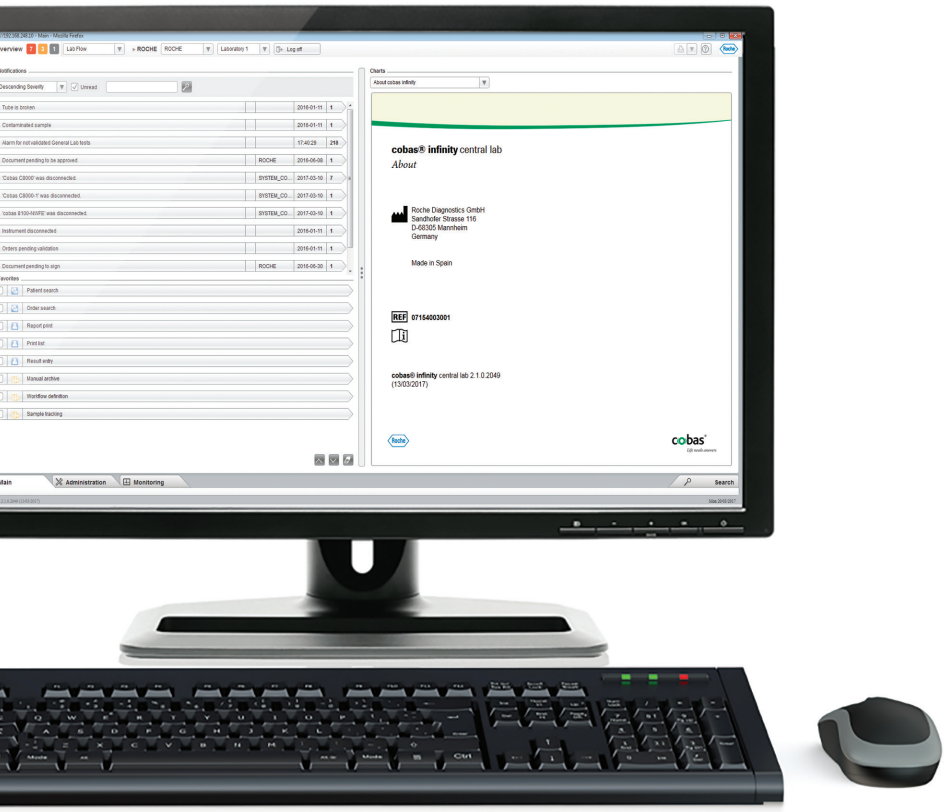
cobas® infinity central lab

cobas® infinity total quality management module

User Guide

Publication version 4.3

Software version 3.01



Publication information

Publication version	Software version	Revision date	Change description
1.0	2.0	June 2016	First edition
1.1	2.0	June 2016	New features of software version 2.0
1.2	2.0	June 2016	Minor updates
1.3	2.0	September 2016	New features of software version 2.0 and new chapters added
2.0	2.1	May 2017	New features of software version 2.1
2.1	2.1.2	July 2017	New features of software version 2.1.2
2.2	2.1	November 2017	Software version changed to include all 2.1 patches
3.0	2.2	November 2017	New features of software version 2.2
3.1	2.3	March 2018	New features of software version 2.3
3.2	2.4	September 2018	New features of software version 2.4
3.3	2.5	November 2018	New features of software version 2.5
3.4	2.5	January 2019	Minor changes coming from 2.5 service patches
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4.1	3.01	May 2019	New features of software version 3.01
4.2	3.01	July 2019	Minor changes coming from 3.01 service patches
4.3	3.01	April 2020	Update of intended use statement **Note:** this publication version is only available in English.

Revision history of User Guide

Edition notice

This publication is intended for operators of the **cobas**® **infinity** central lab.

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:

- Safety
- Routine operation
- Configuration information

The **User Guide** focuses on routine operation. The chapters are organized according to the normal operation workflow.

⚠ General attention

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.

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.

Screenshots

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

Warranty

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

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

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

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This publication may contain information and references to products that may not be available in your country or sold by Roche Diagnostics. This publication makes no claims regarding the use or performance of those products. Selected third-party products are available for use with **cobas® infinity** central lab.

Contact addresses

Roche Diagnostics GmbH
Sandhofer Strasse 116
D-68305 Mannheim
Germany
Made in Spain

Distributed in the United States by:
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46256

USA

REF 07154003001

Table of contents

Intended use

The **cobas® infinity** central lab application is intended to be used for

- the configuration and connectivity management of instruments and software systems
- the management of data regarding
  - Samples
  - Technical validation including automatic release
  - Quality control (both qualitative and quantitative)
  - Test results and their entry (offline workplaces)
- the management and storing of information, such as
  - Samples Archiving Storage information
  - Rule engine for technical validation
  - Notifications from any part of the system
  - Reagent and Calibrator management
  - Turn Around Time management
  - Production statistics

In addition to the above intended use, the **cobas® infinity** central lab application is intended for:

- the management of data regarding
  - Order Data
  - Patient Data
  - Medical Validation support
  - Result Consolidation and Reporting
  - Billing support
- the management and storing of information, such as
  - General statistics (Data Warehouse)
- Microbiology workflows and data for: (Microbiology module)
  - human samples

Use environment and intended users

The **cobas® infinity** central lab software is intended for Clinical Laboratories.

The **cobas® infinity** central lab software is not intended for blood donor screening.

You can find different user profiles using the **cobas®** **infinity** central lab software.

Field Service Engineer (global and local)	Field Service Engineers will configure the system and master data (test, test groups, senders, instruments, reports, interfaces, etc.) according to specific requirements of the customers with regards to connected hosts, instruments and sample workflow. Access level depends on specific user rights.
Lab Technician	Lab technicians will utilize the solution to perform technical validation on patient and QC results, manually edit orders (add or remove tests, edit patient-demographic data), enter patient and QC results that have been obtained from offline workplaces, print-out patient and QC reports, archive samples, retrieve samples from the archive, etc. Access level depends on specific user rights.
Lab Physician/Director	Lab Physicians/Directors will utilize the solution to check technically validated results, search for samples or test results on patient results, and add comments to the results or order. Access level is depending on specific user rights.
Lab IT Admin	Lab IT Admin will maintain users and authorization, and maintain tests and senders. Access level will depend on specific user rights.
GP/Hospital doctor/Hospital nurse/ Community nurse	Those users are no employers of the laboratory thus their access is restricted to the WebLab module only. The user enters orders manually within the WebLab module, releases print-outs of barcode labels for the tubes for positive patient/sample identification, releases print-outs of reports for the patient for blood drawing, view and print the patient result report of their patients.
Phlebotomist	Those users are employers of the laboratory but their access is restricted to the WebLab module only. The Phlebotomist confirms in the system that the samples have been taken according to the order.

Symbols and abbreviations

Product names

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

Product name	Descriptor
cobas® infinity central lab	software
cobas® infinity general lab	module
cobas® infinity emergency lab	module
cobas® infinity lab flow	module
cobas® infinity lab link	module
cobas® infinity microbiology	module
cobas® infinity total quality management	module

Product names

Symbols used in the publication

Symbol	Explanation
•	List item
	Related topics containing further information
	Tip. Extra information on correct use or useful hints.
	Start of a task
	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.
	Topic. Used in cross-references to topics.
	Task. Used in cross-references to tasks.
	Figure. Used in figure titles and cross-references to figures.
	Table. Used in table titles and cross-references to tables.
√xy	Equation. Used in cross-references to equations.

Symbols used in the publication

Symbol	Explanation
	Code example. Used in code titles and cross-references to codes.
	Context search. Used on the context search tab.
	Search. Used on the search tab.
	Table of contents. Used on the table of contents tab.
	Hardware explorer. Used on the hardware explorer tab.
	History. Used on the history tab to show previously viewed topics.
	Favorites. Used on the favorites tab and on the content panel.
	Enlarge. Button used on images.
	Settings. Button used to open the settings dialog.
	Contact. Used in the User Assistance. Functionality currently unavailable.
	Tip. Extra information on correct use or useful hints.
[ ]	Square bracket. Used in the items name as defined by your software administrator.

Symbols used in the publication

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
ANSI	American National Standards Institute
EN	European standard
n/a	not applicable
QC	Quality Control
SD	Standard deviation
UPS	Uninterruptible Power Supply

Abbreviations

Safety classifications

The safety precautions and important user notes are classified according to the ANSI Z535.6 standard. Familiarize yourself with the following meanings and icons.

These symbols and signal words are used for specific hazards:

⚠ WARNING!

Warning...

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

⚠ CAUTION!

Caution...

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

NOTICE!

Notice...

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

Important information that is not safety relevant is displayed as the following icon:

Tip...

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

System safety information

Roche Diagnostics has established a series of recommendations with the aim of allowing the user to work with the software under safe conditions and guaranteeing the correct operation and proper performance of the communication network in which this product has been installed.

Read the following recommendations carefully for the correct operation of the software.

Security

⚠ WARNING!

Secure infrastructure

Risk of privacy violations.

- A secure infrastructure must be established for the software network and security policies must be defined to address potential problems or system failures.
- Access is controlled by a login. Every access to the software is registered and logged, including the unsuccessful ones.
- Pay special attention when configuring the number of logon attempts, the password expiry period, and session management.

⚠ WARNING!

Enabled security parameters

- All security parameters (profiles, access restrictions, etc.) are enabled by default. Remember that disabling security parameters may lead to potentially major risks, e.g. unqualified staff may change instruments or system configurations, or unauthorized users may access confidential information.

UPS

⚠ WARNING!

UPS usage and software shutdown

Risk of data becoming lost or corrupted in the event of a power failure

- It is strongly recommended to use a UPS and to perform regular UPS maintenance.
- It is strongly recommended to keep the journaling feature activated.
- There should be a standard procedure to shut down the software. You must exit the software before shutting down the computer on a daily basis. Having a UPS that can perform a safe shutdown installed mitigates the risk of data loss due to power failure.

⚠ CAUTION!

UPS usage

Risk of data loss in the event of a power failure

- It is strongly recommended to use a UPS.
- It is strongly recommended to keep the journaling feature activated.

User settings

⚠ WARNING!

Restricting access to critical functions

Risk of confidential information being accessed

- It is recommended to grant users the minimum rights necessary to perform their tasks to protect confidential data and configuration items in the database.

⚠ WARNING!

Access to the software and user accounts

- Access to the software should only be granted to users who have been trained and assigned a user name and password. The password must be confidential and must comply with the usual security principles. It must be changed periodically to prevent unauthorized parties from gaining access.
- There must be one account per user. Do not create generic user accounts to be used by more than one person. Create a different account for each user, even if they have the same access rights.
- It is recommended that you develop a Standard Operating Procedure (SOP) to ensure that only qualified staff access the software.

⚠ WARNING!

Passwords, access, and system shutdown

- For security reasons and for patient confidentiality, all users must exit the software or lock their computer before leaving their workplace.
- It is recommended to correctly configure the automatic log-off time.

⚠ CAUTION!

System performance

Risk of delayed results

- To ensure the operation of the system at full capacity, avoid connecting more users or instruments than your infrastructure supports.

System configurations

The preconfigured settings in the system must only be used as a reference. It is recommended that they are not used as default settings since they should be modified to suit the system and the health center requirements.

General

⚠ WARNING!

Regional settings

- Make sure that the configuration of the software matches the regional settings and the local requirements.

⚠ CAUTION!

Servers and software performance

Risk of delayed results

- Use servers that are correctly dimensioned to the needs of your installation to guarantee the best performance of the software.
- It is recommended to configure the servers using a high availability and data redundancy system. The existence of a second server prevents data loss in the event of severe or critical failures in the system.

⚠ CAUTION!

Alarms on validation screens and reports

Risk of incomplete results that could lead to a wrong diagnosis

- To prevent users from validating results without taking into account important information, always configure alarms for validation screens and reports.

⚠ CAUTION!

Barcodes

Risk of delayed results

- It is strongly recommended to have appropriate Standard Operating Procedures (SOP) to avoid an incorrect handling of tubes.
- It is recommended to use barcodes for tubes and trays to easily identify and locate samples.

All the changes made in the software are recorded using an audit trace.

⚠ CAUTION!

Errors in identification of orders, tubes or patients

Wrong results or delayed results.

- If the archived database is not available, do not use the local database.

Backups

⚠ WARNING!

Backups and updates

- Before upgrading the software, make backups of all databases and system configurations.

Instruments and reading devices

⚠ WARNING!

Repeated values

Results may be misinterpreted if instruments do not show the time when results were sent, or if the same results are received for the same test with the same timestamp.

- Keep in mind that, in this case, results could be repeated simply due to data being transmitted twice and not because a test was repeated.

Reading devices

Risk of results being misinterpreted

- It is recommended that you use reading devices (optical readers, barcode readers, card readers, etc.) to take results. Check the reading devices are operating correctly before using them in real environments.

Results

⚠ WARNING!

Result format

Risk of results being misinterpreted or wrong results

- To prevent the software to misinterpret results, do not use separators for thousands when entering results. Only decimal separators must be used.
- Ensure that instruments and hosts are also configured to not use separators for thousands.

21 CFR Part 11 compliance

The Food and Drug Administration (FDA) of the United States under Title 21 of the US Code of Federal Regulation Part 11 (21 CFR Part 11) establishes the requirements to ensure that electronic records and electronic signatures are trustworthy, reliable, and equivalent to paper records with traditional handwritten signatures.
cobas® infinity central lab provides the capability to meet the requirements of part 11 compliance if the system is configured and used properly within the

customer's processes. This section describes the steps and settings that are necessary to ensure that the software is configured to meet the requirements of this regulation.
The final responsibility of 21 CFR Part 11 compliance relies on the adequate implementation by the customer ensuring both procedural controls (that is, Standard Operating Procedures, training) and administrative controls.

In case customers need to be compliant with 21 CFR Part 11 regulatory requirements, the software should be configured according to the customer's policies and needs. Otherwise, the following configurations are recommended:

General parameters

Administration > General > General parameters

ID	Parameter	Description	Recommended value
1	**Accessing the application via Direct Access without having to log on**	When accessing the software using a link or externally, this parameter allows you to access only the screens marked as accessible without having to enter the password and user name on the logon screen.	No (default value)
2	**Backup** (Folder path)	This parameter allows you to configure the directory where the backups of the application databases are stored.	Folder path configured
3	**Session timeout (min)**	This parameter allows you to specify how long the session is kept open (in minutes) since activity was last detected. Once this time is exceeded, the software logon screen appears, and the user name and password must be entered again.	15
4	**Direct access session timeout (min)**	This parameter only applies to sessions accessed from an external environment. This parameter allows you to specify how long the session is kept open (in minutes) since activity was last detected. Once this time is exceeded, the session closes.	15
5	**Days configuration trace is kept**	Indicates the number of days the configuration trace will be kept before deleting it.	9999
6	**History retention period (d)**	Days before the deletion the order traces.	9999
7	**Delete the orders and patients from the recycle bin after (hours)**	When deleting orders and patients, the application sends them to the recycle bin. These orders / patients remain in the recycle bin until they exceed the number of hours set in this parameter. The system then proceeds to permanently delete these items from the database via the end of day process.	24 (default value)
8	**Number of logon attempts before the user is blocked**	Indicates the number of consecutive mistakes that the you can make when logging in.	5
9	**Password renewal period (d)**	Period of time when the system will request to change the password for a user.	90 (default value)
10	**Password expiry warning (d)**	Period of time when the system will start reminding you to change the password before the password renewal period.	10

Parameter configuration for 21 CFR Part 11 compliance

ID	Parameter	Description	Recommended value
11	**Minimum number of uppercase letters in password**	Minimum number of uppercase letters that the password must contain.	1 (default value)
12	**Minimum number of digits or symbols in password**	Minimum number of digits or symbols that the password must contain.	1 (default value)
13	**Minimum password length**	Minimum length required for the password.	6 (default value)
14	**Request password when accessing the validation screen (positive user identification) and the rule engine administration screen**	Indicates if the password for the user will be requested when entering the validation screen or Rule Engine validation screen.	Yes
15	**Enable automatic data removal in database**	Indicates if the system will remove order data automatically from the database.	No (default value)
16	**Add comment when editing validated tests** (for all required applications: General Lab, Emergency Lab and Microbiology)	When enabling this parameter, the application forces the user who edits validated results and wants to save them, to enter a comment. The callout that appears for entering the comment cannot be left empty. It is possible to enter a coded comment. These comments do not appear by default in the report. If you want to view them there, the check box of the Imp./Host column on the Comments screen should be selected.	Yes
17	**Request confirmation when changing results** (for all required applications: General Lab and Emergency Lab)	If this parameter is enabled, the system requests you to confirm whether the test result change should actually be saved in the database. This option helps you avoid mistakes.	Yes

Parameter configuration for 21 CFR Part 11 compliance

Reports **Administration > Reports > Definition**

ID	Configuration	Procedure
18	Report configuration includes the user that validates the result.	1. Choose the corresponding report. 2. Choose the **Design** button. 3. Include the **Validation user name list** field in the report.

Report configuration for 21 CFR Part 11 compliance

The following settings must be properly configured to comply with this regulation:

ID	Configuration
19	Check Backup List (Database configuration)
20	Check Backup Task (Database configuration)
21	The communication channel uses SSL or HTTPS between client and server

Backup and communication configuration for 21 CFR Part 11 compliance

To ensure that these settings are properly configured, contact your Roche Service Representative.

It is recommended that customers keep evidence of this configuration according the required regulations.

Interface overview

Interface overview

In this chapter 1

Accessing the software

In this section

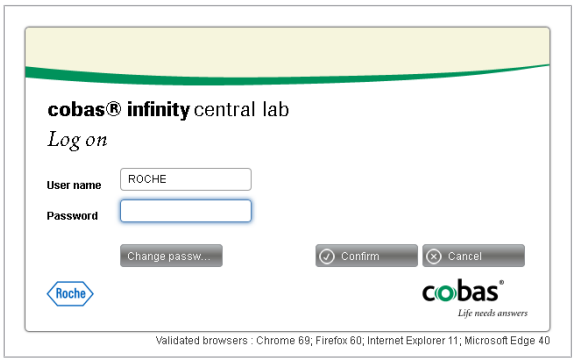
Logging on to the software

You need to log on to the software to carry out any tasks.

- ☐ A compatible browser
- ☐ A valid user name and password

To log on to the software

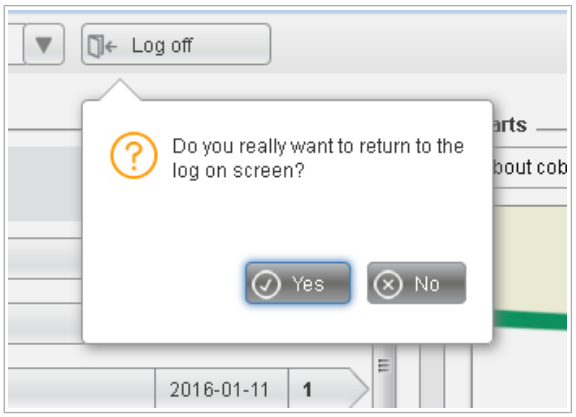
1. Open the software or type the server address as provided by your administrator.
2. If you are working with LDAP, from the **Domain** drop-down list, choose an option.
   - ℹ The first time that you log on to the software, in the **Domain** field, you must enter the domain of the server that you are using for LDAP authentication.
3. On the logon screen, fill in the following fields:
   - **User name**
   - **Password**
4. Choose the **Confirm** button.
   - ℹ If you exceed the number of logon attempts available, contact your system administrator.
5. If a Java callout appears, select the [Allow] option to be able to detect printers later on.



Logging off the software

For safety reasons, you need to exit the software after completing your task.

To log off the software



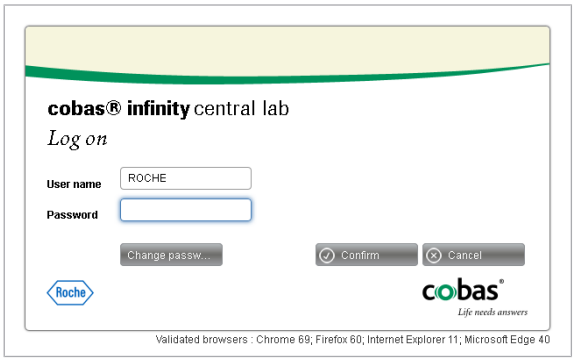
1 From any screen, choose the **Log off** button located in the information area.

2 To confirm that you want to exit the software, choose the **Yes** button from the callout.

Changing the password

You can change the software password whenever you want, whenever the system requires it, or when your current password is about to expire or is no longer safe.

To change the software password



1 On the logon screen, fill in the **User name** field, and then press the Tab key.

2 Choose the **Change password** button.

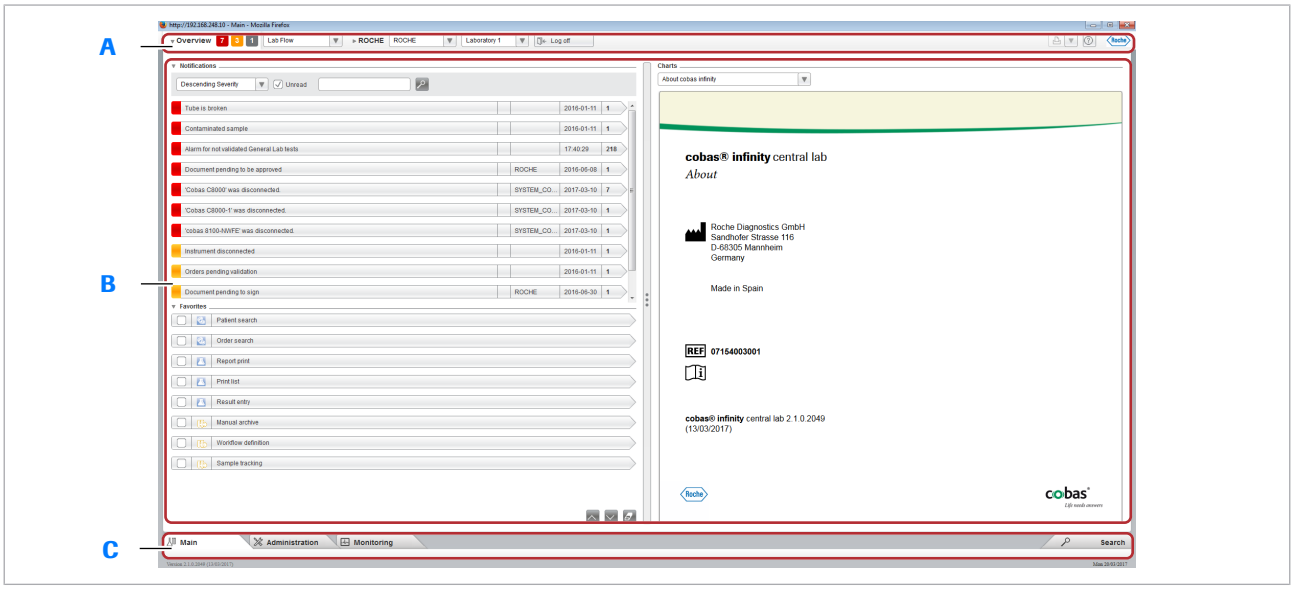
3 In the dialog box, enter your current password, enter the new password twice, and then choose the **Confirm** button.

4 Log onto the software using your new password.

ⓘ If you have forgotten your password, contact your system administrator.

About the software framework

The software framework consists of different areas that allow you to perform several tasks.



A Global information area

B Overview area

C Working space

Software framework

Global information area

From this area, you can do the following:

- Change the software module
- Change the user profile
- Change the profile location
- Export tables
- Print barcode labels

Overview area

From this area, you can do the following:

- View notifications
- Assign and manage shortcuts
- View work area and monitoring charts
- View the software information

Working space

From this area, you can do the following:

- Perform a quick search
- Navigate through tabs, menus, and screens

Related topics

- Changing the software module (30)

- Changing the user profile (30)
- Changing the profile location (31)
- Exporting tables (42)
- Viewing notifications (34)
- Assigning and managing shortcuts (36)
- Searching for general information (37)
- Navigating through tabs, menus, and screens (36)

Performing basic tasks in the software

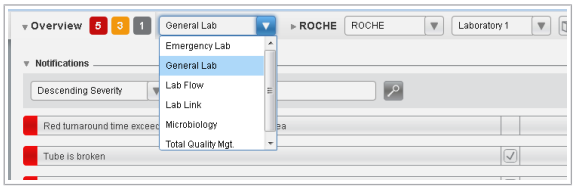
From the main page, you can access the various modules and tabs of the software, as well as perform some basic tasks.

In this section

Changing the software module

If you need to perform any tasks in a different module, you can switch to it without logging off the software.

For example, to print both General Lab and Microbiology worklists, you can easily switch from one module to the other, if you have access rights.



To change the software module

1. From the drop-down list located in the global information area, choose the desired module.
   ➔ The **Main** tab menu is refreshed with the options available for the selected module.
2. If you log off the software and log on again, the last module used is displayed.

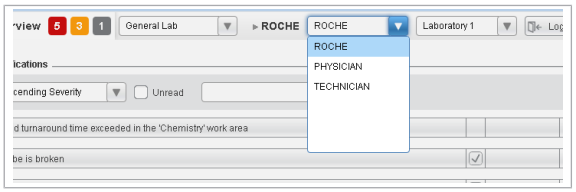
Changing the user profile

You can switch to a different user profile to perform some tasks without logging off the software.

Your user ID can be associated with more than one profile with different access and work rights. You can easily switch from a profile to another to carry out some tasks in the software.

☐ More than one profile assigned to your user ID

To change the user profile



1 On any screen, look for the profile drop-down list located in the global information area.

2 Open the drop-down list and choose the desired profile.

ⓘ If you log off the software and log on again, the last profile used is displayed.

Related topics

- Changing the profile location (31)

Changing the profile location

If you are working in more than one health center or in different services, you can select one of the locations associated with your profile.

When you log on to the software, the last location used is displayed.

☐ More than one location assigned to your user ID

To change the profile location

1 On any screen, look for the location drop-down list located in the global information area.

2 Open the drop-down list and choose the desired location.

➔ The **Main** tab menu is displayed.

Related topics

- About location and multisite (32)

About location and multisite

A multisite environment allows you to access patient information from any of the locations you are working in.

About location

A multisite environment consists of having patient information accessible from different locations. A location can be a laboratory area or a hospital service and each user profile can log on to one or more locations.

In the software, a location is a configurable demographic that can have one or more values. Consider the following:

- All the user profiles must be associated with at least one location.
- All the tests and orders in the database must be assigned a location.
- All instruments and hosts must be assigned a location.

In **Main > Queries > Order traces**, you can check the location of orders and tests at any time.

Selecting the profile location

If your profile is associated with more than one center or service, you can select the location you are working in. This affects the assignment of location to orders and tests.

Changing the profile location (31).

Manual or automatic location assignment to orders and tests

When you perform manual tasks such as entering orders, tests, or test results, a location is assigned to orders and tests. In some cases, you can change the order location.

Some automatic actions performed by hosts, instruments or by the rule engine also result in the assignment of a location to orders, tests, and test results.

If you are not working in a multisite environment, you do not have any location associated with your profile. In this case, all the tests and orders in the database are automatically assigned to the default location Laboratory1.

Type of task or action	Task or action	Location assignment	Reference
Creating orders	You create an order from **Main > Order entry > Order entry**.	▪ The order gets the profile location. However, you can change the order location by selecting it from the **Location** drop-down list in the **Demographics** group box (if displayed). ▪ All the tests entered at this time get the same location as the order.	
	You create a pre-order from **Main > Order entry > [Pre-order entry]**.	▪ The order gets the profile location. However, you can change the location by selecting it from the **Location** drop-down list in the **Order details** group box (if displayed). ▪ All the tests entered at this time get the same location as the order.	
	You retrieve a pre-order in **Main > Order entry > Collection**.	The order gets the pre-order location and cannot be edited.	
	An instrument sends an order.	The order and all its tests get the instrument location.	Contact your Roche Service representative.
	A host creates an order.	The order and test locations depend on the host configuration.	Contact your Roche Service representative.
	The rule engine creates an order based on an existing order.	The new order and all its tests get the location of the existing order.	Contact your system administrator.
Adding tests	You add a test to an existing order in **Main > Order entry > Order entry**.	The added test gets the profile location, regardless of the order location.	
	You add a test to an existing order from a validation screen.	The added test gets the profile location, regardless of the order location.	
	You retrieve a test affected by a rejection rule.	The retrieved test gets the order location.	
	The rule engine adds a test to an existing order.	The added test gets the order location. This action also applies in the case of rejection rules.	Contact your system administrator.
Entering or editing test results	You enter or edit the results of a test from a validation screen.	The test gets the profile location. If you relate the test result to an instrument, the test gets the location of the instrument.	
	You enter or edit results of a test from a worklist.	The test location does not change and you can only enter or edit results from tests with the same location as your current location.	
	The rule engine reruns a test with dilution or assigns an automatic result to a test.	The test location does not change.	Contact your system administrator.
	The rule engine enters or edits the results of a test.	The test location does not change.	Contact your system administrator.
	An instrument sends test results or makes a query.	The test gets the instrument location.	Contact your Roche Service representative.

Manual or automatic location assignment to orders and tests

Type of task or action	Task or action	Location assignment	Reference
	A host sends the results of a test.	The test location depends on the host configuration.	Contact your Roche Service representative.

Manual or automatic location assignment to orders and tests

Filtering work areas by location

Since all the orders and tests have an assigned location, you can use this demographic to filter your work area items. This way, you can narrow down the number of items displayed.

Filtering and printing worklists

Since all worklists are assigned to at least one location, you can use this demographic to filter your worklists. The software considers the locations assigned to the worklists and your current location to display or print worklists. If you have more than one location assigned, you can choose the location to consider when adding tests in the worklist.

Filtering QC results by location

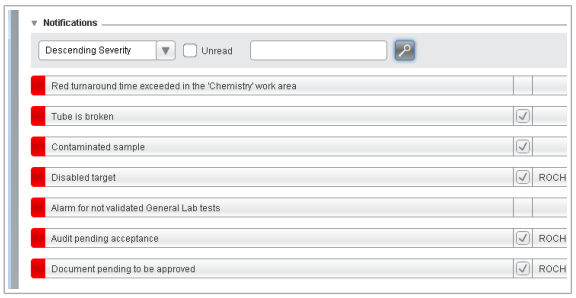
Since all analyzers are assigned to one location, you can use this demographic to filter your QC results. The software considers the locations assigned to the analyzers and the locations you can access.

Viewing notifications

In the overview area, you can view the alarms and warnings issued by the system when the events configured as alarm triggers take place (orders are not validated, instruments get disconnected, etc.).

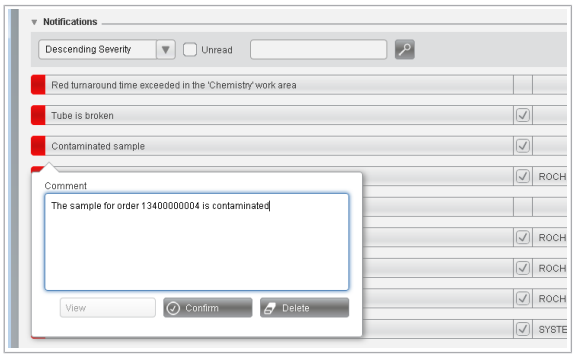
☐ Notification severity conditions configured by your system administrator

To view notifications



1 **From the global information area, choose the Overview button to display all the available notifications.**

2 **To filter the notifications, do one of the following:**
- Enter a search term in the search field.
- Select the **Unread** check box.



3 Choose the desired notification to see its description, and then do one of the following:

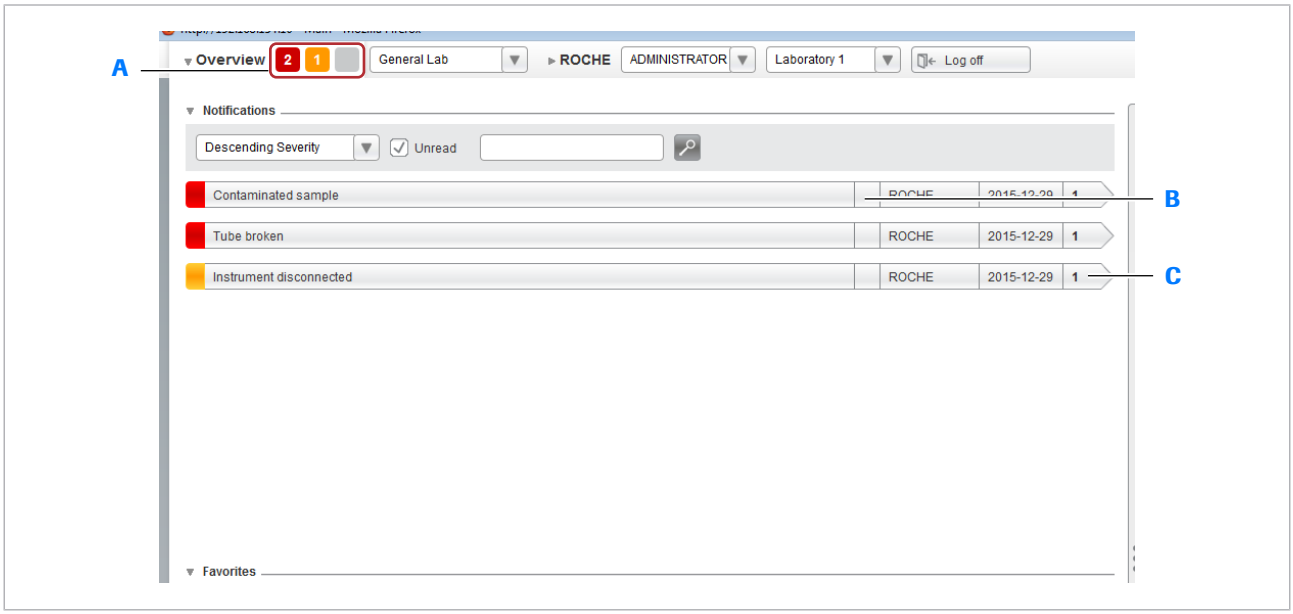
- To access the screen where the error is detected and solve the issue, choose the **View** button, if enabled.
- To confirm that you have read the notification, choose the **Confirm** button.
- To delete the notification, choose the **Delete** button.

➔ If you choose the **Confirm** button, the notification is marked as read and the notification icon is displayed without any number or with the number of remaining pending notifications.

➔ If you choose the **Delete** button, the notification disappears.

About the Notifications screen

From the **Notifications** screen, you can view the number and type of pending notifications, as well as any related comments.



A Number of unread notifications of each type:
- Red: high-severity notifications
- Orange: medium-severity notifications
- Gray: low-severity notifications

B Check box indicating that the notification has been read.

C Number of items affected by the corresponding notification.

Notification screen

Assigning and managing shortcuts

You can assign up to 25 shortcuts to your most frequently used screens to be able to access them quickly from the **Overview** screen.

To assign or delete a shortcut

1 Go to the screen that you want to assign to your favorites list, and then choose the ★ icon.
   ➔ A bookmark for the selected screen is displayed in the **Favorites** panel of the **Overview** screen.
   ➔ The star icon turns black.

2 To delete the shortcut, choose it from the **Favorites** panel in the **Overview** screen, and then choose the button.

To sort shortcuts

1 In the **Overview** screen, go to the **Favorites** panel.

2 Select the check box of the item that you want to move.

3 Choose the buttons to move it up or down in the list.

Related topics

- List of common icons (44)

Navigating through tabs, menus, and screens

You can navigate through tabs, menus, and working screens to perform tasks.

You can access the tabs, menus, and screens associated with your user profile. Therefore, some of the described items may not be visible to you.

Tabs

The working space includes four tabs to perform different actions:

- **Main**: it allows you to perform daily tasks, such as entering, processing, and printing orders.
- **Administration**: it allows you to perform configuration tasks.
- **Monitoring**: it allows you to check the software performance.
- **Search**: it allows you to quickly find orders and patients.

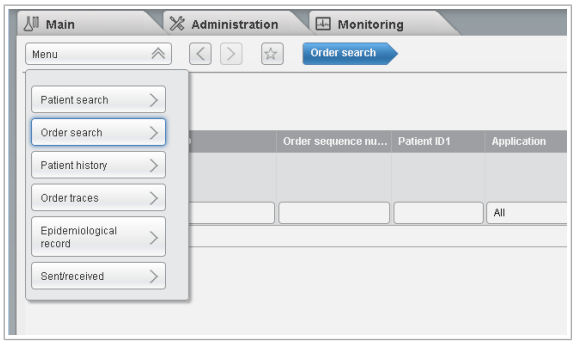
Keyboard shortcuts for tab and menu navigation

Use the following keyboard shortcuts to navigate through tabs and menus:

Item	Key	Action
Tabs	Ctrl+Page Down	Move to the right tab
Ctrl +Page Up	Move to the left tab	
Menus	Up Arrow	Move to the upper menu point
Down Arrow	Move to the lower menu point	
Right Arrow	Open the submenu	
Left Arrow	Close the submenu	
Enter	Access the selected screen	
Esc	Close the menu	

Keyboard shortcuts to navigate through tabs and menus

Searching for general information



You can search for patients and orders from the main screen without needing to access the corresponding submenus.

To search for general information

1 From the working space, choose the **Search** tab.

2 From the **Menu** drop-down list, choose one of the following options:

- **Patient search**: search for a given patient in the software.
- **Order search**: search for a given order in the software.
- **Patient history**: search for orders and tests associated with a given patient.
- **Order traces**: check the actions performed on a given order or on all the orders of a given patient.
- **Epidemiological record**: search for existing epidemiological records, declared microorganisms, etc.
- **Sent/received**: search for samples already sent or pending to be sent to health centers, as well as sample results received by health centers.

Filtering

Several screens in the software include tables displaying orders, patients, and tests, among others. Also, some drop-down lists contain long lists of items to choose from. You can filter the items on such tables or drop-down lists to find the information you need more easily.

Wild-card characters in filter fields

When entering text in filter fields, you can use the following wild-card characters:

- * matches one or more characters. For example, in the **Order ID** filter field, enter GL201307* to obtain the available Order IDs starting with this sequence number, such as GL20130710 and GL20130711.
- ? matches a single character. For example, in the **First name** filter field, enter J?an if you do not know if the patient's name is Joan or Juan.

In this section

Filtering drop-down list values

You can reduce the values displayed in drop-down lists to find the desired value easily.

To filter drop-down list values

1 From any drop-down list, enter the desired characters to narrow down your search.
   - If you are uncertain about some characters, enter wild-card characters.

2 Press Enter.

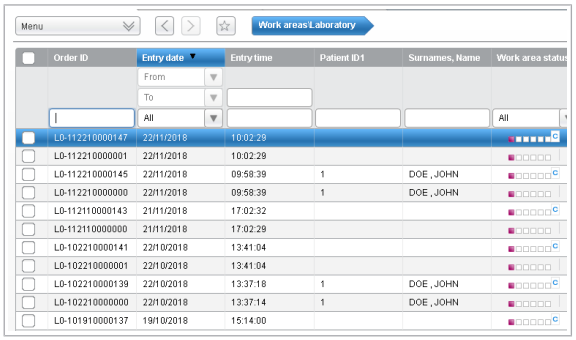
Filtering information

You can reduce the information displayed on tables to see only the items that you need.

Depending on the screen, you can filter the information in two ways. Choose the desired procedure:

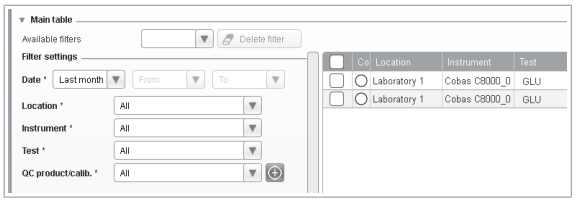
To filter information via table (39)
To filter information via panel (39)

To filter information via table



1 From the screen, choose the **Filter** button.
   ➔ The available filter fields and drop-down lists are displayed.
2 Choose the desired filters, and then choose the **Apply** button.

To filter information via panel



1 In the **Filter settings** panel, from the drop-down lists, choose the relevant options.
   - Alternatively, from the **Available filters** drop-down list, choose a saved filter.

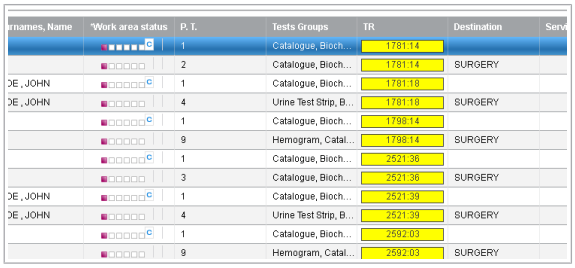
   ⓘ If you already have a **Default filter**, it is automatically applied. The **Parameter time** option in the **Date** field depends on configuration.
2 Optionally, to add more fields, choose the ⊕ button.
   - Alternatively, to delete additional fields, choose the ⊖ button.
3 Choose the **Apply** button.

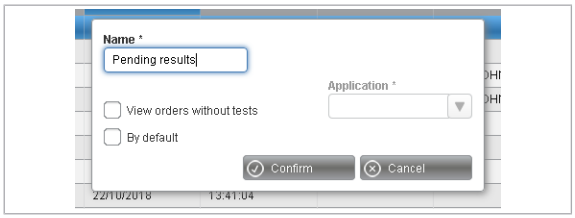
Saving/deleting a filter

You can save, edit, and delete frequently used search configurations to easily apply them when you access the screen again.

Choose the procedure corresponding to the filtering area:

To save a filter via table (40)
To save a filter via panel (40)
To delete a saved filter via table (41)
To delete a saved filter via panel (41)





To save a filter via table

1 From any screen, choose the desired filters. Then, choose the **Apply** button.

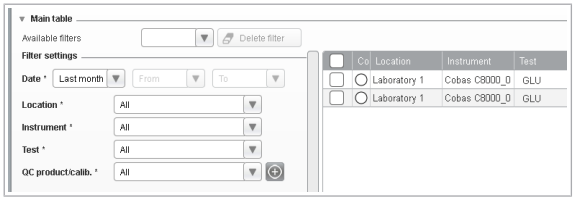
2 Choose the **Capture filter** button.

3 In the callout, enter the following:

- **Name** of the filter.
- **By default** check box: the filter is automatically applied whenever you access the screen.
- **View orders without tests** check box and **Application** drop-down list (only for work areas): the filter shows the orders belonging to the selected module that do not contain tests.

4 Choose the **Confirm** button.

➔ The new filter is displayed in the **Filter** drop-down list.



To save a filter via panel

1 From any screen with a **Filter settings** panel, use the drop-down lists to choose the relevant options.

ⓘ The **Parameter time** option in the **Date** field depends on configuration.

2 Optionally, to add more fields, choose the ⊕ button.

- Alternatively, to delete additional fields, choose the ⊖ button.

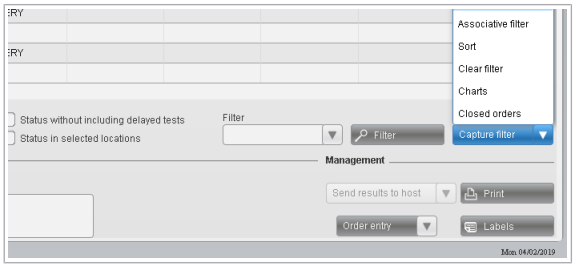
3 Choose the **Save filter** button.

4 In the dialog box, enter a name in the **Filter name** field.

5 Optionally, to define the filter you are saving as a default filter, select the **Default filter** check box.

ⓘ This filter is automatically applied when you enter the corresponding screen.

6 Choose the **Save** button.

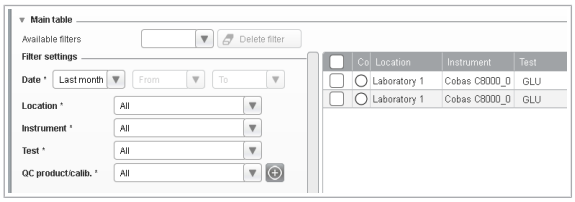


To delete a saved filter via table

1 From any screen, use the **Filter** drop-down list to choose the filter you want to delete.

2 Choose the **Clear filter** button, and then confirm that you want to delete the filter.

ⓘ The **Clear filter** button can be displayed in a drop-down list depending on the type of screen.



To delete a saved filter via panel

1 From any screen with a **Filter settings** panel, use the **Available filters** drop-down list to choose the filter you want to delete.

2 Do one of the following:

- To clear the fields defined for that filter, choose the **Clear fields** button.
- To delete the filter, choose the **Delete filter** button.

Sorting and exporting table information

Several screens in the software, such as work area or validation screens, include tables displaying orders, patients, and tests, among others. You can sort the items on such tables to display them in certain ways, only the information you need, as well as export them to a convenient format.

In this section

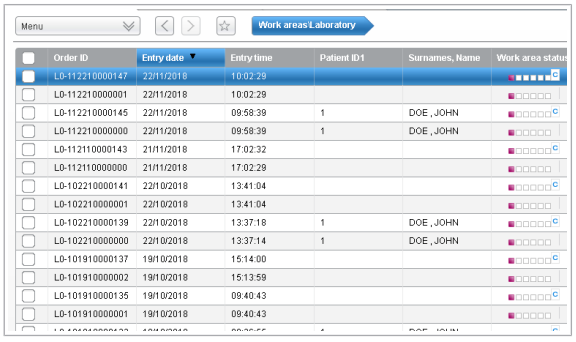
Sorting table information

You can quickly sort table items in ascending or descending order.

Table items are sorted using the ASCII-code order. Therefore:

- Digits come before letters.
- Numbers are sorted as strings. For example, 02, 2, 10 are sorted as follows: 02, 10, 2.
- Non-ASCII characters, such as *ñ*, are placed at the end.

To sort table items

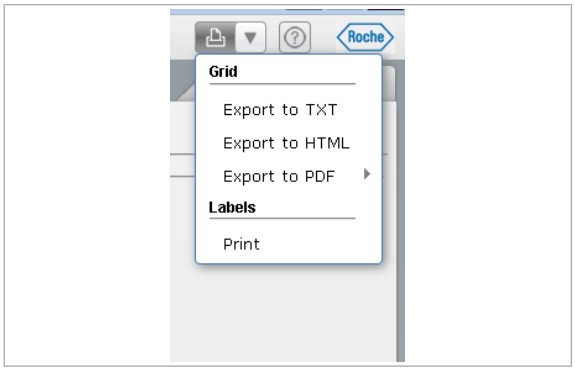


1 Choose the column header to sort the desired items in ascending order.

2 Choose the column header again to sort the items in descending order.

Exporting tables

From the global information area, you can export the information displayed on a table to different file formats.



To export tables

1 From the global information area, choose the drop-down list.

2 From the **Grid** group box, choose one of the following options:

- **Export to** TXT: to produce a text file using the current browser.
- **Export to** HTML: to produce a web file using the current browser.
- **Export to** PDF in **Vertical** or **Horizontal** format: to produce a PDF file using the current PDF viewer.
- **Export to >** CSV: the exported file is in CSV format. Each line of this file corresponds to a row from the grid. In the **General parameters** screen, you can define the character that separates the data within each cell.

ⓘ The button performs the last selected action. To print tables again, choose it or press F5.

➔ The table is exported with the information sorted as displayed on the screen.

If a table in the **Query/Validation by test** screen, **Validation** screen, or **QC Result review** screen contains **cobas e** flow main tests, all their embedded tests and calculated QCs are exported even if they are not displayed on the screen.

About the common interface items

In this section

List of common function keys

Use your keyboard to perform a series of actions in the software.

Common function keys

You can use these function keys to perform tasks throughout the software.

Screen-specific function keys are described in the corresponding tasks.

Key	Corresponding buttons	Action
F1	-	Opens the User Assistance.
F2	**Confirm** or **Save** buttons	Saves data.
F3	**Delete** button	Deletes data.
F4	**Cancel** button	Undoes changes.
F5	button	Performs the last action selected from the drop-down list, that is, printing labels or tables.
F6	button	Returns to the previous screen.
F7	**Add** button	Enables the configuration area to assign a new item in the **Administration** tab.
F8	**Filter** and **Apply** buttons	Enables or applies filters.
F9	-	Enables the configuration area to edit a new item in the **Administration** tab.
F10	**Menu** drop-down list	Opens and closes the main menu.

Common function keys

List of common icons

Module icons

These icons indicate that the adjacent item belongs to a specific software module.

Icon	Description
	General Lab module
	Microbiology module
	Shared between the General Lab and the Microbiology module
	Emergency Lab module
	Lab Flow module
	Total Quality Management module

Module icons

Routine tasks

Quality management

In this chapter 2

Document management

You can manage all documentation regarding the quality process of the laboratory, including instructions, audits, templates, etc.

In this section

Creating documents

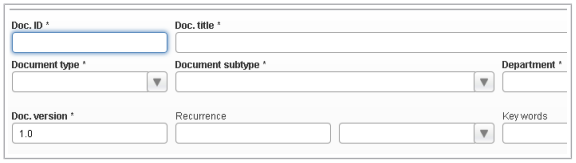
An editor can create a document for a specific need within the laboratory and upload it into the system so the corresponding users can review them.

☐ Configured rights, centers, units, departments, and user profiles

To create documents

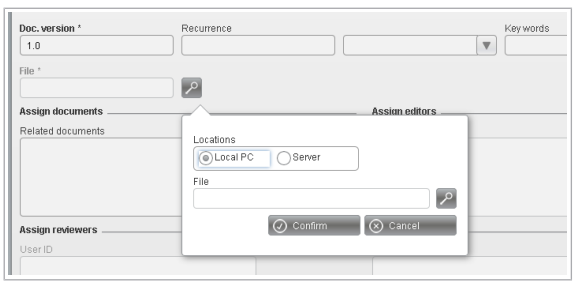
1 Choose **Main > Document management > Document edition**.

2 Choose the **Add** button.



3 Fill in the following fields:
- **Doc. ID**
- **Doc. title**
- **Doc. version**

4 Choose an option from the following drop-down lists:
- **Document type**
- **Document subtype**
- **Department**
- **Date of entry into force**



5 In the **File** field, attach the desired document.

6 Choose the **Confirm** button.

➔ The document changes to **Pending review** status.

Reviewing documents

Once a document has been created and uploaded into the system, an appointed user can review its content.

To stop the distribution flow of **Pending review** status documents, choose the **Reject** button. The document changes to **Rejected** status.

☐ The corresponding rights configured

To review documents

1 Choose **Main > Document management > Document edition**.

2 Double-click the desired document to enable the lower screen tabs.
- The **Related documents** tab, displays the attached files.
- The **History** tab, displays the review-approval flow trace.
- The **Properties** tab, displays the modifications and distribution list.
- The **Obsolete documents** tab, displays previous versions of the document.

3 Optionally to enter comments to the document, choose the **Comments** button.

4 To enter the comment, choose the **Save** button.
➔ The document remains in **Pending review** status.

Related topics

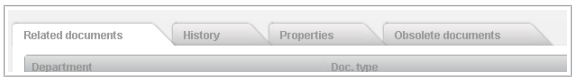
- Re-editing and modifying documents (53)

Approving and distributing documents

Once a document has been reviewed, an appointed user or several appointed users can approve it, and distribute it to the users present in the distribution list.

To stop the distribution flow of **Pending review** status documents or **Pending approval** status documents, choose the **Reject** button. The document changes to **Rejected** status.

☐ The corresponding rights configured



To approve and distribute documents

1 Choose **Main > Document management > Document edition**.

2 To approve and distribute documents, select the desired **Pending review** status document.

3 Optionally to enter comments to the document, choose the **Comments** button.

4 To continue the distribution flow, choose the **Save** button.

ℹ To continue the distribution flow and change the document status, all reviewers or approvers have to do this action.

➔ The document changes to **Pending approval** status.

5 To come into force the **Pending approval** status document, choose the **Save** button.

ℹ To continue the distribution flow and change the document status, all reviewers or approvers have to do this action.

➔ The document changes to **In force** status.

To access the document in force, the user included in the distribution list can access it from **Main > Document management > My documents**.

6 To reject documents **In force**, choose the **Mark obsolete** button.

Related topics

- Re-editing and modifying documents (53)

Re-editing and modifying documents

After a document has been approved, an appointed user may re-edit it and alter its content.

☐ Configured rights, centers, units, departments, and user profiles

To re-edit rejected documents

1 Choose **Main > Document management > Document edition** and select the rejected status document.

2 To change the document content:
- Choose the **Open** button.
- Save the document in a location external to the system (hard disk, USB memory, etc.) and change the document from there.
- Include the document in the system.

3 To change the document properties, choose the **Edit** button.

4 From the **Date of entry into force** drop-down list, change the date.

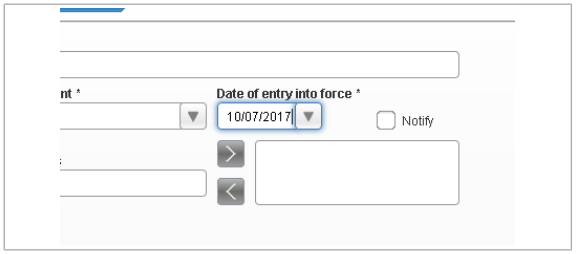
5 Edit the desired fields.

6 To restart the review-approval flow, choose the **Confirm** button.
➔ The document changes to **Pending review** status.

To modify documents in force

1 Choose **Main > Document management > Document edition** and select the in force document.

2 To change the document content:
- Choose the **Open** button.
- Save the document in a location external to the system (hard disk, USB memory, etc.) and change the document from there.
- Include the document in the system.



3 To change the document properties, choose the **Edit** button.

4 From the **Date of entry into force** drop-down list, change the date.

5 Edit the desired fields.

6 In the **Modifications** field, enter the changes.

7 To save the changes, choose the **Confirm** button.

Audit management

You can upload and edit audit reports into the system and manage its follow-up.

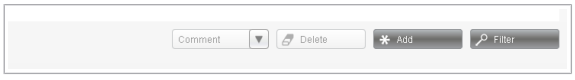
In this section

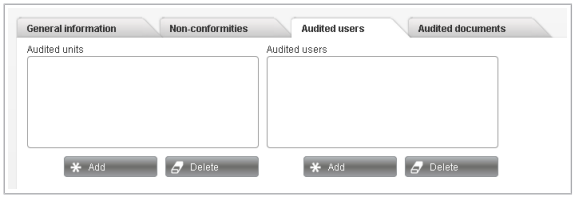
Editing audit reports

You can create audit reports and send it to the corresponding audited users and QM.

☐ Audit types, users, and profiles configured

To edit audit reports





1 Choose **Main > Audit management > Audit entry**.

2 To enable the configuration area, choose the **Add** button.

3 Choose the **General information** tab.

4 Fill in the following fields:
- **ID**
- **Title**

5 Choose an option from the following drop-down lists:
- **Type**
- **Date**

6 To attach users as internal auditors, choose the **Add** button in the **Auditing team** field.

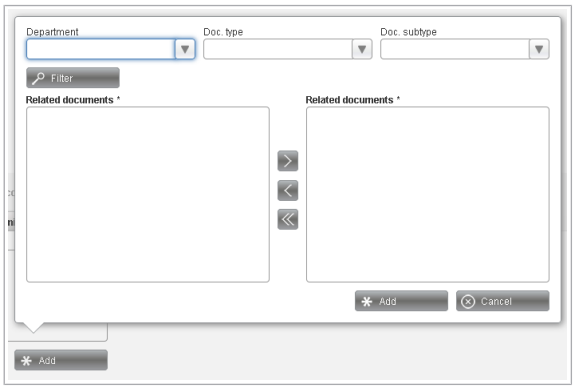
7 Optionally in the **File** field, attach the desired document.

8 Enter the non-conformity Entering non-conformities in audit reports (56).

9 Choose the **Audited users** tab.

10 To fill in the **Audited units** field and the **Audited users** field, choose the **Add** button.

11 Choose the **Audited documents** tab.



12 To select the related documents from the **Document management** drop-down list, choose the **Add** button.

13 Do one of the following:

- To forward the audit report, if the information is completed, choose the **Send** button.
- To save the report in the database, if the information is incomplete, choose the **Confirm** button.

➔ When you choose the **Send** button, the audit report changes to **Pending** status.

➔ When you choose the **Confirm** button, the audit report changes to **Draft** status.

Entering non-conformities in audit reports

You can enter non-conformities associated to an audit report.

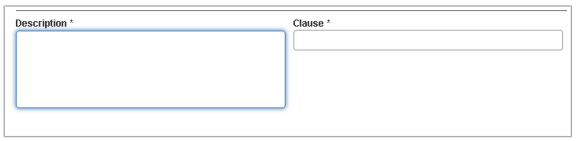
☐ Choose **Main > Audit management > Audit entry** and create an audit report.

☐ Choose the **Non-conformities** tab.

To enter non-conformities in audit reports

1 Choose the **Add** button.

2 In the **Description** field, enter information about the non-conformity.



3 In the **Clause** field, enter the clause of the standard affected by the non-conformity.

4 Optionally in the **File** field, attach the desired document.

5 Choose the **Confirm** button.

Accepting and rejecting audits

When the editor user has sent the audit, an appointed user can accept or reject the audit.

☐ The corresponding units and profiles configured

To accept and reject audits

1 Choose **Overview > Notifications** and select the corresponding **Audit pending acceptance** warning.

2 Choose the **Fix** button, the **Confirm** button, or the **Delete** button depending on the action to perform.

➔ The **Fix** button redirects to the **Audit entry** screen.

3 Double-click the corresponding report.

4 To unavailable the lower area of the screen and enable the upper one, choose the **Cancel** button.

5 Do one of the following:

- To accept the report, choose the **Accept** button.
- To reject the report, choose the **Reject** button.

Non-conformities

You can enter and manage anomalies found while working in the system.

In this section

Entering non-conformities

You can enter a non-conformity and start a workflow to enter corrective actions and measure its efficacy.

☐ The corresponding units and profiles configured

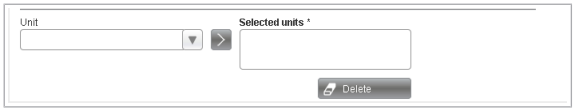
To enter non-conformities

1 Choose **Main > Non-conformities > Entry of non-conformities**.

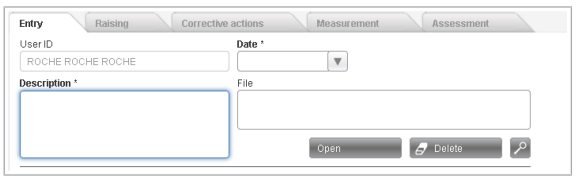
2 Choose the **Add** button.

3 Choose the **Entry** tab.

4 From the **Date** drop-down list, choose the date and then fill in the **Description** field.



5 From the **Unit** drop-down list, choose the units involved and enter them to the **Selected units** field.



6 Optionally in the **File** field, attach the desired document.

7 Choose the **Confirm** button.

➔ The non-conformity changes to **Pending raising** status.

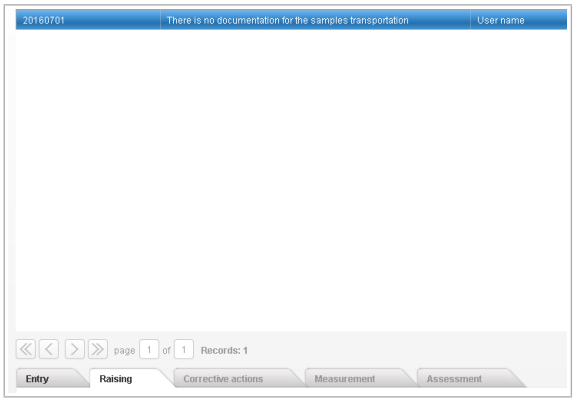
Raising non-conformities

After a non-conformity has been entered, the appointed user has to raise it in order to define corrective actions and solve it.
The appointed user is usually the quality manager.

☐ A non-conformity entered

To raise non-conformities

1 Choose **Main > Non-conformities > Entry of non-conformities**.



2 Double-click the corresponding non-conformity.

3 Choose the **Raising** tab.

4 From the **Person responsible** drop-down list, choose the responsible person.

5 Fill in the **Clause** field.

6 To open the non-conformity, choose the **Confirm** button.

➔ The non-conformity changes to **Raised** status. The responsible person and the QM and users responsible for the affected units, receive the **Open non-conformities** warning.

Defining corrective actions

You can define corrective actions that aim to solve the problem the non-conformity refers to.

☐ A non-conformity entered and raised

To define corrective actions

1 Choose **Main > Non-conformities > Entry of non-conformities**.

ⓘ You can also choose **Overview > Notifications** and choose the **Fix** button from the selected **Open non-conformities** warning.

2 Double-click the corresponding non-conformity.

3 Choose the **Corrective actions** tab.

4 Choose the **Add** button.

5 Fill in the **Corrective actions** field.

6 Choose an option from the following drop-down lists:
- **Person responsible**
- **Deadline**

7 Optionally to send regular warnings to the user responsible for the corrective actions, enter the desired number of days or weeks in the **Remind every** field.

8 Choose the **Confirm** button to save the corrective action.
➔ The responsible users receive the **Modified corrective actions from the following non-conformities** warning.

Measuring actions and closing non-conformities

You can measure actions previously set up and close the non-conformity afterwards.

☐ A non-conformity raised and corrective actions entered

To measure actions and close non-conformities

1 Choose **Main > Non-conformities > Entry of non-conformities**.
ⓘ You can also choose **Overview > Notifications** and choose the **Fix** button from the selected **Modified corrective actions from the following non-conformities** warning.

2 Double-click the corresponding non-conformity.

3 Choose the **Measurement** tab.

4 Choose the **Add** button.

5 Fill in the following fields:
- **Description**
- **Method**
- **Accepted value**

6 From the **Date reviewed** drop-down list, choose the date in which the item was reviewed.

7 Optionally in the **File** field, attach the desired document.

8 Choose the **Confirm** button.

Preventive actions

You can enter preventive actions into the system in order to improve performance and prevent malfunctions.

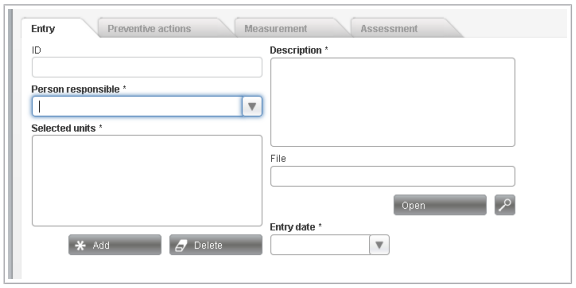
In this section

Entering actions for improvement

You can enter actions for improvement into the system so that a responsible user can set up the corresponding preventive actions.

☐ Editing rights

To enter actions for improvement



1 Choose **Main > Preventive actions > Entry of preventive actions**.

2 Choose the **Add** button.

3 Choose the **Entry** tab.

4 Choose an option from the following drop-down lists:
- **Person responsible**
- **Entry date**

5 Fill in the **Description** field.

6 Choose the **Add** button below the **Selected units** field.
➔ The unit dialog box is displayed.

7 From the **Available units** drop-down list, choose the units involved and enter them to the **Selected units** field. To confirm, choose the **Add** button.

8 Optionally in the **File** field, attach the desired document.

9 Choose the **Confirm** button.
➔ The preventive action changes to **Open** status. A warning is sent to the responsible users.

Creating preventive actions to actions for improvement

You can enter a preventive action once the action for improvement has been entered into the system

☐ An action for improvement entered

To create preventive actions to action for improvement

1 Choose **Main > Preventive actions > Entry of preventive actions**.

ⓘ You can also choose **Overview > Notifications** and choose the **Fix** button from the selected **Actions pending introduction from the following preventive actions** warning.

2 Choose the **Preventive actions** tab.

3 Choose the **Add** button.

4 Fill in the **Preventive action** field.

5 Choose an option from the following drop-down lists:
- **Person responsible**
- **Entry date**

6 Optionally to send regular warnings to the user responsible for the preventive action, enter the desired number of days or weeks in the **Remind every** field.

7 Choose the **Confirm** button.

Implementing preventive actions

You can implement the preventive action once it has been entered and choose a measurement method.

☐ A preventive action for an action for improvement entered

To implement preventive actions

1 Choose **Main > Preventive actions > Entry of preventive actions**.

2 Double-click the corresponding preventive action.

3 Choose the **Measurement** tab.

4 Choose the **Add** button.

5 Fill in the following fields:

- **Description**
- **Method**
- **Accepted value**

6 From the **Date reviewed** drop-down list, choose the date in which the item was reviewed.

7 Optionally in the **File** field, attach the desired document.

8 Choose the **Confirm** button.

Closing preventive actions

You can close a preventive action once it has been measured.

To close preventive actions

1 Choose **Main > Preventive actions > Entry of preventive actions**.

2 Double-click the corresponding preventive action.

3 Choose the **Assessment** tab, and then to enter the value, double-click the **Obtained value** field.

4 Do one of the following:

- To close the action, if the value is accepted, choose the **Yes** option in the **Success** field.
- To define new preventive actions, if the value is not accepted, choose the **No** option in the **Success** field.

➔ When you choose the **Yes** option, then go to the **Preventive actions** tab and in the **Status** option, choose the **Completed** status.

➔ When you choose the **No** option, the corresponding users receive the **Unsolved preventive actions** warning.

Issue management

You can enter issues found during your performance in the system and define the actions needed to solve them.

In this section

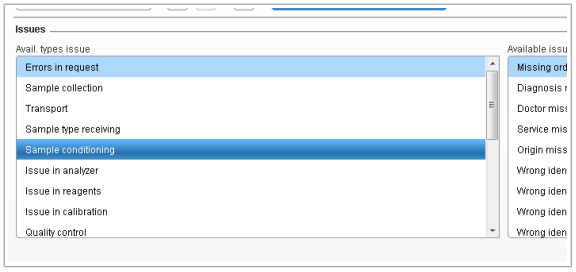
Entering issues

You can enter issues in the system.

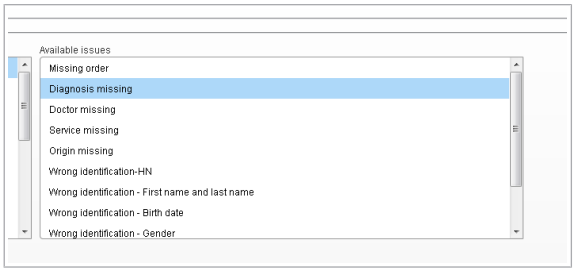
- ☐ Editing rights
- ☐ Issue types, units, and profiles configured

To enter issues

1 Choose **Main > Issue management > Entry of issues**



2 In the **Avail. types issue** check box, select the type of issue.

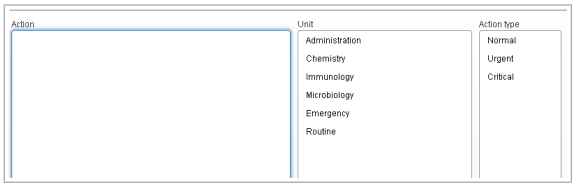


3 In the **Available issues** check box, double-click the issue subtype.

4 In the **Origin of the issue** field, enter the **Order ID**, or the **[Tube ID]** of the issue referring to.
→ The **Selected orders** field or the **Selected tubes** field are filled in.

5 In the **Selected tests** field, select the tests related to the issues orders.

6 Choose the **Actions** button to enter new actions.



➔ Preassigned actions appear automatically.

7 In the **Actions** screen, select the corresponding items for the following areas and enter the actions:
- **Action**
- **Unit**
- **Action type**

8 Choose the **Confirm** button.
➔ It appears the **Entry of issues** screen. The action changes to **Pending** status.

9 Choose the **Finish** button.
➔ The issue together with its associated actions appears in the **History of issues** screen and the **History of issues with actions** screen.

10 In the callout, enter your user name and password.

Assigning actions

Once an issue has been entered, the appointed user can include corrective actions in order to solve it.

☐ An issue entered

To assign actions

1 Choose **Main > Issue management > Action management**.

2 Select the pending action to be assigned and choose the **Add** button.

3 In the callout, enter your user name and password.

4 Choose the **Confirm** button.
➔ The action changes to **Assigned** status.

Reassigning actions

You can reassign an action if it has been deemed as not fit for the corresponding issue.

To reassign actions

1 Choose **Main > Issue management > Action management**.

2 Select the action to be reassigned and choose the **Reassign** button or the **Deassign** button.

➔ The action changes to **Pending** status.

Completing actions

Once an action has been applied, the appointed user has to close it in order to complete the issue.

To complete actions

1 Choose **Main > Issue management > Action management**.

2 Select the action to be closed.

3 Choose the **Finish** button.

Indicator management

You can enter values to calculate and analyze indicators that can show useful statistical information about various aspects of the laboratory workflow, for example the working days or the amount of calibrations programmed.

In this section

Entering values

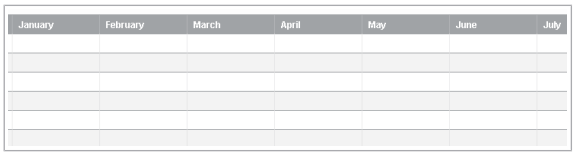
You can enter manually the values needed to calculate an indicator.

☐ Editing rights

To enter values

1 Choose **Main > Indicator management > Entry of manual variables**.

2 To enter the variable value, choose the corresponding year from the **Year** drop-down list.



3 To calculate the associated indicator, enter the corresponding value to the corresponding variable and month.

4 Choose the **Save** button.

Viewing quality indicators

You can view the graphical representation of an indicator.

To view quality indicators

1 Choose **Main > Indicator management > Indicator analysis**.

2 To view the indicators, choose the indicators from the **Group of indicators** drop-down list.

3 To check a calculation, double-click the corresponding type of indicator.

4 Choose the range date for which you want to calculate the indicator from the following drop-down lists:
   - **From**
   - **To**

   ➔ The resulting indicator is displayed.

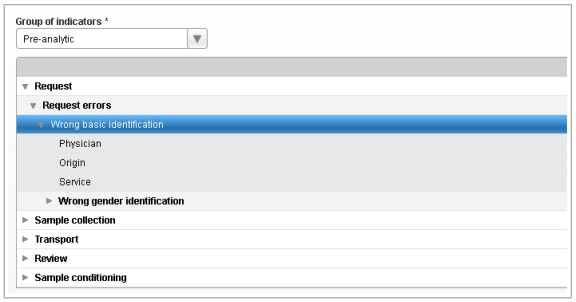
Analyzing the results of an indicator

You can analyze the results of an indicator, select a certain period and review said indicator.

☐ Indicators, rights, and profiles configured

To analyze the results of an indicator

1 Choose **Main > Indicator management > Indicator analysis**.



2 To analyze an indicator, select the indicator.

3 To display the indicator pending revision, choose the **Analyze** button.

4 Optionally filter by year the pending indicators choosing a year from the **Year** drop-down list.

5 To mark indicators as reviewed, select the adjacent check box of those indicators.

6 To turn the marked indicators into reviewed indicators, choose the **Review** button.

7 Optionally to generate a report for the marked indicators, choose the **Report** button.

Calculating indicators manually

You can select an indicator, calculate it and its graphical representation manually.

☐ Indicators, rights, and profiles configured

To calculate indicators manually

1 Choose **Main > Indicator management > Indicator analysis**.

2 To calculate an indicator, select the indicator.

3 Choose the **Calculate** button.

4 From the **Month** drop-down list, choose an option.

5 To view the calculation, choose the **Confirm** button.

Instrument management

You can create and set up a calendar of procedures for each of the instruments in the laboratory. The calendar serves as a reminder for procedures related to each instrument to be performed periodically.

In this section

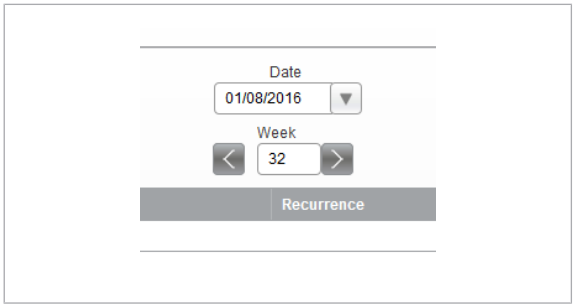
Consulting pending procedures

You can consult pending procedures for each instrument, and accept them if they are suitable, or reject and change them otherwise.

Procedures planned for non-working days are automatically rescheduled for the next working day.

☐ Instrument types, instruments, assigned users, and profiles configured

To consult pending procedures and execute or reject them



1. Choose **Main > Instrument management > Calendar of procedures**.
2. To consult the procedure, choose the date from the **Date** drop-down list.
3. To consult the procedure, enter a week in the **Week** field.
4. Optionally to filter the information displayed on screen, choose the **Filter** button.
5. To perform pending procedures, choose the **Perform** button.
6. To reject pending procedures, choose the **Reject** button.

Consulting procedures associated with each instrument

You can individually consult procedures related to specific instruments.

To consult procedures associated with each equipment

1 Choose **Main > Instrument management > Procedure per instrument query**

2 Select the equipment whose associated procedures you want to consult.

3 Choose the **Procedure** button.

4 Once the procedure information has been consulted, choose the button to return to the main screen.

Glossary

access rights

Authorization to perform operations associated with a specific shared resource, such as a file, folder, or printer. They must be granted by the system administrator to individual users or user groups.

caution

Safety alert symbol indicating a hazardous situation which, if not avoided, could result in minor or moderate injury.

check box

User interface element that indicates whether an option is selected.

database

Collection of data formatted/arranged to allow for easy search and retrieval.

drop-down list

Interactive user interface element that contains predefined values. It drops down when requested and remains open until the user chooses a value or closes it.

error

Fault condition classification for events occurring on the system. An error occurs when a condition exists on the system requiring corrective action by a user or by a Roche Service representative.

instrument

Medical device that automates steps in a laboratory, health facility, or at home.

keyboard

Input device consisting of a set of individual keys similar to those on a typewriter. It is used to convey information from a user to a computer or data communications circuit.

malfunction

Device failure causing degradation of performance, loss of function, or unintentional responses.

medical validation

Evaluation of technically released test results in terms of their plausibility and in comparison with the patient's diagnosis.

operator

Person who physically interacts with the instrument on a regular basis.

password length

Number of characters that a password contains.

patient

Person whose sample is tested on an instrument or system.

power supply

Electronic circuit that converts an input AC voltage into an output DC voltage.

safety precautions

Measures that are taken to avoid potential hazards.

technical validation

Validation of a patient result based on technical information such as valid QC results or calibration, as well as verifying and either confirming that measurements have been carried out according to the rules of laboratory best practices or taking the necessary actions if they have not.

test

Measuring procedure that requires laboratory equipment and assays in a specific clinical context and for a specific clinical purpose, in a specific population.

uninterruptible power supply

Device with a battery that allows limited continued operation of an instrument or other device during a power outage.

unit

Component of a module or an instrument that fulfills a specific function.

work area

Main user interface area for performing tasks and viewing data.

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