version 2.1

Software version 1.5

Publication information

Publication version	Software version	Revision date	Change description
1.0	1.4	May 2021	First edition
2.0	1.5	April 2022	▪ New task about exporting CSV files. ▪ Updated information on result formatting, repeating tests, predefined result reports, list of audit trail entries, and software updates. What is new in publication version 2.0 (10)
2.1	1.5	November 2022	▪ New task about enabling and disabling remote access for Roche Support. ▪ Updated description for repeating tests. What is new in publication version 2.1 (10)

Revision history

Edition notice

This publication is intended for users of the x800 Data Manager.

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 instrument.

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

The **Quick Reference Guide** gives a brief introduction to important routine tasks and daily maintenance.

The **Host Interface Manual** provides references for implementing connections from external laboratory information systems (LIS) to the product.

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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.

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To avoid incorrect results, ensure that you are familiar with the instructions and safety information.

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

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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 perform software updates in accordance with the instructions described in the user documentation and instructions delivered with the software packages.

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Approvals

The x800 Data Manager 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.

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

The following marks demonstrate compliance:

For *in vitro* diagnostic use.

Complies with the provisions of the applicable EU directives.

Issued by CSA Group for Canada and the US.

Issued by the TÜV SÜD for Canada and the US.

Equipment de Laboratoire / Laboratory Equipment

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

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eLabDoc

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

dialogportal.roche.com

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Intended use

The **cobas**® 5800 System supports an automated and integrated workflow to run polymerase chain reaction (PCR) based nucleic acid testing (NAT) for use by trained professionals in laboratory settings. The **cobas**® 5800 System combines the functionalities of instrumentation, consumables, reagents, and data management to provide an efficient workflow from sample processing to result interpretation.

Product names, symbols, and abbreviations

Product names

Product name	Descriptor
cobas® 5800 System	System
cobas® 5800 Instrument	Instrument
x800 Data Manager	Data manager

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
▶	Start of a task
	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

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
CSV	Comma-separated values
EC	European Commission
HIS	Hospital information system
IHE	Integrating the Healthcare Enterprise
IVD	In vitro diagnostics
LAN	Local area network
LIS	Laboratory information system
MGP	Magnetic glass particles
n/a	Not applicable
NAT	Nucleic acid testing
PCR	Polymerase chain reaction
QC	Quality control
RFID	Radio frequency identification
SFTP	Secure File Transfer Protocol
SSL	Secure Sockets Layer
USB	Universal Serial Bus
WLAN	Wireless local area network
WPA2	Wi-Fi Protected Access 2
XML	Extensible Markup Language

Abbreviations

What is new in publication version 2.1

Repeating tests

Information updated about the rules for repeating tests: For multiple-target tests like CT/NG, TV/MG, or MPX, and high-target tests, the test is repeated only for the invalid targets.

Repeating tests (66)

Enabling and disabling remote access

Depending on the configuration for the remote access, you can enable or disable the remote access for Roche Support.

Enabling and disabling remote access (123)

What is new in publication version 2.0

Exporting results to a CSV file

New task about exporting results to a CSV file. You have now 2 options:

- Exporting the **Results overview** table as it is displayed in the **Results** app.
- Exporting the **Results overview** table and adding columns with additional information.

Exporting results to a CSV file (71)

Result formatting

Information added that in the **Results overview** table results of quantitative tests are always displayed with a gray colored-in circle.

About test result formatting (57)

Repeating tests

Information added to avoid repeating tests for blood screening. If necessary, the middleware creates an order to repeat the test.

Repeating tests (66)

Predefined result reports

The information displayed in the predefined result report is now based on the run ID. Besides the already existing choices, you can now choose the result status as a filter.

About predefined result reports (80)

List of audit trail entries

21 new audit trail event codes are available.

List of audit trail event codes (102)

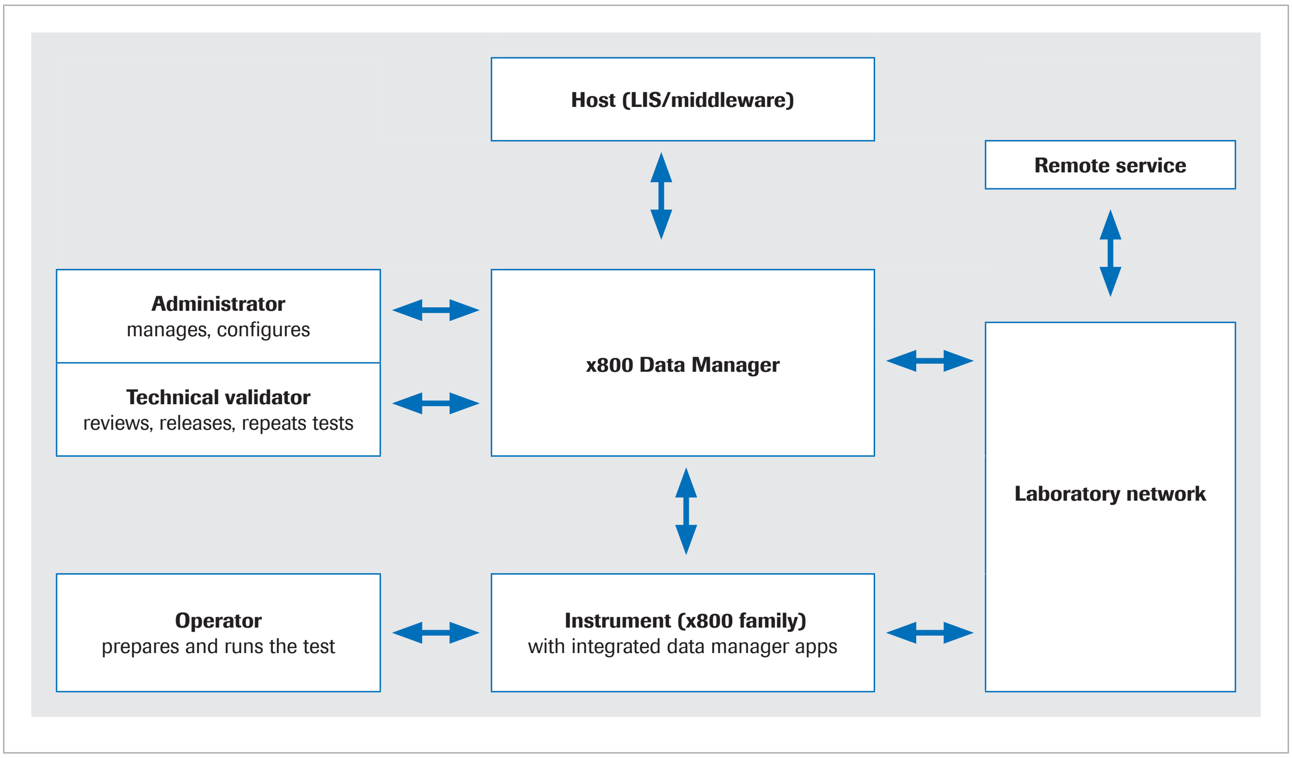
Uploading and installing updates

If a dependent previous software patch is not installed, the data manager prohibits the installation of an update.

Uploading and installing updates (135)

About the x800 Data Manager

The x800 Data Manager is a software platform for the Roche x800 family of analyzers. Up to 3 analyzers can be connected to 1 data manager. They build together 1 cluster.



Function

The data manager has the following main functions:

- Sample order execution
- Control handling
- Result handling
- Report generation
- Technical validation of sample orders and controls
- Management of system settings
- User management
- Storage of relevant data

Modular design

The data manager consists of a number of apps with defined user roles (operator, technical validator, administrator). According to the defined user role the corresponding apps are displayed.

Accessibility

The data manager access is web-based. The user interface of the data manager can be displayed from any computer with a supported browser and a connection to the laboratory network. You access the data manager by typing the following URL in the address bar of your browser: www.x800dm.com.

The following apps of the data manager are also available on the touch screen monitor of the instrument:

- **Orders**
- **Results**
- **Controls**

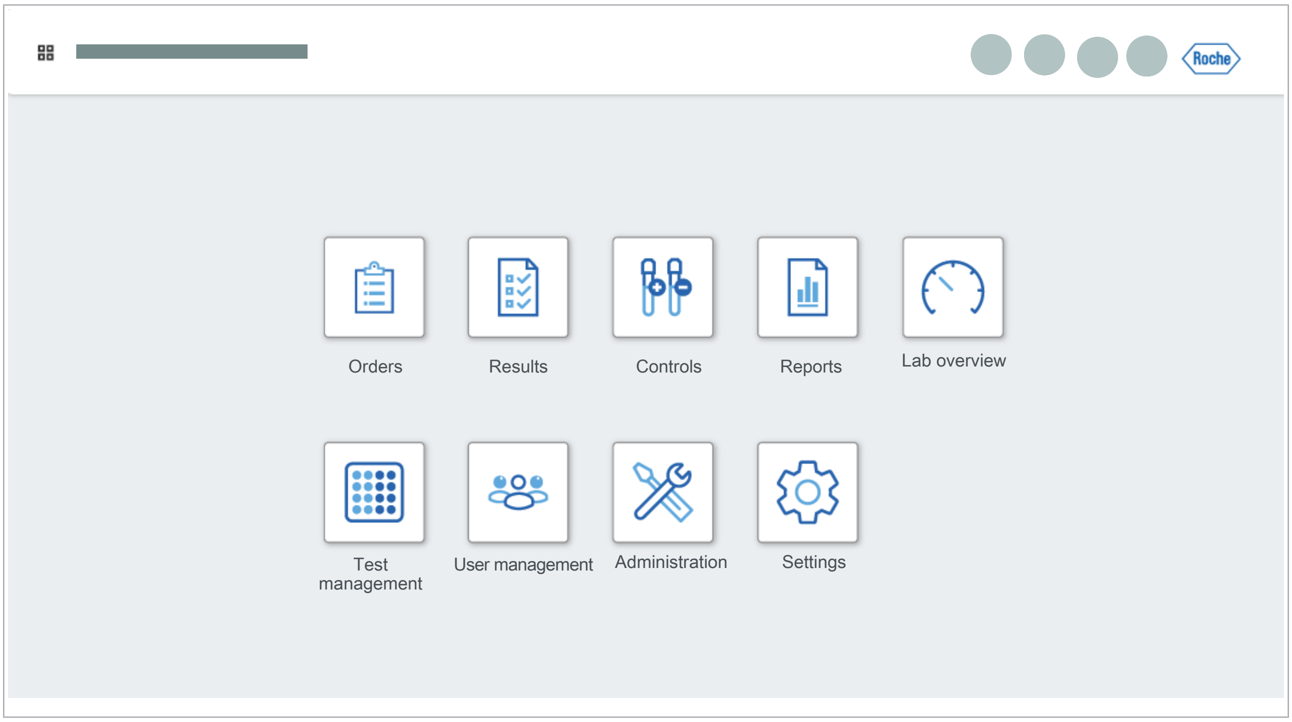
- **Reports**

Data manager mini PC

The data manager software is deployed on to a mini PC that can be embedded in the instrument. Your Roche Service representative sets up the data manager and integrates the mini PC in the instrument.

Interconnectivity

The data manager provides interconnectivity with analyzers and host systems/LIS that communicate with standard protocols.



Apps overview in the data manager with administrator user role

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Operation

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Frequently performed tasks

1

In this chapter

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Logging on to the system

To work on the system, you must be logged on. You are logged off automatically after the configured idle period. To continue working, you must log on again.

A locked user account due to invalid logon attempts is automatically unlocked after a configured account lockout duration. If you enter the wrong password for the locked user account during this account lockout duration, the account lockout duration starts again.

- ☐ A compatible browser
- ☐ Active user account

To log on to the system

1 To open the data manager and display the logon screen, enter the following URL in the address bar of your browser: www.x800dm.com.

   If you have more than 1 data manager connected to your laboratory network, check the correct URL with your laboratory administrator or with your Roche Service representative.

2 In the dialog box, enter your credentials in the following fields:
   - **User name**
   - **Password**

3 Choose the **Log on** button.

   If you exceed the number of attempts available, contact your administrator.

   → In the global information area, your initials are displayed on the user profile button.

Logging off from the system

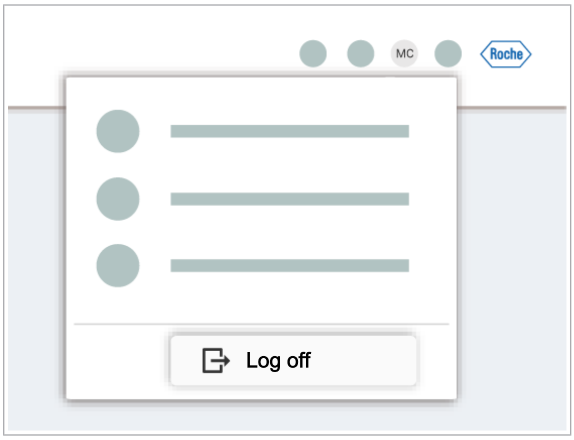
When you leave the system unattended, log off from the system for security reasons.

You are logged off automatically after the configured idle period.

☐ You are logged on to the system

To log off from the system

1 In the global information area, choose the user profile button.



2 Choose the **Log off** button.

Filtering tables

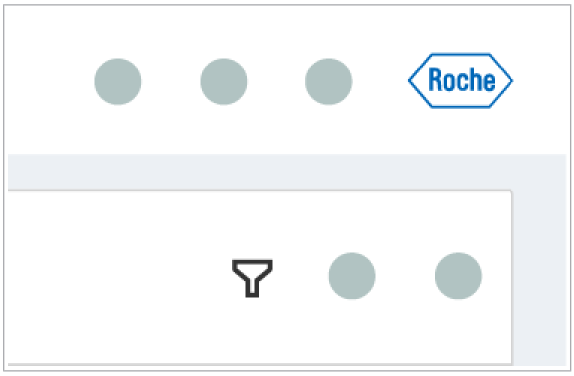
In this section

Applying filters

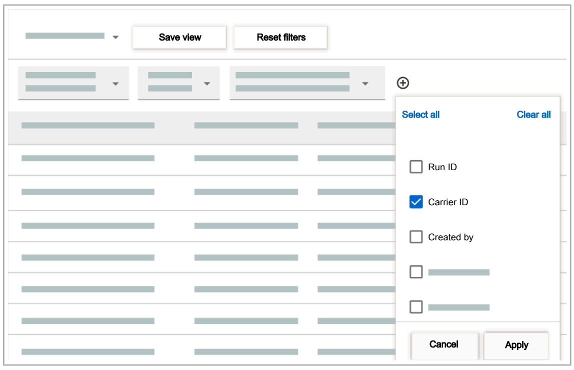
Several screens in the software have tables containing sample IDs, tests, and results among others. You can filter the items in these tables to find the information you need more easily.

You can set filters for tables that display a filter button.

▸ To apply filters



1 In a table that allows filtering, choose the button.
   ➔ On the top left side of the table, a set of filter functions is displayed.



2 To add additional filter options, do the following:
   - Choose the ⊕ button.
   - From the drop-down list, choose 1 or more check boxes.
   - Choose the **Apply** button.

   ➔ At the top of the table, additional drop-down lists for filtering are displayed.

3 To filter the table, do the following:
   - From the filter drop-down lists, select 1 or more check boxes. If needed, add a value in the corresponding text field.
   - Choose the **Apply** button.

- If you added the **Run ID** field, **Carrier ID** field, or **Created by** field, enter a value in the text field and press the enter key on the keyboard.

  → A blue notification badge on the button informs you that a filter is applied to the table.

4 To clear applied filters, choose the **Reset filters** button.

Related topics

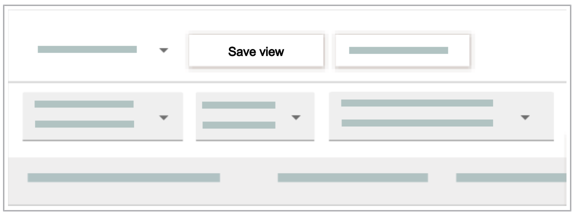
- Creating customized filters (22)

Creating customized filters

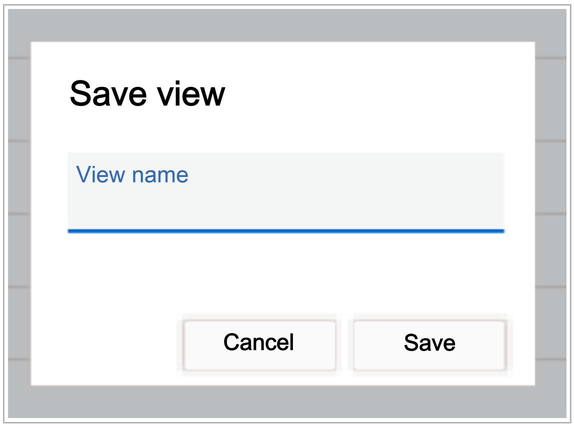
You can save frequently used filter views and apply them when you access the screen again.

☐ A filter view is applied to the table

To create customized filters



1 To save the filter view you applied to a table, choose the **Save view** button on the top left side of the table.



2 In the **Save view** dialog box, in the **View name** field, enter a name.

3 Choose the **Save** button.

→ The name of your customized view is displayed at the top of the table with a drop-down list.

Related topics

- Applying filters (21)

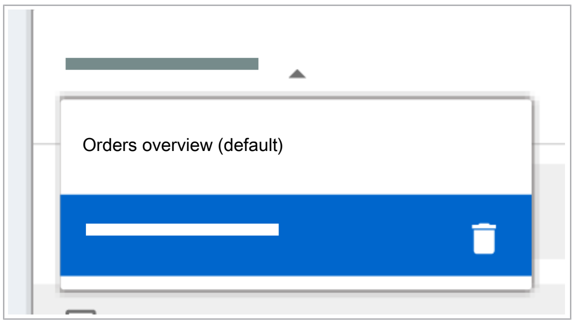
Applying customized filter views

If you created a customized filter, you can choose between the customized filter view and the default filter view of the table.

☐ A table with customized filters

▶ To apply customized filter views

1 Open a table containing a customized filter.



2 From the filter view drop-down list at the top left side of the table, choose between your customized view and the default option.

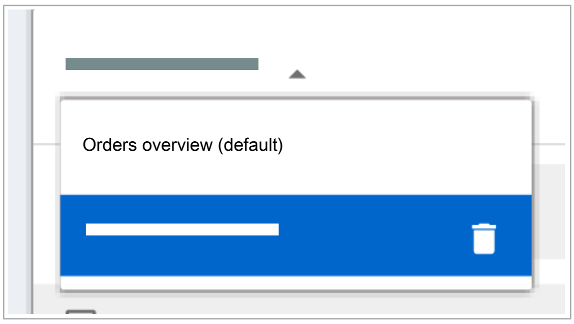
Editing customized filters

You can change the filters of your customized filter view and save them under a different name.

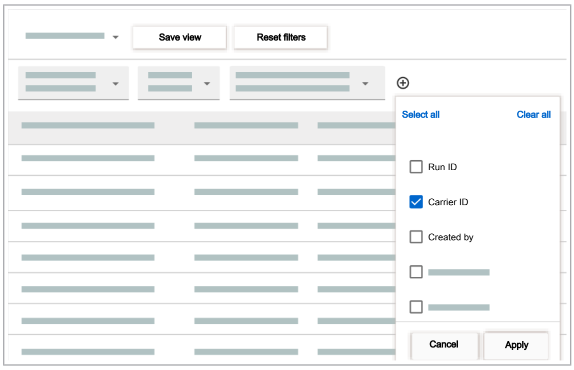
☐ A customized filter

▶ To edit customized filters

1 Open a table containing a customized filter.



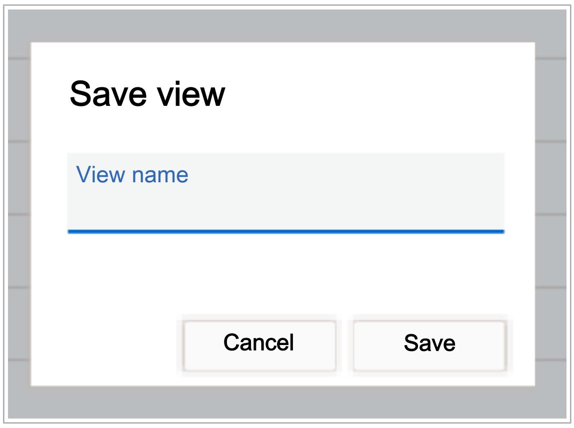
2 From the filter view drop-down list, choose the customized filter you want to edit.



3 From the filter drop-down list, change the filter options and choose the **Apply** button.

4 Choose the **Save view** button.

5 Enter a new name for the customized filter.



6 Choose the **Save** button.

Related topics

- Applying filters (21)
- Creating customized filters (22)

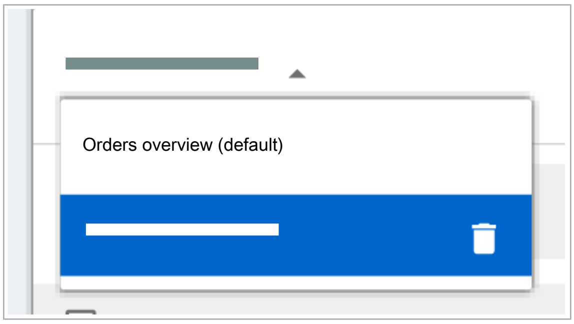
Deleting customized filters

You can delete customized filters. You cannot delete the default filters of the software.

☐ A table with customized filters

To delete customized filters

1 Open a table containing a customized filter.



2 From the filter view drop-down list at the top left side of the table, choose the 🗑 button next to the name of the customized filter.
→ The customized filter is removed.

Related topics

- Applying filters (21)
- Creating customized filters (22)

Customizing tables

In this section

Choosing columns

Every table in the software has a predetermined number of columns. You can customize tables, by adding or removing columns.

To choose columns

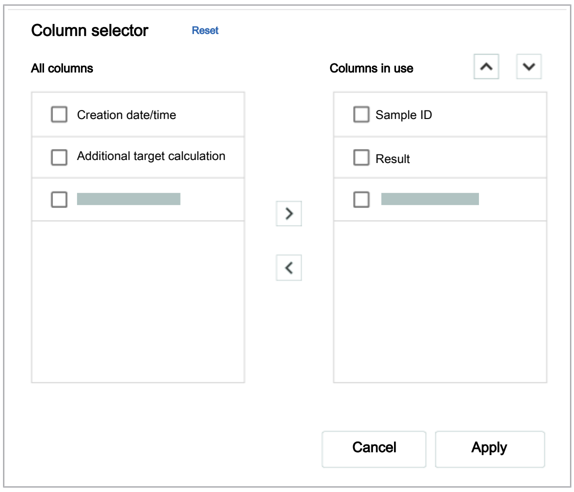
1 In a table that allows editing columns, choose the button.

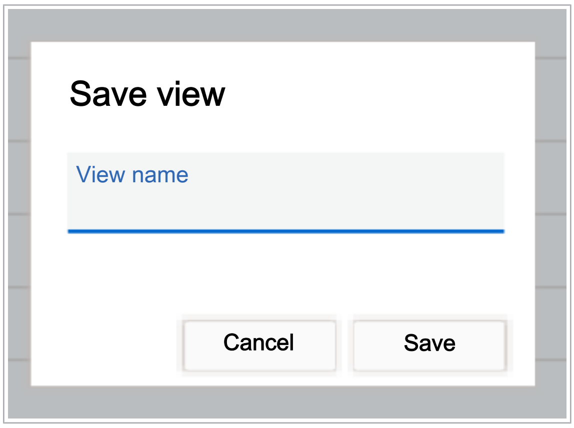
2 To add columns, in the **All columns** table, choose the check boxes of the columns you want to add, and then choose the > button.

3 To delete columns, in the **Columns in use** table, choose the check boxes of the columns you want to delete from your view, and then choose the < button.

4 Choose the **Apply** button.
- → The table is displayed with your selected columns.
- → A blue indicator on the button indicates that the table is customized.
- → Depending on the number of columns, a scroll bar is displayed.

5 To save a customized view, choose the **Save view** button.
- ▪ In the **Save view** dialog box, enter a name in the **View name** field.
- ▪ Choose the **Save** button.
- → The name of the customized view is displayed at the top of the table with a drop-down list.

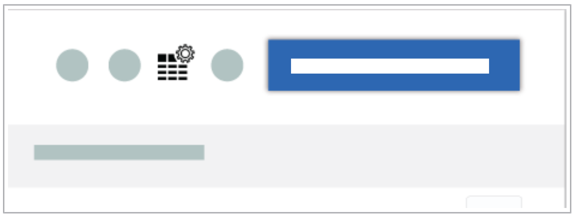




Sorting columns

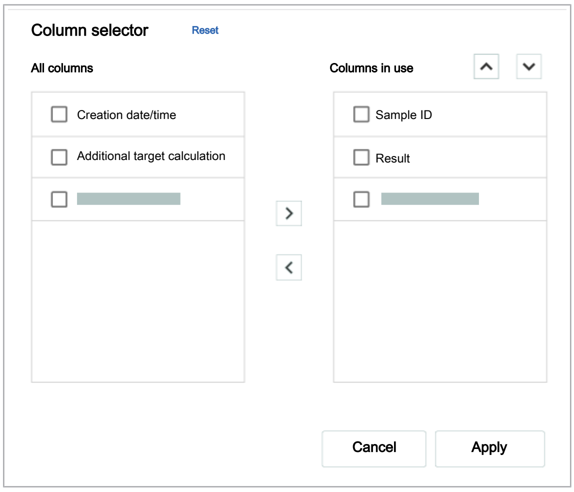
In every table, the columns have a preselected order. The software allows you to sort the order of the columns.

To sort the order of columns



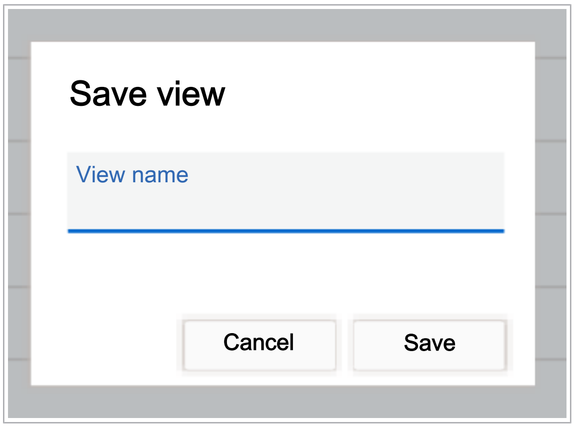
1 Choose a table with a button.

2 In a table that allows editing columns, choose the button.



3 To move a column, in the **Columns in use** table, choose the check boxes of the columns you want to move and then do the following:
- To move the selected column to the left, choose the ∧ button.
- To move the selected column to the right, choose the ∨ button.

4 Choose the **Apply** button.
→ The customized table with the sorted columns is displayed.
→ A blue notification badge on the button indicates that the table is customized.



5 To save the customized view, choose the **Save view** button.
- In the **Save view** dialog box, enter a name in the **View name** field.
- Choose the **Save** button.

→ The name of the customized view is displayed at the top of the table with a drop-down list

6 Optionally, in the drop-down list of the customized view, choose between the customized view and the default option.

Sorting the order of tables by column content

In some tables, you can change the order in a table by choosing the header of a column. You can choose between an alphanumerically ascending or descending order. For example, you can sort the **Orders overview** table by creation date with the latest creation date on top or bottom of the table.

☐ Table with a sorting function in the header when you choose the ↑ button or the ↓ button.

▸ To sort the order of tables by column content

1 Choose the column by which you want to sort the table.

2 Choose the column header.
→ The order of the table is sorted according to the content of the column, either in an ascending or descending sequence.
→ In the column that defines the order of the table, the ↑ button or ↓ button is displayed in the header.

3 To change from descending to ascending, or vice versa, choose the column header again.

Performing a search

Depending on the app, the software allows you to search in a table for a sample ID, a keyword from a comment, or another predefined search item, for example, a flag code or run ID.

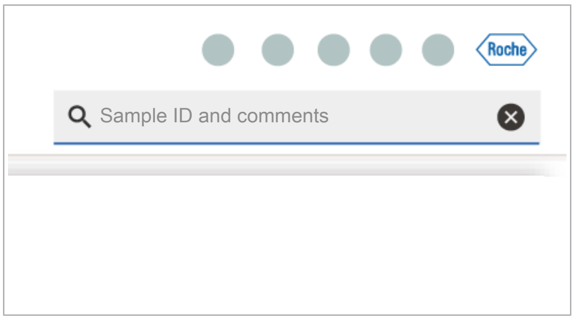
In the following apps, you can search for the corresponding content:

- **Orders** app, **Controls** app:
  - Sample ID
  - Keyword from a comment
- **Results** app:
  - Sample ID
  - Keyword from a comment
  - Predefined search types: **Control ID**, **Reagent lot No.**, **Flag code**, **Run ID**.
- **Controls** app:
  - Control ID

▸ To perform a search

1 From the app launcher, choose the **Orders** app, **Results** app, or **Controls** app.

2 Below the global information area, choose the 🔍 button.



3 In the search field, enter your search term according to the app you use:

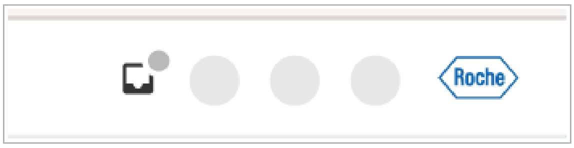
- In the **Orders** app or **Results** app, enter a sample ID or keyword from a comment.
- Optionally, in the **Results** app, from the drop-down list, choose a search item and enter the data.
- In the **Controls** app, enter the control ID.

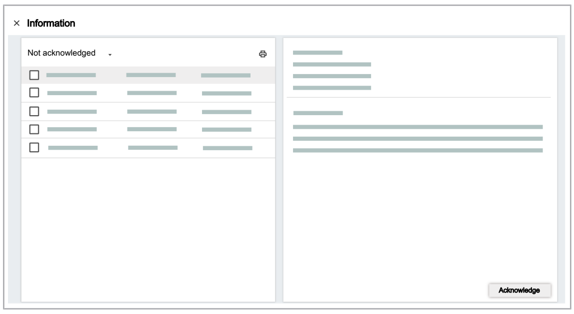
4 Press the enter key.

→ The table displays the results of your search.

Viewing and acknowledging information inbox notifications

The information inbox displays notifications of the type information. You can filter the table to see only acknowledged or unacknowledged notifications.





To view and acknowledge notifications

1 In the global information area, choose the button.
  → The number of unacknowledged notifications is displayed at the top of the screen.

2 To filter for acknowledged and unacknowledged notifications, choose the view you want to see from the drop-down list.

3 From the table, choose a notification.
  → The full text is displayed on the right side of the screen.

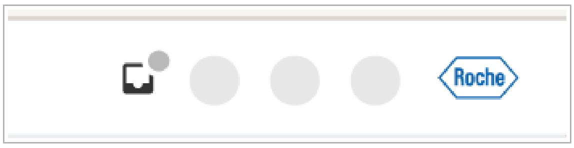
4 To acknowledge the notification, choose the **Acknowledge** button.
  → The logged-on user who acknowledged the notification and the time of acknowledgment is saved.

5 To close the information inbox, choose the button.

Printing notifications from the information inbox

From the data manager, you can print a list of notifications which are displayed in the information inbox.

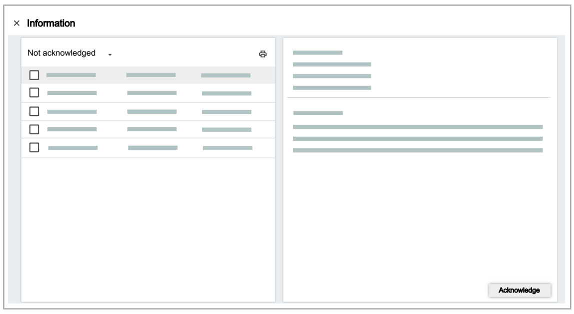
To print notifications



1 In the global information area, choose the button.

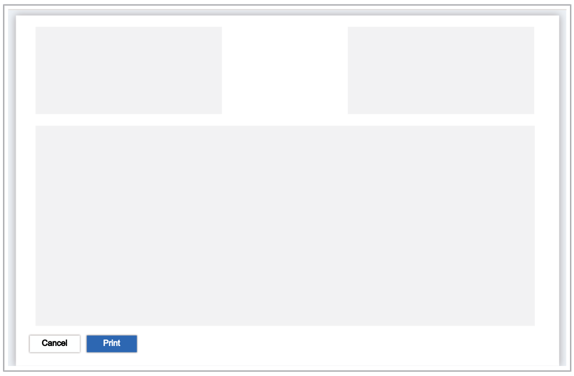
2 To filter the table by acknowledged and unacknowledged notifications, from the drop-down list, choose the corresponding option.

Applied filters are applied in the print.



3 Choose the button.

→ The **Print preview** screen is displayed.



4 Choose the **Print** button.

5 On the web browser **Print** screen, choose the **Print** button.

Routine operation

In this chapter

2

Checking the lab status

The **Lab overview** app gives you the following information:

- Connection to the host
- Connection to the remote service platform
- Data manager disk space
- Connection to the instruments
- Status of the instrument
- Time to next result
- Time to next run

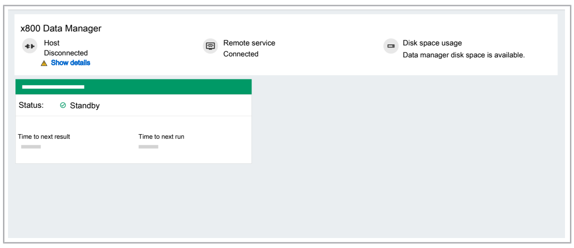
Time to next result field: In the field, the earliest estimated completion time available among all active runs in the instrument is displayed. When a run is either finished or aborted, the time to next result entry for that run is removed. The time to next result field is updated only when the instrument sends an update on the estimated completion time to the data manager.

Time to next run field: In the field, the earliest available estimated start time from the schedule information received from the instrument is displayed. The time to next run field is empty when the status of the instrument is not in **Processing** status or when the instrument sends no schedule information to the data manager.

The color in the header of the instrument card is the same as the status light of the corresponding instrument.

The host connectivity status auto refreshes every 30 seconds and the disk space status is auto refreshed every 30 minutes.

To check the lab status



1 Choose the **Lab overview** app.

2 For detailed information on the available disk space, choose the **Show details** button.

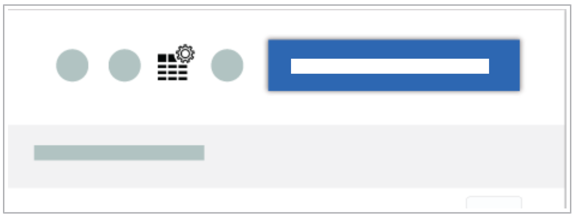
Order handling

In this section

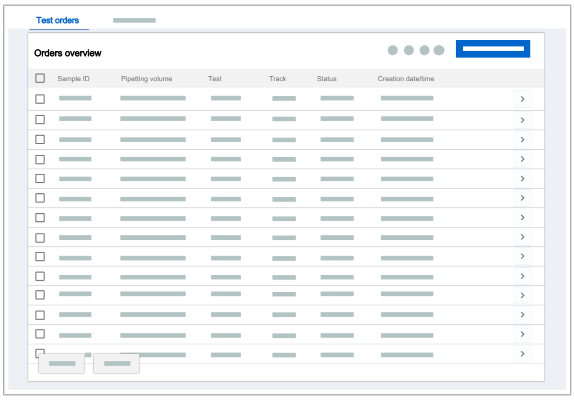
About the orders app

The **Orders** app provides an overview of all orders that the host has sent to the system, and all manually created orders. It also provides an overview of all missing orders; samples loaded on the system without existing orders.

Test orders tab



The **Test orders** tab gives you an overview of all existing orders. Using the button, you can customize the **Orders overview** table and display the columns you need.



The **Orders overview** table provides the following information:

- Sample ID.
- The test name, the sample type, and the pipetting volume.
- If the sample is loaded on the instrument:
  - Location of the sample: track, carrier ID, position in the carrier
  - Run ID
  - Instrument
  - Estimated end time of the run
- The status of the order.
- Creation date and time of the order.
- If the target is from a high-target test.

The order can be in the following statuses:

- **New**: The order is created in the data manager.
- **Pending**: The instrument assigned and accepted the order.
- **Processing**: The instrument processes the order in a run.
- **Unreleased**: Order results are available for review.
- **Released**: Order results are released.
- **Rejected**: Order results are rejected.
- **Calculating**: The data manager sent the measurement data to the calculator system.
- **Repeat test pending**: A repeat test is ordered and the test has yet to be repeated.
- **Repeating test**: The test for the sample is repeated.

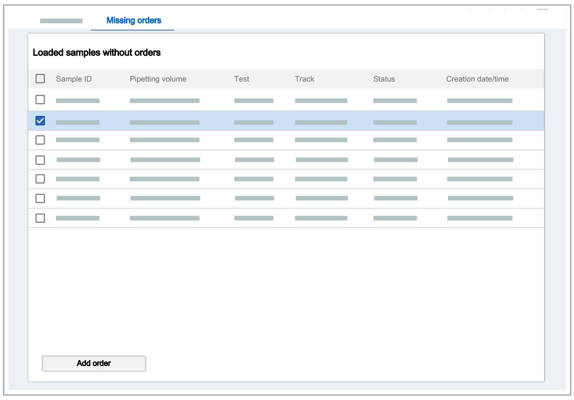
If the test is repeated or more than 1 run is involved for the test order, the order information of the most recent instrument and run is displayed.

Order details screen

On the **Order details** screen, detailed information on the order, sample, and run is displayed. To open the **Order details** screen, in the **Orders overview** table, at the end of the row, choose the › button.

The estimated end time is displayed in hh:mm and in the time format defined in the regional and language settings. The estimated end time is updated only when there is a corresponding notification on schedule change from the instrument. For the update, the test order must be in 1 of the following status: **Pending**, **Repeat test pending**, or **Processing** status. The estimated end time is calculated from the estimated start time plus the duration in minutes plus 2 minutes. If the order is in **Pending** or **Repeat test pending** status, the value is rounded off to nearest 10 minutes.

Missing orders tab



The **Orders > Missing orders** tab provides you an overview of all samples loaded on the instrument without an existing order.

In the following cases, missing orders are displayed on the **Missing orders** tab:

- No orders from the host, and no manual order is available for the loaded sample.
- No manual order is available and the data manager rejects the host order. Host orders are rejected if, for example, the required test is not installed.
- The sample type of the loaded carrier ID does not match with the sample type from the order.
- Duplicate orders for 2 loaded samples. The data manager accepts the order for the first loaded sample and creates a missing order for the second sample.

For samples with missing orders, you must create the order manually.

Related topics

- Filtering tables (21)

About manually creating orders

You can create a maximum of 3 orders for a sample ID with the same sample type. If 1 or more of the originally created 3 orders are in **Released** status or **Rejected** status, you can create additional orders for that sample ID.

If you add tests to an order and the targets of the tests overlap with each other, you cannot create the overlapping test orders. For example, on the **Create new order** screen you already added the CT/NG test. You can not add an additional CT test and an additional NG test. For the same sample ID, no duplicate tests are allowed.

For high-target test, target groups must be configured. You can create more than 3 multiplex tests of different target groups per sample ID. The data manager creates 1 test order with a distinct set of targets, even if there are duplicate targets within the selected target groups.

Creating orders manually

Creating orders manually is necessary if, for example, the connection to the host is interrupted, or an order is missing for a loaded sample.

If a manual order is not in **Processing** status yet and an identical order from the host exists, the data manager deletes the manual order. A notification in the information inbox appears.

⚠ CAUTION!

Disclosure of confidential data due to entry in open text fields

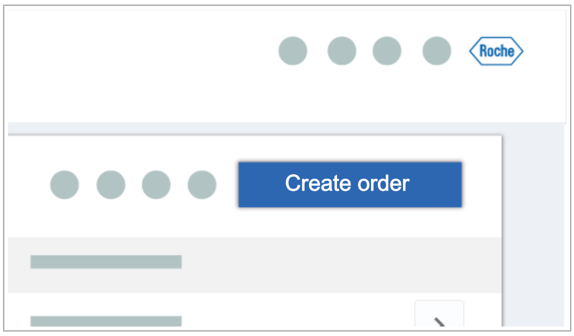
Adding personal health information of patients to open text fields increases the risk of privacy incidents and exposure of sensitive data. If you enter confidential data (such as patient data, test results interpretation, service account credentials), for example, into the comment field or as a sample ID, an unauthorized person can view it.

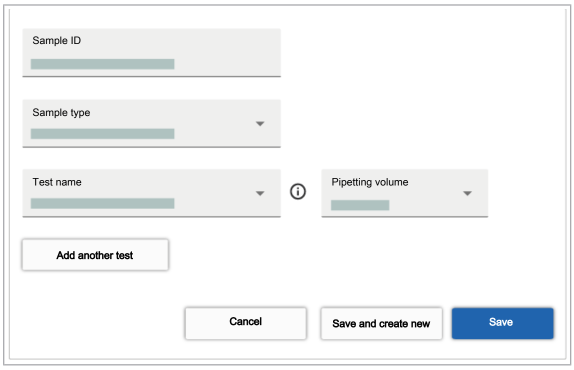
- Do not use sensitive data like patient identifiers or a social security number as a sample ID.
- Do not enter any confidential patient-related information into the comment field of the **Orders** app or **Results** app. There is the risk of unauthorized access to patient data.
- Restrict physical access to the system and all attached IT infrastructure (computer, cables, network equipment, etc.).

☐ Sample ID, sample type, test name, volume

To create orders manually

1. Choose **Orders > Test orders**.
2. On the **Test orders** tab, choose the **Create order** button.





3 On the **Create new order** screen, enter the sample ID with the hand-held barcode reader or type it manually.

4 In the **Secondary sample ID (optional)** field, you can enter an additional sample ID.

ⓘ This option is only available if a secondary sample ID is enabled in the data manager settings.

5 From the **Sample type** drop-down list, choose the sample type.

ⓘ The available sample types depend on the installed and activated tests.

6 From the **Test name** drop-down list, choose the required test.

ⓘ The available test names depend on the installed and activated tests. Only tests that support the selected sample type are displayed.

7 To check the targets of the selected test, choose the ⓘ button.

8 From the **Pipetting volume** drop-down list, choose the available pipetting volume.

9 To add a comment, choose the 🗨 button next to the **Pipetting volume** drop-down list.

- Write the comment.
- Choose an area outside the comment field to close it.

→ The comment is added to the order.

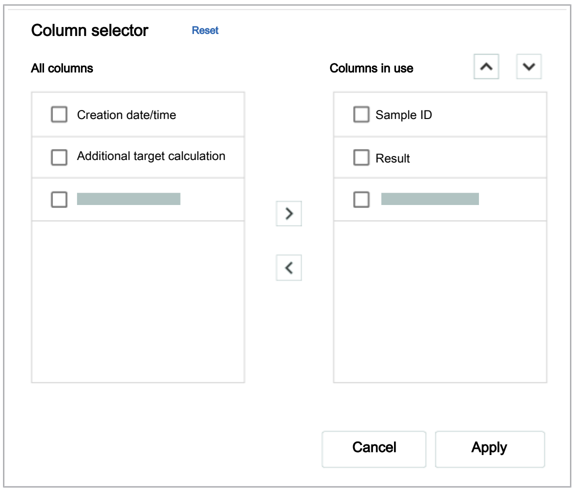
10 To add another test for this sample, choose the **Add another test** button.

ⓘ You can define a maximum of 3 tests per sample ID. For high-target tests, you can create more than 3 multiplex tests of different target groups per sample ID.

11 To create another order, choose the **Save and create new** button.

12 To save the order and leave the **Create new order** screen, choose the **Save** button.

→ In the **Orders overview** table, the new orders are listed in the first rows of the table.



13 To display in the **Orders overview** table a column for orders with additional target calculation, do the following:

- At the top of the **Orders overview** table, choose the button.
- In the **All columns** table, choose the **Additional target calculation** check box.
- Choose the > button, and then the **Apply** button.

→ In the **Additional target calculation** column, a **Yes** status is displayed if additional targets are calculated for the order. The column is empty for orders without additional target calculation.

Related topics

- About high-target tests (92)

Initiating additional target calculation

You only can initiate additional target calculation for a high-target test within the additional target calculation interval configured in the data manager settings.

For manually created orders, you can manually initiate the additional target calculation.

For high-target tests from a host order, the additional target calculation is automatic. On the data manager **Settings > General settings > IHE profile** screen, the **Laboratory Analytical Workflow (LAW)** option must be configured.

In the **Orders overview** table, the order with additional target calculation is displayed as a separate row.

An ongoing additional target calculation cannot be deleted. Once the order for the additional target calculation is saved, the results are available within a few seconds.

⚠ CAUTION!

Disclosure of confidential data due to entry in open text fields

Adding personal health information of patients to open text fields increases the risk of privacy incidents and exposure of sensitive data. If you enter confidential data (such as patient data, test results interpretation, service account credentials), for example, into the comment field or as a sample ID, an unauthorized person can view it.

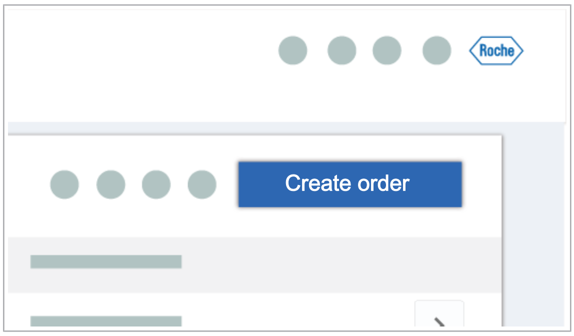
- Do not use sensitive data like patient identifiers or a social security number as a sample ID.
- Do not enter any confidential patient-related information into the comment field of the **Orders** app or **Results** app. There is the risk of unauthorized access to patient data.
- Restrict physical access to the system and all attached IT infrastructure (computer, cables, network equipment, etc.).

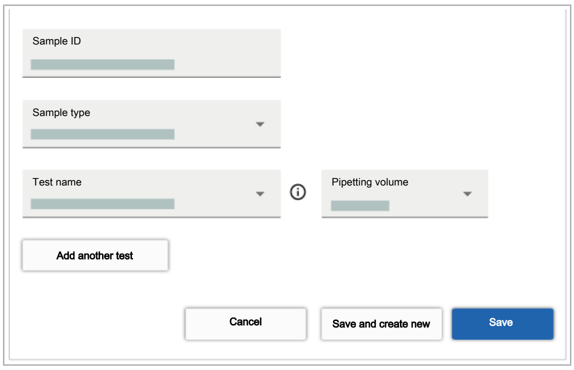
- ☐ The results of the initial high-target test order are released.
- ☐ The additional target calculation interval for the test is still valid.

To initiate additional target calculation manually

1 Choose **Orders > Test orders**.

2 On the **Test orders** tab, choose the **Create order** button.





3 On the **Create new order** screen, enter the same sample ID as in the initial test order.

4 From the **Sample type** drop-down list, choose the same sample type as in the initial test order.

5 From the **Test name** drop-down list, choose a target group that does not overlap with the targets of the initial test order.

6 From the **Pipetting volume** drop-down list, choose the same pipetting volume as in the initial test.

7 To add a comment, choose the button next to the **Pipetting volume** drop-down list.
- Write the comment.
- Choose an area outside the comment field to close it.

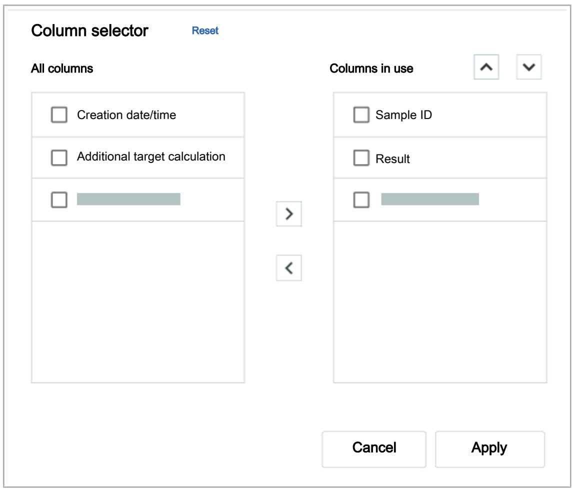
→ The comment is added to the order.

8 To add another test for this sample, choose the **Add another test** button.

You can define a maximum of 3 tests per sample ID. For high-target tests, you can create more than 3 multiplex tests of different target groups per sample ID.

9 To save the order and leave the **Create new order** screen, choose the **Save** button.

→ In the **Orders overview** table, the new orders are listed in the first rows of the table.



10 To display in the **Orders overview** table a column for orders with additional target calculation, do the following:
- At the top of the **Orders overview** table, choose the button.
- In the **All columns** table, select the **Additional target calculation** check box.
- Choose the button and then the **Apply** button.

→ In the **Additional target calculation** column, a **Yes** status is displayed if additional targets are calculated for the order. The column is empty for orders without additional target calculation.

Related topics

- About high-target tests (92)

Searching orders

In the **Orders** app, you can search for orders by sample ID or order comments.

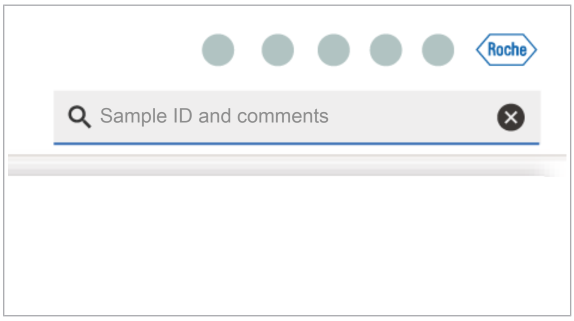
You also find specific test orders by filtering the orders.

☐ Sample ID or keyword from the order comment

To search orders

1 Choose the **Orders** app.

2 On the **Orders** screen, choose the 🔍 button.



3 In the search field, enter the sample ID or a keyword from the order comment.

4 To view order details, at the end of the row, choose the › button.

Related topics

- Applying filters (21)
- Performing a search (28)

Editing orders

The software allows you to edit manually created orders before they are in **Processing** status.

You can edit order comments with the following order status: **New**, **Pending**, **Processing**, **Repeat test pending**, or **Unreleased**.

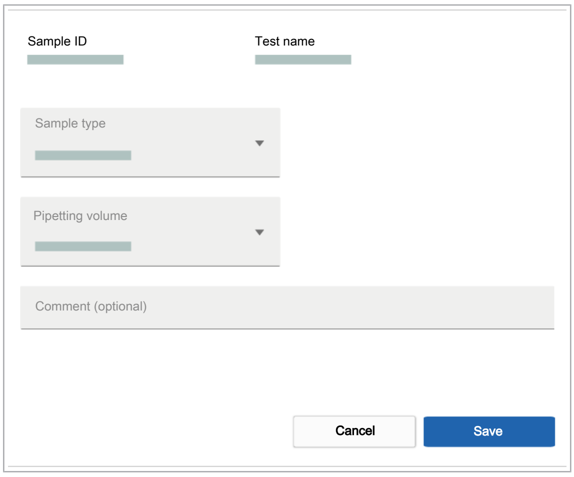
☐ Order is in **New** status.

To edit orders

1 Choose **Orders > Test orders**.

2 In the **Orders overview** table, choose the order you want to edit. At the end of the row, choose the › button.
→ The **Order details** screen is displayed.

3 Choose the **Edit** button.



4 You can edit the content of the following fields:
- **Secondary sample ID**
- **Sample type**
- **Pipetting volume**
- **Comment (optional)**

ⓘ The **Secondary sample ID** button is only available if it is configured in the **Settings** app.

5 After editing the content, choose the **Save** button.

Related topics

- Adding comments (43)

Adding comments

You can add or edit order comments with the following order status:
- **New**
- **Pending**
- **Processing**
- **Repeat test pending**
- **Unreleased**

⚠ CAUTION!

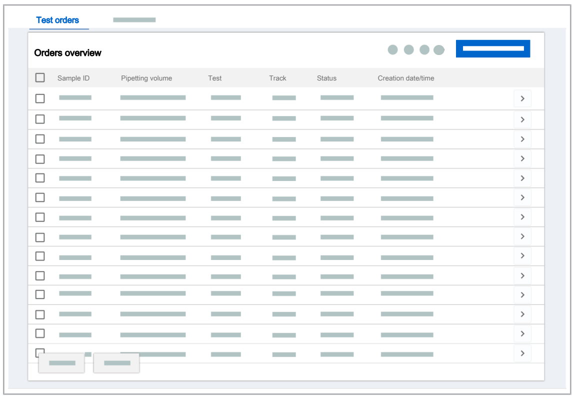
Disclosure of confidential data due to entry in open text fields

Adding personal health information of patients to open text fields increases the risk of privacy incidents and exposure of sensitive data. If you enter confidential data (such as patient data, test results interpretation, service account credentials), for example, into the comment field or as a sample ID, an unauthorized person can view it.

- Do not enter any confidential patient-related information into the comment field of the **Orders** app or **Results** app. There is the risk of unauthorized access to patient data.
- Restrict physical access to the system and all attached IT infrastructure (computer, cables, network equipment, etc.).

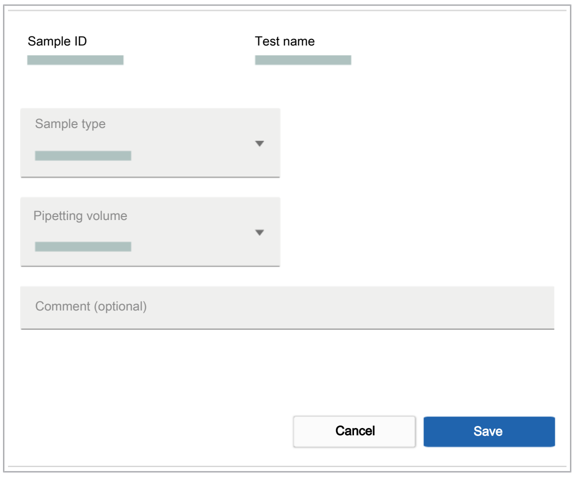
To add comments

1 Choose **Orders > Test orders**.



2 In the **Orders overview** table, choose the order you want to edit. At the end of the row, choose the › button.
  → The **Order details** screen is displayed.

3 Choose the **Edit** button.



4 In the **Comment (optional)** field, you can add a comment or edit an existing comment.

5 After adding or editing the comment, choose the **Save** button.

6 After editing the content, choose the **Save** button.

About deleting orders

Order status

The software only allows you to delete manually created orders that are in **New** status or **Pending** status. You cannot delete test orders for which a repeat test is initiated and which are in **Repeat test pending** or **Processing** status.

Reasons for deleting an order

Orders are typically deleted in the following cases:

- A wrong test order is created manually.

- At the end of the shift, the orders are not processed because the samples are not available.

Consequences

When you delete an order, all order information is removed from the system. The order is not archived and not uploaded.

When deleting an order, no sample material is lost and no results are affected, because the order processing has not started. If the order processing starts, you cannot delete the order.

Workflow

If the data manager has not sent the order to the instrument yet, orders in **New** status are deleted immediately.

If the data manager has already sent the order to the instrument and the order is in **New** status or **Pending** status, the following workflow starts:

- An ⊖ indicator next to the sample ID informs you that the deletion request has been sent to the instrument.
- If the instrument accepts the revoke request, the order is deleted.
- If the instrument rejects the revoke request, the ⊖ indicator remains.
- If the deletion operation fails, the ⊖ indicator is cleared.

The failure to delete orders with **New** status or **Pending** status is due to the following cases:

- The instrument is disconnected.
- The instrument is just about to start processing the sample.

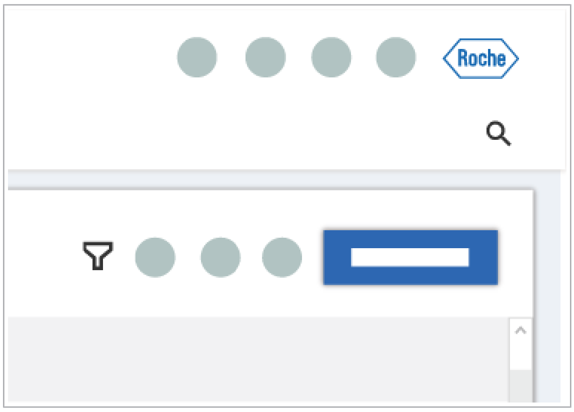
Information inbox notification

If you cannot delete the order, a notification in the information inbox states the reason.

Deleting orders

The software only allows you to delete manually created orders that are in **New** status or **Pending** status.

☐ Order is in **New** status or **Pending** status.

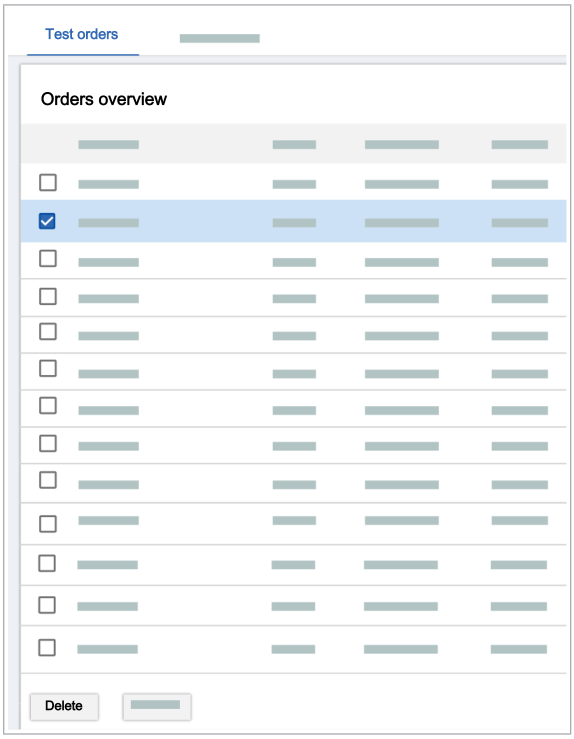


To delete orders

1 Choose **Orders > Test orders**.

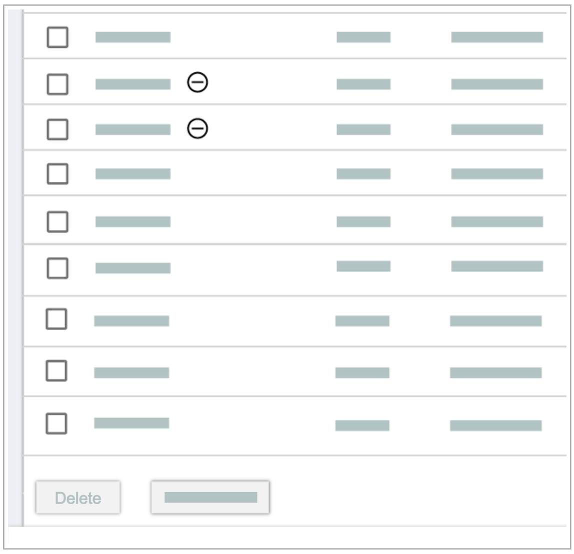
2 In the **Orders overview** table, choose 1 or more check boxes of the orders you want to delete.

  ℹ To find your order, use the search or filter function of the software.



3 On the bottom of the **Orders overview** table, choose the **Delete** button.

  → A dialog box is displayed.



4 After you have read the message and you are sure that you want to delete the orders, choose the **Delete** button.

  ℹ An ⊖ indicator next to the sample ID means that the deletion request has been sent to the instrument. If the instrument rejects the revoke request, the ⊖ indicator remains. If the deletion operation fails, the ⊖ indicator is cleared. If the instrument accepts the revoke of the order, the order is deleted.

  → If the order is deleted, a confirmation message is displayed.

Related topics

- Applying filters (21)
- Searching orders (41)

About cleaning up orders

A user with **Administrator** user role can manually clean up orders that are in **New**, **Pending**, or **Processing** status. If an order is cleaned up, the order is deleted from the system without callback.

If you clean up orders with **Processing** status, the measurement data of these orders is no longer available. Therefore, clean up orders only in an emergency or in critical situations.

Orders with Processing status

Orders that are in **Processing** status are updated to **Unreleased** status after they are cleaned up. In the **Results** app, the result is displayed with a red flag. All targets are invalid.

If no data is available from the instrument after cleaning up an order, on the **Track run** card, the following tables are empty:

- **Consumables**
- **Reagents**
- **Controls**

Orders with Pending status

Orders that are in **Pending** status are updated to **New** status after they are cleaned up. If a host order is cleaned up while in **Pending** status, the data manager deletes the order from the system.

Orders with associated controls

If a control is associated with a cleaned-up order, the control order is automatically cleaned up if no other order is associated with the control. The data manager generates a result for the cleaned-up control order: All control results have an **Invalid** status. The result is displayed in the **Controls** app and **Results** app.

If not cleaned-up orders are associated with the same control, the control order is not cleaned up. The data manager produces a result for the cleaned-up order only. On the **Result details** screen, on the **Track run** card, each control is displayed with an **Invalid** status.

Related topics

- Cleaning up orders manually (48)

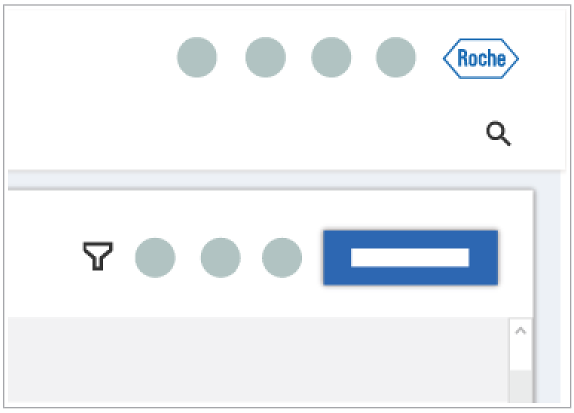
Cleaning up orders manually

The software allows you to clean up manually orders that are in **New**, **Pending**, or **Processing** status. Only clean-up an order in an emergency or critical situation.

- ☐ Order in **New**, **Pending**, or **Processing** status
- ☐ A user account with **Administrator** user role

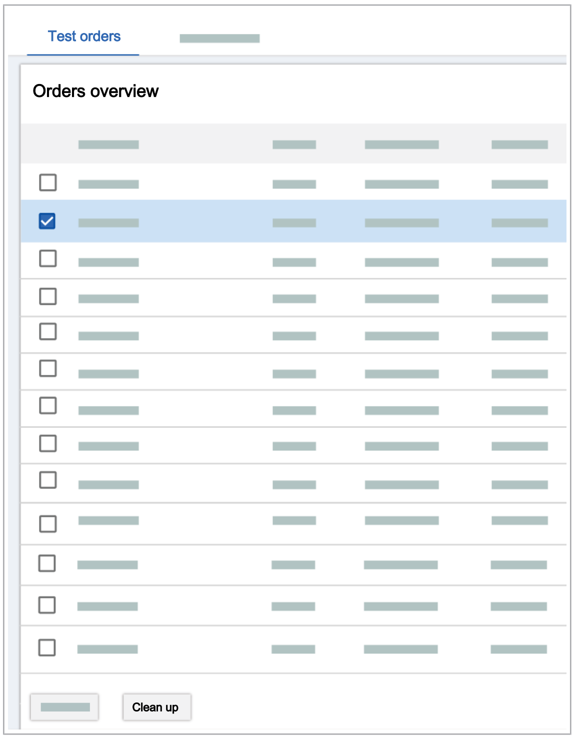
To clean-up orders manually

1 Choose **Orders > Test orders**.

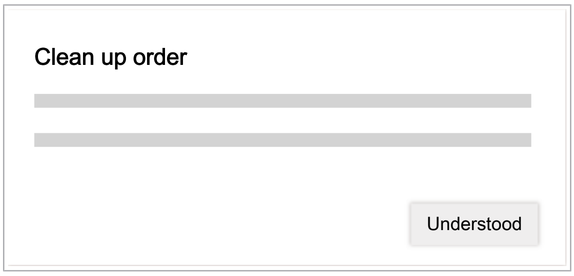


2 In the **Orders overview** table, choose the check box of the order you want to clean-up.

To find your order, use the search or filter functions.



3 At the bottom of the **Orders overview** table, choose the **Clean up** button.



4 In the **Clean up order** dialog box, choose the **Understood** button.
→ Orders that are in **Processing** status are updated to **Unreleased** status. All test results are invalid.
→ Orders that are in **Pending** status are updated to **New** status after they are cleaned up. If a host order is cleaned up while in **Pending** status, the data manager deletes the order from the system.
→ Results of a cleaned-up order are invalid.

Related topics

- About cleaning up orders (47)

Exporting orders to a CSV or XML file

The system allows you to export orders to a CSV or an XML file. The number of results in the XML or CSV export is based on the filter or search applied to the **Orders overview** table.

Additional columns are included in the XML or CSV export, even if they are not displayed in the current view of the table,

To export orders to a CSV or XML file

1 Choose **Orders > Test orders**.

2 At the top of the **Orders overview** table, choose the button.

3 From the drop-down list, choose the **CSV** option or **XML** option.
→ The orders from the **Orders overview** table are downloaded to your computer in the selected format.

Missing orders

In this section

Viewing missing orders

An order is missing if a sample is loaded on the instrument with a sample ID that has no order on the data manager.

The **Orders > Missing orders** tab provides you an overview of all samples loaded on the instrument without an existing order.

In the following cases, missing orders are displayed on the **Missing orders** tab:

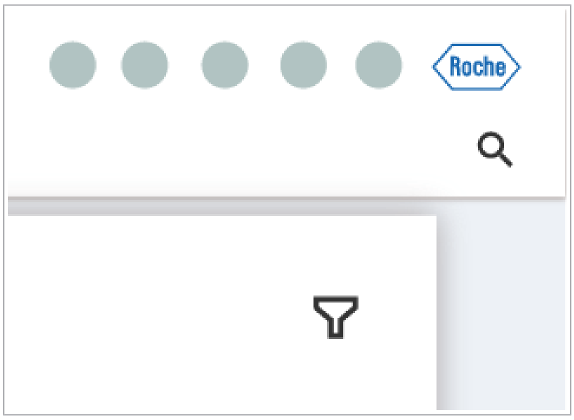
- No orders from the host, and no manual order is available for the loaded sample.
- No manual order is available and the data manager rejects the host order. Host orders are rejected if, for example, the required test is not installed.
- The sample type of the loaded carrier ID does not match with the sample type from the order.
- Duplicate orders for 2 loaded samples. The data manager accepts the order for the first loaded sample and creates a missing order for the second sample.

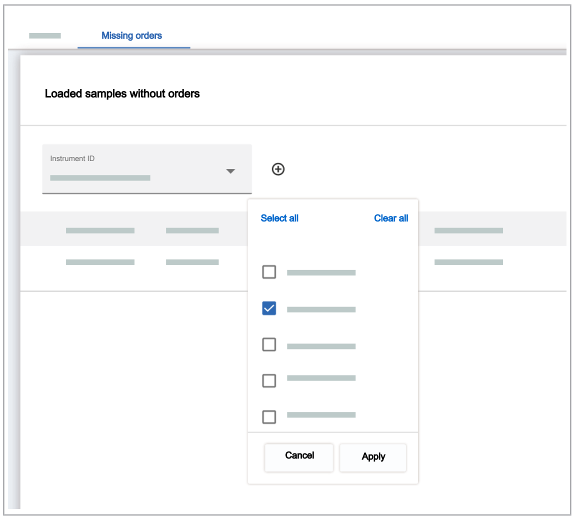
For samples with missing orders, you must create the order manually.

▸ To view missing orders

1 Choose **Orders > Missing orders**.

2 To filter the sample IDs with missing orders by instrument, on the **Missing orders** tab, choose the ⛛ button.





3 From the **Instrument ID** drop-down list, choose one of the following options:
   - To choose specific instruments, choose the instrument check boxes.
   - To choose all instruments, choose the **Select all** button.
   - To clear all check boxes, choose the **Clear all** button.

4 Choose the **Apply** button.

Related topics

- Applying filters (21)

Creating orders for samples with missing orders

For loaded samples with missing orders, you must create the order manually. You can create multiple orders for missing orders at once.

To create an order for a sample with a missing order, the sample type of the configured carrier must match with the sample type of the order. Otherwise, you cannot create the order.

The data manager validates that there are no duplicate tests and overlapping targets, for example, CT and CT/NG.

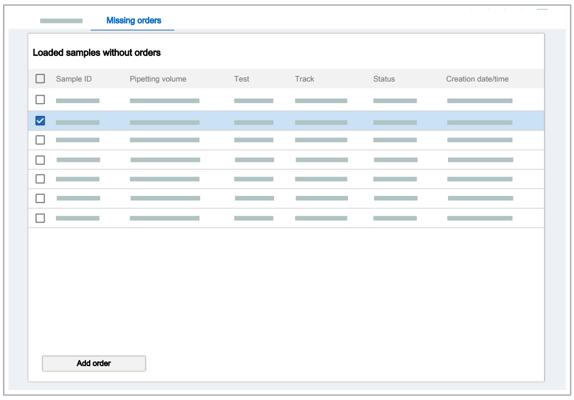
To create orders for sample IDs with missing orders

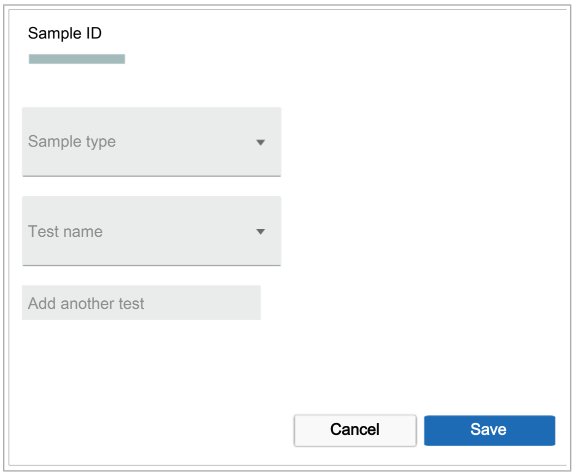
1 Choose **Orders > Missing orders**.

2 On the **Missing orders** tab, choose 1 or multiple sample IDs for which you want to create an order.

3 Choose the **Add order** button.

   Do not unload the samples with missing orders until the order is saved.





4 On the **Add order** screen, from the **Sample type** drop-down list, choose an option.

5 From the **Test name** drop-down list, choose an option.

6 To add another test for the sample ID, choose **Add another test** button.

7 Choose the **Save** button.

Printing orders

In this section

Printing order lists

The system allows you to print a list of orders from the **Orders overview** table. You can print a maximum of 1000 orders in 1 list.

☐ For a printout: printer connection

▸ To print lists of orders

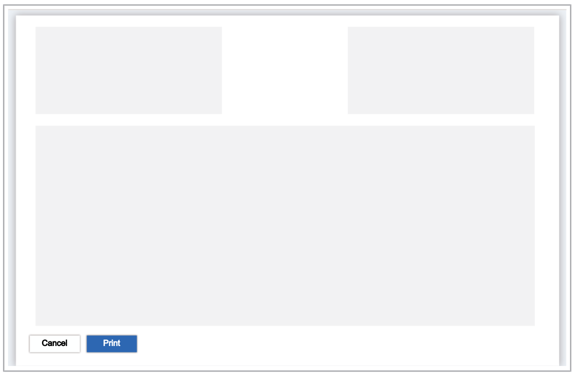
1 Choose the **Orders** app.

2 Optionally, in the **Orders overview** table, choose the orders you want to print:
- To filter orders, choose the button.
- To search orders, choose the button.
- To print individual orders, choose the check boxes of the orders.

Applied filters, search functions, and column selection are applied in the print out.

3 Choose the button.

→ The **Print preview** screen is displayed.



4 Choose the **Print** button.

5 On the **Print** screen, choose the printer. You can also save the list of orders as PDF.

6 Depending on the selected option, print or save the list of orders.

→ The list of orders is printed on the selected printer or saved in a local folder.

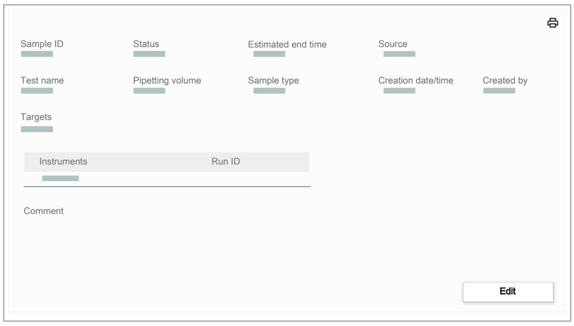
Printing order details

The system allows you to print the detailed information of the selected order from the **Order details** screen.

☐ For a printout: printer connection

▸ To print order details

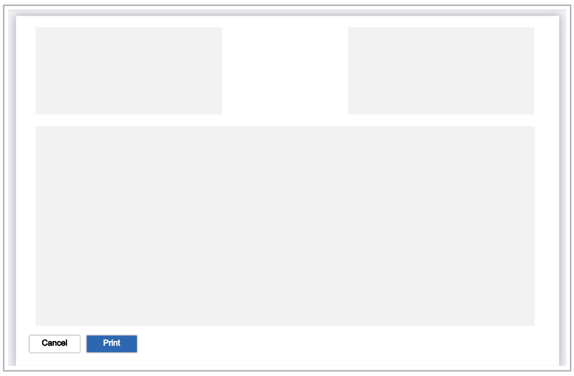
1 Choose **Orders > Test orders**.



2 To open the **Order details** screen, in the **Orders overview** table, at the end of the row, choose the › button.

3 Choose the button.

→ The **Print preview** screen with the order details is displayed.



4 Choose the **Print** button.

5 On the **Print** screen, choose the printer. You can also save the result details as PDF.

6 Depending on the selected option, print or save the order details.

→ The entire page of the **Order details** screen is printed on the selected printer or saved in a local folder.

Result handling

In this section

About flags

In the **Results overview** table, flags indicate if a test order result is valid, invalid, not available, or if additional information is provided in the result. Results can have more than 1 flag. In the **Results overview** table, always the most severe flag is displayed.

On the **Results > Result details** screen, the flags, the flag code, and the additional information, or the reason why the result is invalid or cannot be generated is displayed.

There are 3 severity levels for flags:

Information: Result is valid and contains additional information.

Critical: Result is invalid.

Fatal: Result cannot be generated. Result is invalid.

Flag codes

Every flag has a flag code, which presents a specific information or issue. You can search results by the flag code.

Performing a search (28)

List of flag codes

Every flag has a flag code, which presents a specific information or issue. You can search test results by the flag code. The flag codes have a pattern.

Character	Code	Flag description
1st character	Y	System failure
	U	User failure
	C	Calculation failure
	P	Processing failure
	Q	Control failure
	R	Resource failure
2nd and 3rd character	01-99	2-digit running number
4th character	T	Sample transfer unit
	A	Analytic unit
	F	Infrastructure
	P	Sample processing
	B	Consumable
	M	Instrument software
	X	Test specific
	D	Data manager software

Flag pattern

Flag code	Severity level	Description
P02T	Fatal	**Clot detected while aspirating or mixing sample in sample tube. Sample not transferred.**
P03T	Fatal	**Clot detected while dispensing sample.**

List of flag codes and description

Flag code	Severity level	Description
P04T	Fatal	An error occurred during control volume check. Transferred control volume is insufficient.
P05T	Fatal	Droplet detected during sample transfer.
P06T	Fatal	Volume check detects no liquid level in the sample tube during sample transfer.
P08T	Fatal	Pipetting error occurred during aspiration of control. Control not transferred.
P09T	Information	Risk of cross-contamination
P10T	Fatal	Maximum allowed time for the sample transfer was exceeded.
P06P	Fatal	An error occurred while dispensing reagent. Volume is insufficient.
P07P	Fatal	Insufficient supernatant was removed.
P09P	Fatal	Temperature in heating station is out of range.
P10P	Critical	Timeout was reached.
P13P	Fatal	Pipette tip dropped.
P14P	Fatal	Consumable dropped.
P15P	Fatal	Consumable pickup/release error
P16P	Fatal	Pipette tip could not be picked up by processing transfer head during aspiration.
P17P	Fatal	Sealing station could not be woken.
P18P	Fatal	Thermal cycler could not be woken.
P19P	Fatal	Incubation temperature cannot be set.
P20P	Fatal	Error during the sealing process
P21P	Critical	Handling of filled, unsealed amplification plate took too long.
P22P	Critical	Handling of filled, sealed amplification plate took too long.
P23P	Fatal	Sealer loading error
P24P	Fatal	Bottom search of processing transfer head failed.
P11A	Fatal	Thermal profile error during PCR
P12A	Critical	Fluorescence signal saturated.
P13A	Fatal	Camera temperature out of range error
P14A	Fatal	LED intensity error
P15A	Fatal	Heated lid temperature out of range error
P16A	Critical	Maximum time defined in the PCR profile was exceeded.
P17A	Fatal	Camera connection error
Y11	Fatal	An unhandled hardware failure occurred and the result cannot be guaranteed anymore.
Y13	Fatal	Mechanical movement error of the MGP cassette shaker
Y14	Fatal	Mechanical error of the sample transfer head
Y15	Fatal	Mechanical error of the reagent transfer head
Y16	Fatal	Mechanical error of the processing transfer head
Y17	Fatal	Mechanical error of the separation station
Y18	Fatal	Mechanical error of the heating station
Y19	Fatal	Mechanical error of downholder on the processing unit
Y20M	Fatal	An instrument software error occurred.
Y21A	Fatal	Mechanical error of thermal cycler drawer
Y31D	Fatal	Work order was interrupted by a power failure.

List of flag codes and description

Flag code	Severity level	Description
Y32D	Fatal	**Processing order aborted manually.**
Y44	Fatal	**Reagent supply unit temperature exceeded upper limit.**
Y45	Fatal	**Temperature in control mini rack drawer exceeded upper limit.**
Y47	Fatal	**Onboard temperature dropped below lower limit.**
Y48	Fatal	**Onboard temperature exceeded upper limit.**
U06T	Fatal	**Insufficient volume aspirated. Sample not transferred.**
U07T	Fatal	**Control mini rack RFID parameter error**
U12M	Information	**Sample ID entered manually by keyboard or scanned using hand-held barcode reader.**
Q03D	Critical	**Result validation error**
Q04D	Critical	**Result enrichment error**
Q05D	Critical	**Result validation failed because of an invalid positive control.**
Q06D	Critical	**Result validation failed because of an invalid negative control.**
C01	Fatal	**Calculation error**
C02	Critical	**Data analysis not possible**

List of flag codes and description

Filtering result tables by flags

You can filter a table by the severity level of the flags.

To filter result tables by flags

1. Choose the **Results** app or the **Controls** app.
2. In the **Results overview** table, choose the ▽ button.
3. Choose the ⊕ button.
4. From the drop-down list, choose the **Flag** option.
5. Choose the severity level of the flag.

About test result formatting

Test results identification

In the **Results overview** table, in the **Result** column, you can identify a reactive, non-reactive, an invalid result, or results from a repeat test by the coloured-in circle.

Gray	Negative/non-reactive result Result from quantitative test
Pink	Positive/reactive result

Orange	Invalid result
Blue	Repeat testing

Non-Roche controls In the Results overview table and in the Result report, non-Roche controls are highlighted in light blue.

Viewing results

In the **Results** app, you can view the results of a completed run.

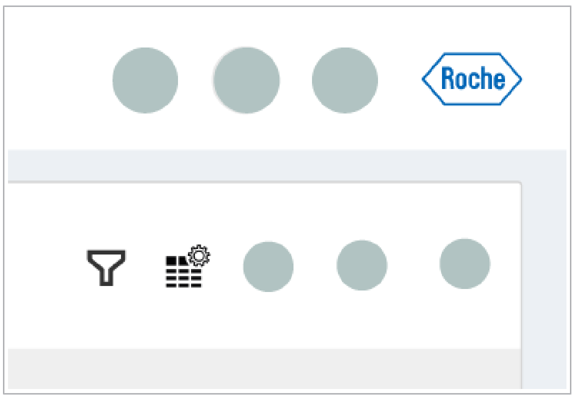
The result of an cleaned up order is displayed with a red flag. All test results are marked as invalid.

If the test order results are in **Unreleased** status for 14 days, the data manager changes the status automatically to **Rejected**. Rejected test order results are not sent to the host. A flag informs you that the instrument rejected the results.

The **Results** app is connected to the **Controls** app. To display the **Controls** app, on the **Result details** screen, next to the **Control ID** entry, choose the button.

- ☐ Run completed
- ☐ Results available in **Results overview** table

To view results

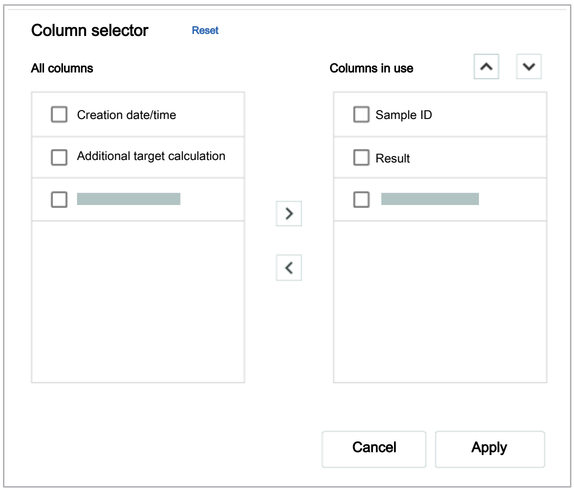


1 Choose **Results > Ready to review**.

2 To filter the **Results overview** table, choose the button.

3 To add or delete columns to or from the **Results overview** table, choose the button.

You can add the following columns: **Run ID**, **Instrument name**, **IC result/Ct value**, and **QS result/Ct value**. If multiple runs are associated with the test order result, the values displayed in these columns are always associated with the most recent run. To identify whether the test order result has multiple runs associated with it, an icon is displayed near the sample ID.



4 To check if the result is from an order with additional target calculation of a high-target test, add the **Additional target calculation** column:

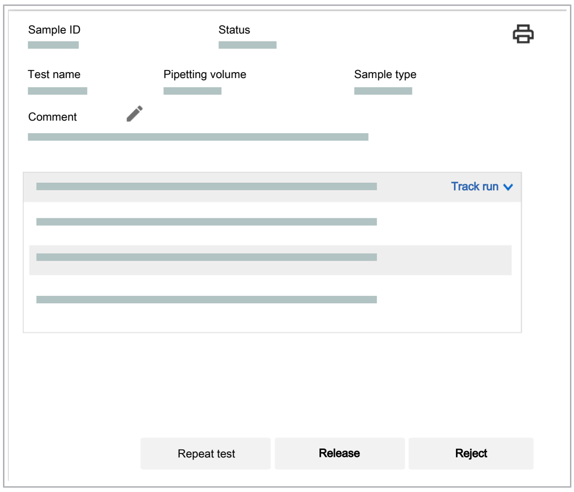
- Choose the button.
- In the **All columns** table, choose the **Additional target calculation** check box.
- Choose the > button
- Choose the **Apply** button.

5 If more than 3 test results are available for a high-target test, choose the ··· button.

→ A dialog box with the results of the high-target test is displayed.

6 To view result details, at the end of the row, choose the > button.

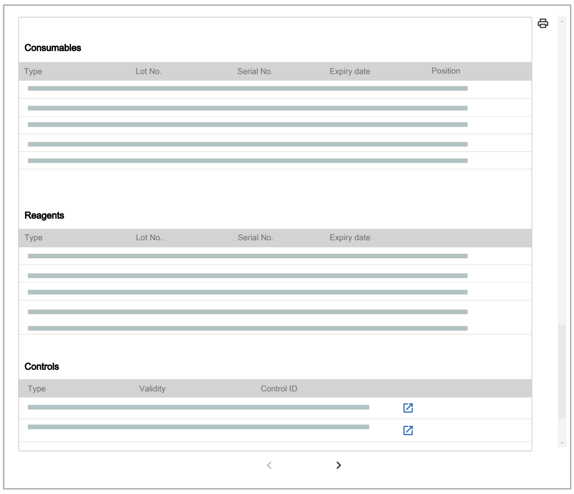
→ The **Result details** screen is displayed.



7 To view tracking information on the run, on the **Result details** screen, choose the **Track run** button.

ⓘ If no data is available from the instrument for a cleaned-up run, the **Consumables** table, **Reagents** table, and **Controls** table are empty.

→ Information is displayed on consumables, reagents, and controls used to generate the results.



8 To view the associated control results, do the following:

- On the **Result details** screen, choose the **Track run** button.
- Scroll down to the **Controls** table.
- To view detailed information on the specific control, choose the ↗ button next to the **Control ID** entry. The **Controls** app is displayed.
- For more information on the specific control, at the end of the row, choose the > button.
- To return to the **Results** app, in the **Controls > Results overview** table, choose the ↗ button next to the **Control ID** entry.

Related topics

- Applying filters (21)
- Choosing columns (25)
- Sorting columns (26)

Searching for results

In the **Results overview** table you can search results by sample ID or order comments.

You can also find results for specific tests by filtering the results.

- ☐ Run completed
- ☐ Results available in **Results overview** table
- ☐ Sample ID or keyword from order comment

▸ To search results

1 Choose the **Results** app.

2 On the **Result** screen, choose the 🔍 button.

3 In the search field, the following options are available:
- Enter the sample ID or a keyword from the order comment.
- Choose 1 of the options from the drop-down list: **Control ID**, **Reagent lot No.**, **Flag code**, or **Run ID**. Enter the respective ID, lot number, or flag code.

4 To view the result details, at the end of the row, choose the › button.

Related topics

- Applying filters (21)

Adding comments

Before a result is released, you can add or update an order comment.

If an automatic release is configured on your system, it is not possible to add or update order comments, because these orders have released results.

⚠ CAUTION!

Disclosure of confidential data due to entry in open text fields

Adding personal health information of patients to open text fields increases the risk of privacy incidents and exposure of sensitive data. If you enter confidential data (such as patient data, test results interpretation, service account credentials), for example, into the comment field or as a sample ID, an unauthorized person can view it.

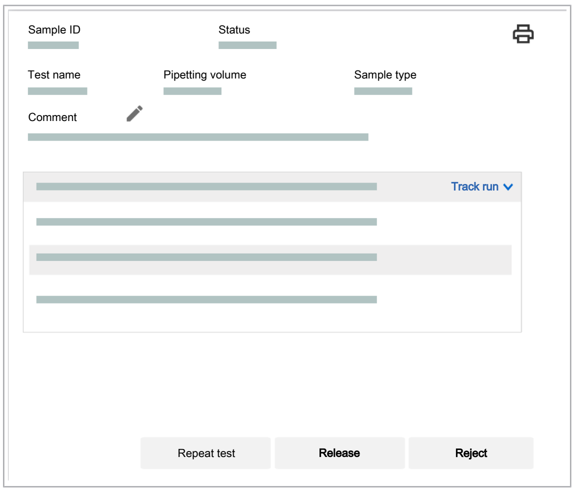
- Do not enter any confidential patient-related information into the comment field of the **Orders** app or **Results** app. There is the risk of unauthorized access to patient data.
- Restrict physical access to the system and all attached IT infrastructure (computer, cables, network equipment, etc.).

☐ Result not released

To add comments

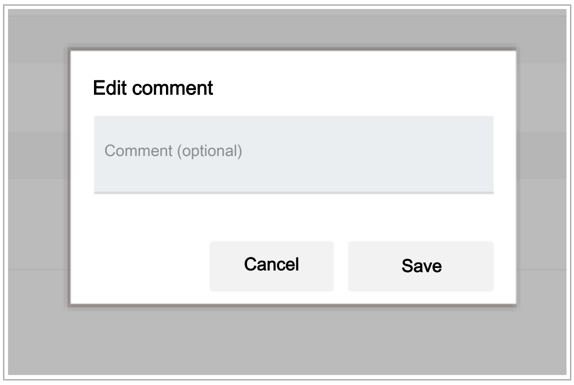
1 Choose **Results > Ready to review**.

2 In the **Results overview** table, at the end of the row of the result, choose the > button.



3 On the **Result details** screen, choose the button.

If the button is not available, the result is released or rejected. To add or update a comment is not possible.



4 Write or update a comment.

5 Choose the **Save** button.

Releasing results

After a run is completed, the system allows you to release the results.

For the following scenarios you cannot release the results:

- The order of the result is in **Repeat test pending** status.
- The result is released.
- An automatic release is configured for both valid and invalid results.

Once the result is released, you cannot edit the comments and you only can repeat the test by creating an order.

If there is a host connection, the released results are automatically sent to the host.

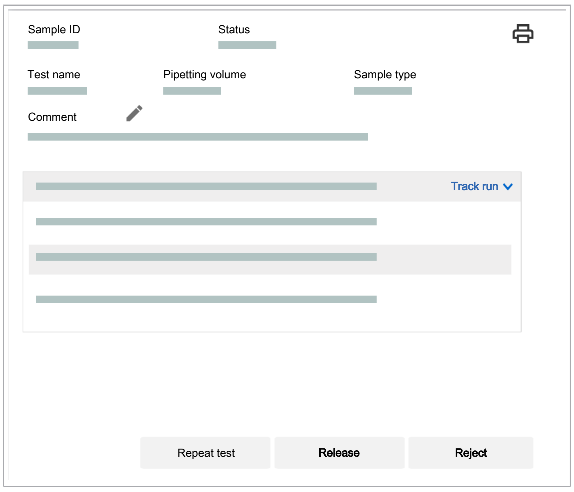
☐ Run completed
☐ Results are in **Unreleased** status
☐ A user account with **Technical validator** user role

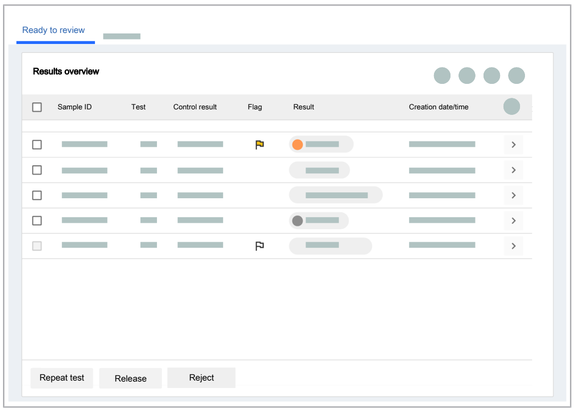
▸ To release results

1 Choose **Results > Ready to review**.

2 Filter the **Results overview** table.
   - Choose the button.
   - From the **Status** drop-down list, choose the **Unreleased** option.
   - Choose the **Apply** button.

   → Only unreleased results are displayed.





3 Review results.

- To view result details, at the end of the row, choose the › button.
- To add a comment, on the **Result details** screen, choose the ✎ button.
- To track information on the sample result, on the **Result details** screen, choose the **Track run** button.
- To release a result on the **Result details** screen, choose the **Release** button.
- To reject a result on the **Result details** screen, choose the **Reject** button.
- To repeat a test on the **Result details** screen, choose the **Repeat test** button.

4 To release results from the **Results overview** table, choose the check boxes of the results you want to release. If your selection includes invalid results, a dialog box is displayed. Choose if you want to release only valid results or all selected results.

5 Choose the **Release** button.

→ A message informs you that the results have been successfully released.

→ The results are sent to the host.

→ On the **Released** tab, the released results are listed.

→ On the **Result details** screen, the **Release date/time** field, **Released by** field, and **Received by host** field are displayed.

Related topics

- Viewing results (58)
- Searching for results (60)
- Applying filters (21)
- Adding comments (60)
- Repeating tests (66)

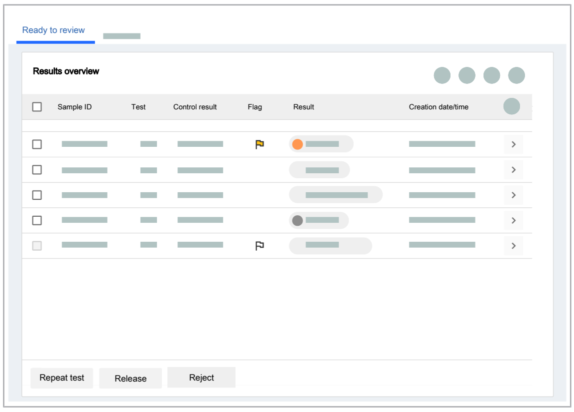
Releasing all results

After a run is completed, the system allows you to release all results at once. Results that are already released or orders for repeat tests are disabled.

☐ Run completed

☐ Results are in **Unreleased** status

☐ A user account with **Technical validator** user role



To release all results

1 Choose **Results > Ready to review**.

2 In the **Results overview** table, choose the check box in the table header.

→ All check boxes in the table are selected except check boxes from released results and orders for repeat tests.

3 Choose the **Release** button.

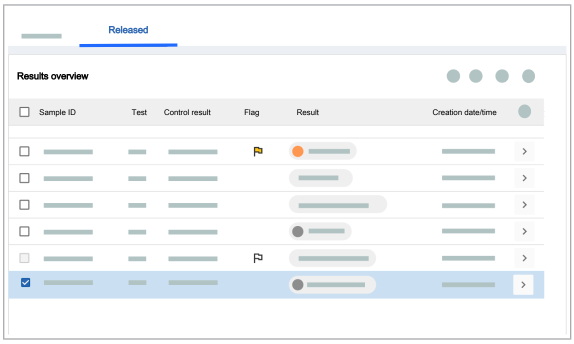
- If selected results include invalid results, a dialog box is displayed. In the dialog box, choose one of the options.
- Choose the **Release** button.

→ A message is displayed indicating how many results are released from your selected results.

Related topics

- Releasing results (62)

Viewing released results



On the **Results > Released** tab, you can view all released results.

To view released results

1 Choose **Results > Released**.

2 To view detailed information on released results, at the end of the row of the respective result, choose the › button

→ The **Result details** screen is displayed.

Rejecting results

If results are available for an order, but you do not want to release the results, you can reject them. Rejected results are not sent to the host.

For the following scenarios you cannot reject the results:

- The order of the result is in **Repeat test pending** status.
- The result is released.
- An automatic release is configured for both valid and invalid results.

Once the result is rejected, you cannot edit the comments and you only can repeat the test by creating an order.

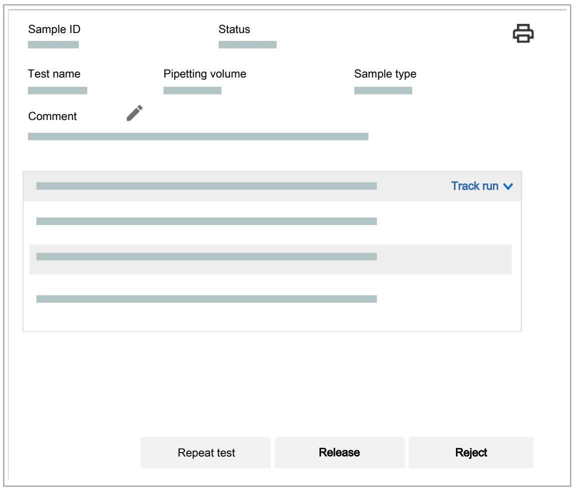
- ☐ Run completed
- ☐ Results are in **Unreleased** status
- ☐ A user account with **Technical validator** user role

To reject results

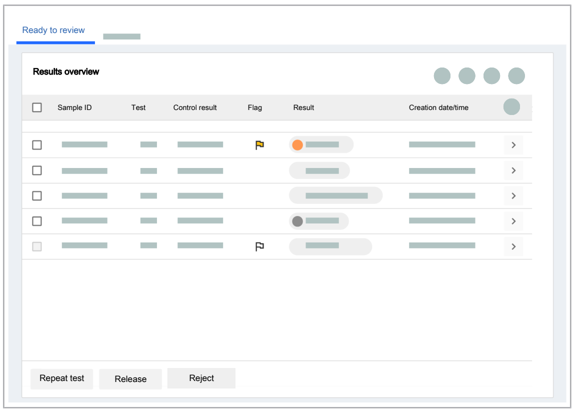
1 Choose **Results > Ready to review**.

2 Filter the **Results overview** table.
- Choose the button.
- From the **Status** drop-down list, choose the **Unreleased** option.
- Choose the **Apply** button.

→ Only unreleased results are displayed.



3 To view result details, at the end of the row, choose the > button. To reject a result on the **Result details** screen, choose the **Reject** button.



4 To reject results from the **Results overview** table, choose the check boxes of the results you want to reject and choose the **Reject** button.

ⓘ Rejected results are not sent to the host.

→ On the **Released** tab, the rejected results are listed.

Repeating tests

After a run is completed, in the **Results** app, information is displayed about invalid results or not available results. Invalid results are indicated with a flag, not available results with a flag. You can repeat a test for samples with invalid or missing results.

The following rules apply to repeating tests:

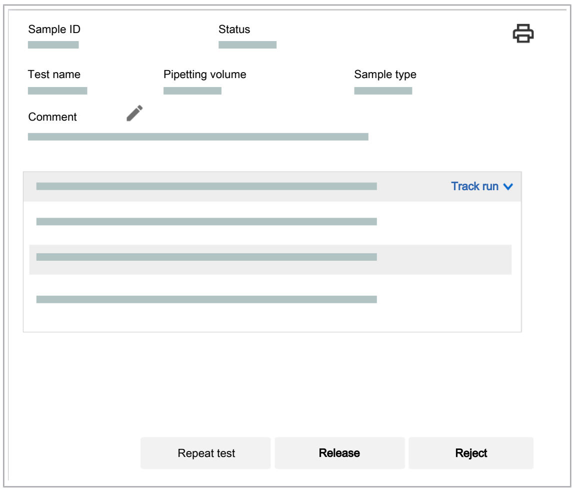
- If 1 or more target results of the order are invalid, you can manually repeat tests any number of times.
- Tests for non-Roche controls cannot be repeated.
- Tests are only automatically repeated if repeat tests are enabled in the data manager settings and if the tests were not repeated before for the same order.
- If the automatic release of both valid and invalid results is enabled, you cannot repeat the tests. The **Repeat test** button is not available.
- For multiple-target-based tests like CT/NG, TV/MG, or MPX and high-target tests, the test is repeated only for the invalid targets.
- Avoid repeating tests for blood screening. Instead release the results. If necessary, the middleware creates orders to repeat the tests.

- ☐ Run completed
- ☐ Invalid or missing results indicated
- ☐ A user account with **Technical validator** user role

To repeat tests

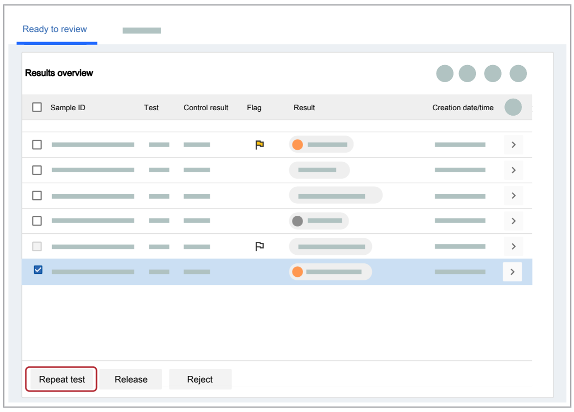
1. Choose **Results > Ready to review**.
2. Filter the **Results overview** table.
   - Choose the button.
   - From the **Result** drop-down list, choose the **Invalid** option.
   - Choose the **Apply** button.

   → Only invalid results are displayed.



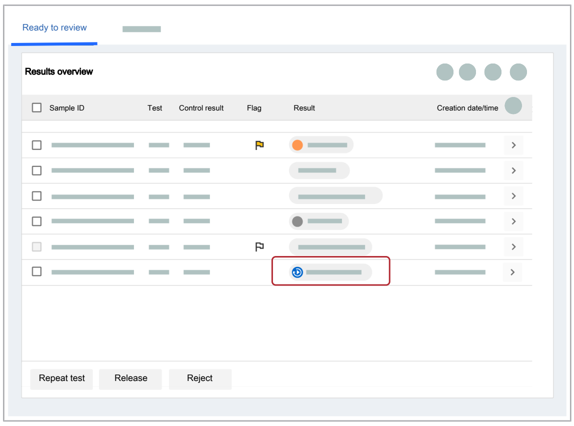
3 To check result details, in the **Results overview** table, at the end of the row, choose the › button.

- To add a comment, on the **Result details** screen, choose the button.
- To track information on the run, on the **Result details** screen, choose the **Track run** button.



4 In the **Results overview** table, choose the check boxes of invalid results:

- To repeat testing of individual samples, choose the check boxes one by one.
- To repeat testing of all samples with invalid results, choose the check box in the table header.



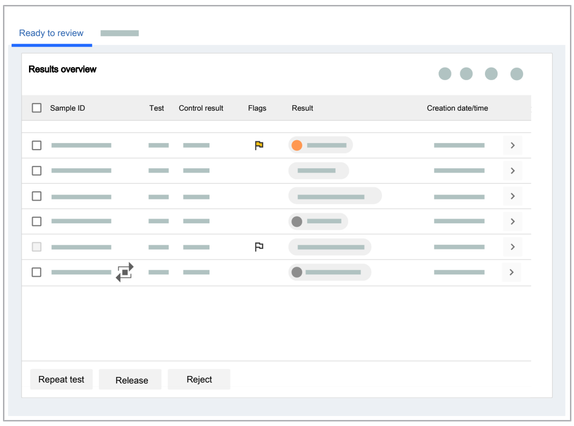
5 Choose the **Repeat test** button.

→ A message informs you how many samples have been sent for repeat testing.

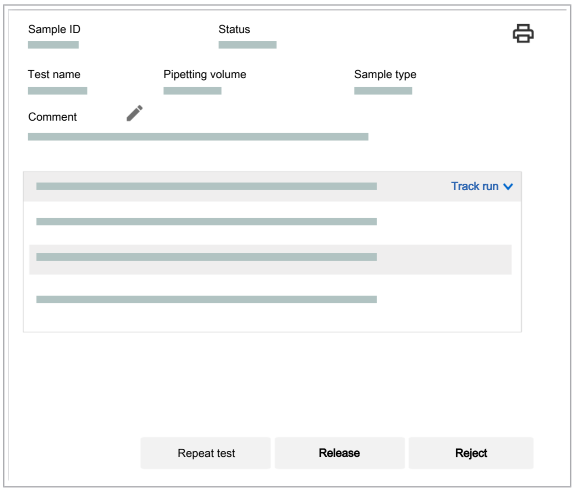
→ If samples for repeat testing are loaded, in the **Results overview** table, the order is in **Repeating test** status. In the **Result** column, next to the target that is tested again, the icon is displayed.

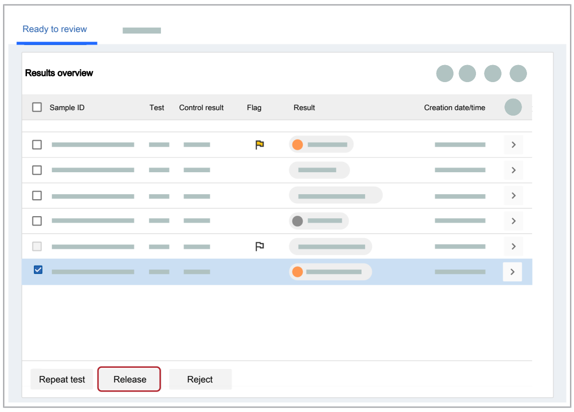
→ If samples for repeat testing are not loaded, the order is in **Repeat test pending**status.

6 If samples for repeat testing are not loaded, load them. Load sufficient supplies to process the samples.



7 After the test is repeated, in the **Results overview** table, next to the sample ID, the icon is displayed.





8 To view detailed information after the test is repeated, in the **Results overview** table, at the end of the row of the repeat test result, choose the > button.
- On the **Result details** screen, an additional table for the run with the repeat test is displayed.
- To track information on the run, choose the **Track run** button.

9 If results are invalid after the test was repeated and you want to repeat the test, start again with step **4**.

10 If results are valid after the test was repeated, you can release the results:
- Choose the check boxes of the result of the repeat test.
- Choose the **Release** button.

Related topics

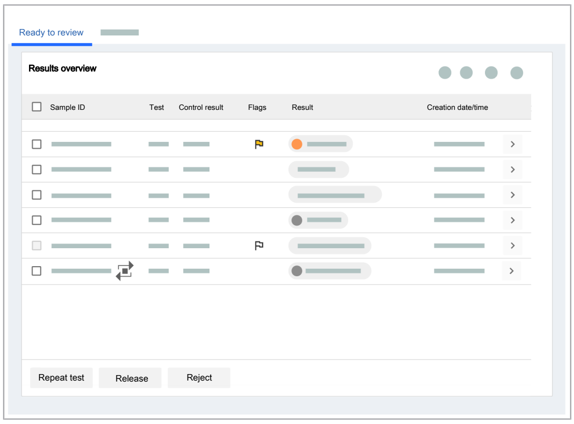
- Applying filters (21)
- Viewing results (58)
- Releasing results (62)

Canceling repeat tests

The following preconditions must be fulfilled to cancel repeat tests:
- The order is in **Repeat test pending** status.
- The data manager has not sent the order to repeat the test to the instrument or the instrument has not started to process the order.

To cancel repeat test

1 Choose **Results > Ready to review**.



2 In the **Results overview** table, at the end of the row of the order that is in **Repeat test pending** status, choose the › button.

3 Choose the **Cancel repeat test** button.

The indicator next to the sample ID means that the cancellation request has been sent to the instrument. If the instrument rejects the cancel request, the indicator remains. If the cancelation operation fails or the instrument is about to process the repeat test order, the indicator is cleared.

→ If the instrument accepts the request for repeat test cancelation, the order is reverted to the previous **Unreleased** status.

Sending again results not received by the host

A host is a system that sends orders and receives results to and from the data manager. Usually, it is a laboratory information system (LIS) or hospital information system (HIS).

If the connection from the data manager to the host is interrupted while releasing, the release is not successful. Sending the results manually to the host is necessary.

On the **Result details** screen, in the **Received by host** field, the status of the result is displayed:

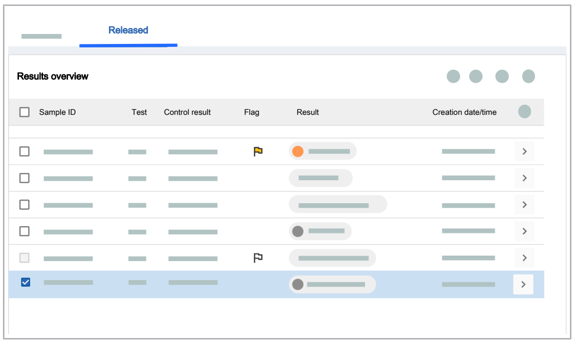

Result received by host


Result not received by host

Released results can be sent multiple times to the host. You must send the results individually to the host.

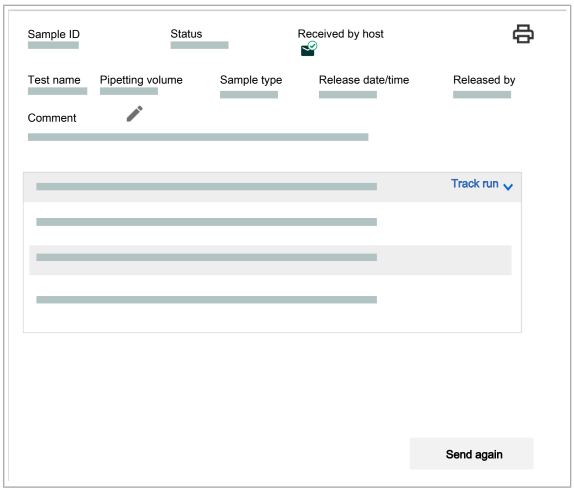
- ☐ Results released
- ☐ Host connection enabled
- ☐ A user account with **Technical validator** user role

To send results to the host manually



1 Choose **Results > Released**.

2 In the **Results overview** table, choose the result you want to send again. At the end of the row, choose the › button.



3 On the **Result details** screen, choose the **Send again** button.

The **Send again** button is displayed only if there is a connection to the host.

Related topics

- Creating customized filters (22)
- Choosing columns (25)

Exporting and downloading result data

In this section

Exporting results to an XML file

The system allows you to export result information to an XML file. The number of results in the XML file is based on the filter or search applied to the **Results overview** table.

Additional columns are included in the XML export, even if they are not displayed in the current view of the table,

The creation time and date is displayed in UTC.

- ☐ Results available in **Results overview** table

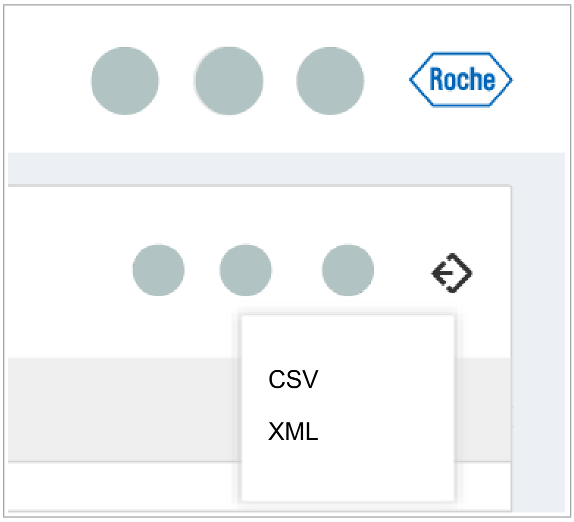
To export results to a XML file

1 Choose **Results > Ready to review** or **Results > Released**.

2 At the top of the **Results overview** table, choose the button.

3 From the drop-down list, choose the **XML** option.

→ When you choose the XML option, the result table is downloaded in the XML format.



Exporting results to a CSV file

There are 2 options for a CSV export:

- **Export the result overview**:
  - The number of results in the CSV file is based on the filter or search applied to the **Results overview** table.
  - The columns displayed in the **Results overview** table are exported.
  - You can export a maximum of 1000 results.

- **Export the result overview with additional columns**:
  - The number of results in the CSV file is based on the filter or search applied to the **Results overview** table.
  - Besides the columns displayed in the **Results overview** table, you can choose additional columns for the export.
  - You can download an unlimited amount of result data.
  - The export is based on targets. For every target there is a separate row in the exported table.
  - You can download the exported result data from the **Reports** app.

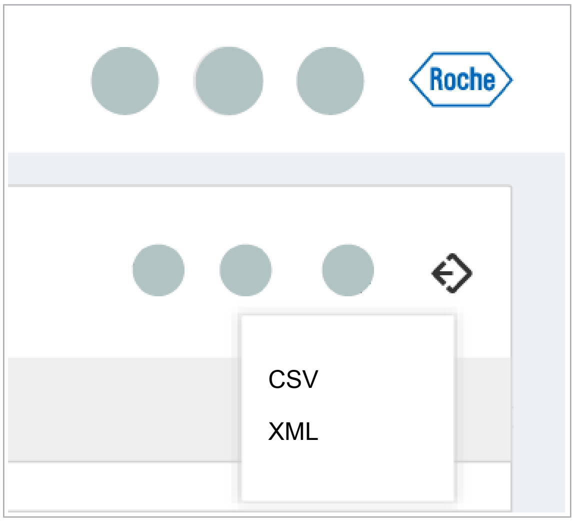
The creation time and date is displayed in UTC.

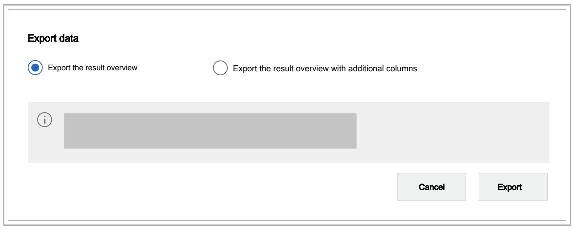
☐ Results available in **Results overview** table

To export results to a CSV file

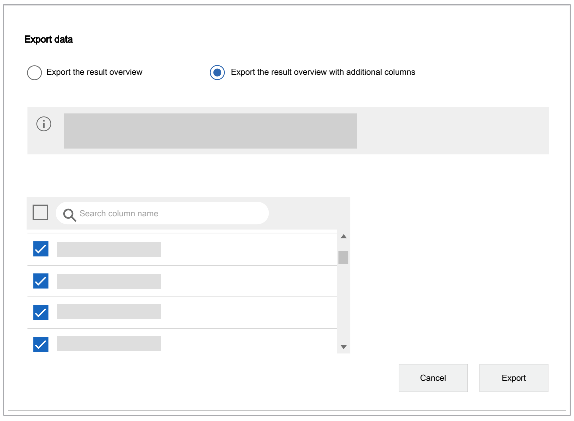
1 Choose **Results > Ready to review** or **Results > Released**.

2 At the top of the **Results overview** table, choose the button.





3 From the drop-down list, choose the **CSV** option. From the dialog box, choose 1 of the following options:
  - **Export the result overview**: If you choose this option, choose the **Export** button. The data from the result overview is downloaded.
  - **Export the result overview with additional columns**: If you choose this option, follow steps 4–7.



4 When you choose the **Export the result overview with additional columns** option, a table with all additional columns is displayed. By default, all columns are selected. Do the following:
   - In the search field, enter the column name you want to clear.
   - Clear the check boxes of the columns you want to exclude from the export. Some columns are inactive. You cannot clear the check boxes of those columns, as they are mandatory.

   ⓘ With the next logon, the check boxes are preselected from your last session.

5 Choose the **Export** button.

6 In the **Test order result export** dialog box, choose the **Understood** button.
   → The result data is exported to the **Reports** app.

7 To download the exported data to an external storage devise or your personal computer, choose the **Reports > Exported data** screen.

About exporting measurement, calculation and troubleshooting data

The following rules apply to the result data export:

- The data export is based on the selected results in the **Results overview** table.
- The data export includes results in **Unreleased** status, **Released** status, and **Repeat test pending** status.
- The export is a server-side export. It includes much more data than is being displayed in the **Results overview** table.
- The maximum number of data that can be exported is restricted to 1000 records.
- The exported sample information includes the related control information in the same export file.

The following data export options are available in the data manager:

- **Data export for customer**: XML file with the following data:
  - Measurement data: Measured data, Ct ranges for controls, position in the amplification plate.
  - Calculation data: Intermediate results of the calculator, additional x/y curves.
- **Data export for cobas omni Utility Channel Tool**: JSON file (password protected) with the following data:

  - Measurement data: Measured data, Ct ranges for controls, position in the amplification plate.
  - Calculation data: Intermediate results of the calculator, additional x/y curves.
- **Data export for Roche**: JSON file (password protected) with the following data and additional options:
  - Measurement data: Measured data, Ct ranges for controls, position in plate.
  - Calculation data: Intermediate results of the calculator, additional x/y curves.
  - Processing data details.
  - **Troubleshooting data**: Pressure curves in addition to the above-mentioned data.
  - **Cleanse data**: Sample ID and user information are cleansed.

The exported data files are available in the **Reports** app. After exporting, you can download the data to a preferred storage location.

The data manager deletes exported data automatically from the system after 7 days.

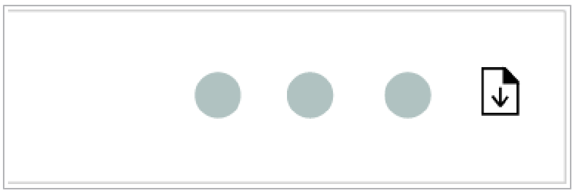
Exporting measurement, calculation, and troubleshooting data

The system allows you to export.

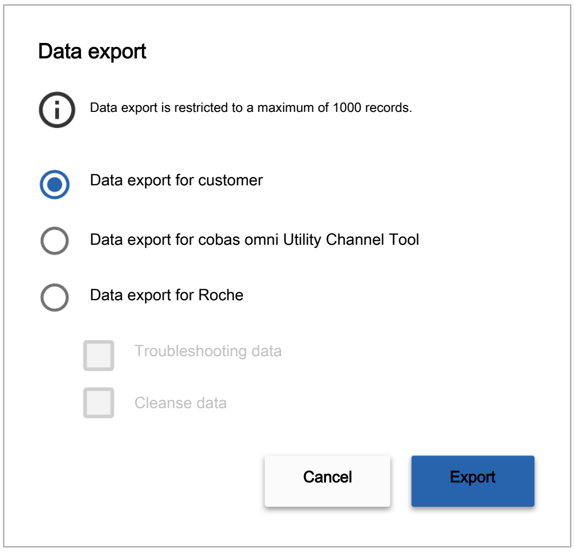
☐ Results available in **Results overview** table

To export result data

1 Choose **Results > Ready to review** or **Results > Released**.



2 On top of the **Results overview** table, choose the button.



3 From the **Data export** combo box, choose an option.

When choosing the **Data export for Roche** option, to protect personal data, choose the **Cleanse data** check box.

4 Choose the **Export** button.

→ In the **Reports** app, the exported data is saved as a ZIP file. You can download the data files from the **Reports > Exported data** screen.

→ A gray notification badge is displayed on the app launcher and guides you to the **Reports** app.

Related topics

- About exporting measurement, calculation and troubleshooting data (73)
- Generating result reports (82)

Downloading data files

After exporting the CSV or Zip files, you can download the data from the **Reports** app.

⚠ CAUTION!

Disclosure of confidential data

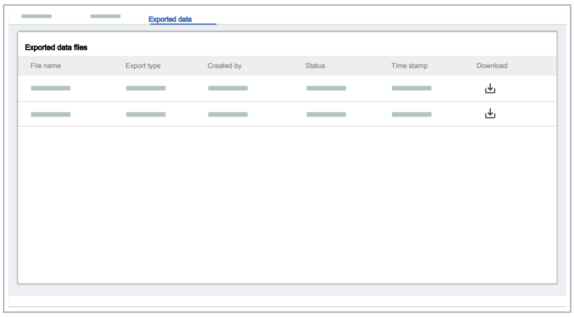
If you back up stored information on an external device or local network, you are responsible for the security of the external device or local network.

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

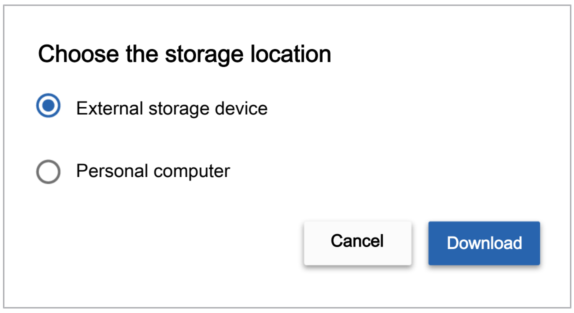
☐ Results exported

To download exported data files

1 Choose **Reports > Exported data**.



2 In the **Exported data files** table, in the respective row, choose the ⤓ button.



3 In the dialog box, choose the storage location, and then choose the **Download** button.

4 Save the file.

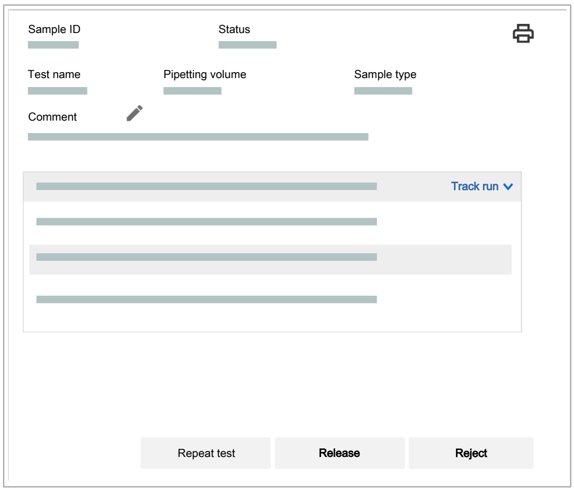
5 Optionally, create a result report.

Tracking results

For each test order result and each control result, you can track how the result was generated. The **Track run** card gives you information on used consumables and controls.

▶ To track information on test order results

1 Choose **Results > Ready to review** or **Results > Released**.



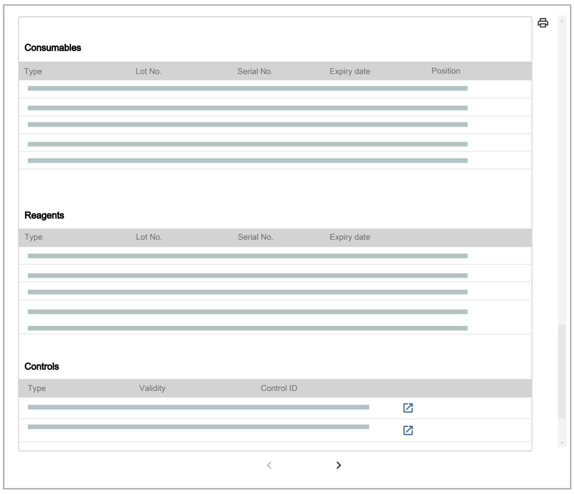
2 At the end of the row of the result you want to track, choose the › button.

→ The **Result details** screen is displayed.

3 Choose the **Track run** button.

ⓘ If no data is available from the instrument for an aborted run, the **Consumables** table, **Reagents** table, and **Controls** table are empty.

→ The **Track run** card is expanded.



4 To view detailed information on the associated control results, do the following:

- On the **Track run** card, scroll down to the **Controls** table.
- Choose the ☐ button next to the **Control ID** entry. The **Controls** app is displayed.
- For more information on the specific control, at the end of the row, choose the › button.
- To return to the Results app, in the **Controls > Results overview** table, choose the ☐ button next to the **Control ID** entry.

▶ To track information on control results

1 Choose the **Controls** app.

2 In the **Results overview** table, at the end of the row of the result you want to track, choose the › button.

→ The **Control details** screen is displayed.

3 To view tracking information on the used consumables and reagents, on the **Control details** screen, choose the **Tracking information** button.

ⓘ The tracking information of reagents and consumables for an aborted control order depends on the information provided by the instrument at the time of the abort. If no information is available, the tables are empty.

Printing results

In this section

Printing result lists

The system allows you to print a list of results from the **Results overview** table. You can print a maximum of 1000 results in 1 list.

☐ Results available in **Results overview** table

☐ For a printout: printer connection

To print a result list

1 Choose **Results > Ready to review** or **Results > Released**.

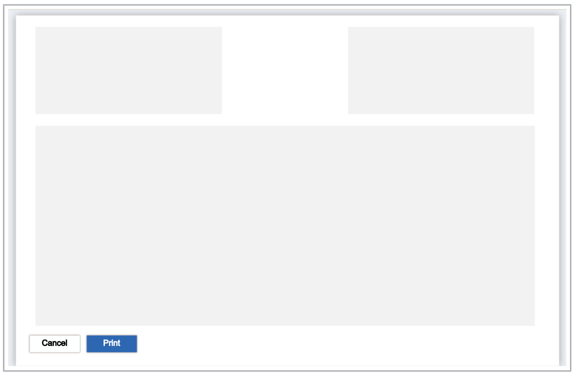
2 Optionally, in the **Results overview** table, choose the results you want to print:

- To filter results, choose the button.
- To search results, choose the button.
- To print individual results, choose the check boxes of the results.

Applied filters, search functions, and column selection are applied in the print.

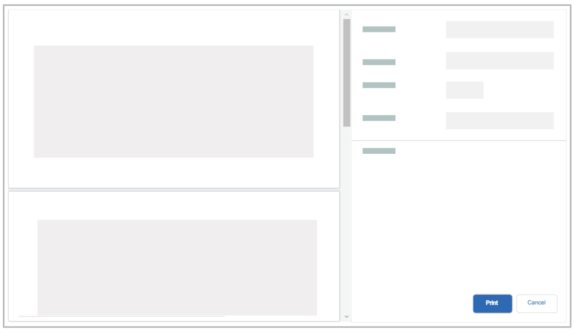
3 Choose the button.

→ The **Print preview** screen is displayed.



4 Choose the **Print** button.

5 On the **Print** screen, choose the printer. You can also save the result list as PDF.



6 Depending on the selected target, print or save the result list.

→ The list of results is printed on the selected printer or saved in a local folder.

Related topics

- Applying filters (21)
- Searching for results (60)
- Printing result details (79)

Printing result details

The system allows you to print the detailed information of the results from the **Result details** screen.

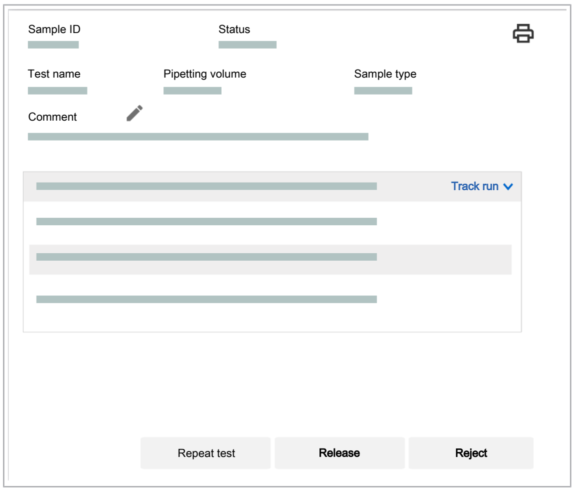
☐ Results displayed on **Result details** screen

☐ For a printout: printer connection

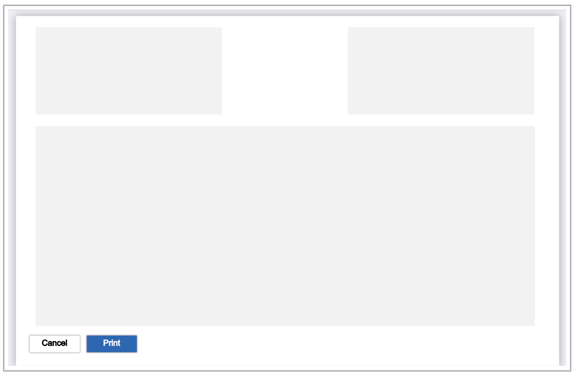
▸ To print result details

1 Choose **Results > Ready to review** or **Results > Released**.

2 To open the **Result details** screen, in the **Results overview** table, at the end of the row, choose the › button.

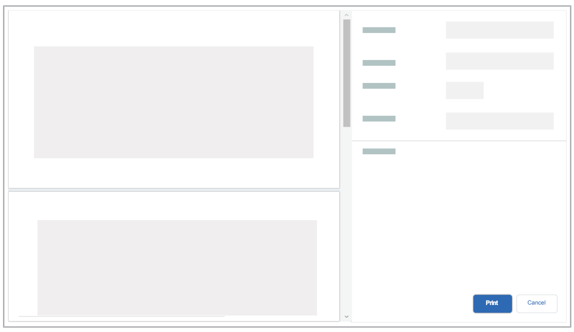


3 Choose the 🖶 button.
→ The **Print preview** screen containing the result details and the information in the Track run fields is displayed.



4 Choose the **Print** button.

5 On the **Print** screen, choose the printer. You can also save the result details as PDF.



6 Depending on the selected target, print or save the result details.
→ The entire page of the **Result details** screen is printed on the selected printer or saved in a local folder.

Related topics

- Printing result lists (77)

Reports

In this section

About predefined result reports

The data manager allows you to generate a predefined result report with a report summary and information on sample and control results, used consumables, and assays. The information is based on the run ID.

If the result report is generated for more than 1 run, the information is displayed in separate tables for each run ID. For repeated tests, the results are displayed twice: In the sample results table of the original run and in the sample results table of the repeated test

The predefined result reports consist of the following elements:

Report summary

The report summary consists of the following information:

- Laboratory details
- Report duration
- Selected instruments
- Selected run IDs
- Selected test names
- Selected result status

List of consumables

For every run ID the used consumables are displayed in a table with the following information:

- Serial number
- Lot number
- Expiry date

List of assays

For every run ID the used tests are displayed in a table with the following information:

- Reagent cassette serial number
- Reagent lot number
- Expiry date
- Analysis package version

List of sample results

For every run ID the sample results are displayed in a table with the following information:

- **Sample ID**
- **Test name**
- **Type**
- **Pipetting volume**
- **Flag**
- **Test result**
- **Ct value**
- **IC result/Ct value**
- **QS result/Ct value**
- **Result creation date/time**
- **Status**
- **Additional target calculation**
- **Reagent cassette serial No.**: Based on the run ID. If the test was repeated, multiple reagent cassette serial numbers are displayed.
- **Control ID**

List of control results

For every run ID the control results are displayed in a table with the following information:

- **Control ID**
- **Test name**
- **Control name**
- **Flag**
- **Test result**
- **Ct value**
- **IC result/Ct value**
- **QS result/Ct value**
- **Run ID**
- **Reagent cassette serial No.**: Based on the run ID. If the test was repeated, multiple reagent cassette serial numbers are displayed.
- **Control cassette lot No.**
- **Creation date/time**

Generating result reports

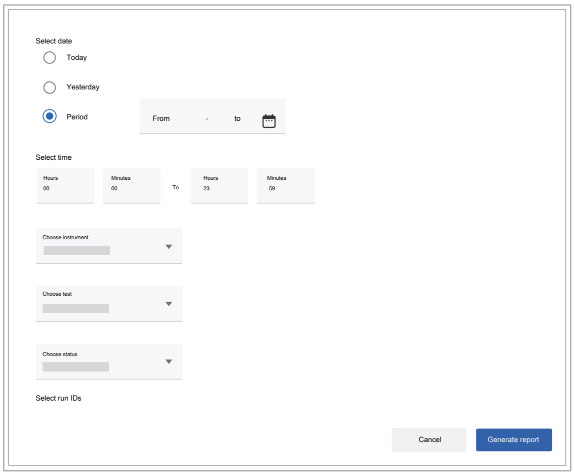
Result reports provide an overview of released results with run and tracking information, for example, for auditing. Filter for status, Unreleased, released. rejected, repeat test. All result status can be selected.

- ☐ Results are in **Released** or **Rejected** status
- ☐ Predefined result report template available

To generate result reports

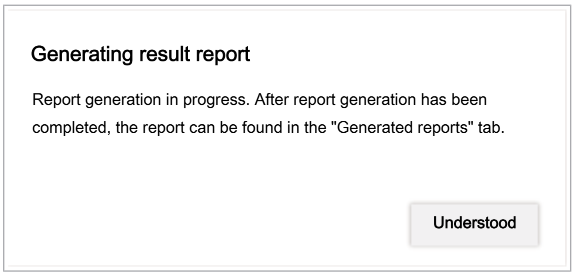
1. Choose **Reports > Generate reports**.
2. On the **Generate reports** tab, choose the **Result report** card.
3. On the **Generate result report** screen, choose the available filters according to your need:
   - **Select date**
   - **Select time**
   - If you have more than 1 instrument connected, from the **Choose instrument** drop-down list, choose the instrument.
   - From the **Choose test** drop-down list, choose the test. You can choose multiple tests.
   - From the **Choose status** drop-down list, choose the result status. You can choose multiple statuses.

   → The number of selected run IDs is displayed.



4. To edit the selection of run IDs, choose the **Edit selection** button.
   - To search for a specific run ID, enter the run ID in the search field.
   - To clear or choose all check boxes at once, choose the **Clear all** button or the **Select all** button respectively.
   - To apply your selection to the result report, choose the **Apply** button.
5. Choose the **Generate report** button.
6. In the **Generating result report** dialog box, after reading the message, choose the **Understood** button.

   → Report is available on the **Reports > Generated reports** tab.



Related topics

- About predefined result reports (80)
- Viewing result reports (83)

- Downloading and printing result reports (83)
- Deleting result reports (84)

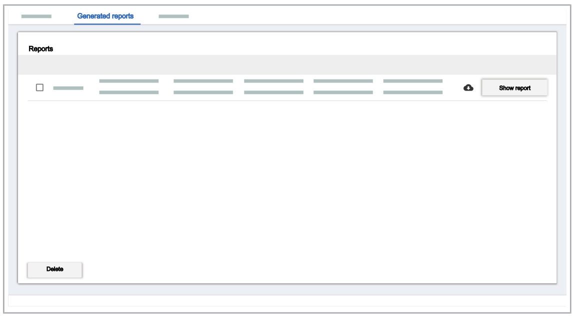
Downloading and printing result reports

On the **Reports > Generated reports** tab, you can download all generated result reports.

A printed result report with run and tracking information is needed, for example, for auditing purposes.

- ☐ Result report generated
- ☐ Printer connection

▶ To download and print result reports



1. Choose **Reports > Generated reports**.
2. In the **Reports** table, in the respective row, choose the download button.
   → The predefined result report is downloaded as PDF file in a local folder.
3. Print the result report on a connected printer.

Viewing result reports

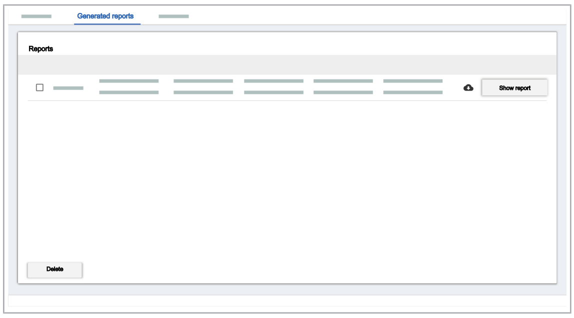
On the **Reports > Generated reports** tab, all generated result reports are listed. The **Generated reports** tab also lists when the generation of a result report failed.

> A gray notification badge is displayed on the app launcher when a new report is available and guides you to the **Generated reports** tab.

- ☐ Result report generated

▶ To view result reports

1. Choose **Reports > Generated reports**.



2 In the **Reports** table, in the respective row, choose the **Show report** button.
   → The result report is displayed as a preview.

3 To close the **Report preview** screen, choose the **Cancel** button.

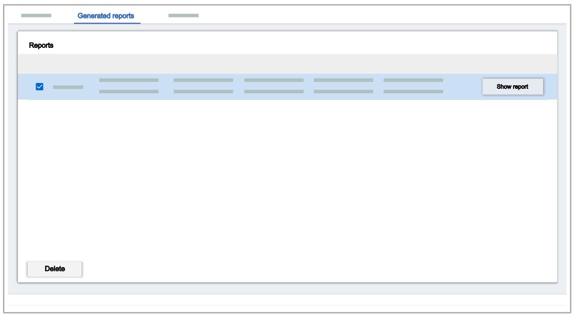
Deleting result reports

The software allows you to delete result reports that are listed on the **Reports > Generated reports** tab.

☐ Result report generated

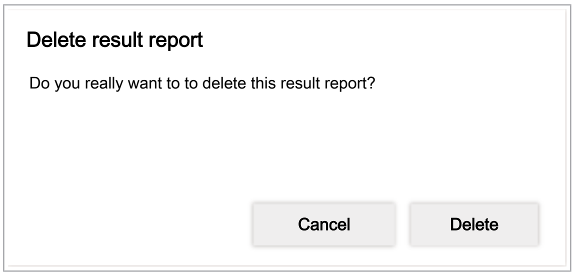
▸ To delete result reports

1 Choose **Reports > Generated reports**.



2 Choose the check boxes of the reports you want to delete.

3 Choose the **Delete** button.
   → A dialog box asks you for confirmation.



4 To delete the result reports, choose the **Delete** button.

Controls handling

In this section

About controls

Controls verify the integrity of test-specific reagents and indicate potential contamination of the reagents and the system. You can run positive and negative controls on the instrument.

Positive controls

- Run separately from clinical sample
- Supplied as kit components
- Verify the integrity of test reagents
  - Check the integrity of the master mix reagents
  - Check the measuring in the appropriate channel
  - Check for reagent contamination

Negative controls

- Run separately from clinical sample
- Indicate potential contamination of the reagents and the system

Control settings

The control settings indicate when and for which tests controls are used.

Aborted control orders

When the instrument aborts a control order or the user manually aborts a control order, a control result is generated. The control results are marked as invalid.

Control ID

Every control has a control ID. The control ID starts with a C followed by a 20-digit number.

Viewing control results

The software informs you when new control results are available after a control is processed.

The **Controls > Results overview** table gives you an overview of all control results.

The **Control details** screen gives you detailed information on a specific control result. The **Control details** screen also gives you information which instrument processed the control and if the host received the result.

The **Controls** app is connected to the **Results** app. To display the **Results overview** table of the **Results** app, do the following: In the **Results overview** table of the **Controls** app, next to the **Control ID** entry, choose the ↗ button.

- ☐ Control processed or aborted
- ☐ Control results available on **Results overview** table

To view control results

1. Choose the **Controls** app.
2. To navigate to the associated test results for each control result, on the **Results overview** table, choose next to the Control ID the ↗ button.
3. To view control details, at the end of the row, choose the > button.
   → The **Control details** screen is displayed.
4. To view tracking information on the consumables and reagents used, on the **Control details** screen, choose the **Tracking information** button.

   The tracking information of reagents and consumables for an aborted control order depends on the information provided by the instrument at the time of the abort. If no information is available, the tables are empty.

Related topics

- Applying filters (21)

Searching control results

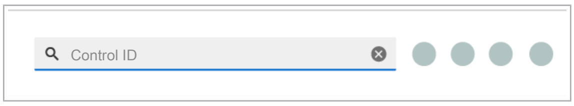
The system provides a search function to find results by control ID in the **Results overview** table.

You also find control results for specific tests by filtering the **Results overview** table.

Filtering tables (21)

- ☐ Run completed
- ☐ Control results available in **Results overview** table
- ☐ Control ID available

To search control results



1 Choose the **Controls** app.

2 On the **Controls** screen, choose the button.

3 In the search field, enter the control ID.

4 To view control result details, at the end of the row of the located control choose the > button.

Related topics

- Applying filters (21)

Reviewing control results

You can review control results in the **Controls** app.

There are 2 options:

- Review the control results on the **Results overview** table.
- Review a specific control result on the **Control details** screen.

After choosing the **Review** button, the review status changes from **No** to **Yes** status.

Control results are automatically sent to the host if the automatic release of control results is enabled in the settings by a user with administrator user role.

- ☐ Control processed
- ☐ Control results available on **Results overview** table
- ☐ A user account with **Technical validator** user role

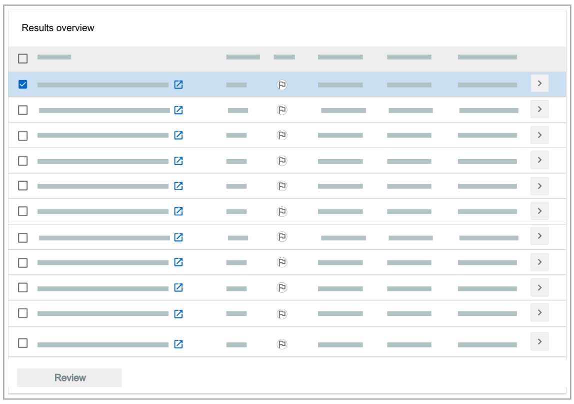
To review control results

1 Choose the **Controls** app.

2 To view only control results that have not been reviewed, filter the **Results overview** table.
   - Choose the button
   - Choose the ⊕ button
   - In the drop-down list, choose the **Reviewed** check box and then, choose the **Apply** button.
   - In the **Reviewed** drop-down list, choose the **No** check box and then, choose the **Apply** button.

3 To review details about a specific control result, at the end of the row of the control you want to review, choose the › button.
   - On the **Control details** screen, review the results.
   - Choose the **Review** button.

   → The review status changes to **Yes**.



4 To review the results from **Results overview** table, choose the check boxes of the controls you want to review.

5 To choose all control results, in the **Results overview** table, choose the check box in the table header.

   → All check boxes in the table are selected.

6 Choose the **Review** button.

   → In the **Reviewed** column, a **Yes** status is displayed.

Related topics

- Applying filters (21)

Sending again control results not received by the host

A host is a system that sends orders and receives results to and from the data manager. Usually it is a laboratory information system (LIS) or hospital information system (HIS).

If there is a failure in the connection between the data manager and the host, control results are not sent to the host. Sending again is only possible when the data manager attempts to send control results but either fails or sends them successfully. You can send the control results then manually to the host.

On the **Controls > Control details** screen in the **Received by host** field the status of the result is displayed:

Result received by host.

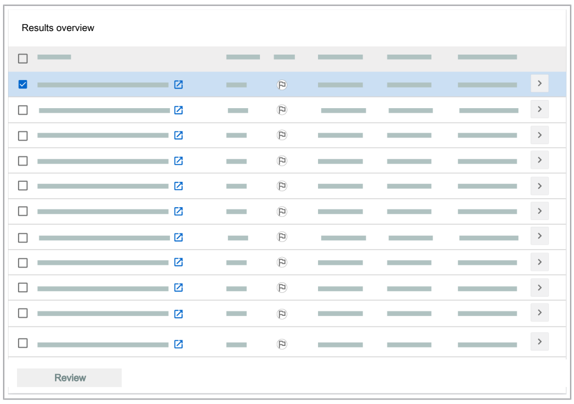
Result not received by host.

- ☐ Control results reviewed
- ☐ Host connection enabled
- ☐ A user account with **Technical validator** user role

To send results to the host manually

1 Choose the **Controls** app.

2 In the **Results overview** table, choose the control result you want to send again. At the end of the row, choose the > button.



3 On the **Control details** screen, choose the **Send again** button.

The **Send again** button is displayed only if there is a connection to the host.

Related topics

- Creating customized filters (22)
- Choosing columns (25)

Printing control results

In this section

Printing control result lists

The system allows you to print a list of control results from the **Results overview** table. You can print a maximum of 1000 control results in 1 list.

Additional columns are included in the XML export, even if they are not displayed in the current view of the table,

- ☐ Results available in **Results overview** table.

☐ For a printout: printer connection

To print control results

1 Choose the **Controls** app.

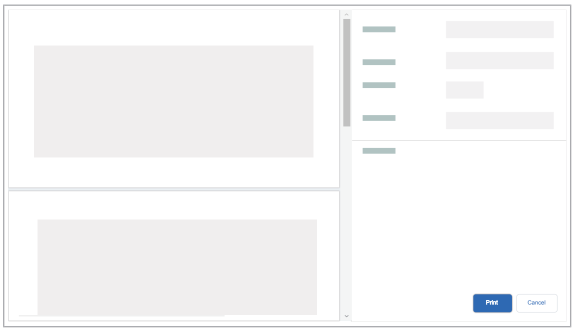
2 Optionally, in the **Results overview** table, choose the results you want to print:
- To filter results, choose the button.
- To search results, choose the button.
- To print individual results, choose the check boxes of the control results you want to print.

Applied filters, search functions, and column selection are applied in the print.

3 Choose the button.
→ The **Print preview** screen is displayed.

4 Choose the **Print** button.

5 On the **Print** screen, choose the printer. You can also save the result list as PDF.



6 Depending on the selected target, print or save the result list.
→ The list of results is printed on the selected printer or saved in a local folder.

Related topics
- Applying filters (21)

Printing control details

The system allows you to print the detailed information of the controls from the **Control details** screen.

☐ Results available in **Results overview** table.

☐ For a printout: printer connection

To print control results

1 Choose the **Controls** app.

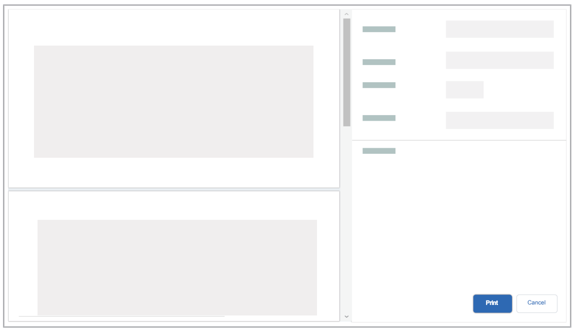
2 To open the **Control details** screen, in the **Results overview** table at the end of the row, choose the › button.

3 Choose the button.

→ The **Print preview** screen is displayed.

4 Choose the **Print** button.

5 On the **Print** screen, choose the printer. You can also save the control details as PDF.



6 Depending on the selected target, print or save the control details.

→ The entire page of the **Control details** screen is printed on the selected printer or saved in a local folder.

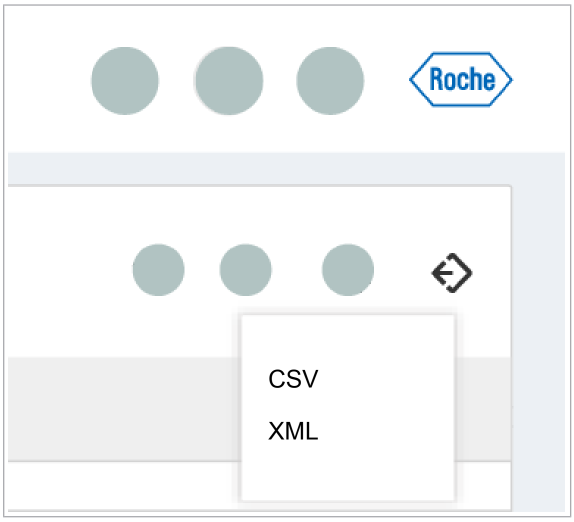
Exporting control results to a CSV or XML file

The system allows you to export control results to a CSV or an XML file. The number of results in the XML or CSV export is based on the filter or search applied to the **Results overview** table.

☐ Results available in **Results overview** table

▸ To export control results to a CSV or XML file

1 Choose **Controls** app.



2 At the top of the **Results overview** table, choose the button.

3 From the drop-down list, choose the **CSV** option or the **XML** option.

→ The result table is downloaded in the selected format to your computer.

About high-target tests

High-target tests enable the simultaneous detection and discrimination of multiple DNA or RNA targets in a single sample and run. Based on the test results, you can order additional targets out of a multiplex test panel without the sample being processed again. The additionally ordered targets are calculated based on the already measured data for the initially ordered targets.

Initiating additional target calculation

Additional target calculation is initiated by creating a new order with the same sample ID and sample type than the initial order.

Requirements

- An additional target calculation is only possible when the ordered targets do not overlap with the targets of the initial test order.
- The results of the initial order must be released before you can calculate additional targets.
- Orders that are not eligible for additional target calculation are processed in the instrument and have a new set of measurement data.

Additional target calculation interval

- An additional target calculation is always limited to a calculation interval configured in the data manager settings. The interval is maximum 48 hours.
- The additional target calculation interval starts right after the initial target results are released.
- The additional target calculation interval ends when there is an additional target calculation order created within the interval. The additional target calculation interval also ends if an equivalent high-target test order for the same sample ID is created.
- Once the additional target calculation interval has elapsed, any additionally ordered targets are considered as an independent test order or add-on test order. They are processed in the instrument and have a new set of measurement data.
- Additional target calculation is allowed only once for a released high-target test order.

Results from additional target calculation

The data manager creates the target results from the additionally calculated data. The results are displayed in the **Results** app, in the **Results overview** table as a row, and they are in **Unreleased** status.

Repeating tests

If there are 1 or more invalid target results after additional target calculation, you can repeat the tests. The instrument must process the sample again.

Releasing additionally calculated target results

If results from an additional target calculation are released, no additional target calculation interval is initiated for these results. Additional target calculation is not possible for an additional target calculation order.

Abortion of additional target calculation

If the target result calculation from an additional target calculation order is aborted at any stage of processing, a result is automatically created. The order changes to **Unreleased** status. In the **Results** app, the results of the ordered targets are displayed as invalid.

Additional target calculation of host orders

For the additional target calculation from a host order, no target groups are necessary. The additional target calculation is automatic:

- At the end of the additional target calculation interval of the host order, the data manager sends a query to the host to check for additional targets to calculate.
- If the requirements for additional target calculation are satisfied, the data manager creates a test order with the measurement data of the initial order. The data manager calculates the additional targets. No samples have to be loaded.
- If the requirements for additional target calculation are not satisfied and the sample is still loaded, the data manager creates a host order. The sample must be processed again. If the sample is not loaded, the host order is rejected.
- When the technical validator releases the results, the data manager sends the results of the additionally calculated targets to the host.

The additional target calculation for host orders is only possible if, in the data manager **Settings** app, the **Laboratory Analytical Workflow (LAW)** option is configured.

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Non-routine operation

In this chapter

3

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Logging on to the system for the first time

To log on to the system for the first time, use your default credentials as provided by your administrator.

- ☐ A compatible browser
- ☐ Credentials provided by your administrator

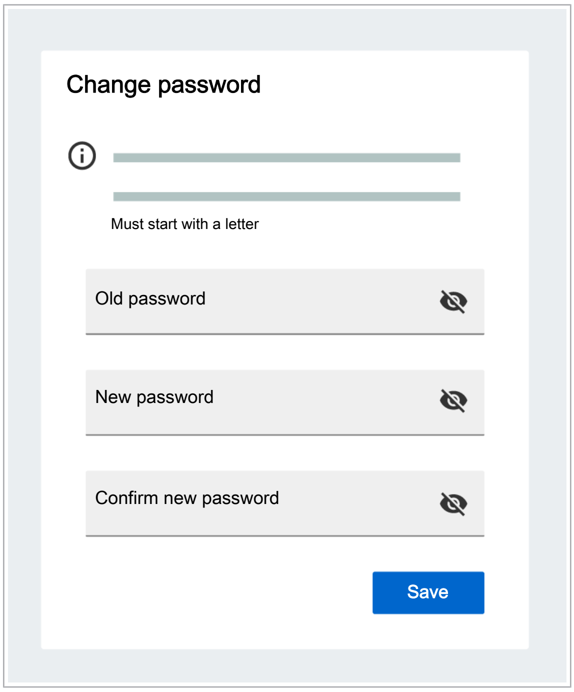
To log on to the system for the first time

1 To open the data manager and display the logon screen, enter the following URL in the address bar of your browser: www.x800dm.com.

   If you have more than 1 data manager connected to your laboratory network, check the correct URL with your laboratory administrator or with your Roche Service representative.

2 On the logon screen, enter your credentials in the following fields:
   - **User name**
   - **Password**

3 Choose the **Log on** button.



4 On the **Change password** screen, enter your default password, and then a new password twice. For letters, use the Latin alphabet, for numbers, use Arabic numerals.

   Passwords must respect the password policy that is displayed on the **Change password** screen. A user with administrator access rights can change the password policy in the data manager user management settings.

5 Choose the **Save** button.

Changing user profiles

In this section

Changing the password

The software allows you to change your password at any time.

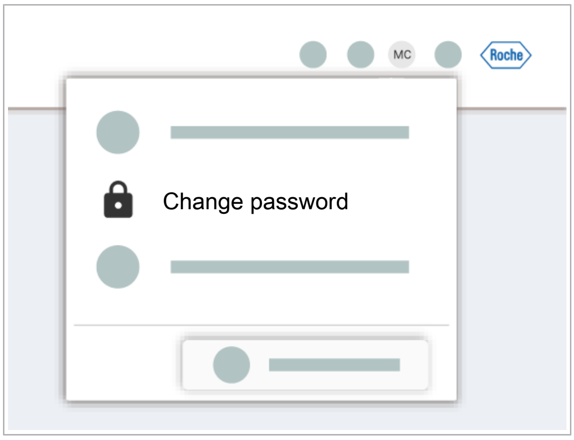
You must change your password in the following circumstances:

- You log on for the first time.
- Your current password is about to expire.
- Your current password is no longer safe.
- The password has been reset.

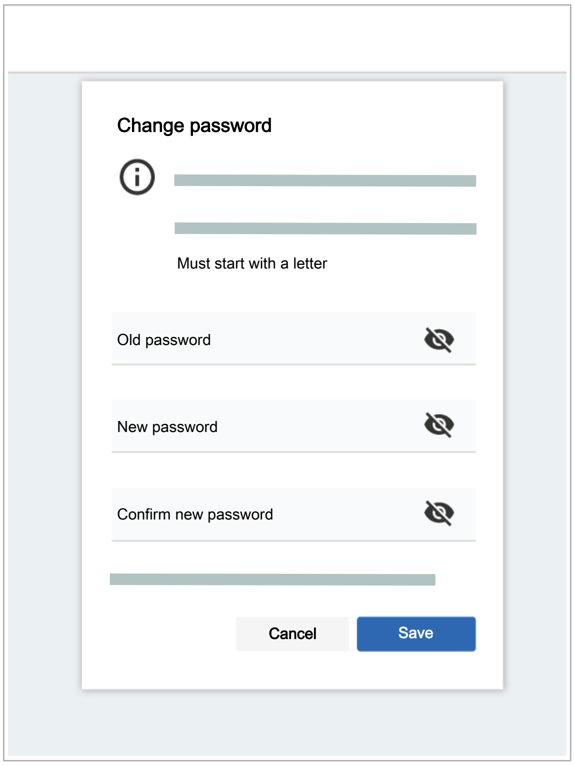
☐ You are logged on

To change the password

1 In the global information area, choose the user profile button.



2 From the drop-down list, choose the **Change password** option.



3 On the **Change password** dialog box, enter the current password, and the new password twice. For letters, use the Latin alphabet, for numbers, use Arabic numerals.

4 Choose the **Save** button.
→ The Log on screen is displayed.

Changing the user interface language

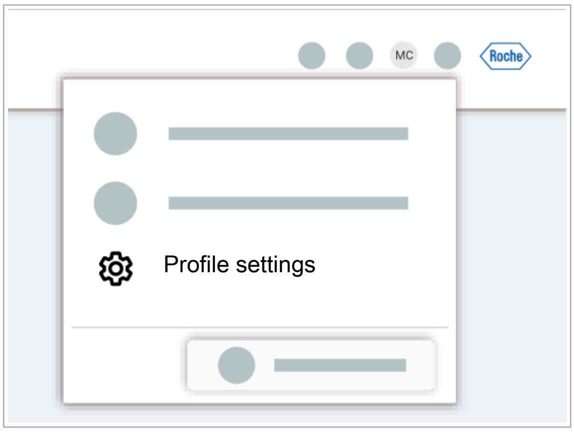
The software allows you to change the user interface language according to your preferences.

A user with **Administrator** role can change the user profile of any user. A user without **Administrator** role can only change their own profile.

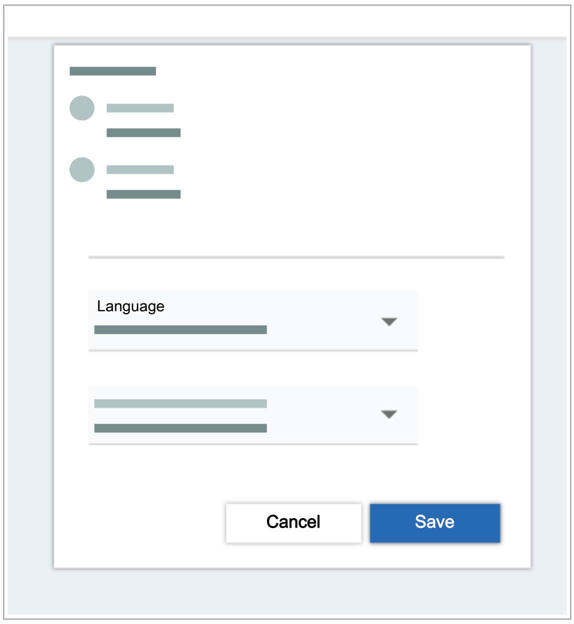
☐ You are logged on

To change the user interface language

1 In the global information area, choose the user profile button.



2 From the drop-down list, choose the **Profile settings** option.



3 On the **Profile settings** screen, from the **Language** drop-down list, choose the language you want to use.

The language options depend on the installed language packages.

4 Choose the **Save** button.

→ The Log on screen is displayed.

Changing the virtual keyboard layout

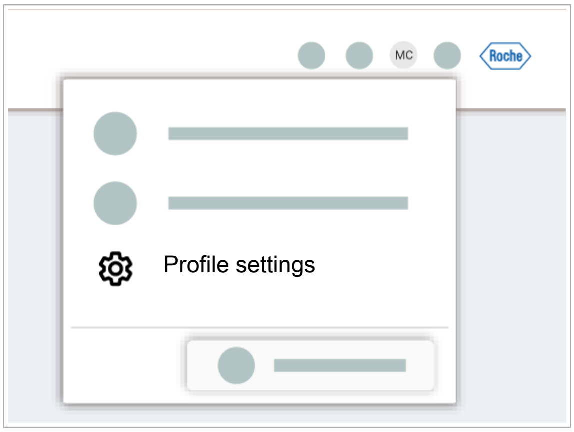
You can change the virtual keyboard layout on the instrument touch screen monitor to your language and region preferences.

A user with **Administrator** role can change the user profile of any user. A user without **Administrator** role can only change their own profile.

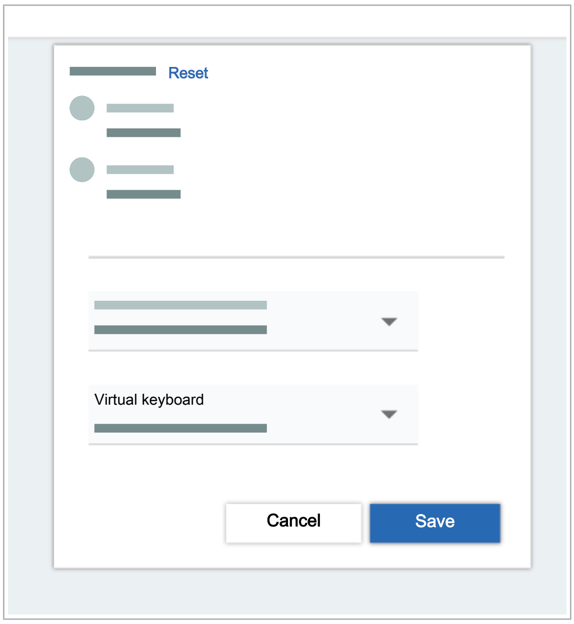
- ☐ You are logged on

To change the virtual keyboard layout

1 In the global information area, choose the user profile button.



2 From the drop-down list, choose the **Profile settings** option.



3 On the **Profile settings** screen, from the **Virtual keyboard** drop-down list, choose the country setting you want to use.

4 Choose the **Save** button.

→ The Log on screen is displayed.

Audit trail

In this section

List of audit trail event codes

Every audit trail entry has an event code that refers to a specific event. The event codes for the data manager start with the letter D, for the instrument, with the letter I. You can search or filter the audit trail table by the event code.

Event code	Audit trail entry
D0001	**User logged on successfully**
D0002	**User logon failed**
D0003	**User logged off successfully**
D0004	**Password changed successfully**
D0005	**Password for user "<params.userId>" set successfully**
D0011	**Barcode settings created successfully**
D0012	**Barcode settings edited successfully**
D0013	**Host settings created successfully**
D0014	**Host settings edited successfully**
D0015	**Region settings created successfully**
D0016	**Region settings edited successfully**
D0017	**Laboratory settings created successfully**
D0018	**Laboratory settings edited successfully**
D0019	**Non-Roche control settings created successfully**
D0020	**Non-Roche control settings edited successfully**
D0021	**IHE profile settings created successfully**
D0022	**IHE profile settings edited successfully**
D0030	**Carrier/rack configuration created successfully for visual ID range from <objectnewvalue.rackIdRangeStart> to <objectnewvalue.rackIdRangeEnd>.**
D0031	**Carrier/rack configuration edited successfully for visual ID range from <objectnewvalue.rackIdRangeStart> to <objectnewvalue.rackIdRangeEnd>.**
D0032	**Carrier/rack configuration deleted successfully for visual ID range from <objectnewvalue.rackIdRangeStart> to <objectnewvalue.rackIdRangeEnd>.**

Data manager event codes and audit trail entries

Event code	Audit trail entry
D0033	Target group created successfully
D0034	Target group edited successfully
D0036	Secondary sample ID settings created successfully
D0037	Secondary sample ID settings edited successfully
D0038	Additional target calculation interval settings created successfully
D0039	Additional target calculation interval edited successfully
D0041	Test order created successfully. Sample ID: <objectnewvalue.sampleId>; test: <objectnewvalue.testName>; sample type: <objectnewvalue.sampleTypeName>.
D0042	Test order for sample ID <objectnewvalue.sampleId> edited successfully
D0043	Test order for sample ID <objectnewvalue.sampleId> deleted successfully
D0044	Test order for sample ID <objectnewvalue.sampleId> cleaned up successfully
D0051	Test result settings created successfully
D0052	Test result settings edited successfully
D0061	Test results for sample ID <objectnewvalue.testOrderResult.sampleId> released successfully
D0066	Test results for sample ID <objectnewvalue.testOrderResult.sampleId> released successfully
D0067	Repeat test for sample ID <objectnewvalue.testOrderResult.sampleId> was successful
D0068	Test results for sample ID <objectnewvalue.testOrderResult.sampleId> rejected successfully
D0071	Control settings created successfully
D0072	Control settings edited successfully
D0076	Control results for control ID <objectnewvalue.controlResult.controlId> reviewed successfully
D0081	Password policy edited successfully
D0086	User with user name "<objectnewvalue.userName>" created successfully
D0087	User with user name "<objectnewvalue.userName>" edited successfully
D0088	User with user name "<objectnewvalue.userName>" deleted successfully
D0089	User with user name "<objectnewvalue.userName>" retired successfully
D0090	User with user name "<objectnewvalue.userName>" activated successfully
D0101	Control allocation settings for analysis package "<objectnewvalue.asapName>" created successfully
D0102	Control allocation settings for analysis package "<objectnewvalue.asapName>" edited successfully
D0103	Unit settings for analysis package "<objectnewvalue.asapName>" created successfully
D0104	Unit settings for analysis package "<objectnewvalue.asapName>" edited successfully
D0105	Control allocation settings for analysis package "<objectnewvalue.asapName>" deleted successfully
D0106	Analysis package "<objectnewvalue.asapName>" installed successfully
D0107	Analysis package "<objectnewvalue.fileName>" imported successfully
D0108	Analysis package "<objectnewvalue.asapName>" activated successfully
D0109	Analysis package "<objectnewvalue.asapName>" deactivated successfully
D0110	Analysis package "<objectnewvalue.fileName>" deleted successfully

Data manager event codes and audit trail entries

Event code	Audit trail entry
D0111	Archiving settings created successfully
D0112	Archiving settings edited successfully
D0113	Backup settings created successfully
D0114	Backup settings edited successfully
D0115	Purge settings created successfully
D0116	Purge settings edited successfully
D0117	Problem report settings created successfully
D0118	Problem report settings edited successfully
D0119	Remote service agent settings created successfully
D0120	Remote service agent settings edited successfully
D0121	Data upload settings created successfully
D0122	Data upload settings edited successfully
D0123	Session settings edited successfully
D0124	Session settings created successfully
D0130	Backup of data manager started successfully
D0131	Archiving of results and audit trail records started successfully
D0132	Scheduled automatic purge of archived test order results and control results completed successfully
D0133	Problem report generated successfully
D0134	Update package uploaded successfully. Package type: <objectnewvalue.packageType>; package name: <objectnewvalue.packageName>
D0135	Update package installation started successfully. Package type: <objectnewvalue.packageType>; package name: <objectnewvalue.packageName>
D0136	Unregistration started successfully in data manager. Instrument: <objectnewvalue.instrumentType>; serial number: <objectnewvalue.instrumentSerialNumber>
D0137	Restart of data manager support services started for troubleshooting purposes
D0138	Restart of data manager support services started for troubleshooting purposes
D0139	Custom SSL certificate uploaded successfully
D0140	Custom SSL certificate removed successfully
D0141	Backup of data manager completed
D0142	Data manager backup file "<objectnewvalue.fileName>" downloaded successfully
D0143	Archiving of results and audit trail records completed
D0144	Data manager archive file "<objectnewvalue.fileName>" downloaded successfully
D0145	Update package installation completed. Package type: <objectnewvalue.updateType>; package name: <objectnewvalue.packageName>
D0146	Update package deleted successfully. Package type: <objectnewvalue.updateType>; package name: <objectnewvalue.packageName>
D0147	Unregistration completed in data manager. Instrument: <objectnewvalue.instrumentType>; serial number: <objectnewvalue.instrumentSerialNumber>
D0148	Unregistration failed in data manager. Instrument: <objectnewvalue.instrumentType>; serial number: <objectnewvalue.instrumentSerialNumber>

Data manager event codes and audit trail entries

Event code	Audit trail entry
D0149	**Result data export completed. Package type: <objectnewvalue.exportType>; package name: <objectnewvalue.exportFileName>**
D0150	**Problem report file "<objectnewvalue.name>" downloaded successfully**
D0151	**Data upload completed. Package type: <objectnewvalue.packageType>; package name: <objectnewvalue.packageName>**

Data manager event codes and audit trail entries

Event code	Audit trail entry
I0001	**User "{userId}" logged on successfully**
I0002	**User "{userId}" logged off**
I0051	**User opened the amplification plate drawer.**
I0052	**User closed the amplification plate drawer.**
I0053	**User opened the eluate tip tray drawer.**
I0054	**User closed the eluate tip tray drawer.**
I0055	**User opened the liquid waste plate drawer.**
I0056	**User closed the liquid waste plate drawer.**
I0057	**User opened the MGP cassette drawer.**
I0058	**User closed the MGP cassette drawer.**
I0059	**User opened the processing plate drawer.**
I0060	**User closed the processing plate drawer.**
I0101	**User opened the eluate tip tray drawer.**
I0102	**User closed the eluate tip tray drawer.**
I0103	**User loaded an eluate tip tray. Lot number: {lotNumber}; serial number: {serialNumber}; ID: {barcode}; position: {trayPosition}.**
I0104	**User unloaded an eluate tip tray. ID: {barcode}; position: {trayPosition}.**
I0105	**User loaded a processing tip tray. Lot number: {lotNumber}; serial number: {serialNumber}; ID: {barcode}; position: {trayPosition}.**
I0106	**User unloaded a processing tip tray. ID: {barcode}; position: {trayPosition}.**
I0107	**Number of empty tip trays in empty tip tray position: {wastedTipTrays}. Capacity changed to: {capacity}%.**
I0108	**User opened the liquid waste plate drawer.**
I0109	**User closed the liquid waste plate drawer.**
I0110	**User opened the processing plate drawer.**
I0111	**User closed the processing plate drawer.**
I0112	**User opened the processing tip tray drawer.**
I0113	**User closed the processing tip tray drawer.**
I0114	**User loaded a processing plate. Position: {position}; ID: {barcode}.**
I0115	**User unloaded a processing plate. Position: {position}; ID: {barcode}.**
I0116	**User loaded a liquid waste plate. Position: {position}; ID: {barcode}.**
I0117	**User unloaded a liquid waste plate. Position: {position}; ID: {barcode}.**
I0151	**User opened the upper reagent cassette drawer.**
I0152	**User closed the upper reagent cassette drawer.**
I0153	**User opened the lower reagent cassette drawer.**
I0154	**User closed the lower reagent cassette drawer.**

Instrument event codes and audit trail entries

Event code	Audit trail entry
I0155	**User loaded a reagent cassette with ID "{cassetteUniqueIdentifier}", SAP number "{cassetteSapNumber}", and remaining onboard stability "{cassetteRemainingOnBoardTime}" to position "{cassettePosition}".**
I0156	**User unloaded a reagent cassette with ID "{cassetteUniqueIdentifier}" from position "{cassettePosition}".**
I0201	**> User opened the MGP cassette drawer.**
I0202	**User closed the MGP cassette drawer.**
I0203	**User loaded an MGP cassette with ID "{mgpCassetteUniqueIdentifier}" and SAP number "{mgpCassetteSapNumber}".**
I0204	**User unloaded an MGP cassette with ID "{mgpCassetteUniqueIdentifier}".**
I0221	**User opened the control mini rack drawer.**
I0222	**User closed the control mini rack drawer.**
I0223	**User loaded a control mini rack with ID "{cmrUniqueIdentifier}", SAP number "{cmrSapNumber}", and remaining onboard stability "{cmrRemainingOnBoardTime}" to position "{cmrPosition}".**
I0224	**User unloaded a control mini rack with ID "{cmrUniqueIdentifier}" from position "{cmrPosition}".**
I0251	**User opened the solid waste drawer.**
I0252	**User closed the solid waste drawer.**
I0253	**Solid waste fill level is {currentFillLevel}%.**
I0254	**User loaded a liquid waste container on position "{position}".**
I0255	**User unloaded a liquid waste container on position "{position}".**
I0256	**User unlocked a bulk reagent container/bottle on position "{position}".**
I0298	**User manually entered sample ID for sample container loaded on track {sampleRackPosition}, position {positionInRack}. Sample ID: {sampleId}; barcode: {barcode}; barcode type: {barcodeType}.**
I0299	**User removed manually entered sample IDs for sample containers. {groupedSampleBarcodes}**
I0301	**User prepared the instrument for processing.**
I0302	**User started a new run.**
I0303	**User postponed the processing of runs.**
I0304	**User resumed the processing of runs.**
I0305	**User entered "Maintenance" status.**
I0306	**User entered "Service" status.**
I0307	**User reinitialized the instrument.**
I0308	**User shut down the instrument.**
I0351	**User opened the front cover.**
I0352	**User closed the front cover.**
I0401	**User started a "Clean instrument" maintenance action.**
I0402	**Status of the "Clean instrument" maintenance action progressed. User cleaned the instrument.**
I0403	**User canceled a "Clean instrument" maintenance action.**
I0404	**User started a "Clean reagent needles" maintenance action.**
I0405	**Status of the "Clean reagent needles" maintenance action has progressed. User cleaned the reagent needles.**

Instrument event codes and audit trail entries

Event code	Audit trail entry
I0406	User canceled a "Clean reagent needles" maintenance action.
I0407	User started an "Exchange dust filter" maintenance action.
I0408	Status of the "Exchange dust filter" maintenance action has progressed. User exchanged the air inlet filter.
I0409	User canceled an "Exchange dust filter" maintenance action.
I0410	User started an "Exchange reagent needles" maintenance action.
I0411	Status of the "Exchange reagent needles" maintenance action progressed. User exchanged the reagent needles.
I0412	User canceled an "Exchange reagent needles" maintenance action.
I0413	User started a "Manual cleanup" maintenance action.
I0414	Status of the "Manual cleanup" maintenance action has progressed. User completed the manual cleanup.
I0415	User canceled a "Manual cleanup" maintenance action.
I0416	User started a "Manual cleanup with decontamination" maintenance action.
I0417	Status of the "Manual cleanup with decontamination" maintenance action progressed. User completed the manual cleanup with decontamination.
I0418	User canceled a "Manual cleanup with decontamination" maintenance action.
I0419	User started an "Empty overflow bottle" maintenance action.
I0420	User canceled an "Empty overflow bottle" maintenance action.
I0421	User started a "Processing transfer head tightness check" maintenance action.
I0422	User canceled a "Processing transfer head tightness check" maintenance action.
I0423	User started a "Reagent transfer head tightness check" maintenance action.
I0424	User canceled a "Reagent transfer head tightness check" maintenance action.
I0425	User started a "Sample transfer head tightness check" maintenance action.
I0426	User canceled a "Sample transfer head tightness check" maintenance action.
I0427	User started a "Processing transfer head teaching" maintenance action.
I0428	User canceled a "Processing transfer head teaching" maintenance action.
I0429	User started a "Reagent transfer head teaching" maintenance action.
I0430	User canceled a "Reagent transfer head teaching" maintenance action.
I0431	User started a "Sample transfer head teaching" maintenance action.
I0432	User canceled a "Sample transfer head teaching" maintenance action.
I0433	Status of the "Clean instrument" maintenance action progressed. User emptied the solid waste.
I0501	User acknowledged the system message stating that the list of available analysis packages has changed.
I0502	User acknowledged the system message stating that an MGP cassette had an RFID reading error.
I0503	User acknowledged the system message stating that a reagent cassette had an RFID reading error.
I0504	User acknowledged the system message stating that a lysis reagent bottle had an RFID reading error.
I0505	User acknowledged the system message stating that a control mini rack had an RFID reading error.
I0506	User acknowledged the system message stating that a wash reagent container had an RFID reading error.

Instrument event codes and audit trail entries

Event code	Audit trail entry
I0507	**User acknowledged the system message stating that a diluent bottle had an RFID reading error.**
I0508	**User acknowledged the system message stating that the system changed to "Standby" status due to instrument idle time of more than 6 hours in "Ready" status.**
I0509	**User acknowledged the system message stating that a time frame has been exceeded.**
I0510	**User acknowledged the system message stating that a software update failed.**
I0511	**User acknowledged the system message stating that an automatic problem report was generated.**
I0512	**User acknowledged the system message stating that the thermal profile time exceeded in thermal cycler 1 during PCR. If the error persists, contact your Roche Service representative.**
I0513	**User acknowledged the system message stating that the thermal profile time exceeded in thermal cycler 2 during PCR. If the error persists, contact your Roche Service representative.**
I0514	**User acknowledged the system message stating that the exchange of the filter of the bulk reagent drawer was due.**
I0515	**User acknowledged the system message stating that the lysis reagent tubing check was due.**
I0516	**User acknowledged the system message stating that the exchange of the stop discs and O-rings of the processing transfer head was due.**
I0517	**User acknowledged the system message stating that the exchange of the stop disc set of the sample transfer head pipetter 1 was due.**
I0518	**User acknowledged the system message stating that the exchange of the stop disc set of the sample transfer head pipetter 2 was due.**
I0519	**User acknowledged the system message stating that there was an amplification plate barcode reading error. If the error persists, contact your Roche Service representative.**
I0520	**User acknowledged the system message stating that the software update was completed.**
I0521	**User acknowledged the system message stating that the software update was completed.**
I0522	**User acknowledged the system message stating that a clot was detected during control mixing.**
I0523	**User acknowledged the system message stating that a clot was detected during control aspiration.**
I0524	**User acknowledged the system message stating that control arrival check has failed.**
I0525	**User acknowledged the system message stating that a clot was detected during control dispensing.**
I0526	**User acknowledged the system message stating that control dispensing failed.**
I0527	**User acknowledged the system message stating that the instrument software and data manager versions are not compatible.**
I0601	**The following check was started: {name}**
I0602	**The following check was aborted: {name}**
I0603	**The following check was approved by "{approver}": {name}**
I0653	**The following software update package was scheduled: {packageId}**
I0654	**The following software update package was canceled: {packageId}**
I0700	**User disabled the analytic unit 1.**

Instrument event codes and audit trail entries

Event code	Audit trail entry
I0701	**User disabled the analytic unit 2.**
I0703	**User disabled the right track of the control mini rack drawer.**
I0800	**Manual control requested. Test name: {assayName}; negative control: {negativeControl}, positive control: {positiveControl}.**

Instrument event codes and audit trail entries

Related topics

- Viewing audit trail entries (109)

Viewing audit trail entries

All interactions between users and the system that trigger system changes are logged in an audit trail entry. The system archives the audit trail entries automatically.

The audit trail entry includes information on what was done, when, by which user ID, on which device. Audit trails are important, for example, for QC, audit purposes, and troubleshooting.

The **Audit trail** table gives you an overview of all audit trail entries from the data manager and the instrument.

On the **Administration > Audit trail > Details** screen, the values before and after an event happened are displayed.

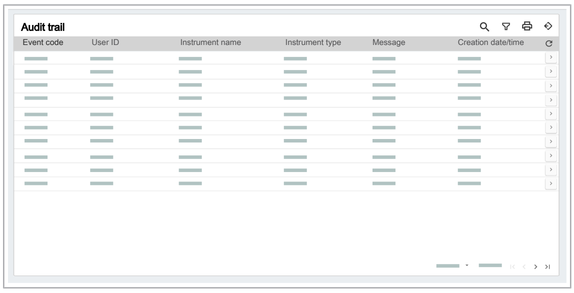
You can search the **Audit trail** table by the event code or by the following content in the **Message** column:

- Rack or carrier ID: range start
- Rack or carrier ID: range end
- Test name
- Sample type
- Sample ID
- Control ID
- User name
- Analysis package name
- Asap/ucap file name
- Cassette ID
- Loading time
- Tray position
- Lot number
- Serial number
- Barcode
- Wasted tip trays
- Capacity

- Position
- Cassette name
- Current fill level
- Position in carrier
- Barcode type
- Grouped sample barcodes

☐ A user account with **Administrator** user role

To view audit trail entries



1 Choose **Administration > Audit trail**.

2 To filter the **Audit trail** table, choose the button. The following filter options are displayed:
   - **Event code**: Choose the event code of the audit trail entry.
   - **User ID**: Choose the logged-on user who executed the event.
   - **Creation date/time**: Choose a time range or specific dates.
   - **Instrument name**: Choose the name of the instrument and/or the data manager
   - **Instrument type**: Choose the instrument and/or the data manager.

3 To search for a specific audit trail entry, choose the button and enter the event code of the audit trail entry or the content of the **Message** column in the search field.

4 The **Audit trail** table has a pagination at the bottom:
   - To display the next or previous page of the table, choose the › button or the ‹ button.
   - To display the last or first page of the table, choose the ›I or the I‹ button.
   - To change the number of audit trail entries displayed per page, from the **Items per page** drop-down list, choose an option.

5 To refresh the **Audit trail** table, in the table header, choose the button.

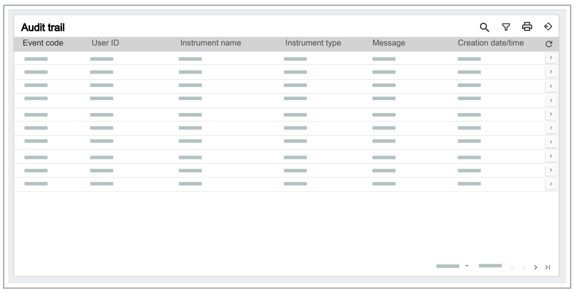
6 To track changes in the system, in the **Audit trail** table, at the end of the row, choose the › button.
   → The **Details** screen is displayed.

Printing a list of audit trail entries

The system allows you to print a list of audit trail entries from the **Audit trail** table. You can print a maximum of 1000 audit trail entries in 1 list.

- ☐ Audit trail entries available in **Audit trail** table
- ☐ For a printout: printer connection

▸ To print a list of audit trail entries



1 Choose **Administration > Audit trail**.

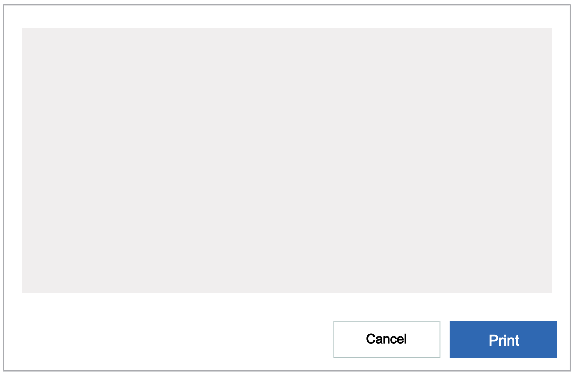
2 To filter the **Audit trail** table, choose the button. The following filter options are displayed:
- **Event code**: Choose the event code of the audit trail entry, starting with a D for data manager and I for instrument audit trail entries.
- **User ID**: Choose the logged-on user who executed the event.
- **Creation date/time**: Choose a time range or specific dates.
- **Instrument name**: Choose the name of the instrument and/or the data manager
- **Instrument type**: Choose the instrument and/or the data manager.

3 To search for a specific audit trail entry, choose the button and enter the event code of the audit trail entry in the field.

Applied search functions are applied in the print.

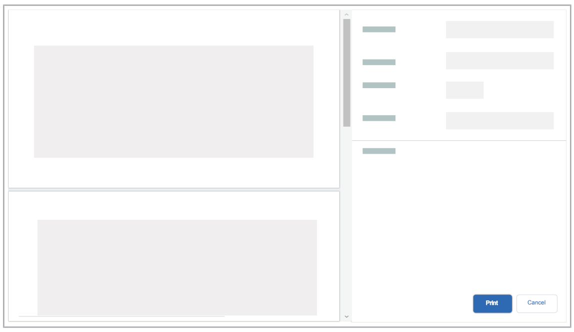
4 Choose the button.

→ The **Print preview** screen is displayed.



5 Choose the **Print** button.

6 On the **Print** screen, choose the printer. You can also save the list of audit trail entries as PDF.



7 Depending on the selected target, print or save the list of audit trail entries.

→ The list of audit trail entries is printed on the selected printer or saved in a local folder.

Printing audit trail entry details

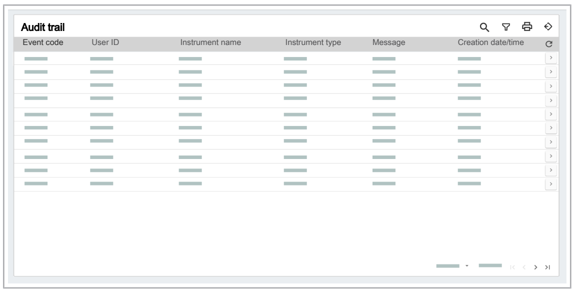
The system allows you to print detailed information of the audit trail entries.

☐ Audit trail entries available in **Audit trail** table

☐ For a printout: printer connection

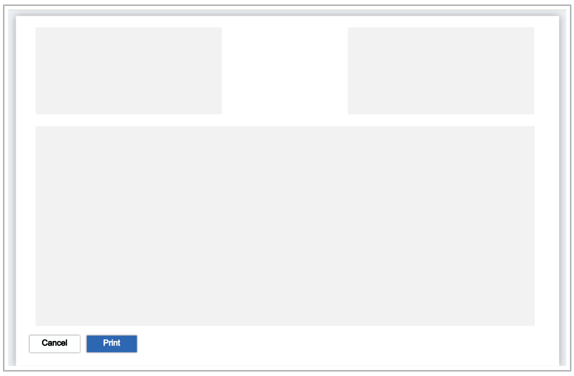
▶ To print audit trail entry details

1 Choose **Administration > Audit trail**.



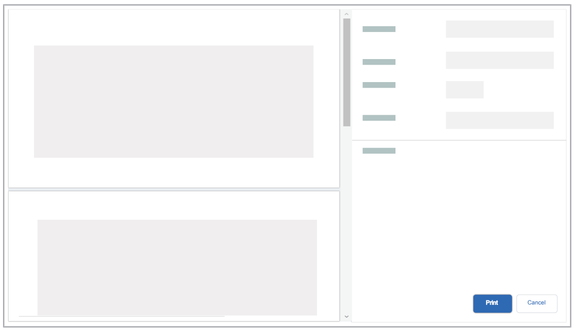
2 To open the **Details** screen, in the **Audit trail** table, at the end of the row, choose the › button.

3 Choose the 🖶 button.
→ The **Print preview** screen is displayed.



4 Choose the **Print** button.

5 On the **Print** screen, choose the printer. You can also save the audit trail entry details as PDF.



6 Depending on the selected target, print or save the audit details.
→ The entire page of the **Details** screen is printed on the selected printer or saved in a local folder.

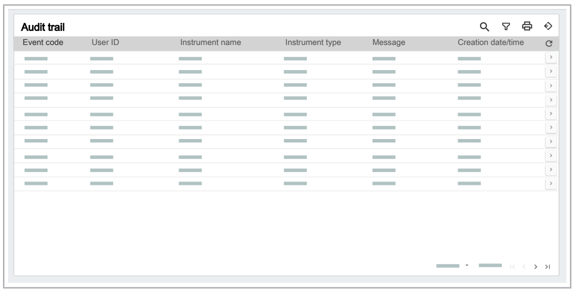
Exporting audit trail entries

The system allows you to export a list of audit trail entries to a CSV file. The number of audit trail entries in the CSV export is determined by the filter or search applied to the **Audit trail** table.

- ☐ Audit trail entries available in **Audit trail** table
- ☐ A user account with **Administrator** user role

▸ To export a list of audit trail entries

1 Choose **Administration > Audit trail**.



2 At the top of the **Audit trail** table, choose the button. The following columns are exported:

- **Event code**
- **User ID**
- **Creation date/time**
- **Instrument type**
- **Instrument name**
- **Message**

Search, sort, or filter options applied to the table are applied to the exported list.

→ The **Audit trail** table is downloaded to your computer as CSV file.

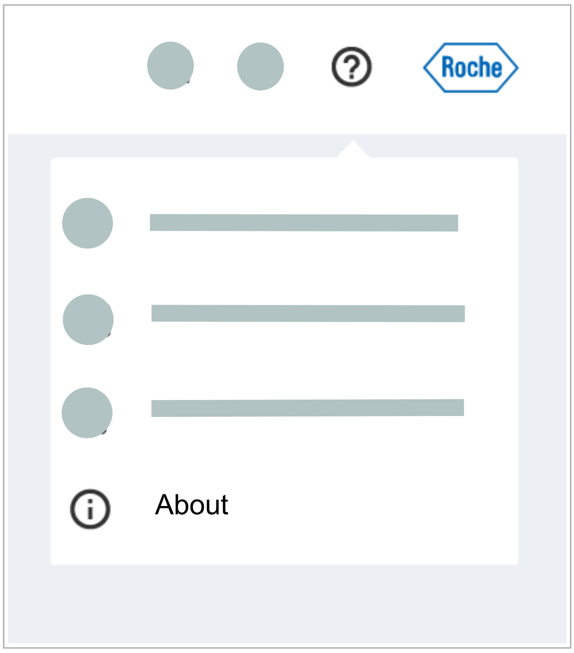
Checking the installed software, software version, and software license

On the **About** screen, the following information is displayed:

- Data manager software version
- Data manager software license
- Software inventories currently installed on the data manager:
  - **Data manager application components** drop-down list: Data manager software components are categorized under the safety classifications of IVD software components, non-IVD software components, and MDDS software components.
  - **Language and User Assistance packages** drop-down list: List of installed language and User Assistance packages. If a specific language package is not compatible with the current data manager version, an **Outdated** icon is displayed next to the language.
  - **Analysis packages** drop-down list: List of installed and activated ASAPs or UCAPs.
  - **Companion software** drop-down list: List of optional software applications that are installed in addition to the data manager. The companion software relies on and uses the data manager. Companion software causes no changes to the data manager. Each companion software application is a dedicated configuration item and is independently versioned.
  - **Supplemental modifications** drop-down list: Supplemental modifications are additional software modifications that do not entail a data manager software version change. To identify the software after the change, each applied supplemental modification is listed. Each supplemental modification is a dedicated configuration-item.
- Software version and software license for open source and commercial software
- General application information

▶ To check the software version and the software license

1 In the global information area, choose the ? button.



2 From the drop-down list, choose the ⓘ **About** button.

3 On the **About** tab, check the software version, software license of the data manager, and software inventories currently installed on the data manager.

4 To check the software version and software license for open source and commercial software, choose the **Legal notice** tab.

5 To check general application information, choose the **Application** tab.

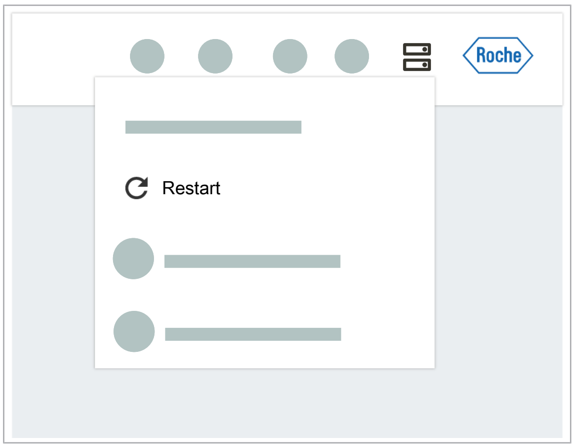
Restarting the data manager

Beside the scheduled automatic restart of the data manager, you can restart the data manager manually anytime.

20 minutes

☐ A user account with **Administrator** user role

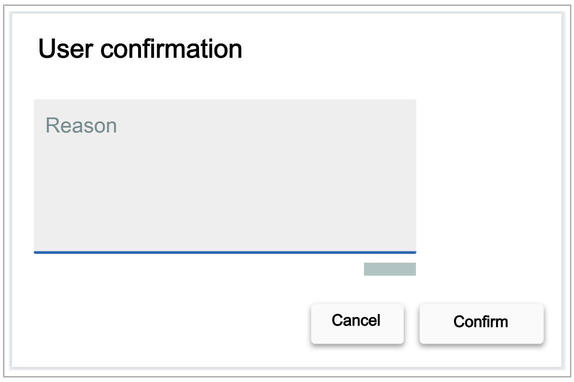
▸ To restart the data manager



1 In the global information area of the data manager, choose the button.

2 Choose the **Restart** button.

You can only restart the data manager if no archiving, backup, and purge activities are in progress. If test orders are pending or processing, the data manager asks you if you want to proceed with the restart. Pending or processing orders are not lost during the restart of the data manager.



3 In the **User confirmation** dialog box, enter the reason why you are restarting the data manager and choose the **Confirm** button.

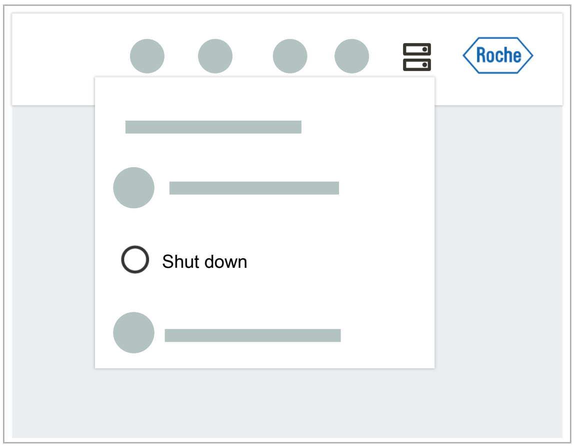
4 After the data manager has restarted, log on to the data manager.

Shutting down the data manager

The data manager is intended to be turned on permanently. Only a user with administrator user role can shut down the data manager.

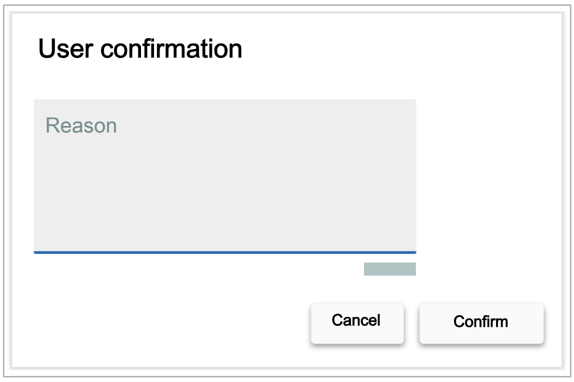
- ☐ A user account with **Administrator** user role

To shut down the data manager



1. In the global information area of the data manager, choose the button.
2. Choose the **Shut down** button.

   You only can shut down the data manager if no archiving, backup, and purge activities are in progress. If test orders are pending or processing, the data manager asks you if you want to proceed with the shutdown.



3. In the **User confirmation** dialog box, enter the reason why you shut down the data manager and choose the **Confirm** button.

Related topics

- Turning on the data manager mini PC (119)

Turning on the data manager mini PC

The data manager is intended to be turned on permanently. Only the laboratory administrator can shut down the data manager. To make the data manager available again after it was shut down, you must turn on the data manager mini PC.

▸ To turn on the data manager mini PC

1 Press the power button of the data manager mini PC.

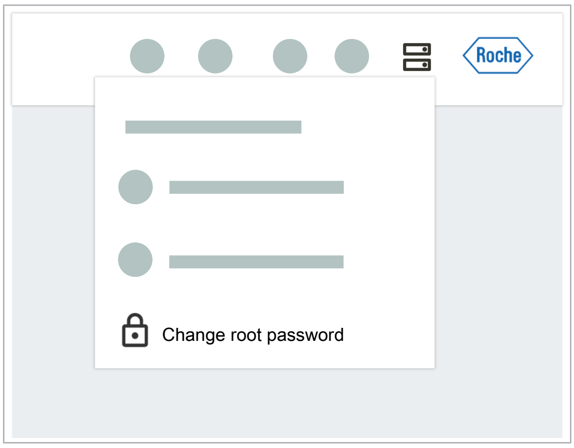
➔ The power button has a blue light.

Changing the root password

During the installation of the data manager, the Roche Service representative provides a root password. The software allows you to change the root password.

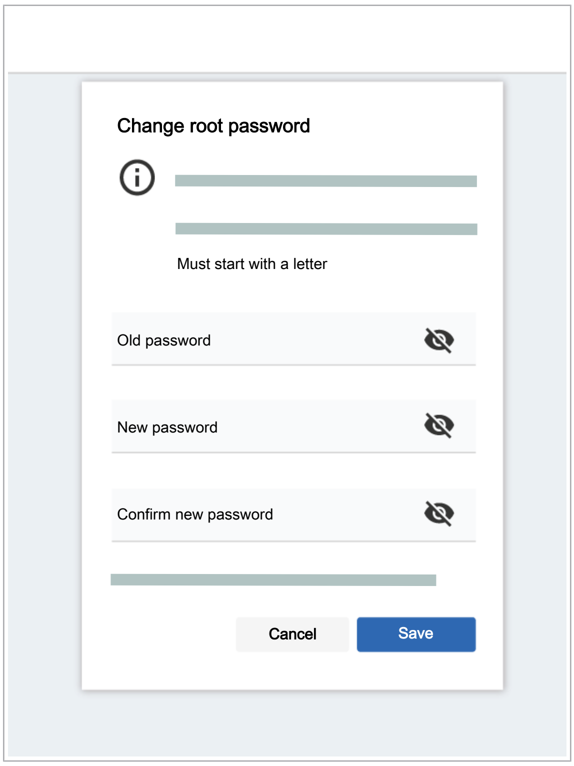
☐ A user account with **Administrator** user role

To change the root password



1 In the global information area of the data manager, choose the button.

2 Choose the **Change root password** option.



3 In the **Change root password** window, enter the current password, and the new password twice.

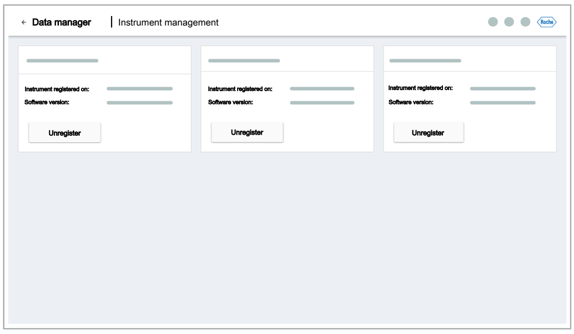
4 Choose the **Save** button.

Unregistering an instrument

The data manager can be linked to several instruments. If an instrument is not used anymore, you can unregister it.

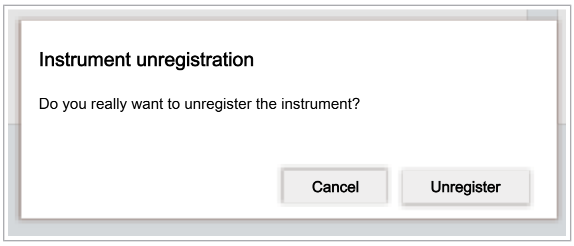
☐ A user account with **Administrator** user role

To unregister an instrument



1 Choose **Administration > Instrument management**.

2 Choose the instrument that you want to unregister and choose the **Unregister** button.



3 In the **Instrument unregistration** dialog box, choose the **Unregister** button.

Checking the time server information

The instruments and the data manager must run on a synchronized time.

There are 2 options:
- The Roche firewall is the reference clock: The Roche firewall is connected to a network and has access to at least 1 time server. The instruments and the data manager are time synchronized with the Roche firewall.
- The data manager is the reference clock: The Roche firewall cannot be connected to a reference-clock. The Roche firewall is, for example, not connected to any other network than the Roche laboratory network. The data manager internal clock is the reference clock for the instruments and the data manager.

On the **Administration > Time server information** screen, the reference source, the current time, and the last time synchronization are displayed.

- ☐ A user account with **Administrator** user role

To check the time server information

1 Choose **Administration > Time server information**.

2 On the **Time server information** card, check the source of the reference clock, the current time, and the last time synchronization.

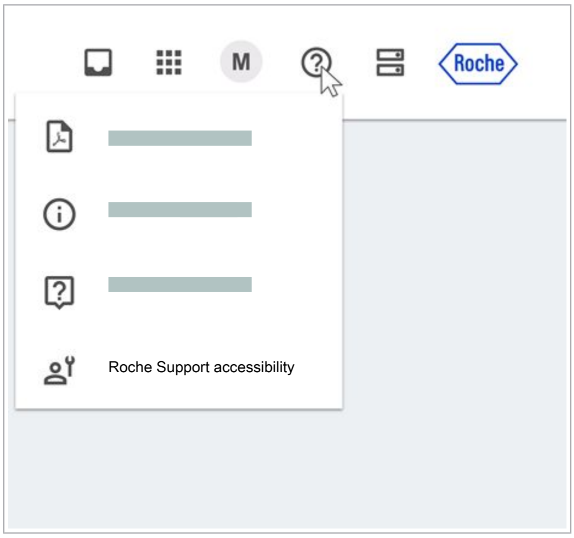
Enabling and disabling remote access

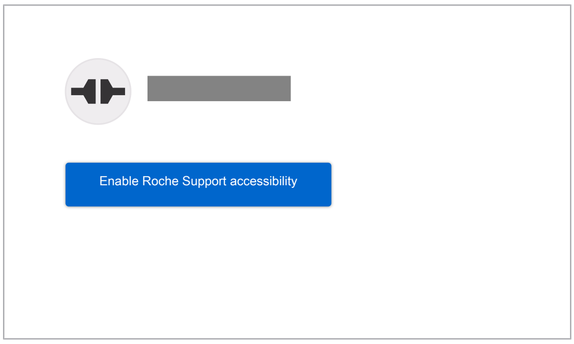
You can only enable or disable the remote access for Roche Support if, in the configuration of your data manager, the **Roche Support can only access data manager when explicitly allowed by the user** option is selected.

▸ To enable remote access

1 In the global information area, choose the ⓘ button.

2 In the drop-down list, choose the **Roche Support accessibility** option.





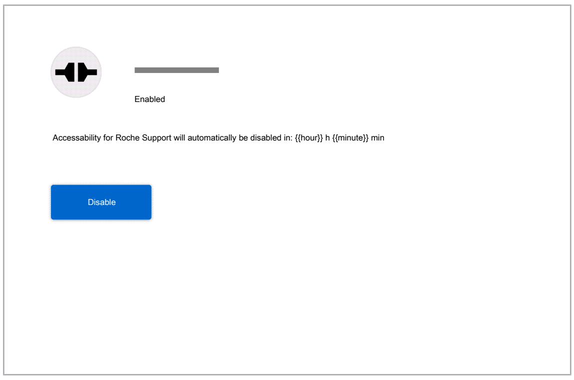
3 On the **Roche Support** screen, choose the **Enable Roche Support accessibility** option.

→ A message informs you that the remote access for Roche Support is enabled.

→ In the global information area, the button is displayed.

→ The remote access for Roche Support is automatically disabled after a configured time span.

▸ To disable remote access



1 In the global information area, choose the button.

2 On the **Roche Support** screen, the time span when the remote access is automatically disabled is displayed. To change the time span permanently, contact your Roche Service representative.

3 To disable the remote access for Roche Support immediately, on the **Roche Support** screen, choose the **Disable** option.

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Maintenance

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Maintenance

In this chapter

4

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Data maintenance

In this section

About archive files

On the **Administration > Data maintenance** screen, the latest archive files for download are available.

Requirements for archiving

Test orders can be archived only when the results are released or rejected. The data manager includes test orders that are in released or rejected status in the archive package.

Format and naming convention of archive files

The archive files are encrypted TAR files and have the following naming convention:

- *Archive_X800*
- Software license number
- Date and time of archiving.

Content of archive files

After extracting the TAR file, the following folders are displayed:

- Folder with archive bundles containing the main archive records: Released or rejected test and control results as XML file, information inbox notifications, flags.
- Security folder with a signature XML file and a security certificate for the digitally signed archive ZIP file. The security certificate contains information on the security key and the used fingerprint.
- Audit records folder with bundled audit information as XML file.
- Package manifest with detailed information about the archive bundles.

Data range

The data range in the archive file consists of the content between 2 consecutive archive jobs.

Test orders in the archive file

All test orders that are released or rejected on the same day are combined into 1 file. If no test order was released or rejected on a given day, a file is generated for every day in the period covered by the archive.

Control orders in the archive file

The information of all control orders that are finalized on the same day are combined into 1 file. If no control order was finalized on a given day, a file is generated for every day in the period covered by the archive. If the control order is already archived and is related to a test order that is released and archived later, the control order is not included in the package.

Audit trail entries in the archive file

An archive file must include all audit entries that were not archived previously. All audit trail entries created on the same day are combined into a single file. If no audit trail entry was created on a given day, a file is generated for every day in the period covered by the archive.

Purging of archive files

The archive files once downloaded are automatically purged after 5 days. The purge of results is performed as per the configured retention period, and it is performed only if the archive file is downloaded.

Storage location

The previously selected storage location is preselected.

If you choose the **Local drive** option as storage location, the archive file is stored on the data manager mini PC and is in **New** status.

If you choose the **SFTP server** option as storage location and the archive file is successfully copied to the SFTP server, it is in **Downloaded** status.

If the file cannot be copied to the SFTP server, the archive file is available in the local data manager mini PC. The archive file is in **New** status.

Archiving manually

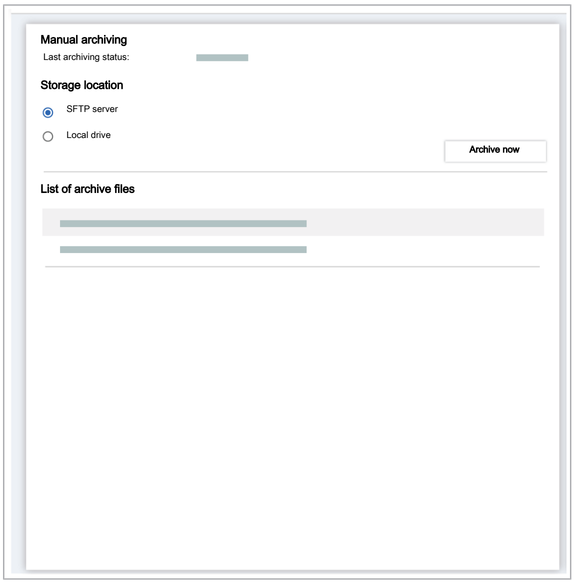
The system automatically archives audit trail entries, messages, test results, and control results at a configured time. If necessary, in the **Administration** app, you can manually archive at any time.

If no new released results are available for archiving, on the **Administration > Data maintenance** screen, the last archive status is displayed. There is no new archive file generated and available for download.

☐ A user account with **Administrator** user role

To archive manually

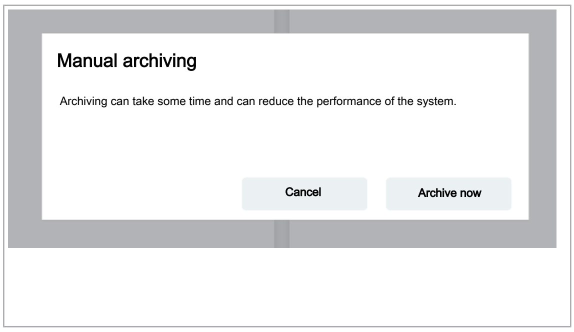
1 Choose **Administration > Data maintenance**.



2 On the **Manual archiving** card, choose the storage location.

- **SFTP server**: The archive file is stored on the configured SFTP server and is in **Downloaded** status.
- **Local drive**: The archive file is stored on the data manager mini PC and is in **New** status.

SFTP facilitates data access and data transfer over a secure data stream.



3 To start archiving immediately, choose the **Archive now** button.

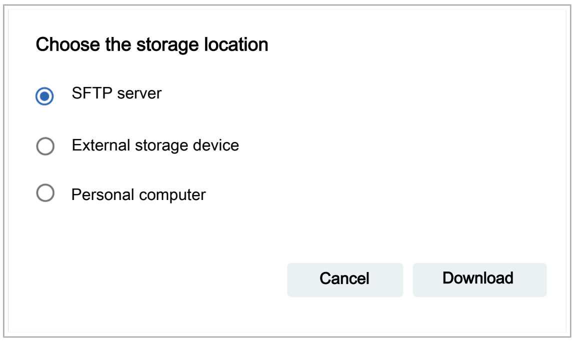
To download archive files manually

1 Choose **Administration > Data maintenance**.

2 From the **List of archive files**, choose the file you want to download.

The status of these files, the user who has created them, and the time they have been created are available.

3 Choose the button.



4 In the **Choose the storage location** dialog box, choose the storage location:
- **SFTP server**: SFTP server must be configured.
- **External storage device**: On the instrument, connect an external storage device to 1 of the data manager USB ports.
- **Personal computer**: The archive file is downloaded to the downloads folder of your personal computer.

5 Choose the **Download** button.
→ The files are downloaded to the configured location.

Backing up manually

In the **Administration** app, you can back up the database manually, for example, before a system update. After backing up the database, you can download the backup file to a preferred storage location.

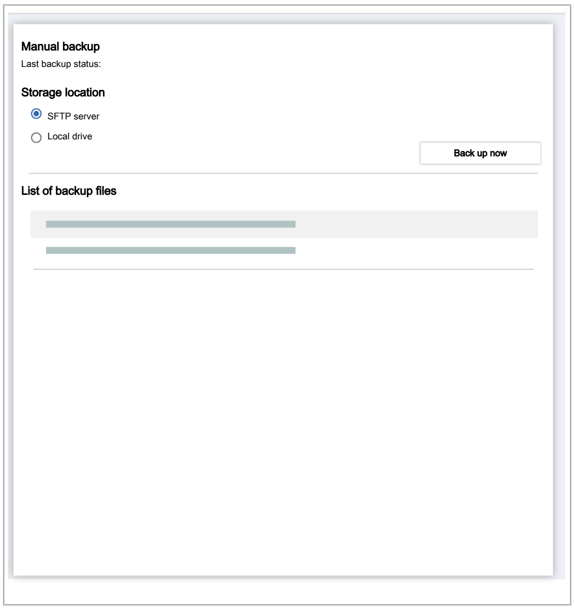
If the automatic backup is configured in the data manager **Settings** app, the database is backed up automatically. The latest 2 backup files are saved in the data manager‘s internal storage and are available in the **Administration** app, on the **Data maintenance** screen.

If a server crash or data corruption occur, to restore the database, call your Roche Service representative.

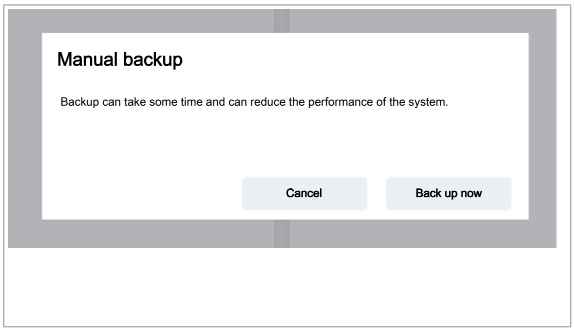
☐ A user account with **Administrator** user role

▸ To back up manually

1 Choose **Administration > Data maintenance**.



2 On the **Manual backup** card, choose the storage location.
   - **SFTP server**: The backup file is stored on the configured SFTP server and is in **Downloaded** status.
   - **Local drive**: The backup file is stored on the data manager mini PC and is in **New** status.
   - → The data is backed up to the selected option.



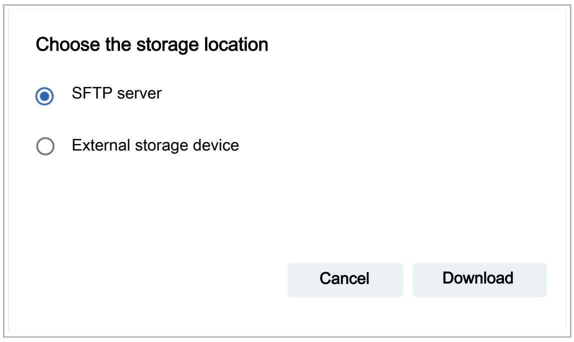
3 If you want the backup to start immediately, choose the **Back up now** button.
   - → Once the backup is completed, a backup file is available in **New** status in the **List of backup files**.

To download backup files manually

1 Choose **Administration > Data maintenance**.

2 From the **List of backup files**, choose the file you want to download.

3 Choose the button.



4 In the **Choose the storage location** dialog box, choose the storage location. The previously selected storage location is preselected.
   - **SFTP server**: SFTP server must be configured.
   - **External storage device**: Connect an external storage device to your computer.

5 Choose the **Download** button.
   - → The backup files are downloaded to the configured location.

Installing updates

In this section

About uploading and installing updates

To maintain the good operation of the system, you must install security, system, and software updates regularly. Roche provides you with updates. You are responsible for installing them.

When an update is available on the data manager, a gray notification badge on the app launcher guides you to the **Administration > Updates** screen.

If an update is available on a local drive of your computer or on an external device, do the following:

1. Upload the update on the **Administration > Updates** screen.
2. Install the update.

Updates are available for installation on the following tabs:

- **Security** tab: All security updates
- **System** tab: Patches, supplementary modifications with no impact on the data manager software version
- **Software** tab: Data manager software updates, companion software
- **Language packages** tab: List of pending language packages
- **User Assistance packages** tab: User Assistance updates

Companion software applications are optional. They are installed in addition to the data manager. The companion software relies on and uses the data manager. Companion software causes no changes to the data manager. Each companion software application is a dedicated configuration item.

On the **Settings > App settings > Companion software** screen, you can enable or disable the installed companion software applications. By default on installation, the companion software is enabled.

Uploading and installing updates

On the **Administration > Updates** screen you upload and install security, system, and software updates.

You must install the updates in a sequential order. If a dependent previous patch is not installed, the data manager prohibits the installation of an update.

⚠ CAUTION!

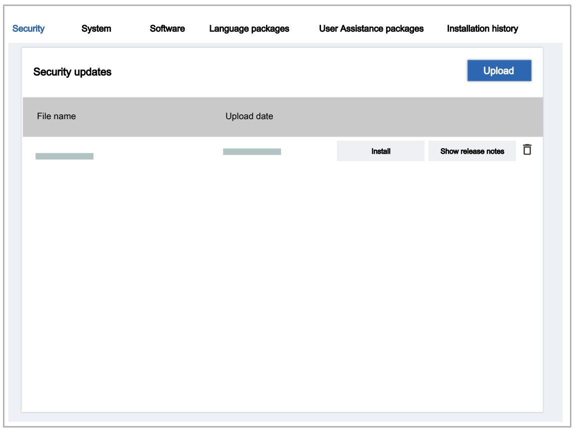
Invalid results

If after a software update the customer-defined validation is not completed and you start a run, there is a risk of obtaining invalid results. The invalid results can lead to sample loss and delayed treatment.

- Do not start a run before completing the customer-defined validation.

- ☐ A user account with **Administrator** user role
- ☐ No orders in **Pending** or **Processing** status
- ☐ All results released

To upload updates from your computer or an external device



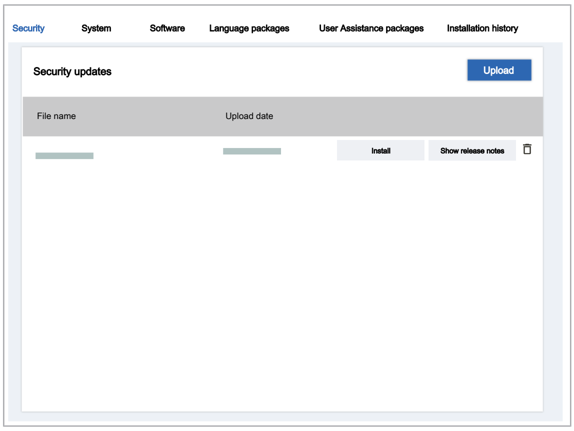
1 Choose **Administration > Updates**.

2 To perform individual updates, choose one of the following tabs:
   - **Security**
   - **System**
   - **Software**
   - **Language packages**
   - **User Assistance packages**

3 To upload updates from your computer or an external device, choose the **Upload** button.
   - Choose the corresponding update file.
   - Open the file.

To install updates

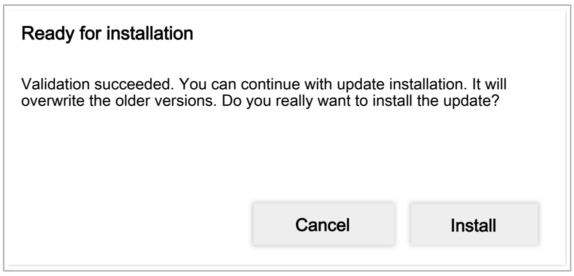
1 Choose **Administration > Updates**.



2 Choose the tab with the available update:
- **Security**
- **System**
- **Software**
- **Language packages**
- **User Assistance packages**

3 To get more information about the update you want to perform, do the following:
- In the corresponding row, choose the **Show release notes** button.
- To close the release notes, choose the **Close** button.

4 To install the software, choose the **Install** button.



5 In the **Ready for installation** dialog box, choose the **Install** button.

→ Installed software updates are displayed on the **Installation history** tab.

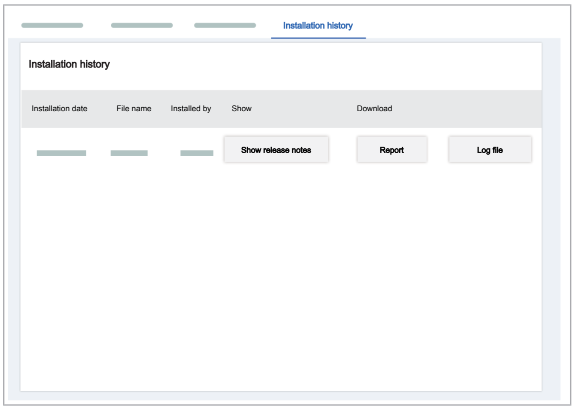
→ If a restart of the system is required, the system is automatically restarted. The restart can take up to 20 minutes.

Viewing the installation history

Installed updates are displayed on the **Administration > Updates > Installation history** tab.

☐ A user account with **Administrator** user role

▸ To view the installation history



1 Choose **Administration > Updates**.

2 Choose the **Installation history** tab.

3 To get more information on the update, choose the **Show release notes** button.

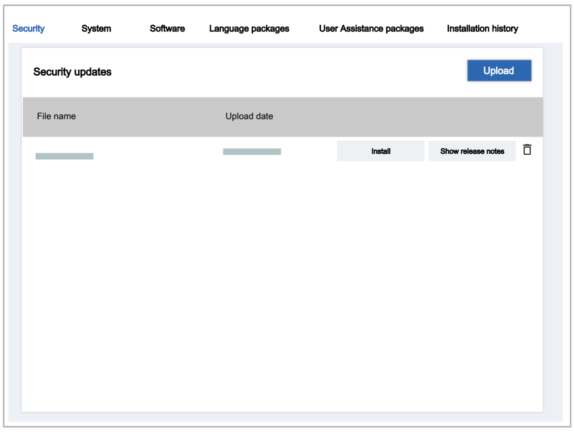
4 To download the report of the update, choose the **Report** button.

5 To download the log file of the update, choose the **Log file** button.

Deleting an update

The system allows you to delete available updates that you do not need.

- ☐ A user account with **Administrator** user role
- ☐ No orders in **Pending** or **Processing** status
- ☐ All results released



▶ To delete an update

1 Choose **Administration > Updates**.

2 On the **Updates** screen, choose the update you want to delete.

3 Choose the 🗑 button.

4 In the dialog box, choose the **Delete** button.

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Troubleshooting

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Troubleshooting

In this chapter

5

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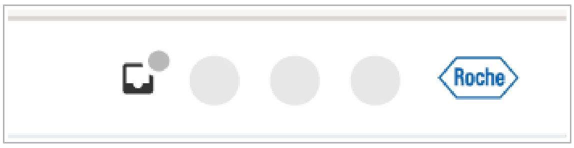
About system alarms

Indicator

An indicator displays the status of an issue. The visualization of the icon depends on the case, it can be, for example, a ⚠ warning icon or a colored-in circle. Some indicators are selectable. When you choose them, more information on the issue is displayed.

Notification badge

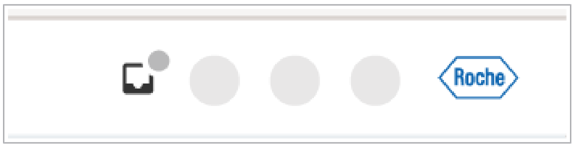


Notification badges guide you on the user interface to where an issue occurred and what you have to do to solve the issue. Notification badges are circular and have the following color coding:

Gray	Information. Low priority task. No immediate action required.
Yellow	Warning. Medium priority task. Perform the procedure soon.
Red	Alarm. High priority task. Perform the procedure immediately. If you do not perform a high priority task, you risk loosing samples.

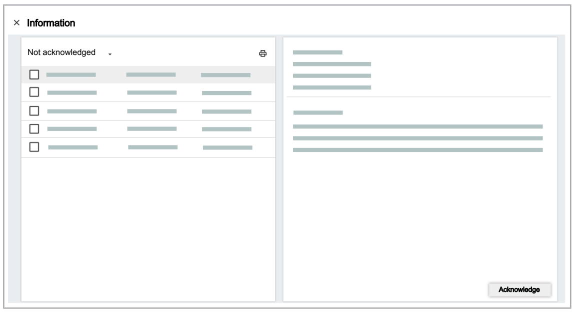
Information inbox notifications

The information inbox displays notifications of the type information.



Every unacknowledged notification creates a gray notification badge on the button.

To access the information inbox, in the global information area, choose the button.



Follow the instructions on the right side of the information inbox or acknowledge the information.

Viewing and acknowledging information inbox notifications (29)

Problem reports

In this section

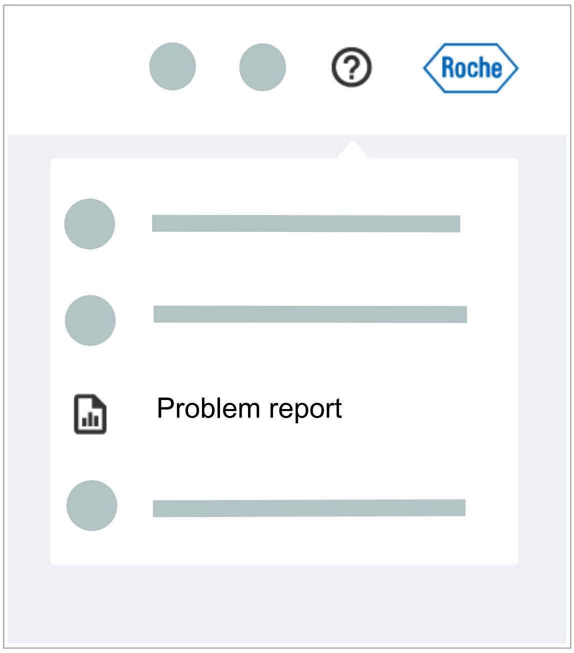
Generating problem reports

Problem reports provide information about the status of the system at the time they are generated. Roche Service uses problem reports for troubleshooting.

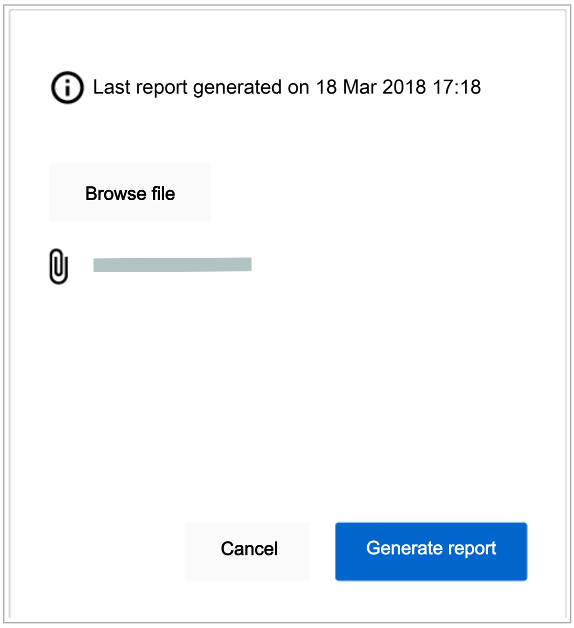
The problem report consists of a ZIP file. This ZIP file includes trace log files and log files from the last few days (number of days as defined in the problem report settings). They also include general information about the system configuration and settings.

The data manager saves only the 2 last generated problem reports.

To generate problem reports



1 In the global information area, choose the ? button.
2 From the drop-down list, choose the **Problem report** option.



3 To add a file to the problem report, choose the **Browse file** button.

4 Choose the file and open the file.

5 Choose the **Generate report** button.

Downloading problem reports

After the problem report is generated, you can download and export it for your Roche Service representative for further investigation. The problem report is available on the **Administration > Problem management** screen.

The problem report is a password-protected ZIP file and has the following naming convention:

- *PR-X800DM*
- License number
- Date and time of problem report generation

The problem report contains the following information:

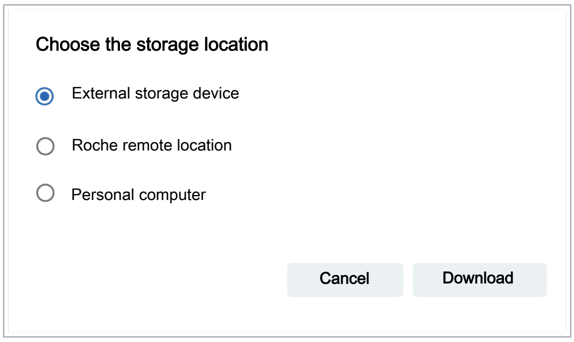
- Audit trail entries
- Data manager version and release notes
- Active notification badges and not acknowledged information inbox notifications
- All settings saved in the data manager
- Log file data and memory usage by the data manager
- Attached images while generating the problem report
- Order information

☐ A user account with **Administrator** user role

To download problem reports

1 Choose **Administration > Problem management**.

2 Choose the problem report you want to download, then choose the button.



3 In the **Choose the storage location** dialog box, choose the storage location:
- **External storage device**: The problem report is downloaded to the external storage device connected to your computer.
- **Roche remote location**: The problem report is downloaded to the Roche remote service platform.
- **Personal computer**: The problem report is downloaded to the downloads folder of your personal computer.

4 Choose the **Download** button.

Resolving failure in generating problem reports

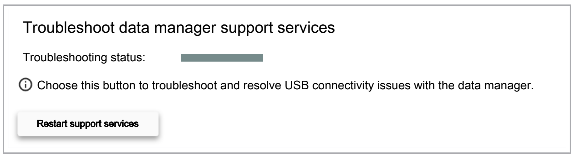
If there is a failure in generating a problem report, restart the data manager support services. The data manager then restarts the services that are responsible for establishing the communication between the data manager software and the data manager platform services.

As required

☐ A user account with **Administrator** user role

To restart the data manager support services

1 Choose **Administration > Troubleshooting**.



2 On the **Troubleshoot data manager support services** card, choose the **Restart support services** button.
- → The status of the restart is updated.
- → The communication between the data manager software and the data manager platform services is reestablished.

Resolving problems with USB connectivity

An incorrectly connected USB device can prevent the uploading of software update files or analysis packages. It can prevent, for example, saving backup files.

2 minutes

- ☐ USB device

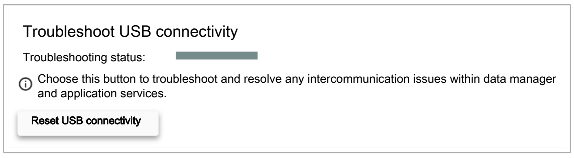
- ☐ A user account with **Administrator** user role

To resolve problems with USB connectivity

1 On the instrument or the data manager mini PC, connect a USB device to one of the data manager USB ports.

   To find the location of the data manager USB ports on the instrument, see the user documentation of the instrument.

2 Choose **Administration > Troubleshooting**.



3 On the **Troubleshoot USB connectivity** card, choose the **Reset USB connectivity** button.

   → If a USB device is connected to 1 of the data manager USB ports on the instrument or to the data manager mini PC, the connection is automatically disabled and enabled again.

Resolving failures in backup execution

If there are failures during backup execution, restart the data manager support services. The data manager then restarts the services that are responsible for establishing the communication between the data manager software and the data manager platform services.

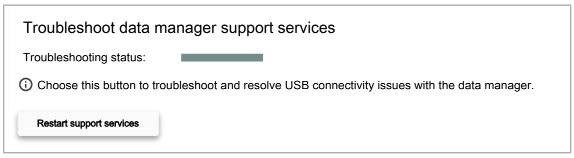
As required

2 minutes

☐ A user account with **Administrator** user role

▸ To restart the data manager support services

1 Choose **Administration > Troubleshooting**.



2 On the **Troubleshoot data manager support services** card, choose the **Restart support services** button.
   → The status of the restart is updated.
   → The communication between the data manager software and the data manager platform services is reestablished.

Order conflicts

In this section

About order conflicts

Order conflicts with different sample types

When a sample is loaded, the data manager queries for manual orders or orders from the host. Conflicts occur when test orders with different sample types are available for a loaded sample. The data manager does not know which of the test orders fits to the loaded sample and a conflict is identified.

If a manual order and a host order are created for the same sample ID, the following general rules apply:

- In case an order from the host is identical to an existing manual order, the manual order is deleted.
- If the sample types of the orders are different, a conflict is stated and the orders stay in **New** status. The orders are not processed.

By configuring sample types to visual carrier ID ranges or visual rack ID ranges, the data manager is able to solve conflicts with different sample types automatically. The carrier or rack must be configured in the data manager settings.

Order conflicts with duplicate orders

There is an order conflict if 2 samples are loaded on the same carrier or rack with duplicate orders. The data manager does not accept duplicate orders, it creates a missing order for 1 of the samples.

Information inbox notifications of the data manager

Every order conflict creates a notification in the information inbox of the data manager with the following information:

- Reason for the order conflict
- Action of the data manager
- Sample ID
- Instrument number
- Carrier ID

- Sample position in carrier

Sample status tab of the instrument

The data manager informs the instrument about the order conflict. On the **Run manager > Sample status** tab, the information about the order conflict is displayed.

Resolving order conflicts with different sample types

If you load a sample on the instrument, there is an order conflict with different sample types in the following cases:

- 1 manual and 1 host order exist with the same sample ID but with different sample types. The data manager revokes the manual order and rejects the host order. The orders stay in **New** status and are not processed.
- 2 manual orders exist with the same sample ID but with different sample types. The orders stay in **New** status and are not processed.

You have 3 options to solve the order conflict:

- Load the sample on a defined carrier or rack for that sample type. The data manager solves the conflict automatically.
- If the manual order is incorrect, delete it.
- If the order conflict affects 2 manually created orders and both are incorrect, do the following: Delete the manual orders with the order conflicts and create an order with the correct sample type and test.

Creating orders manually (37)

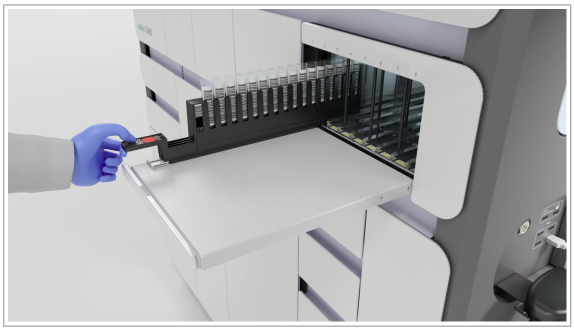
Deleting orders (45)

If there are more than 2 orders with different sample types and tests for the same sample ID, only 1 notification is displayed in the information inbox.

- ☐ Wear personal protective equipment
- ☐ Notification in information inbox
- ☐ Carrier or rack configured for the sample type

To resolve order conflicts by using a defined carrier for the sample type

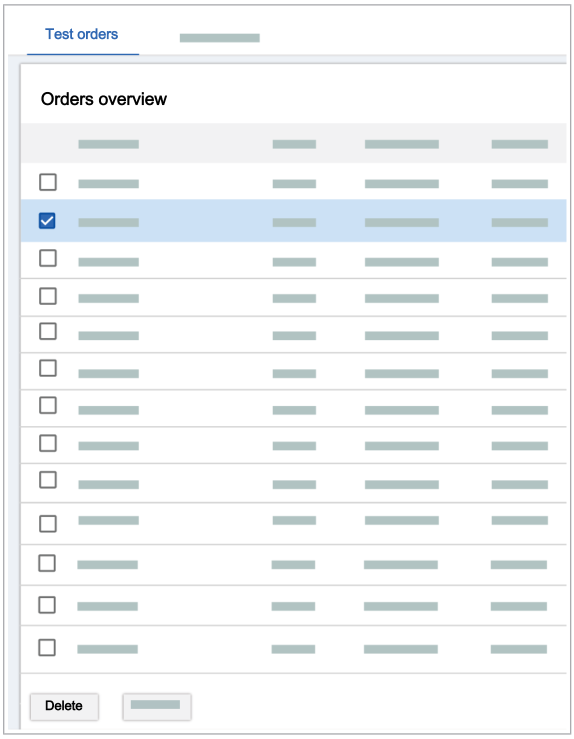
1 Unload the carrier with the order conflict.



2 Load the sample on a defined carrier for that type of sample.

3 Load the carrier.

▶ To resolve order conflicts by deleting the incorrect manual order

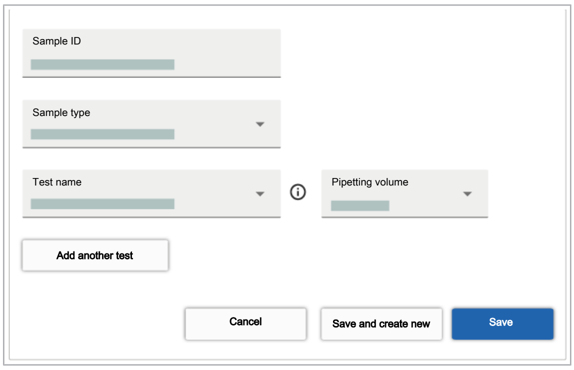


1 If the manual order is incorrect, delete the order.

2 Unload the carrier with the order conflict.

3 Load the carrier again.

▶ To resolve order conflicts by creating an order



1 Unload the carrier with the order conflict.

2 Delete the manual orders with the order conflicts.

3 Create an order for the sample ID with the correct sample type and test.

4 Load the carrier.

Resolving order conflicts with duplicate orders

If 2 samples are loaded and have identical orders and sample IDs, there is an order conflict. The data manager does not accept duplicate orders. It only accepts the order for the first loaded sample and creates a missing order for the other sample.

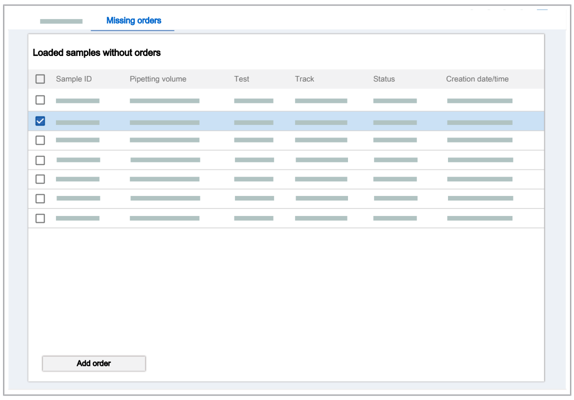
To resolve the conflict, you have 2 options:

- Unload the sample with the missing order.
- On the **Missing orders** tab, create an order for the sample with the missing order with a different test.

The following procedure describes how to create an order for the sample with the missing order.

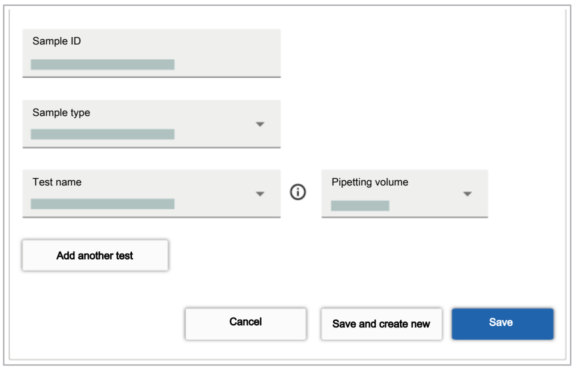
▸ To resolve order conflicts with duplicate orders

1 Choose **Orders > Missing orders**.



2 On the **Missing orders** tab, choose the sample ID for which an order conflict exists.

3 Choose the **Add order** button.



4 On the **Add order** screen, from the **Sample type** drop-down list, choose an option.

5 From the **Test name** drop-down list, choose a different test than the order for the other sample with the same sample ID.

6 Choose the **Save** button.

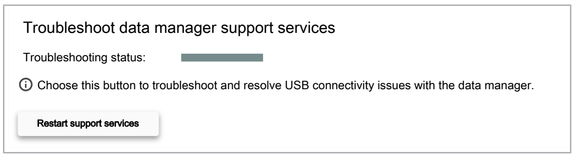
Resolving failure when installing software updates

If there are failures when installing a software update, it can be necessary to restart the data manager support services. The data manager then restarts the services that are responsible for establishing the communication between the data manager software and the data manager platform services.

☐ A user account with **Administrator** user role

▸ To restart the data manager support services

1 Choose **Administration > Troubleshooting**.



2 On the **Troubleshoot data manager support services** card, choose the **Restart support services** button.
- → The status of the restart is updated.
- → The communication between the data manager software and the data manager platform services is reestablished.

Resolving connectivity failure with a host

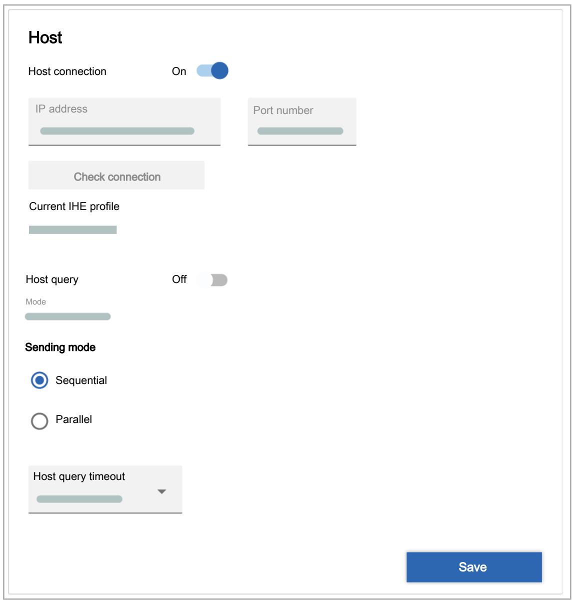
When the data manager cannot communicate with the host system, in the **Lab overview** app, the host connectivity is displayed as **Disconnected**.

5 minutes

- ☐ Host disconnected
- ☐ A user account with **Administrator** user role

▸ To resolve failure in connectivity with a host

1 Choose **Settings > Host**.

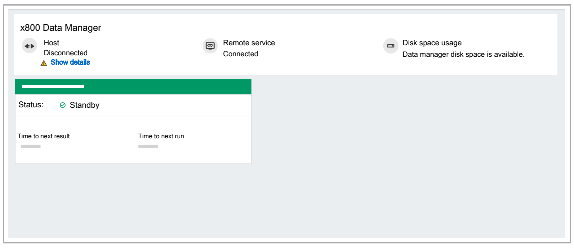


2 Choose **Check connection** button.

3 If the **Connection failed** message is displayed, do the following:

- In the **IP address** field, enter the correct IP address.
- In the **Port number** field, enter the correct port number.
- Choose the **Save** button.

4 To check the connection to the host, choose the **Check connection** button.



5 Choose the **Lab overview** app.

→ After 30 seconds, the host connectivity status is displayed as **Connected**.

Resolving failure in order or results availability

If critical services like orders or results are not available, a red notification badge is displayed on the **Lab overview** app. The data manager restarts the services automatically and resolves the issue.

When the orders and results are resumed and functioning, the notification badge automatically disappears. If the alarm notification is displayed for more than 10 minutes, contact your Roche Service representative.

About connection loss between instrument and data manager

When the connection between instrument and data manager is lost, no new runs are started. The following actions are still possible:

- Remote data manager access, for example, for result handling through the network connection of the laboratory.
- The instrument continues processing only already started runs and stores data until connectivity is reestablished.

The connection can be lost during different scenarios. The instrument reacts accordingly:

- If no connection to the data manager can be established or the connection is interrupted, the instrument does not start a run automatically. The instrument also does not allow the operator to start a run manually.
- If the connection to the data manager is interrupted while performing a run, the instrument finishes the run without any data loss. The instrument sends the results to the data manager after the connection is reestablished.
- If the connection is interrupted after run completion and before all results are calculated, the calculation is resumed when the connection is reestablished.

When the lost connection between instrument and data manager is recovered, the instrument uploads the data stored during the connection loss to the data manager.

Resolving a connection loss between instrument and data manager

If the connection to the data manager is interrupted or cannot be established, no new runs are started. Begin with the first troubleshooting step. When there is a connection established, you can stop troubleshooting.

- ☐ Data manager open, web access available
- ☐ A user account with **Administrator** user role

▸ To resolve a connection loss between instrument and data manager

1 Verify that the data manager is running, by using a laboratory computer that is connected to the data manager.

2 If there is no connection, restart the data manager.

3 Check if the LAN cable to the Roche external firewall is connected and not damaged. If the LAN cable is damaged, call your Roche Service representative.

4 Restart the instrument.

5 If there is still no connection, restart the data manager again.

6 If no connection can be established, contact your Roche Service representative.

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Glossary

additional target calculation

Process of obtaining additional targets from the measured raw data for the initially ordered targets.

analysis package

Bundle of files that contains parameters and specifications relevant for one or multiple tests.

audit trail

Log file with events that are relevant for an audit. It cannot be manipulated by a user.

audit trail entry

Event that is recorded in an audit trail.

card

Descriptive user interface element with a rectangular shape that contains unique related data. A card can contain interactive content such as buttons or check boxes.

comma-separated values file

Data file that consists of fields and records which are separated from each other by commas.

dialog box

User interface element that is displayed after invoking a command and can be closed by the user.

flag

Marker caused by an abnormal condition that includes additional information associated with a particular item.

global information area

Area containing information that is always accessible from any point in the UI.

high-target test

Multiplex test that allows the simultaneous detection and discrimination of multiple DNA or RNA targets per channel by using different temperatures during the generation of signal and thus allowing to test for a high number of targets.

host

External information system of higher level that provides services or a connection to a wider network.

LAN cable

Twisted category 5 pair cable used for computer networks such as Ethernet.

notification badge

Color-filled circle on a user interface element that notifies the users of recent events they have not yet acted upon.

remote service platform

Global platform for data exchange between diagnostic systems and Roche Diagnostics.

secondary sample ID

Additional identification of a sample. Depending on the configuration it may contain information about sample type and/or selected tests.

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